WSR 13-06-008 PERMANENT RULES TACOMA COMMUNITY COLLEGE

[Filed February 22, 2013, 10:49 a.m., effective March 25, 2013]

Effective Date of Rule: Thirty-one days after filing.

Purpose: To provide a structured, equitable process for students to appeal final course grades that may have been assigned in an arbitrary and capricious manner.

Statutory Authority for Adoption: RCW 28B.50.140 (13).

Adopted under notice filed as WSR 12-08-015 [12-21-108] on March 26 [October 23], 2012.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's Own Initiative: New 4, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted Using Negotiated Rule Making: New 4, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 0, Repealed 0.

Date Adopted: February 20, 2013.

Mary A. Chikwinya Vice-President for Student Services

Chapter 132V-123 WAC

FINAL COURSE GRADE APPEAL PROCESS

NEW SECTION

WAC 132V-123-010 Definitions. For purposes of this chapter, the following definitions apply.

Appropriate dean or manager means the administrator responsible for the respective department offering the course which is under appeal.

Arbitrary or capricious manner means in a manner deemed to be inappropriately subjective or otherwise inconsistent with the learning assessment process stated on the syllabus.

Documentation means all materials relevant to the grade determination and to the grade appeal process. Examples include grade reports, graded work, syllabus, student/faculty correspondence, etc.

Final grade means the grade received in the course and reported to enrollment services.

Hearing committee means a group consisting of:

- (a) Two students selected by the president of the associated student body.
- (b) Two faculty members selected from four faculty elected each fall in instructional council to serve for the year.

(c) One instructional administrator, appointed by the executive vice-president for academic and student affairs.

Written appeal means a document that includes:

- (a) A clear statement of why the student believes his or her final grade was not properly awarded.
 - (b) What the student has done to resolve the issue.
 - (c) What remedy the student is seeking.

Written communication means either electronic (TCC e-mail) or traditional correspondence.

NEW SECTION

WAC 132V-123-020 Informal resolution. If a student feels his or her final course grade was awarded incorrectly, in error, or in an arbitrary or capricious manner, his or her actions shall follow the steps below to address the discrepancy. Every effort will be made to resolve the discrepancy at the first level.

- (1) Step 1.
- (a) The student shall contact the instructor to discuss the student's concerns. This contact shall occur prior to the fifth instructional day of the next quarter. For a spring quarter grade this step may occur prior to the fifth instructional day in either of the following summer or fall quarters.
 - (b) This contact shall include:
- (i) Discussing reasons the student believes there is a discrepancy;
- (ii) Presenting other documentation that may have been overlooked in the determination of the final course grade.
- (c) If the student believes his/her concern has not been adequately resolved in step 1, he/she may proceed to step 2.
 - (2) Step 2.
- (a) The student shall contact the program/department chair or designated faculty member to discuss the student's concerns. This contact shall occur prior to the tenth instructional day of the next quarter.
 - (b) This contact shall include:
 - (i) Reasons the student believes there is a discrepancy;
 - (ii) Documentation;
 - (iii) The results of the meeting with the faculty member.
- (c) The chair or designated faculty member will discuss the situation with the faculty member before giving the student his or her recommendation.
- (d) The chair or designated faculty member will inform the student of his or her recommendation. This shall occur prior to the 15th instructional day of the next quarter. The chair or designated faculty member's recommendation is not binding.
- (e) The chair or designated faculty member will inform the student of the formal appeal process if the chair's recommendation is not satisfactory to the student.

NEW SECTION

WAC 132V-123-030 First level of formal appeal. If a student is not satisfied with the informal resolution, he or she may begin the formal appeal.

(1) Step 1. The student must contact the appropriate dean or manager and present documentation and a written grade appeal. This contact shall occur prior to the 20th instructional day of the next quarter.

[1] Permanent

- (2) Step 2. The dean or manager will investigate the grade appeal and provide written communication of the findings and decision to the faculty member and the student. The findings and decision shall be provided to the student within ten instructional days after receiving the written appeal. The investigation will include:
 - (a) Reviewing the faculty member's documentation;
- (b) Reviewing the student's written appeal and documentation:
- (c) Discussion with the student and faculty member individually or together.

NEW SECTION

- WAC 132V-123-040 Second level of formal appeal. If either party is not satisfied with the first level of formal appeal decision, he or she may begin the second level of the formal appeal process.
- (1) Step 1. The applicable party will present the executive vice-president for academic and student affairs with a written appeal of the first level decision and documentation.
- (2) Step 2. The executive vice-president or his or her designee will investigate the appeal. This investigation shall be completed within ten instructional days of receiving the appeal. The investigation will consist of a review of all student and faculty member documentation and the findings of the dean or manager.
- (3) Step 3. The executive vice-president shall within ten instructional days of receiving the appeal:
 - (a) Make a final decision; or
- (i) The final decision will be conveyed in writing to the student, faculty member, and dean.
- (ii) Any decision made by the executive vice-president and pursuant to this section is a final agency decision.
- (b) Convene a hearing committee pursuant to WAC 132V-123-010.
- (i) The committee will hear testimony from the student and from the faculty member.
 - (ii) The committee will examine documentation.
- (iii) A decision shall be made by majority vote in deliberations.
- (iv) The decision shall be communicated to the student and the faculty member within five instructional days of the hearing after all testimony and documentation have been presented.
- (v) Any decision made by the committee is a final agency decision.

WSR 13-06-012 PERMANENT RULES DEPARTMENT OF FINANCIAL INSTITUTIONS

(Division of Consumer Services) [Filed February 25, 2013, 9:35 a.m., effective April 1, 2013]

Effective Date of Rule: April 1, 2013.

Purpose: To increase the number of required prelicensing education hours specific to Washington law. On April 1, 2013, a uniform state test section will be added to the

National SAFE test. The Washington specific component test will be phased out. An increase in the number of Washington specific prelicensing education hours will ensure mortgage loan originator applicants have knowledge of Washington law prior to licensing.

The rule making was proposed under OFM Guideline 3.d.

Citation of Existing Rules Affected by this Order: Amending WAC 208-620-720 and 208-620-725.

Statutory Authority for Adoption: Chapter 43.320 RCW; RCW 31.04.165.

Adopted under notice filed as WSR 13-01-085 on December 18, 2013 [2012].

Changes Other than Editing from Proposed to Adopted Version: WAC 208-620-720(2):

Insert the words "SAFE required" in front of the words "prelicensing education" in two places to clarify that applicants who complete the SAFE required prelicensing education hours in any state will be deemed compliant for only those requirements in Washington; the applicants will still have to comply with the requirement for Washington specific prelicensing education hours.

Change the words "nationwide mortgage licensing system and registry" to "NMLS" for consistency with references to the licensing system as provided for in the definitions.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's Own Initiative: New 0, Amended 2, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted Using Negotiated Rule Making: New 0, Amended 2, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 0, Repealed 0.

Date Adopted: February 25, 2013.

Deborah Bortner, Director Division of Consumer Services

AMENDATORY SECTION (Amending WSR 09-24-090, filed 12/1/09, effective 1/1/10)

WAC 208-620-720 Loan originator—Prelicensing education. Must I complete prelicensing education in order to receive a loan originator license? Yes.

- (1) You must complete at least ((twenty)) twenty-two hours of prelicensing education approved by the NMLSR. The prelicensing education must include:
 - (a) Three hours of federal law and regulations;
- (b) Three hours of ethics, which includes instruction on fraud, consumer protection, and fair lending issues;
- (c) Two hours of training related to lending standards for the nontraditional mortgage product marketplace; and

Permanent [2]

- (d) At least ((two)) <u>four</u> hours of training specifically related to Washington law.
- (2) You will receive credit for having completed the <u>SAFE required</u> prelicensing education for every state once you have successfully completed the <u>SAFE required</u> prelicensing education requirements approved by the ((nationwide mortgage licensing system and registry)) <u>NMLS</u> for any state.
- (3) Must I take continuing education in the year I complete the prelicensing education? No. You will not have a continuing education requirement in the year in which you complete the core twenty hours of prelicensing education.

AMENDATORY SECTION (Amending WSR 12-18-047, filed 8/29/12, effective 11/1/12)

WAC 208-620-725 Mortgage loan originator—Testing. Must I pass a test prior to becoming a loan originator? Yes.

- (1) You must take and pass the NMLS sponsored loan originator test. The test has two parts; one on federal law and regulation((5)) and one on ((Washington specifie)) uniform state law and regulation. You must receive a score of seventy-five percent or higher to pass the test.
- (2) Where may I find information about the loan originator test? The NMLS web site will publish the names and contact information of approved testing providers.
- (3) How much does the loan originator test cost? Testing costs are set by the test provider and the NMLS and may be modified from time to time. The NMLS web site will publish the current testing fee with the testing provider contact information.
- (4) **How do I register to take the loan originator test?** Register through the NMLS web site.
- (5) What topics may be covered in the loan originator test? At a minimum, the test topics will include ethics, federal and state law and regulation pertaining to mortgage origination, federal and state law and regulation on fraud, consumer protection, nontraditional mortgage products, and fair lending.
- (6) After passing the loan originator test, will I have to take it again? If you fail to maintain a valid license for a period of five years or longer you must retake the test, not taking into account any time during which you were a registered mortgage loan originator.
- (7) How soon after failing the loan originator test may I take it again? After taking and failing the test you must wait thirty days before taking it again. After failing three consecutive times, you must then wait at least six months before taking the test again.

WSR 13-06-014 PERMANENT RULES DEPARTMENT OF ECOLOGY

[Order 08-07—Filed February 25, 2013, 11:31 a.m., effective September 1, 2013]

Effective Date of Rule: September 1, 2013.

Purpose: The department of ecology is adopting amendments to chapter 173-204 WAC, Sediment management standards (SMS) rule. The amendments:

- 1. Integrate the SMS and Model Toxics Control Act (MTCA), chapter 173-340 WAC cleanup requirements where appropriate.
- 2. Clarify requirements for protection of human health from sediment contamination.
- 3. Clarify requirements for protection of higher trophic level species from sediment contamination.
- 4. Promulgate numeric chemical and biological criteria for freshwater sediment to protect the benthic community.
- 5. Clarify requirements for coordinating source control and cleanup actions at cleanup sites.

Citation of Existing Rules Affected by this Order: Amending chapter 173-204 WAC.

Statutory Authority for Adoption: The MTCA, chapter 70.105D RCW for WAC 173-204-500 through 173-204-590; the MTCA, chapter 70.105D RCW and the Water Pollution Control Act, chapter 90.48 RCW for WAC 173-204-100, 173-204-110, 173-204-130, 173-204-200, 173-204-310, 173-204-320, 173-204-350, 173-204-410, 173-204-412, and 173-204-415.

Adopted under notice filed as WSR 12-21-034 on October 9, 2012.

Changes Other than Editing from Proposed to Adopted Version: List of SMS Rule Changes from Proposed to Adopted Rule:

Part I - WAC 173-204-100 through 173-204-130:

To ensure clarity and consistency, the following revisions were made:

- Rule citations were changed to appropriately correspond to definition changes.
- The underlying authorities for Part V were revised to reflect ecology's decision to adopt Part V, Sediment cleanup standards, under chapter 70.105D RCW, the MTCA.

Part II - WAC 173-204-200 and 173-204-505:

The proposed amendments were originally made to existing WAC 173-204-200. Adopted amendments to the definitions that only apply to Part V have been moved to new WAC 173-204-505 to clearly indicate that they apply to Part V only.

Therefore, to ensure clarity and consistency, the following revisions were made:

• The following definitions were moved from WAC 173-204-200 to Part V WAC 173-204-505: Active cleanup action, applicable laws, beneficial reuse, biologically active zone, cleanup action, cleanup screening level, contaminant, enhanced natural recovery, include monitored natural recovery, natural background, natural recovery, point of compliance, practical quantitation limit, regional background, sediment cleanup level, sediment cleanup objective, sediment cleanup standard, sediment recovery zone, sediment cleanup unit, and technically possible.

 The original definitions in WAC 173-204-200 for the following terms were restored: Acute, beneficial use, bioassay, person, and surface sediment(s)/ sediment(s).

In response to comments received, the following revisions to the definitions were made:

- "Active cleanup action" was revised to clarify types of cleanup actions.
- "Anthropogenic" was deleted because the term is not used in Part V, which is the focus of the rule revisions.
- "Applicable laws" was revised to include relevant and appropriate requirements of local and tribal laws
- "Beneficial reuse" was revised to clarify the definition for levels of contamination and types of reuse.
- "Best management practices" was revised by deleting the requirement for department approval.
- "Cleanup action" was revised to clarify contaminants and when a remedial action is considered a final cleanup action or an interim action.
- "Contaminant" was revised to be consistent with MTCA.
- "Contaminated sediment" was revised to restore "surface" to the term ["]sediment.["]
- "Control sediment sample" was revised to clarify that it applies to benthic criteria.
- "Enhanced natural recovery" was revised to change "remedy" to "cleanup action."
- "Minor adverse effects" was revised to reflect comparison to control for freshwater criteria.
- "Monitored natural recovery" was revised to include benthic infauna.
- "Natural recovery" was revised to clarify the example in the definition.
- "No adverse effects" was revised to reflect comparison to control for freshwater criteria.
- "Nonanthropogenically affected" was deleted because the term is not used in Part V, which is the focus of the rule revisions.
- A new definition of "practicable" was added to Part V to clarify the term as it applies to WAC 173-204-570 and 173-204-590.
- "Regional background" was revised to eliminate duplicative phrasing in WAC 173-204-560.
- "Sediment cleanup level" was revised to clarify that it can be established between the sediment cleanup objective (SCO) and the cleanup screening level (CSL).
- "Sediment cleanup standard" was revised to clarify its relationship to relevant terms.
- "Sediment cleanup unit" was revised to include regional background as a consideration in defining a
- "Sediment quality standard" was removed because the term does not apply to Part V.
- "Sediment recovery zone" was revised consistent with revisions to WAC 173-204-500, 173-204-570, and 173-204-590.

• "Surface sediment or sediment" was revised for Part V to clarify the definition.

Part III - WAC 173-204-300 through 173-204-350:

 The references to definition numbers in WAC 173-204-200 have been revised to accurately reflect the revisions to that section.

Part IV - WAC 173-204-400 through 173-204-420:

 The references to definition numbers in WAC 173-204-200 have been revised to accurately reflect the revisions to that section.

Part V:

WAC 173-204-500:

To meet the intent of chapter 70.105D RCW, the following revision was made:

 The authorizing statute and how Part V provisions will be used were clarified in WAC 173-204-500(1).

To ensure clarity and consistency, and in response to comments received, the following revisions were made:

- The relationship between the restoration time frame and cleanup actions and ecology's expectations and preference regarding the type of cleanup actions for specific types of sites were clarified in WAC 173-204-500 (4)(c).
- Ecology's expectations regarding discharge monitoring were revised in WAC 173-204-500 (4)(d).
- The terminology regarding protection of human health at "no significant health threat" in WAC 173-204-500(5) was made consistent with Part I.
- The relationships between sediment cleanup standards, sediment cleanup levels, sediment cleanup objectives, cleanup screening levels, and points of compliance were clarified in WAC 173-204-500 (5)(a).
- The use of passive cleanup actions was clarified in WAC 173-204-500 (5)(b).
- Compliance with applicable laws was included in the presumption of protectiveness provision in WAC 173-204-500 (5)(c).

WAC 173-204-510:

To ensure clarity and consistency, and in response to comments received, the following revisions were made:

- Language was clarified in WAC 173-204-510 (2)(a) through (d) regarding when a station cluster of concern is identified based on benthic, human health, or background criteria.
- Language was clarified in WAC 173-204-510 (2)(c)(i) so that the reference to background is regional background.
- The term "contaminant" was replaced with "chemical" to ensure consistent usage of the term and to clarify the intent of separating evaluations based on chemical and biological criteria.
- Language was revised in WAC 173-204-510(3) to state that notification is dependent on the results of the hazard assessment and evaluation process in WAC 173-204-520.

Permanent [4]

WAC 173-204-520:

To ensure clarity and consistency, the following revisions were made:

- WAC 173-204-520 (2)(a)(vi) was revised for consistency with other subsections.
- Clarification was added to WAC 173-204-520 (3)(a) on how background concentrations are incorporated into site identification.
- WAC 173-204-520 (3)(d) was reworded to clarify how human health, background, other deleterious substances, and nonanthropogenically affected criteria are used to identify cleanup sites or areas for potential further investigation.
- The term "contaminant" was replaced with "chemical" to ensure consistent usage of the term and clarify the intent of separating evaluations based on chemical and biological criteria.

WAC 173-204-530:

The rule language in WAC 173-204-530 (6)(a)(i) was revised to reflect the intent of the original rule regarding delisting a site based on meeting cleanup requirements.

WAC 173-204-540:

To ensure clarity and consistency, the following revisions were made:

- The language was revised in WAC 173-204-550(1) to better explain the intent of this section.
- The language was revised in WAC 173-204-550(2) to clarify the authority under MTCA as it applies to a release or threatened release.
- The language was revised in WAC 173-204-550(3) to clarify terms (remedial action), Part V under MTCA authority, and the role of the Comprehensive Environmental Response Compensation and Liability Act.

WAC 173-204-550:

In response to comments received, the following revisions were made:

- WAC 173-204-550(4) Remedial investigation work plan, addition of:
 - o Data gaps analysis.
 - o Receptors and exposure pathways to the conceptual site model requirements.
 - o Analytical methods requirements.
- WAC 173-204-550(5), public participation plan requirements for early coordination and consistency with MTCA were added.
- WAC 173-204-550(6) Remedial investigation report:
 - o Requirements were more clearly specified regarding what must be included in a remedial investigation report for a site or sediment cleanup unit.
 - o Consideration of land use classification was
 - Impact on ecological receptors was included with reference to natural resources and habitat.
 - Contaminant sources were clarified to be confirmed and suspected sources.

- Human health risk assessment language was reinstated.
- WAC 173-204-550(7) Feasibility study report:
 - Language was clarified regarding terminology for sites and sediment cleanup units and contaminants, as well as requirements that must be included in a report for a site or sediment cleanup unit.
 - o Some language in WAC 173-204-550 (7)(i) regarding sediment recovery zone requirements was moved to WAC 173-204-590.
- WAC 173-204-550(8) Sampling access was reinstated.

WAC 173-204-560:

In response to comments received, the following revisions were made:

- Clarified the process of adjusting the sediment cleanup standard upward from the SCO in WAC 173-204-560 (2)(a).
- Clarified that the criterion for higher trophic level species is the no adverse effects level in WAC 173-204-560 (3)(a) and (4)(a).
- Added provisions for regional background in areas where regional background has not been established in WAC 173-204-560(5).
- Clarified the definition of point of compliance in WAC 173-204-560(6).
- Added provisions for compliance monitoring that included area-averaging approaches in WAC 173-204-560(7).

To meet the intent of the authorizing statute, the applicability of Part V in determining cleanup standards was clarified in WAC 173-204-560(1).

WAC 173-204-561:

In response to comments received, the following revisions were made:

- The proposed rule language has been revised to clarify when other factors may be considered when establishing the default reasonable maximum exposure scenario in WAC 173-204-561 (2)(b)(i).
- The "size of the site relative to the fish and shellfish home range" factor has been clarified in WAC 173-204-561 (2)(b)(i)(D) to better reflect its original intent.

WAC 173-204-562:

The following revisions between the proposed and adopted rule amendments were made to clarify and remove inconsistencies between the text and tables in the rule in response to public comment:

- The titles and legends of Tables IV, V, and VI were clarified and corrected.
- Table numbers IV, V and VI were changed to III, IV, and V respectively.
- The benthic abundance criteria were removed from the text in WAC 173-204-562 (3)(b) and added to Table IV to be consistent with the other biological criteria that are in tabular format.

[5] Permanent

- The benthic abundance performance standards were added to the legend of Table IV to be consistent with WAC 173-204-563.
- A performance standard for the larval tests was added to Table IV.
- The equations for the biological criteria in Table IV were updated to commonly used terminology.

The following revisions between the proposed and adopted rule amendments were made based on internal review to clarify and remove inconsistencies between the text and tables in the rule or to be consistent with WAC 173-204-563 provisions:

- To reflect current policy and be consistent with WAC 173-204-563, the confirmatory designation provision was clarified in WAC 173-204-562 (3)(c)(i) to state that any person may perform biological testing to confirm toxicity.
- The "other toxic, radioactive, biological, and deleterious substances" provision in WAC 173-204-562(4) was revised to clarify how to assess toxicity and to include chemicals not in Table V to clarify the intent, reflect current policy, and be consistent with WAC 173-204-563.

WAC 173-204-563:

The following revisions were made in response to comments received to clarify and remove inconsistencies between the text and tables:

- Dry weight normalization was clarified in the text in WAC 173-204-563 (2)(g) and Table VI.
- The benzofluoranthenes criterion was clarified in WAC 173-204-563 (2)(i).
- The explanation of ">" (greater than) values in WAC 173-204-563 (2)(n) was revised to clarify that the CSL is not known but concentrations above the SCO are at the minor adverse effects level.
- Language was revised in WAC 173-204-563 (2)(o) to better define what types of freshwater environments may require alternate technical methods to be used and what types of alternate methods shall be used.
- The CSL criterion for endrin ketone was changed from 0 to >8.5 to differentiate this level from the SCO and for consistency with the technical report. The proposed rule language had a typographical error.
- The titles and legends of Tables VI, VII, and VIII were clarified and corrected.
- The equations for the biological criteria in Table VIII were updated to commonly used terminology.

The following revisions were made for clarity and consistency based on internal review:

- Table numbers VII, VIII, and IX have [been] renumbered to VI, VII, and VIII, respectively.
- The confirmatory designation provision was clarified to state that any person may perform biological testing to confirm toxicity to reflect current policy and be consistent with WAC 173-204-562.

The "other toxic, radioactive, biological and deleterious substances" provision was revised to clarify how to assess toxicity and include chemicals not listed in Table VI to clarify the intent, reflect current policy, and be consistent with WAC 173-204-562.

WAC 173-204-564:

The following revision was made to clarify and meet the intent of the rule language:

The rule language was revised to clarify that sediment cleanup levels must be established at the "no adverse effects" level in WAC 173-204-564(2) to be consistent with the intent of the proposed rule language.

The following revisions were made in response to public comment:

- The language that specified what "no adverse effects" meant for endangered or protected species was removed.
- Language was added regarding coordination with state and federal agencies as appropriate in WAC 173-204-564 (2)(d) to acknowledge the role of other agencies in the cleanup process such as consultation with appropriate agencies for endangered or protected species.

WAC 173-204-570:

In response to comments received, the following revisions were made:

- WAC 173-204-570(3) Minimum requirement for sediment cleanup actions:
 - o Shortened language stating a preference for alternatives with a shorter restoration time frame
 - Clarified language regarding discharges and source control.
 - Changed language on passive cleanup actions from "not rely primarily" to "not rely exclusively" on monitored natural recovery and institutional controls and monitoring.
 - o Added consideration of land use classifications.
 - Added language to clarify public participation requirements.
 - o Clarified periodic review requirements.
- WAC 173-204-570(4) Using permanent solutions to the maximum extent practicable:
 - o Clarified the requirements for assessing whether a cleanup action is permanent to the maximum extent practicable, consistent with MTCA requirements.
 - Specified the requirements and preferred cleanup technologies for assessing long-term effectiveness.
- WAC 173-204-570(5) Providing a reasonable restoration time frame:
 - o Added a presumption that a reasonable restoration time frame is met if cleanup standards are met within ten years of completion of construction of the active components of a cleanup

Permanent [6]

- action. This was changed from the "start" of construction.
- o Clarified when a sediment recovery zone is required to be issued by the department.
- Added that preference shall be given to alternatives that achieve sediment cleanup standards at the site or sediment cleanup unit more quickly.
- o Added consideration of land use classifications.
- Added source control effectiveness.

WAC 173-204-575:

To ensure clarity and consistency the following revisions were made:

- The MTCA law was specified as the administrative authority.
- Terminology was changed from "cleanup action" to "remedial action" and from "chapter" to "part."
- Ecology's expectations were clarified for when other authorities are used to conduct cleanup.
- WAC 173-204-580 was changed to WAC 173-204-575.

WAC 173-204-590:

In response to comments received, and to ensure clarity and consistency based on internal review, the following revisions were made:

- Clarified when a sediment recovery zone (SRZ) is required to be issued by ecology.
- Additions to WAC 173-204-590(2) General requirements:
 - Indicated where the SRZ requirements are described.
 - o Stated when and how adjustments or extensions can be made to the SRZ.
- Additions to WAC 173-204-590(3) Criteria:
 - Added human health effects as factors to consider.
 - Added future uses and land use classifications as factors to consider.
- Additions to WAC 173-204-590(4) Duration:
 - o Clarified that the potentially liable person must submit an application for an extension.
 - o Added automatic enforceability when an SRZ is expiring.
- Added clarification of types of monitoring.
- Included affected tribes in public involvement.

A final cost-benefit analysis is available by contacting Adrienne Dorrah, Department of Ecology, P.O. Box 47600, Olympia, WA 98504, phone (360) 407-7195, fax (360) 407-7154, e-mail adrienne.dorrah@ecy.wa.gov.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at Request of a Nongovernmental Entity: New 4, Amended 5, Repealed 0.

Number of Sections Adopted on the Agency's Own Initiative: New 4, Amended 21, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 4, Amended 21, Repealed 0.

Number of Sections Adopted Using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 0, Repealed 0.

Date Adopted: February 22, 2013.

Maia D. Bellon Director

<u>AMENDATORY SECTION</u> (Amending WSR 96-02-058, filed 12/29/95, effective 1/29/96)

WAC 173-204-100 Authority and purpose. (1) This chapter is promulgated under the authority of chapter 90.48 RCW, the Water Pollution Control Act; chapter 70.105D RCW, the Model Toxics Control Act; chapter 90.70 RCW, the Puget Sound Water Quality Authority Act; chapter 90.52 RCW, the Pollution Disclosure Act of 1971; chapter 90.54 RCW, the Water Resources Act of 1971; and chapter 43.21C RCW, the state Environmental Policy Act, to establish marine, low salinity and freshwater surface sediment management standards for the state of Washington.

- (2) The purpose of this chapter is to reduce and ultimately eliminate adverse effects on biological resources and significant health threats to humans from surface sediment contamination by:
- (a) Establishing standards for the quality of surface sediments:
- (b) Applying these standards as the basis for management and reduction of pollutant discharges; and
- (c) Providing a management and decision process for the cleanup of contaminated sediments.
- (3) Part III, Sediment quality standards of this chapter provides chemical concentration criteria, biological effects criteria, human health criteria, and other toxic, radioactive, biological, or deleterious substances criteria which identify surface sediments that have no adverse effects, including no acute or chronic adverse effects on biological resources and no significant health risk to humans, as defined in this regulation. The sediment quality standards provide a regulatory and management goal for the quality of sediments throughout the state.
- (4) The sediment criteria of WAC 173-204-320 through 173-204-340 shall constitute surface sediment quality standards and be used to establish an inventory of surface sediment sampling stations where the sediments samples taken from these stations are determined to pass or fail the applicable sediment quality standards.
- (5) Part IV, Sediment source control standards of this chapter shall be used as a basis for controlling the effects of point and nonpoint source discharges to sediments through the National Pollutant Discharge Elimination System (NPDES) federal permit program, state water quality management permit programs, issuance of administrative orders or other means determined appropriate by the department. The source control standards establish discharge sediment monitoring requirements and criteria for establishment and maintenance of sediment impact zones.

[7] Permanent

- (6) Part V, Sediment cleanup standards of this chapter establishes administrative procedural requirements and criteria to identify, screen, ((rank)) evaluate and prioritize, and cleanup contaminated surface sediment sites. The sediment cleanup standards of WAC 173-204-500 through 173-204-590 shall be used pursuant to ((authorities)) authority established under chapter((s 90.48 and)) 70.105D RCW.
- (7) This chapter establishes and defines a goal of minor adverse effects as the maximum level of sediment contamination allowed in sediment impact zones under the provisions of Part IV, Sediment source control standards and as the cleanup screening levels for identification of sediment cleanup sites and as the minimum cleanup levels to be achieved in all cleanup actions under Part V, Sediment cleanup standards.
- (8) Local ordinances establishing requirements for the designation and management of marine, low salinity and freshwater sediments shall not be less stringent than this chapter.

Note:

All codes, standards, statutes, rules or regulations cited in this chapter are available for inspection at the Department of Ecology, P.O. Box 47703, Olympia, Washington 98504-7703

<u>AMENDATORY SECTION</u> (Amending Order 90-41, filed 3/27/91, effective 4/27/91)

- **WAC 173-204-110 Applicability.** (1) The sediment quality standards of WAC 173-204-300 through 173-204-315, and 173-204-350, and the sediment cleanup standards of WAC 173-204-500 through ((173-204-580)) 173-204-575 shall apply to all surface sediments.
- (2) The sediment quality standards of WAC 173-204-320, 173-204-330, and 173-204-340 and the applicable sediment cleanup standards of WAC 173-204-560 shall apply to marine, low salinity and freshwater surface sediments, respectively.
- (3) The source control standards of WAC 173-204-400 through 173-204-420 shall apply to each person's actions which exposes or resuspends surface sediments which exceed, or otherwise cause or potentially cause surface sediments to exceed, the applicable standards of WAC 173-204-320 through 173-204-340.
- (4) The sediment recovery zone standards of WAC 173-204-590 shall apply to each person's cleanup action decision made pursuant to WAC ((173-204-580)) 173-204-570 and 173-204-575 where the selected cleanup action leaves in place marine, low salinity, or freshwater sediments that exceed the applicable sediment ((quality)) cleanup standards of WAC ((173-204-320 through 173-204-340)) 173-204-560.
- (5) The sediment quality standards of WAC 173-204-320 through 173-204-340 shall not apply:
- (a) Within a sediment impact zone as authorized by the department under WAC 173-204-415; or
- (b) Within a sediment recovery zone as authorized by the department under WAC 173-204-590; or
 - (c) To particulates suspended in the water column; or
- (d) To particulates suspended in a permitted effluent discharge: or
 - (e) To Part V of this chapter.

(6) Nothing in this chapter shall constrain the department's authority to make appropriate sediment management decisions on a case-specific basis using best professional judgment and latest scientific knowledge for cases where the standards of this chapter are reserved or standards are not available.

AMENDATORY SECTION (Amending WSR 96-02-058, filed 12/29/95, effective 1/29/96)

- WAC 173-204-130 Administrative policies. The department shall implement this chapter in accordance with the following policies:
- (1) The department shall seek to implement, and as necessary modify this chapter to protect biological resources and human health consistent with WAC 173-204-100(2). To implement the intent of this subsection, the department shall use methods that accurately reflect the latest scientific knowledge consistent with the definitions contained in WAC 173-204-200 (((14) and (15))) and 173-204-505, as applicable.
- (2) At the interface between surface sediments, groundwater or surface water, the applicable standards shall depend on which beneficial use is or could be adversely affected, as determined by the department. If beneficial uses of more than one resource are affected, the most restrictive standards shall apply.
- (3) It shall be the goal of the department to modify this chapter so that methods such as confirmatory biological tests, sediment impact zone models, use of contaminated sediment site ((ranking)) models, etc., continue to accurately reflect the latest scientific knowledge as established through ongoing validation and refinement.
- (4) Any person or the department may propose an alternate technical method to replace or enhance the application of a specific technical method required under this chapter. Using best professional judgment, the department shall provide advance review and approval of any alternate technical method proposed prior to its application. Application and use of alternate technical methods shall be allowed when the department determines that the technical merit of the resulting decisions will improve the department's ability to implement and meet the intent of this chapter as described in WAC 173-204-100(2), and will remain consistent with the scientific intent of definitions contained in WAC 173-204-200 (((14) and (15))) and 173-204-505. The department shall maintain a record of the department's decisions concerning application for use of alternate technical methods pursuant to this subsection. The record shall be made available to the public on request.
- (5) Intergovernmental coordination. The department shall ensure appropriate coordination and consultation with federally recognized Indian tribes and local, state, and federal agencies to provide information on and to implement this chapter.
- (6) The department shall conduct an annual review of this chapter, and modify its provisions every three years, or as necessary. Revision to this chapter shall be made pursuant to the procedures established within chapter 34.05 RCW, the Administrative Procedure Act.

Permanent [8]

- (7) Review of scientific information. When evaluating this chapter for necessary revisions, the factors the department shall consider include:
- (a) New or additional scientific information which is available relating surface sediment chemical quality to acute or chronic adverse effects on biological resources as defined in WAC 173-204-200 (1) and (7);
- (b) New or additional scientific information which is available relating human health risk to marine, low salinity, or freshwater surface sediment chemical contaminant levels;
- (c) New or additional scientific information which is available relating levels of other toxic, radioactive, biological and deleterious substances in marine, low salinity, or freshwater sediments to acute or chronic adverse effects on biological resources, or to a significant health risk to humans;
- (d) New state or federal laws which have established environmental or human health protection standards applicable to surface sediment; or
- (e) Scientific information which has been identified for addition, modification or deletion by a scientific review process established by the department.
- (8) Public involvement and education. The goal of the department shall be to provide timely information and meaningful opportunities for participation by the public in the annual review conducted by the department under subsection (6) of this section, and any modification of this chapter. To meet the intent of this subsection the department shall:
- (a) Provide public notice of the department's decision regarding the results of its annual review of this chapter, including:
- (i) The department's findings for the annual review factors identified in subsection (7) of this section;
- (ii) The department's decision regarding the need for modification of this chapter based on its annual review; and
- (iii) Identification of a time period for public opportunity to comment on the department's findings and decisions pursuant to this subsection.
- (b) Provide public notice by mail or by additional procedures determined necessary by the department which may include:
 - (i) Newspaper publication;
 - (ii) Other news media;
 - (iii) Press releases;
 - (iv) Fact sheets;
 - (v) Publications;
 - (vi) Any other method as determined by the department.
- (c) Conduct public meetings as determined necessary by the department to educate and inform the public regarding the department's annual review determinations and decisions.
- (d) Comply with the rule making and public participation requirements of chapter 34.05 RCW, the Administrative Procedure Act, for any revisions to this chapter.
- (9) Test sediments evaluated for compliance with the sediment quality standards of WAC 173-204-320 through 173-204-340 and/or the sediment impact zone maximum criteria of WAC 173-204-420 and/or the sediment cleanup ((sereening levels eriteria)) standards of WAC ((173-204-520)) 173-204-560 shall be sampled and analyzed using the Puget Sound Protocols or other methods approved by the department. Determinations made pursuant to this chapter

- shall be based on sediment chemical and/or biological data that were developed using an appropriate quality assurance/ quality control program, as determined by the department.
- (10) The statutory authority for decisions under this chapter shall be clearly stated in the decision documents prepared pursuant to this chapter. The department shall undertake enforcement actions consistent with the stated authority under which the action is taken. The process for judicial review of these decisions shall be pursuant to the statutes under which the action is being taken.
- (11) When the department identifies this chapter as an applicable, or relevant and appropriate requirement for a federal cleanup action under the Comprehensive Environmental Response, Compensation and Liability Act, the department shall identify the entire contents of this chapter as the appropriate state requirement.

AMENDATORY SECTION (Amending WSR 96-02-058, filed 12/29/95, effective 1/29/96)

- **WAC 173-204-200 Definitions.** For the purpose of this chapter, the following definitions shall apply <u>unless the context indicates otherwise:</u>
- (1) "Acute" means measurements of biological effects using surface sediment bioassays conducted for time periods that are relatively short in comparison to the life cycle of the test organism. Acute effects may include mortality, larval abnormality, or other endpoints determined appropriate by the department.
- (2) "Amphipod" means crustacean of the Class Amphipoda, e.g., Rhepoxynius abronius, Ampelisca abdita, ((or)) Eohaustorius estuarius, or Hyalella azteca.
- (3) "Appropriate biological tests" means only tests designed to measure directly, or through established predictive capability, biologically significant adverse effects to the established or potential benthic or aquatic resources at a given location, as determined by rule by the department.
- (4) "Beneficial uses" means uses of waters of the state which include, but are not limited to, use for domestic, stock watering, industrial, commercial, agricultural, irrigation, mining, fish and wildlife maintenance and enhancement, recreation, generation of electric power, and preservation of environmental and aesthetic values, and all other uses compatible with the enjoyment of the public waters of the state.
- (5) "Best management practices" or "BMPs" means schedules of activities, prohibitions of practices, maintenance procedures, and other management practices to prevent or reduce the pollution of surface sediments of the state. BMPs also include treatment requirements, operating procedures and practices to control plant site runoff, spillage or leaks, sludge or water disposal, or drainage from raw material storage
- (6) "Bioassay" means a test procedure that measures the response of living plants, animals, or tissues to a sediment sample.
- (7) "Chronic" means measurements of biological effects using sediment bioassays conducted for, or simulating, prolonged exposure periods of not less than one complete life cycle, evaluations of indigenous field organisms for long-term effects, assessment of biological effects resulting from

[9] Permanent

bioaccumulation and biomagnification, and/or extrapolated values or methods for simulating effects from prolonged exposure periods. Chronic effects may include mortality, reduced growth, impaired reproduction, histopathological abnormalities, adverse effects to birds and mammals, or other endpoints determined appropriate by the department.

- (8) "Contaminated sediment" means surface sediments ((designated under the procedures of WAC 173-204-310 as)) exceeding the applicable sediment quality standards ((of)) in WAC 173-204-320 through 173-204-340 or the applicable sediment cleanup standards in WAC 173-204-560.
- (9) "Control sediment sample" means a surface sediment sample which is relatively free of contamination and is physically and chemically characteristic of the area from which bioassay test animals are collected. Control sediment sample bioassays provide information concerning a test animal's tolerance for stress due to transportation, laboratory handling, and bioassay procedures. Control sediment samples cannot exceed the applicable sediment quality standards of WAC 173-204-320 through 173-204-340 or the applicable criteria in WAC 173-204-562 and 173-204-563.
 - (10) "Department" means the department of ecology.
- (11) "Freshwater sediments" means surface sediments in which the sediment pore water contains less than or equal to 0.5 parts per thousand salinity.
- (12) "Low salinity sediments" means surface sediments in which the sediment pore water contains greater than 0.5 parts per thousand salinity and less than 25 parts per thousand salinity.
- (13) "Marine finfish rearing facilities" ((shall)) means those private and public facilities located within state waters where finfish are fed, nurtured, held, maintained, or reared to reach the size of release or for market sale.
- (14) "Marine sediments" means surface sediments in which the sediment pore water contains 25 parts per thousand salinity or greater.
- (15) "Minor adverse effects" means a level of effects that:
- (a) Has been determined by rule by the department, except in cases subject to WAC 173-204-110(6); and
 - (b) Meets the following criteria:
- (i) An acute or chronic adverse effect to biological resources as measured by a statistically and biologically significant response relative to reference or control, as appropriate, in no more than one appropriate biological test as defined in WAC 173-204-200(3); or
- (ii) A statistically and biologically significant response that is significantly elevated relative to reference <u>or control</u>, <u>as appropriate</u>, in any appropriate biological test as defined in WAC 173-204-200(3); or
- (iii) Biological effects per (b)(i) or (ii) of this subsection as predicted by exceedance of an appropriate chemical or other deleterious substance standard, except where the prediction is overridden by direct biological testing evidence pursuant to (b)(i) and (ii) of this subsection; and
- (c) Does not result in significant human health risk as predicted by exceedance of an appropriate chemical, biological, or other deleterious substance standard.

- (16) "No adverse effects" means a level of effects that:
- (a) Has been determined by rule by the department, except in cases subject to WAC 173-204-110(6); and
 - (b) Meets the following biological criteria:
- (i) No acute or chronic adverse effects to biological resources as measured by a statistically and biologically significant response relative to reference or control, as appropriate, in any appropriate biological test as defined in WAC 173-204-200(3); and
- (ii) No acute or chronic adverse biological effect per (b)(i) of this subsection as predicted by exceedance of an appropriate chemical or other deleterious substance standard, except where the prediction is overridden by direct biological testing evidence pursuant to (b)(i) of this subsection; and
- (iii) Does not result in significant human health risk as predicted by exceedance of an appropriate chemical, biological, or other deleterious substance standard.
- (17) "Other toxic, radioactive, biological, or deleterious substances" means, except for purposes of Part V of this chapter, contaminants which are not specifically identified in the sediment quality standards chemical criteria of WAC 173-204-320 through 173-204-340 (e.g., organic debris, tributyltin, DDT, etc.).
- (18) "Person" means an individual, firm, corporation, association, partnership, consortium, joint venture, commercial entity, industry, private corporation, port district, special purpose district, irrigation district, unit of local government, state government agency, federal government agency, Indian tribe, or any other entity whatsoever.
- (19) "Practicable" means, except for purposes of Part V of this chapter, able to be completed in consideration of environmental effects, technical feasibility and cost.
 - (20) "Puget Sound basin" or "Puget Sound" means:
- (a) Puget Sound south of Admiralty Inlet, including Hood Canal and Saratoga Passage;
- (b) The waters north to the Canadian border, including portions of the Strait of Georgia;
- (c) The Strait of Juan de Fuca south of the Canadian border: and
- (d) All the lands draining into these waters as mapped in water resources inventory areas numbers 1 through 19, set forth in water resources management program established pursuant to the Water Resources Act of 1971, chapter 173-500 WAC.
- (21) "Puget Sound protocols" means Puget Sound Estuary Program. 1986. As amended. Recommended Protocols for Measuring Selected Environmental Variables in Puget Sound, U.S. Environmental Protection Agency, Region 10, Seattle, WA (looseleaf).
- (22) "Reference sediment sample" means a surface sediment sample which serves as a laboratory indicator of a test animal's tolerance to important natural physical and chemical characteristics of the sediment, e.g., grain size, organic content. Reference sediment samples represent the nonanthropogenically affected background surface sediment quality of the sediment sample. Reference sediment samples cannot exceed the applicable sediment quality standards of WAC 173-204-320 through 173-204-340 or the applicable criteria of WAC 173-204-562 and 173-204-563.

Permanent [10]

- (23) "Sediment impact zone" means an area where the applicable sediment quality standards of WAC 173-204-320 through 173-204-340 are exceeded due to ongoing permitted or otherwise authorized wastewater, storm water, or nonpoint source discharges and authorized by the department within a federal or state wastewater or storm water discharge permit, or other formal department authorization.
- (24) (("Sediment recovery zone" means an area where the applicable sediment quality standards of WAC 173 204-320 through 173-204-340 are exceeded as a result of historical discharge activities, and authorized by the department as a result of a cleanup decision made pursuant to WAC 173-204-580, Cleanup action decision.
- (25) "Siteunits" means discrete subdivisions of an individual contaminated sediment site that are being evaluated for the purpose of establishing cleanup standards. Site units are based on consideration of unique locational, environmental, spatial, or other conditions determined appropriate by the department, e.g., cleanup under piers, cleanup in eelgrass beds, cleanup in navigational lanes.
- (26))) "Surface sediments" or "sediment(s)" means, except for purposes of Part V of this chapter, settled particulate matter located in the predominant biologically active aquatic zone, or exposed to the water column. Sediment(s) also includes settled particulate matter exposed by human activity (e.g., dredging) to the biologically active aquatic zone or to the water column.
- (((27))) (25) "Test sediment" means a sediment sample that is evaluated for compliance with the sediment quality standards of WAC 173-204-320 through 173-204-340 ((and/or)), the sediment impact zone maximum criteria of WAC 173-240-420, ((and/)) or the ((eleanup screening levels)) applicable criteria of WAC ((173-204-520)) 173-204-560.

<u>AMENDATORY SECTION</u> (Amending Order 90-41, filed 3/27/91, effective 4/27/91)

WAC 173-204-310 Sediment quality standards desig**nation procedures.** Any person may use these procedures to determine a sediment's designation using the applicable sediment quality standards of WAC 173-204-320 through 173-204-340. Any person who designates test sediments using the procedures of this section shall meet the sampling and testing plan requirements of WAC 173-204-600 and records management requirements of WAC 173-204-610. Test sediments designated using the procedures of this section shall be sampled and analyzed using the Puget Sound protocols or other methods approved by the department, and shall use an appropriate quality assurance/quality control program, as determined by the department. A sediment sample that passes the initial designation procedures is designated as complying with the applicable sediment quality standards of WAC 173-204-320 through 173-204-340, until such time as any person or the department confirms the sediment designation as failing the applicable sediment quality standards of WAC 173-204-320 through 173-204-340. A sediment sample that fails the initial designation procedures is designated as not complying with the applicable sediment quality standards of WAC 173-204-320 through 173-204-340, until such time as

- any person or the department confirms the sediment designation as passing the applicable sediment quality standards of WAC 173-204-320 through 173-204-340. A sediment sample that passes or fails the confirmatory designation procedures is designated as such under the procedures of WAC 173-204-310. Sediments shall be designated with the applicable sediment quality standards of WAC 173-204-320 through 173-204-340 as follows:
- (1) Initial designation. Sediments that have been chemically analyzed for the applicable chemical concentration criteria of WAC 173-204-320 through 173-204-340 shall be designated as follows:
- (a) Sediments with chemical concentrations equal to or less than all the applicable chemical and human health criteria are designated as having no adverse effects on biological resources, and not posing a significant health threat to humans, and pass the applicable sediment quality standards of WAC 173-204-320 through 173-204-340.
- (b) Sediments with chemical concentrations which exceed any one applicable chemical or human health criterion in WAC 173-204-320 through 173-204-340 are designated as having adverse effects on biological resources or posing significant human health threats, and fail the sediment quality standards of WAC 173-204-320 through 173-204-340, pending confirmatory designation.
- (2) Confirmatory designation. Any person or the department may confirm the designation of sediments which have either passed or failed initial designation procedures listed in subsection (1) of this section using the applicable biological testing of WAC 173-204-315, as required below. Sediment samples that pass all the required confirmatory biological tests are designated as passing the applicable sediment quality standards of WAC 173-204-320 through 173-204-340, notwithstanding the sediment's previous initial designation under subsection (1) of this section. Any sediment sample which fails any one of the required confirmatory biological tests shall be designated as failing the applicable sediment quality standards of WAC 173-204-320 through 173-204-340, notwithstanding the sediment's previous initial designation under subsection (1) of this section. The confirmatory biological test standards are described below.
- (a) To confirm the designation of a sediment which either passed or failed any applicable chemical concentration criterion established in WAC 173-204-320 through 173-204-340, the sediment shall be tested for:
- (i) Two of the acute effects biological tests described in the applicable standards of WAC 173-204-315; and
- (ii) One of the chronic effects biological tests described in the applicable standards of WAC 173-204-315.
- (b) Sediments with chemical concentrations which either passed or failed any applicable human health criterion of WAC 173-204-320 through 173-204-340 shall be eligible for confirmatory designation as follows: Reserved: The department shall determine on a case-by-case basis the criteria, methods, and procedures necessary to meet the intent of this chapter.
- (3) Initial and confirmatory designation of sediments which contain other toxic, radioactive, biological, or deleterious substances. Sediments which contain other toxic, radioactive, biological, or deleterious substances, as defined in

[11] Permanent

CHEMICAL

PARAMETER

1,4-DICHLOROBENZENE

WAC 173-204-200($(\frac{(16)}{)}$)) $(\underline{17}$), shall be designated by the department using the following procedures.

- (a) The department shall:
- (i) Identify individual contaminants of concern;
- (ii) Identify appropriate and practicable sampling and analysis methodologies;
- (iii) Identify test interpretation standards for initial and confirmatory designation; and
- (iv) Identify acceptable levels of sediment contamination for sediments which contain other toxic, radioactive, biological, or deleterious substances.
- (b) Where sediment containing other toxic, radioactive, biological or deleterious substances may also be contaminated by chemicals identified in WAC 173-204-320 through 173-204-340, the department shall require application of the appropriate tests and standards of WAC 173-204-320 through 173-204-340, as determined by the department, in addition to any requirements developed pursuant to (a) of this subsection
- (c) The department may use all or some of the sediment biological tests of WAC 173-204-320 through 173-204-340 to designate sediments with other toxic, radioactive, biological or deleterious substances in cases where those tests are technically appropriate, as determined by the department.

AMENDATORY SECTION (Amending WSR 96-02-058, filed 12/29/95, effective 1/29/96)

WAC 173-204-320 Marine sediment quality standards. (1) Goal and applicability.

- (a) The sediment quality standards of this section shall correspond to a sediment quality that will result in no adverse effects, including no acute or chronic adverse effects on biological resources and no significant health risk to humans.
- (b) The marine sediment quality standards of this section shall apply to marine sediments located within Puget Sound as defined in WAC 173-204-200(((19))) (20).
- (c) Non-Puget Sound marine sediment quality standards. Reserved: The department shall determine on a case-by-case basis the criteria, methods, and procedures necessary to meet the intent of this chapter.
- (2) Chemical concentration criteria. The chemical concentrations in Table I establish the marine sediment quality standards chemical criteria for designation of sediments.
- (a) Where laboratory analysis indicates a chemical is not detected in a sediment sample, the detection limit shall be reported and shall be at or below the Marine Sediment Quality Standards chemical criteria value set in this table.
- (b) Where chemical criteria in this table represent the sum of individual compounds or isomers, the following methods shall be applied:
- (i) Where chemical analyses identify an undetected value for every individual compound/isomer then the single highest detection limit shall represent the sum of the respective compounds/isomers; and
- (ii) Where chemical analyses detect one or more individual compound/isomers, only the detected concentrations will be added to represent the group sum.
- (c) The listed chemical parameter criteria represent concentrations in parts per million, "normalized," or expressed,

- on a total organic carbon basis. To normalize to total organic carbon, the dry weight concentration for each parameter is divided by the decimal fraction representing the percent total organic carbon content of the sediment.
- (d) The LPAH criterion represents the sum of the following "low molecular weight polynuclear aromatic hydrocarbon" compounds: Naphthalene, Acenaphthylene, Acenaphthene, Fluorene, Phenanthrene, and Anthracene. The LPAH criterion is not the sum of the criteria values for the individual LPAH compounds as listed.
- (e) The HPAH criterion represents the sum of the following "high molecular weight polynuclear aromatic hydrocarbon" compounds: Fluoranthene, Pyrene, Benz(a)anthracene, Chrysene, Total Benzofluoranthenes, Benzo(a)pyrene, Indeno(1,2,3,-c,d)pyrene, Dibenzo(a,h)anthracene, and Benzo(g,h,i)perylene. The HPAH criterion is not the sum of the criteria values for the individual HPAH compounds as listed.
- (f) The TOTAL BENZOFLUORANTHENES criterion represents the sum of the concentrations of the "B," "J," and "K" isomers

Table I

Marine Sediment Quality Standards—
Chemical Criteria

MG/KG DRY WEIGHT

(PARTS PER MILLION (PPM) DRY)

3.1

	· , , ,
ARSENIC	57
CADMIUM	5.1
CHROMIUM	260
COPPER	390
LEAD	450
MERCURY	0.41
SILVER	6.1
ZINC	410
CHEMICAL	MG/KG ORGANIC CARBON
PARAMETER	(PPM CARBON)
LPAH	370
NAPHTHALENE	99
ACENAPHTHYLENE	66
ACENAPHTHENE	16
FLUORENE	23
PHENANTHRENE	100
ANTHRACENE	220
2-METHYLNAPHTHALENE	38
HPAH	960
FLUORANTHENE	160
PYRENE	1000
BENZ(A)ANTHRACENE	110
CHRYSENE	110
TOTAL BENZOFLUORANTHENI	ES 230
BENZO(A)PYRENE	99
INDENO (1,2,3,-C,D) PYRENE	34
DIBENZO (A,H) ANTHRACENE	12
BENZO(G,H,I)PERYLENE	31
1,2-DICHLOROBENZENE	2.3

Permanent [12]

CHEMICAL PARAMETER	MG/KG ORGANIC CARBON (PPM CARBON)		
1,2,4-TRICHLOROBENZENE	0.81		
HEXACHLOROBENZENE	0.38		
DIMETHYL PHTHALATE	53		
DIETHYL PHTHALATE	61		
DI-N-BUTYL PHTHALATE	220		
BUTYL BENZYL PHTHALATE	4.9		
BIS (2-ETHYLHEXYL) PHTHALA	TE 47		
DI-N-OCTYL PHTHALATE	58		
DIBENZOFURAN	15		
HEXACHLOROBUTADIENE	3.9		
N-NITROSODIPHENYLAMINE	11		
TOTAL PCB'S	12		

CHEMICAL	UG/KG DRY WEIGHT		
PARAMETER	(PARTS PER BILLION (PPB) DRY)		
PHENOL	420		
2-METHYLPHENOL	63		
4-METHYLPHENOL	670		
2,4-DIMETHYL PHENOL	29		
PENTACHLOROPHENOL	360		
BENZYL ALCOHOL	57		
BENZOIC ACID	650		

- (3) Biological effects criteria. For designation of sediments pursuant to WAC 173-204-310(2), sediments are determined to have adverse effects on biological resources when any one of the confirmatory marine sediment biological tests of WAC 173-204-315(1) demonstrate the following results:
- (a) Amphipod: The test sediment has a higher (statistically significant, t test, $p \le 0.05$) mean mortality than the reference sediment and the test sediment mean mortality exceeds twenty-five percent, on an absolute basis.
- (b) Larval: The test sediment has a mean survivorship of normal larvae that is less (statistically significant, t test, $p \le 0.05$) than the mean normal survivorship in the reference sediment and the test sediment mean normal survivorship is less than eighty-five percent of the mean normal survivorship in the reference sediment (i.e., the test sediment has a mean combined abnormality and mortality that is greater than fifteen percent relative to time-final in the reference sediment).
- (c) Benthic abundance: The test sediment has less than fifty percent of the reference sediment mean abundance of any one of the following major taxa: Class Crustacea, Phylum Mollusca or Class Polychaeta, and the test sediment abundance is statistically different (t test, $p \le 0.05$) from the reference sediment abundance.
- (d) Juvenile polychaete: The test sediment has a mean individual growth rate of less than seventy percent of the reference sediment mean individual growth rate and the test sediment mean individual growth rate is statistically different (t test, $p \leq 0.05$) from the reference sediment mean individual growth rate.
- (e) Microtox: The mean light output of the highest concentration of the test sediment is less than eighty percent of the mean light output of the reference sediment, and the two

- means are statistically different from each other (t test, $p \le 0.05$).
- (4) Marine sediment human health criteria. Reserved: The department may determine on a case-by-case basis the criteria, methods, and procedures necessary to meet the intent of this chapter.
- (5) Marine sediment other toxic, radioactive, biological, or deleterious substances criteria. Other toxic, radioactive, biological or deleterious substances in, or on, sediments shall be at or below levels which cause no adverse effects in marine biological resources, and below levels which correspond to a significant health risk to humans, as determined by the department. The department shall determine on a case-by-case basis the criteria, methods, and procedures necessary to meet the intent of this chapter pursuant to WAC 173-204-310(3).
- (6) Nonanthropogenically affected sediment quality criteria. Whenever the nonanthropogenically affected sediment quality is of a lower quality (i.e., higher chemical concentrations, higher levels of adverse biological response, or posing a greater health threat to humans) than the applicable sediment quality standards assigned for said sediments by this chapter, the existing sediment chemical and biological quality shall be identified on an area-wide basis as determined by the department, and used in place of the sediment quality standards of WAC 173-204-320.

<u>AMENDATORY SECTION</u> (Amending Order 90-41, filed 3/27/91, effective 4/27/91)

WAC 173-204-350 Sediment quality standards inventory. (1) The department shall gather available data on sediments and produce an inventory of sediment sampling stations which pass or fail the applicable sediment quality standards of WAC 173-204-320 through 173-204-340. Sediment sampling stations which are evaluated for compliance with the sediment quality standards of WAC 173-204-320 through 173-204-340 and placed on the inventory shall be sampled and analyzed using the Puget Sound Protocols or other methods approved by the department, and shall use an appropriate quality assurance/quality control program, as determined by the department. The sediment quality standards inventory produced per this section shall be used by the department, and made available upon request to the public and other federal, state, and local agencies for the following uses:

- (a) To identify and target necessary source control activities, such as discharger monitoring, to eliminate adverse effects on biological resources and significant health threats to humans from sediment contamination;
- (b) To identify contaminated sediment cleanup sites per the procedures in WAC 173-204-500 through 173-204-590;
- (c) To establish sediment quality ambient monitoring program status and trends analyses and reports;
- (d) To identify the sediment quality of areas proposed for dredging, in-water construction, and other actions requiring federal, state, and/or local permits; and
- (e) To complete other uses consistent with the intent of this chapter, as determined by the department.

- (2) Sources of data. Sediment biological and chemical data shall be gathered by the department for review to produce and update the sediment quality inventory on a biennial basis. Data sources include, but are not limited to:
- (a) Sediment data collected by the department for the Puget Sound ambient monitoring program, compliance monitoring of permitted discharges, and special environmental investigations.
- (b) Sediment data submitted to the U.S. Army Corps of Engineers in support of dredging permit applications.
- (c) Sediment data collected to identify problem areas and needed source controls in Puget Sound as defined in WAC 173-204-200(((19))) (20), other marine waters, and all low salinity and freshwater areas in Washington state.
- (d) Sediment data used or collected in compliance with chapter 70.105D RCW, and the Model Toxics Control Act cleanup regulation, chapter 173-340 WAC.
- (e) Sediment data used or collected in compliance with the federal Comprehensive Environmental Response, Compensation and Liability Act.
- (f) Sediment data collected as a requirement of a National Pollutant Discharge Elimination System or state discharge permit.
 - (g) Sediment data derived from other studies including:
 - (i) Federally sponsored monitoring studies.
- (ii) Special monitoring studies conducted by local and municipal governments, or private industry.
- (iii) Data derived through Washington state department of natural resources administration of use authorizations.
- (3) The inventory shall be updated and made available to the public on a biennial basis.

AMENDATORY SECTION (Amending WSR 96-02-058, filed 12/29/95, effective 1/29/96)

WAC 173-204-410 Sediment quality goal and sediment impact zone applicability. (1) Goal and policies.

- (a) It is the established goal of the department to manage source control activities to reduce and ultimately eliminate adverse effects on biological resources and significant health threats to humans from sediment contamination.
- (b) The stated policy of the department shall be to only authorize sediment impact zones so as to minimize the number, size, and adverse effects of all zones, with the intent to eliminate the existence of all such zones whenever practicable. The department shall consider the relationship between environmental effects, technical feasibility and cost in determining whether it is practicable to minimize and/or eliminate sediment impact zones.
- (c) The department shall implement the standards of WAC 173-204-400 through 173-204-420 so as to prevent the creation of new contaminated sediment cleanup sites identified under WAC ((173-204-530(4)))) 173-204-520.
- (2) A sediment impact zone authorization issued by the department under the authority of chapter 90.48 RCW does not constitute authorization to trespass on lands not owned by the applicant. These standards do not address and in no way alter the legal rights, responsibilities, or liabilities of the permittee or landowner of the sediment impact zone for any applicable requirements of proprietary, real estate, tort,

- and/or other laws not directly expressed as a requirement of this chapter.
- (3) Except as identified in subsection (6)(d) of this section, any person may apply for a sediment impact zone under the following conditions:
- (a) The person's discharge is provided with all known, available and reasonable methods of prevention, control, and treatment, and meets best management practices as stipulated by the department; and
- (b) The person's discharge activity exposes or resuspends sediments which exceed, or otherwise cause or potentially cause sediments to exceed the applicable sediment quality standards of WAC 173-204-320 through 173-204-340, or the antidegradation policy standards of WAC 173-204-120 (1)(a) and (c) within a period of ten years from the later date of either the department's formal approval of the application for a sediment impact zone authorization or the starting date of the discharge.
- (4) The department shall only authorize sediment impact zones for permitted wastewater and storm water discharges, and other discharges authorized by the department. The department shall authorize all sediment impact zones via discharge permits or other formal administrative actions.
- (5) The department shall not limit the application, establishment, maintenance, or closure of an authorized sediment impact zone via consideration of sediment contamination determined by the department to be the result of unknown, unpermitted or historic discharge sources.
- (6) As determined necessary by the department, any person with a permitted discharge shall be required to meet the standards of WAC 173-204-400 through 173-204-420, as follows:
- (a) Any person with a new or existing permitted wastewater discharge shall be required to meet the standards of WAC 173-204-400 through 173-204-420;
- (b) Any person with a new or existing permitted industrial storm water discharge, regulated as process wastewater in National Pollutant Discharge Elimination System or state discharge permits, shall be required to meet the standards of WAC 173-204-400 through 173-204-420;
- (c) Any person with a new or existing permitted storm water or nonpoint source discharge, which fully uses all known, available and reasonable methods of prevention, control, and treatment, and best management practices as stipulated by the department at the time of the person's application for a sediment impact zone, shall be required to meet the standards of WAC 173-204-400 through 173-204-420;
- (d) Any person with a storm water discharge, existing prior to the adoption of this chapter, and determined by the department to not be fully using best management practices stipulated by the department at the time of the person's application for a permit from the department, shall be eligible for a sediment impact zone as follows:
- (i) The department shall issue sediment impact zone authorizations with requirements for application of best management practices stipulated by the department on an approved time schedule.
- (ii) Sediment impact zones authorized by the department for permitted storm water discharges under the applicability provisions of subsection (6)(d) of this section shall be subject

Permanent [14]

to cleanup action determinations made by the department pursuant to WAC 173-204-500 through 173-204-590 when the sediment impact zone maximum criteria of WAC 173-204-420 are exceeded within the authorized sediment impact

- (iii) The department shall identify and include best management practices required to meet the sediment impact zone design standards of WAC 173-204-415(4) as soon as practicable within sediment impact zone authorizations established for storm water discharges per WAC 173-204-410 (6)(d).
- (7) Dredged material and fill discharge activities subject to authorization under Section 401 of the federal Clean Water Act via chapter 90.48 RCW and chapter 173-225 WAC, establishment of implementation procedures of application for certification, are not subject to the standards of WAC 173-204-415 but are subject to the standards of WAC 173-204-400 through 173-204-410 and 173-204-420 as follows:
- (a) Requirements for dredging activities and disposal sites shall be established by the department using best available dredged material management guidelines and applicable federal and state rules. These guidelines shall include the Puget Sound dredged disposal analysis (PSDDA) dredged material testing and disposal requirements cited in:
- (i) Management Plan Report Unconfined Open-Water Disposal Of Dredged Material, Phase I, (Central Puget Sound), June 1988, or as amended;
- (ii) Management Plan Report Unconfined Open-Water Disposal Of Dredged Material, Phase II, (North And South Puget Sound), September 1989, or as amended; and
- (iii) Users Manual For Dredged Material Management In Puget Sound, November 1990, or as amended.
- (b) In coordination with other applicable federal and state and local dredged material management programs, the department may issue administrative orders to establish approved disposal sites, to specify disposal site use conditions, and to specify disposal site monitoring requirements.
- (c) The department may authorize sediment impact zones for dredged material disposal via federal Clean Water Act Section 401 certification actions.
- (d) As determined necessary by the department, the department may authorize sediment impact zones for dredged material disposal via administrative orders issued under authority of chapter 90.48 RCW. The department shall authorize sediment impact zones for all Puget Sound dredged disposal analysis disposal sites via administrative orders issued under authority of chapter 90.48 RCW.
- (e) Administrative orders and certifications establishing sediment impact zones for dredged material disposal sites shall describe establishment, maintenance, and closure requirements for the authorized site, consistent with the requirements described in (a) of this subsection.
- (8) The source control standards of WAC 173-204-400 through 173-204-420 are applicable in cases where the sediment quality standards of WAC 173-204-320 through 173-204-340 are reserved.

AMENDATORY SECTION (Amending WSR 96-02-058, filed 12/29/95, effective 1/29/96)

WAC 173-204-412 Marine finfish rearing facilities. (1) Purpose. This section sets forth the applicability of this chapter to marine finfish rearing facilities only. This section also identifies marine finfish rearing facility siting, operation,

closure and monitoring requirements to meet the intent of this

chapter, as applicable.

- (2) Applicability. Marine finfish rearing facilities and their associated discharges are not subject to the authority and purpose standards of WAC 173-204-100 (3) and (7), and the marine sediment quality standards of WAC 173-204-320 and the sediment impact zone maximum criteria of WAC 173-204-420, within and including the distance of one hundred feet from the outer edge of the marine finfish rearing facility structure. Marine finfish rearing facilities are not subject to the sediment impact zone standards of WAC 173-204-415.
- (3) Sediment monitoring. Sediment quality compliance and monitoring requirements for marine finfish rearing facilities shall be addressed through National Pollutant Discharge Elimination System or other permits issued by the department for facility operation. Marine finfish rearing facilities shall meet the following sediment quality monitoring requirements:
- (a) Any person with a new facility shall identify a baseline sediment quality prior to facility operation for benthic infaunal abundance, total organic carbon and grain size in the location of the proposed operation and downcurrent areas that may be potentially impacted by the facility discharge;
- (b) Any person with an existing operating facility shall monitor sediment quality for total organic carbon levels and identify the location of any sediments in the area of the facility statistically different (t test, $p \le 0.05$) from the total organic carbon levels identified as facility baseline levels or statistically different from the applicable total organic carbon levels as identified in Table 1:

TABLE 1 - Puget Sound Reference Total Organic Carbon Values

	values
Silt-Clay Particles	Total Organic Carbon (percent
(percent Dry Weight)	Dry Weight)
0-20	0.5
20-50	1.7
50-80	3.2
80-100	2.6

- (c) The locations and frequency of monitoring for total organic carbon, benthic infaunal abundance and other parameters shall be determined by the department and identified in the applicable National Pollutant Discharge Elimination System permit;
- (d) Antibacterials. Reserved: The department shall determine on a case-by-case basis the methods, procedure. locations, and frequency for monitoring antibacterials associated with the discharge from a marine finfish rearing facility;
- (e) Closure. All permitted marine finfish rearing facilities shall monitor sediments impacted during facility operation to document recovery of sediment quality to background

[15] Permanent levels. The department shall determine on a case-by-case basis the methods, procedure, locations, and frequency for monitoring sediments after facility closure.

- (4) Sediment impact zones. Marine finfish rearing facilities and their associated discharges that are permitted under a National Pollutant Discharge Elimination System permit are hereby provided a sediment impact zone by rule for any sediment quality impacts and biological effects within and including the distance of one hundred feet from the outer edge of the marine finfish rearing facility structure.
- (a) The department may authorize an individual marine finfish rearing facility sediment impact zone for any sediments beyond a distance of one hundred feet from the facility perimeter via National Pollutant Discharge Elimination System permits or administrative actions. The authorized sediment impact zone shall meet the benthic infaunal abundance requirements of the sediment impact zone maximum criteria, WAC 173-204-420 (3)(c)(iii). Marine finfish rearing facilities that exceed the sediment quality conditions of subsection (3)(b) of this section beyond a distance of one hundred feet from the facility perimeter shall:
- (i) Begin an enhanced sediment quality monitoring program to include benthic infaunal abundance consistent with the requirements of the National Pollutant Discharge Elimination System permit. The sediment quality monitoring program shall include a benthic infaunal abundance reference sediment sample as required in subsection (3)(a) of this section or a benthic infaunal abundance reference sediment sample in compliance with WAC 173-204-200(((21))) (22); and
- (ii) Be consistent with the sediment source control general considerations of WAC 173-204-400 and the sediment quality goal and sediment impact zone applicability requirements of WAC 173-204-410, apply for a sediment impact zone as determined necessary by the department.
- (b) Administrative orders or permits establishing sediment impact zones for marine finfish rearing facilities shall describe establishment, maintenance, and closure requirements as determined necessary by the department.

AMENDATORY SECTION (Amending WSR 96-02-058, filed 12/29/95, effective 1/29/96)

- WAC 173-204-415 Sediment impact zones. The purpose of this section is to set forth the standards for establishment, maintenance, and closure of sediment impact zones to meet the intent of sediment quality dilution zones authorized pursuant to RCW 90.48.520, except for sediment impact zones authorized under WAC 173-204-410(7). The department shall authorize all sediment impact zones via discharge permits or other formal administrative actions.
- (1) General requirements. Authorization, modification and renewal of a sediment impact zone by the department shall require compliance with the following general requirements:
- (a) Permits authorizing wastewater discharges to surface waters of the state of Washington under authority of chapter 90.48 RCW shall be conditioned so that the discharge receives:

- (i) All known, available and reasonable methods of prevention, control, and treatment prior to discharge, as required by chapters 90.48, 90.52, and 90.54 RCW; and
- (ii) Best management practices as stipulated by the department.
- (b) The maximum area, and maximum chemical contaminant concentration and/or allowable maximum biological effect level within sediments assigned to a sediment impact zone shall be as authorized by the department, in accordance with the standards of this section.
- (c) The department shall determine that the person's activity generating effluent discharges which require authorization of a sediment impact zone is in the public interest.
- (d) The department shall determine that any person's activity generating effluent discharges which require authorization of a sediment impact zone has adequately addressed alternative waste reduction, recycling, and disposal options through application of all known, available and reasonable methods of prevention, control, and treatment to minimize as best practicable the volume and concentration of waste contaminants in the discharge.
- (e) The area boundaries of the sediment impact zone established by the department shall include the minimum practicable surface area, not to exceed the surface area allowed under subsection (4) of this section.
- (f) Adverse effects to biological resources within an authorized sediment impact zone shall be maintained at the minimum chemical contamination and biological effects levels practicable at all times. The department shall consider the relationship between environmental effects, technical feasibility and cost in determining the minimum practicable chemical contamination and biological effects levels. Adverse effects to biological resources within an authorized sediment impact zone shall not exceed a minor adverse effects level as a result of the discharge, as determined by the procedures of subsection (4) of this section.
- (g) The operational terms and conditions for the sediment impact zone shall be maintained at all times.
- (h) Final closure of the sediment impact zone shall be conducted in strict accordance with the department's sediment impact zone authorization.
- (i) Documents authorizing a sediment impact zone shall require that the permitted discharge not result in a violation of the applicable sediment quality standards of WAC 173-204-320 through 173-204-340, outside the area limits of the established zone.
- (j) All applications to the department for sediment impact zone authorizations shall be subject to public notice, comment and hearing procedures defined but not limited to the applicable discharge permit or other formal administrative action requirements of chapter 43.21C RCW, the State Environmental Policy Act, chapter 197-11 WAC, SEPA rules, chapter 90.48 RCW, chapter 163-216 WAC, the State waste discharge permit program, and chapter 173-220 WAC, National Pollutant Discharge Elimination System Permit Program prior to issuance of the authorization. In determining the need for, location, and/or design of any sediment impact zone authorization, the department shall give consideration to all comments received during public review of the proposed sediment impact zone application.

Permanent [16]

- (2) Application requirements.
- (a) Whenever, in the opinion of the department, as a result of an ongoing or proposed effluent discharge, a person violates, shall violate, or creates a substantial potential to violate the sediment quality standards of WAC 173-204-320 through 173-204-340 as applicable within a period of ten years from the later date of either the department's evaluation of the ongoing discharge or the starting date of the proposed discharge, the department may require application for a sediment impact zone authorization under authority of chapter 90.48 RCW.
- (b) Any person with a proposed or permitted effluent discharge shall apply to the department for authorization of a sediment impact zone when:
- (i) The department requires the sediment impact zone application by written notification; or
- (ii) The person independently identifies that the ongoing or proposed effluent discharge violates, shall violate, or creates a substantial potential to violate the applicable sediment quality standards of WAC 173-204-320 through 173-204-340 within a period of ten years from the later date of the person's evaluation of the ongoing discharge or the starting date of the proposed discharge, using the procedures of this section.
- (c) As necessary, the department may require any person to submit a sediment impact zone application in multiple steps concurrent with its ongoing review and determination concerning the adequacy of the application. The application shall provide the sediment impact zone design information required in subsection (4) of this section and other such information the department determines necessary. The application shall also provide the legal location and landowner(s) of property proposed for use as, or potentially affected by, a sediment impact zone, and shall be accompanied by such other relevant information as the department may require. The department shall issue a written approval of the complete sediment impact zone application prior to or concurrent with authorizing a sediment impact zone.
- (d) Submittal of an application to the department for authorization of a sediment impact zone under the terms and conditions of this section shall establish the applicant's interim compliance with requirements of chapter 90.48 RCW and this chapter, as determined by the department. The department may authorize an interim compliance period within a valid discharge permit or administrative order to ensure ultimate compliance with chapter 90.48 RCW and this chapter. The interim compliance period shall not continue beyond the date of issuance of a sediment impact zone authorization within a valid discharge permit issued by the department.
- (e) Prior to authorization, the department shall make a reasonable effort to identify and notify all landowners, adjacent landowners, and lessees affected by the proposed sediment impact zone. The department shall issue a sediment impact zone notification letter to any person it believes to be a potentially affected landowner and other parties determined appropriate by the department. The notification letter shall be sent by certified mail, return receipt requested, or by personal service. The notification letter shall provide:

- (i) The name of the person the department believes to be the affected landowner;
- (ii) The names and addresses of other affected landowners to whom the department has sent a proposed sediment impact zone notification letter;
- (iii) The name and address of the sediment impact zone applicant;
- (iv) A general description of the location, size, and contamination level proposed for the sediment impact zone;
- (v) The intention of the department to release all specific sediment impact zone application information to the public upon written request to the department;
- (vi) The determination of the department concerning whether the proposed sediment impact zone application meets the standards of this section;
- (vii) The intention of the department whether to authorize the proposed sediment impact zone; and
- (viii) Notification that the affected landowners, adjacent landowners, and lessees may comment on the proposed sediment impact zone. Any comments on the proposed sediment impact zone authorization shall be submitted in writing to the department within thirty days from the date of receipt of the notification letter, unless the department provides an extension.
- (f) Prior to authorization, the department shall issue a sediment impact zone notification letter to affected port districts, the Washington state department of natural resources marine lands division, the U.S. Army Corps of Engineers, and other parties determined appropriate by the department. The notification letter shall be sent by certified mail, return receipt requested, or by personal service. The notification letter shall provide the information required under (e) of this subsection.
- (3) Locational considerations. The department shall require any person applying for a sediment impact zone to submit information concerning potential location considerations of the zone. The location of an authorized sediment impact zone shall avoid whenever possible and minimize adverse impacts to areas of special importance. Prior to authorization of a sediment impact zone, the department shall consider all pertinent information from the applicant, all affected parties, local, state and federal agencies, federally recognized Indian tribes, and the public concerning locational considerations, including but not limited to:
 - (a) Spawning areas;
 - (b) Nursery areas;
 - (c) Waterfowl feeding areas;
 - (d) Shellfish harvest areas;
 - (e) Areas used by species of economic importance;
 - (f) Tribal areas of significance;
 - (g) Areas determined to be ecologically unique;
 - (h) Water supply intake areas;
 - (i) Areas used for primary contact public recreation;
- (j) High quality waters that constitute an outstanding national resource; and
- (k) Areas where sediment quality is substantially better than levels necessary for protection of biological resources and human health.
- (4) Design requirements. The location, areal limitations, and degree of effects allowed within an authorized sediment

impact zone shall be determined by application of the department's sediment impact zone computer models "CORMIX," "PLUMES," and/or "WASP," or an alternate sediment impact zone model(s) approved by the department under WAC 173-204-130(4), as limited by the standards of this section and the department's best professional judgment. The models shall be used by the department or by the discharger as required by the department, to estimate the impact of any person's wastewater or storm water discharge on the receiving water and sediment quality for a period of ten years from the later date of either the department's formal approval of the application for a sediment impact zone authorization or the starting date of the discharge.

- (a) Data requirements. The discharger shall submit the following information to determine requirements for establishment and authorization of a sediment impact zone, as required by the department:
- (i) Data reports and analyses results for all samples of wastewater or storm water, receiving water, and sediments collected by the discharger or other parties relating to evaluation of the potential effects of the permitted discharge, as required by WAC 173-204-400.
- (ii) Data reports and analyses results determined necessary to:
- (A) Apply discharge modeling to the permitted discharge; and
- (B) To identify and evaluate potential alternative chemical and biological effects of the discharge on the receiving water and sediments; and
- (C) To identify and evaluate potential alternatives to define the areal size and location of a sediment impact zone needed by the discharge.
- (iii) Data reports and analyses results from the discharger's application of the "CORMIX," "PLUMES," and/or "WASP" or an alternate sediment impact zone model(s) approved by the department under WAC 173-204-130(4), to the permitted discharge to identify and evaluate:
- (A) Potential alternative chemical and biological effects of the discharge on the receiving water and sediments; and
- (B) Potential alternatives for the areal distribution and location of a potential sediment impact zone required by the discharge.
- (iv) Preferred alternative for closure of the potential sediment impact zone by active removal and/or natural recovery, and identified costs of the preferred closure method.
- (b) Overlapping sediment impact zones. Overlapping sediment impact zones, as predicted by the "CORMIX," "PLUMES," and/or "WASP" models or an alternate sediment impact zone model(s) approved by the department under WAC 173-204-130(4), and the department's best professional judgment, shall be authorized only as follows:
- (i) The applicable sediment impact zone maximum criteria of WAC 173-204-420 shall not be exceeded as a result of the multiple discharge sediment impact zones overlap; and
- (ii) If the department determines that the applicable chemical contaminant concentration and biological effects restrictions of WAC 173-204-420 would be exceeded as a result of the overlap of multiple discharge sediment impact zones, the department may authorize the sediment impact zones after:

- (A) Application of a waste load allocation process to the individual permitted discharges to identify individual permit effluent limitations necessary to meet:
- (I) The applicable chemical contaminant concentration and biological effects restrictions for sediment impact zones required by this section; and/or
- (II) Storm water best management practices required by the department; and
- (B) Establishment of individual permit compliance schedules for the multiple permitted discharges to ensure compliance with:
- (I) The permit effluent limitations established by the department using the waste load allocation process and best professional judgment; and
- (II) The standards of WAC 173-204-400 through 173-204-420.
 - (5) Maintenance requirements.
- (a) The department shall review sediment impact zone monitoring conducted by the discharger to evaluate compliance with the department's sediment impact zone authorization and the standards of WAC 173-204-400 through 173-204-420. The department may require additional sediment impact zone monitoring when the department determines that any sediment sampling station within an authorized sediment impact zone exceeds the sediment impact zone maximum criteria of WAC 173-204-420 or violates the sediment impact zone authorization as a result of the discharge.
- (b) Whenever the department can clearly demonstrate that, as a result of an effluent discharge, a discharger violates, shall violate, or creates a substantial potential to violate the department's sediment impact zone authorization, or the sediment impact zone maximum criteria of WAC 173-204-420, the department shall:
- (i) Provide written notification and supporting documentation of the department's clear demonstration determination to the affected discharger;
- (ii) Establish a reasonable time frame for the affected discharger to either submit a written statement and supporting documentation rebutting the department's clear demonstration determination, or accept the department's determination. The discharger may use the clear demonstration methods identified in (c) of this subsection for rebuttal of the department's clear demonstration; and
- (iii) Provide written notification of the department's determination concerning approval or denial of the submitted clear demonstration rebuttal to the discharger.
- (c) For the purpose of this section, a clear demonstration shall consist of:
- (i) Use of the sediment impact zone model(s) "CORMIX," "PLUMES," and/or "WASP" or other model(s) to demonstrate a discharge(s) is the source of the violation or potential violation; and
- (ii) Use of one or more of the following methods to demonstrate a violation of the sediment impact zone authorization or the sediment impact zone maximum criteria of WAC 173-204-420:
- (A) Direct sediment sampling. A violation of the sediment impact zone authorization and/or the sediment impact zone maximum criteria of WAC 173-204-420 is demonstrated when:

Permanent [18]

- (I) The average chemical concentration for three stations within the sediment impact zone exceeds the sediment impact zone maximum criteria of WAC 173-204-420 due to the discharge source. This concentration average shall not include stations for which complete biological testing information shows that the biological effects requirements of WAC 173-204-420, or the authorized sediment impact zone if applicable, are met; or
- (II) The biological effects at each of any three stations within the sediment impact zone exceed the sediment impact zone maximum biological effects criteria of WAC 173-204-420 or the authorized sediment impact zone as applicable, due to the discharge source; or
- (B) Monitoring data which demonstrates a chemical contaminant concentration gradient toward the discharge source exists in sediments which violates the sediment impact zone authorization or the standards of WAC 173-204-420; or
- (C) A trend analysis of the effluent chemical discharge quality and (inplace) sediment monitoring data which statistically demonstrates an ongoing violation or substantial potential to violate the sediment impact zone authorization or the standards of WAC 173-204-420; or
- (D) Field depositional (e.g., sediment traps) and/or effluent particulate (e.g., centrifuge analysis) data which demonstrate an ongoing violation or substantial potential to violate the sediment impact zone authorization or the standards of WAC 173-204-420; or
- (E) Mathematical or computer modeling which demonstrates an ongoing violation or substantial potential to violate the sediment impact zone authorization or the standards of WAC 173-204-420.
- (d) The department's response to a clear demonstration of a violation or potential violation shall be to require maintenance activities in the following order:
- (i) Require reanalysis of whether the discharger's effluent treatment complies with all known, available and reasonable methods of prevention, control, and treatment and best management practices based on the data used to establish the clear demonstration;
- (ii) Alter the authorized sediment impact zone size and/or degree of effects consistent with the standards of this section and the results of direct sediment sampling;
- (iii) Reduce impacts of the existing or potential violation by requiring additional discharge controls or additional sediment impact zone maintenance activities which can include, but are not limited to:
- (A) Dredging and removal of sediments, solely for sediment impact zone maintenance needs or coordinated with maintenance dredging of commercially important areas, e.g., navigational lanes or ship berthing areas;
- (B) Dredging, treatment, and replacement of sediments within the sediment impact zone; and/or
- (C) Capping of sediments within the sediment impact zone:
- (iv) Limit the quantity and/or quality of the existing permitted discharge; and/or
- (v) Withdraw the department's sediment impact zone authorization and require final closure of the zone.
- (e) All sediment impact zone maintenance actions conducted under this chapter shall provide for landowner review

- of the maintenance action plans prior to implementation of the action. In cases where the discharger is not able to secure access to lands subject to the sediment impact zone maintenance actions of this subsection, the department may facilitate negotiations or other proceedings to secure access to the lands. Requests for department facilitation of land access shall be submitted to the department in writing by the responsible discharger.
 - (6) Closure planning and requirements.
- (a) The discharger shall select and identify a preferred method for closure of a sediment impact zone in the application required by WAC 173-204-415(2). Closure methods can include either active cleanup and/or natural recovery and monitoring. The department shall incorporate the discharger's identified closure method in the sediment impact zone authorization
- (b) The department may require closure of authorized sediment impact zones when the department determines that:
- (i) The discharger has violated the sediment impact zone maintenance standards of subsection (5) of this section; or
 - (ii) The department determines that:
- (A) The wastewater or storm water discharge quality will not violate the applicable sediment quality standards of WAC 173-204-320 through 173-204-340; or
- (B) A sediment impact zone is no longer needed or eligible under the standards of WAC 173-204-410 through 173-204-415.
- (7) Modification of sediment impact zones. The department may modify sediment impact zone authorization requirements where the nature of a person's activity which generates, transports, disposes, prevents, controls, or treats effluent discharges has substantially changed and been demonstrated to the department's satisfaction. The modification may occur after consideration of the following:
- (a) Reduction of effects. Assessment of the discharge activities and treatment methods shall be conducted by the discharger to demonstrate to the satisfaction of the department that:
- (i) Elimination of the sediment impact zone is not practicable; and
- (ii) Further reduction in any existing or proposed sediment impact zone area size and/or level of contamination or effects is not practicable in consideration of discharge requirements for all known, available and reasonable methods of prevention, control, and treatment, best management practices, and applicable waste reduction and recycling provisions.
- (b) Alterations. There are substantial alterations or additions to the person's activity generating effluent discharges which require authorization of a sediment impact zone which occur after permit issuance and justify application of permit conditions different from, or absent in, the existing permit.
- (c) New information. Sediment impact zones may be modified when new information is received by the department that was not available at the time of permit issuance that would have justified the application of different sediment impact zone authorization conditions.
- (d) New regulations. The standards or regulations on which the permit was based have changed by amended stan-

[19] Permanent

dards, criteria, or by judicial decision after the permit was issued.

- (e) Changes in technology. Advances in waste control technology that qualify as "all known, available and reasonable methods of prevention, control, and treatment" and "best management practices" shall be adopted as permit requirements, as appropriate, in all permits reissued by the department.
- (8) Renewal of previously authorized sediment impact zones. Renewal of sediment impact zones previously authorized under the standards of WAC 173-204-410 and this section shall be allowed under the following conditions:
- (a) The department determines the discharge activities and treatment methods meet all known, available and reasonable methods of prevention, control, and treatment and best management practices as stipulated by the department; and
- (b) The discharger demonstrates to the department's satisfaction that the discharge activities comply with the standards of WAC 173-204-400 through 173-204-420 and with the existing sediment impact zone authorization; and
- (c) Reduction of effects. The discharger conducts an assessment of the permitted discharge activities and treatment methods and demonstrates to the department's satisfaction that:
- (i) Elimination of the sediment impact zone is not practicable; and
- (ii) A further reduction in any existing or proposed sediment impact zone area size and/or level of contamination is not practicable in consideration of discharge requirements for all known, available and reasonable methods of prevention, control, and treatment, best management practices, and applicable waste reduction and recycling provisions.

<u>AMENDATORY SECTION</u> (Amending Order 90-41, filed 3/27/91, effective 4/27/91)

- WAC 173-204-500 Sediment cleanup decision process and policies. (((1) The standards of WAC 173-204-500 through 173-204-590 are procedures which specify a cleanup decision process for managing contaminated sediments. These procedures include:
- (a) Screening sediment station clusters of potential coneern;
- (b) Conducting hazard assessments to identify cleanup sites:
 - (c) Ranking sites identified in (b) of this subsection;
 - (d) Determining the appropriate site cleanup authority;
 - (e) Conducting a site cleanup study;
 - (f) Determining the site specific cleanup standard;
 - (g) Selecting a site cleanup action; and
- (h) Where necessary, authorizing a cleanup site sediment recovery zone.
- (2) Under this chapter, the department may require or take those actions necessary to implement the standards of WAC 173 204 500 through 173 204 580 for all contaminated sediment stations on the inventory identified in WAC 173 204 350.
- (3) The cleanup process and procedures under this chapter and under other laws may be combined. The department may initiate a cleanup action under this chapter and may upon

further analysis determine that another law is more appropriate, or vice versa.

- (4) It is the policy of the department to manage sediment eleanup actions towards the goal of reducing and ultimately eliminating adverse effects on biological resources and significant health threats to humans from sediment contamination. To achieve this goal, the department will pursue sediment cleanup decisions and cleanup standards that are as close as practicable to the sediment quality standards of WAC 173-204-320 through 173-204-340, including the consideration of net environmental effects, cost and technical feasibility. The department shall only authorize sediment recovery zones so as to minimize the number, size and adverse effects of all zones, with the intent to climinate the existence of all such zones whenever practicable.
- (5) The department shall endeavor to make sediment eleanup decisions in an expeditious manner, as soon as all needed information is available, consistent with the availability of department resources and the priority of the cleanup site.)) (1) Applicability.
- (a) This part is promulgated under the authority of chapter 70.105D RCW, the Model Toxics Control Act. This part establishes requirements for identifying, investigating, and cleaning up a release or threatened release of a contaminant to sediment that may pose a threat to human health or the environment. This part shall be used for the purposes of chapter 70.105D RCW.
- (b) This part shall not be used in the implementation of the federal Clean Water Act (33 U.S.C. Sec. 1251). The sediment cleanup standards and the other cleanup criteria in this part are not sediment quality standards, which are established under Part III of this chapter, or sediment impact zone maximum criteria, which are established under Part IV of this chapter.
- (c) This section describes the decision process and associated policies and principles governing the identification, investigation, and cleanup of contaminated sediment at sites under chapter 70.105D RCW. If there are any inconsistencies between this section and a specifically referenced section, the specifically referenced section shall govern.
- (2) Cleanup decision process. In general, the process for cleanup of contaminated sediments includes the following steps:
- (a) Identifying sediment station clusters of potential concern (WAC 173-204-510);
- (b) Identifying cleanup sites for further evaluation (WAC 173-204-520);
- (c) Evaluating sites identified in (b) of this subsection (WAC 173-204-530);
- (d) Determining the appropriate site cleanup authority (WAC 173-204-540);
- (e) Conducting a remedial investigation and feasibility study (WAC 173-204-550);
- (f) Establishing the applicable sediment cleanup standards (WAC 173-204-560 through 173-204-564);
 - (g) Selecting a cleanup action (WAC 173-204-570);
- (h) Documenting the cleanup action decision and soliciting public review of that decision (WAC 173-204-575); and
- (i) Where necessary, authorizing a sediment recovery zone (WAC 173-204-590).

Permanent [20]

- (3) Coordination with other laws. The cleanup process and procedures under this part and under other laws may be combined.
- (4) Cleanup process expectations. The department has the following expectations regarding the cleanup process for contaminated sediment sites. The department recognizes there may be sites where cleanup actions conforming to these expectations are inappropriate.
- (a) Scale of cleanups. Sediment contamination can be widespread with multiple contaminants from multiple sources that have been intermingled and dispersed by natural processes and human activity. It is the department's intent to address this widespread contamination using multiple approaches that lead to cleanup as effectively and efficiently as possible. This may include:
- (i) The establishment of sediment cleanup unit(s) within a site, and the expedited cleanup of those units consistent with the cleanup strategy and broader scale toxics reduction and source control strategies;
- (ii) Coordinating cleanup of multiple sites and sediment cleanup units on a bay-wide, area-wide, or watershed-wide scale; and
- (iii) Use of source control measures to minimize future contamination.
- (b) Recontamination. Recontamination of sediment at remediated sites or sediment cleanup units may occur from ongoing discharges or other releases. It is the department's expectation that further cleanup of recontamination will not be required by the person(s) conducting the initial cleanup when the person(s) can demonstrate, upon department approval, that the recontamination is caused by ongoing discharges or other releases not under the authority or responsibility of the person(s) conducting the initial cleanup.
- (c) Restoration time frame and cleanup actions. The department expects that the sediment component of sites and sediment cleanup units will achieve sediment cleanup standards as soon as practicable to minimize impacts to aquatic organisms, habitat, and human health. Recognizing there may be sites where the following expectations are inappropriate, the department expects the likely results of the remedy selection process in WAC 173-204-570 will be as follows:
- (i) For sites with a limited areal extent of contamination, the department expects the focus will be on the use of active cleanup actions to achieve sediment cleanup standards quickly and minimize the need for long-term maintenance and monitoring; or
- (ii) For sites with more wide-spread contamination, sediment cleanup standards may not be practicable to achieve using only active cleanup actions. For these types of sites, the department expects the focus will be on the use of active cleanup actions to remove, cap, or treat areas with higher contamination followed by the use of enhanced or monitored natural recovery to achieve sediment cleanup standards as soon as practicable.
- (d) Compliance monitoring. The department expects that post-cleanup monitoring will be conducted at sites and sediment cleanup units to verify compliance with approved sediment cleanup standards.
- (i) Monitoring will typically include analysis of sediment chemistry at a minimum, but may also include bioas-

- says, tissue chemistry, benthic infauna, pore water, and surface water testing.
- (ii) The department expects that, where site-specific circumstances warrant, more discharge monitoring may be required than would normally occur under a discharge permit.
- (e) Scope of information. The scope of information needed to adequately characterize different site or sediment cleanup units will vary depending on site conditions and complexity. It is the department's expectation that sufficient information will be gathered in as few sampling events as feasible to enable appropriate decisions and cleanups to proceed expeditiously.
- (f) Timely decisions. The department shall endeavor to make sediment cleanup decisions in an expeditious manner, as soon as all information required by the department is available, consistent with the availability of department resources and the priority of the cleanup site.
- (5) Relationship between sediment cleanup standards and cleanup actions. It is the policy of the department to establish sediment cleanup standards and select cleanup actions that support the goal of reducing and ultimately eliminating adverse effects on biological resources and significant health threats to humans from sediment contamination.
- (a) Sediment cleanup standards. WAC 173-204-560 establishes requirements for sediment cleanup standards. Sediment cleanup standards consist of sediment cleanup levels for individual contaminants and the locations within the site or sediment cleanup unit where the sediment cleanup levels must be met (points of compliance). Sediment cleanup standards may also include other regulatory requirements that apply to a cleanup action for contaminated sediment because of the type of action and/or location of the site (applicable laws).
- (i) Sediment cleanup level. A sediment cleanup level is the concentration or level of biological effects for a contaminant in sediment that is determined by the department to be protective of human health and the environment. The sediment cleanup level is established in accordance with the requirements in WAC 173-204-560(2). The sediment cleanup level is initially established at the sediment cleanup objective and may be adjusted upward as appropriate based on whether it is technically possible to meet the sediment cleanup objective and whether meeting the sediment cleanup objective will have a net adverse environmental impact on the aquatic environment as specified in WAC 173-204-560 (2)(a)(i)(B). A sediment cleanup level may not be adjusted upward above the cleanup screening level. The sediment cleanup level, in combination with the point of compliance, typically defines the area or volume of sediment at a site or sediment cleanup unit that must be addressed by the cleanup action.
- (A) Sediment cleanup objective. The sediment cleanup objective defines the goal for protection of human health and environment. This goal is expected to be achieved through a combination of cleanup actions and source control. The sediment cleanup objective is established in accordance with the requirements in WAC 173-204-560(3). If a risk-based concentration is below the natural background level or practical quantitation limit, then the sediment cleanup objective is

[21] Permanent

established at a concentration equal to the practical quantitation limit or natural background, whichever is higher.

- (B) Cleanup screening level. The cleanup screening level is established in accordance with the requirements in WAC 173-204-560(4). If a risk-based concentration is below the regional background level or practical quantitation limit, then the cleanup screening level is established at a concentration equal to the practical quantitation limit or regional background, whichever is higher.
- (ii) Point of compliance. A point of compliance is the location within the site or sediment cleanup unit where sediment cleanup levels must be achieved. The point of compliance is established in accordance with the requirements in WAC 173-204-560(6).
- (b) Cleanup actions. WAC 173-204-570 establishes requirements for cleanup actions for contaminated sediment. The cleanup actions must achieve sediment cleanup standards within the site or sediment cleanup unit, as applicable. Cleanup actions usually consist of a combination of active and passive actions. At sites and sediment cleanup units where there are ongoing sources, the cleanup actions will usually also include source control measures.
- (i) Active cleanup actions. Sediment contamination may be addressed by active cleanup actions such as dredging, capping, treatment, and enhanced natural recovery. Active cleanup actions are preferred over passive cleanup actions.
- (ii) Passive cleanup actions. When appropriate, passive cleanup actions, such as monitored natural recovery and institutional controls, may be used in combination with active cleanup actions and source control measures to address sediment contamination.
- (iii) Source control. Source control measures consist of controlling ongoing sources to limit discharges of contaminants that accumulate in sediment. Source control measures may be required as part of a cleanup action to prevent recontamination of the site or sediment cleanup unit above the sediment cleanup level.
- (c) Presumption of protectiveness. Sediment cleanup actions that achieve sediment cleanup levels at the applicable points of compliance and comply with applicable laws are presumed to be protective of human health and the environment.

(6) Applicability of new sediment cleanup standards.

- (a) The department shall determine the sediment cleanup standards that apply to a site or sediment cleanup unit based on the rules in effect under this part at the time the department issues a final cleanup action plan or similar decision document as described in WAC 173-204-575.
- (b) A site or sediment cleanup unit cleaned up with sediment cleanup standards determined in (a) of this subsection shall not be subject to further cleanup action due solely to subsequent amendments of the requirements in this part governing the establishment of sediment cleanup standards, unless the department determines on a case-by-case basis that the previous cleanup action is no longer sufficiently protective of human health and the environment.

NEW SECTION

- WAC 173-204-505 Definitions. For purposes of this part, in cases where a definition does not exist in this part or WAC 173-204-200 the definitions in chapter 173-340 WAC will apply unless the context indicates otherwise. For the purpose of this part, the following definitions shall apply:
- (1) "Active cleanup action" means a cleanup action requiring physical construction to achieve sediment cleanup standards. Active cleanup actions include dredging, capping, treatment, and enhanced natural recovery. Passive cleanup actions such as monitored natural recovery and institutional controls are not active cleanup actions for purposes of sediment cleanup only.
- (2) "Applicable laws" means all legally applicable requirements specified in WAC 173-340-710(3) and those requirements that the department determines, based on the criteria in WAC 173-340-710(4), are relevant and appropriate requirements. Relevant and appropriate requirements may also include those requirements established under local or tribal laws that the department determines meet the criteria in WAC 173-340-710(4).
- (3) "Beneficial reuse" means reuse of sediment from the site, or a separated portion of the sediment (such as the gravel fraction), that utilizes the physical characteristics and properties of the sediment in place of other material without requiring the use of engineered or institutional controls to protect human health or the environment. Examples of beneficial reuse include habitat restoration or enhancement, mine reclamation, landfill cover material, asphalt or concrete aggregate, or use of organic fines in manufactured topsoil.
- (4) "Biologically active zone" means the sediment depth determined by the department where the species critical to the function, diversity, and integrity of the benthic community are located. Metrics such as biomass and abundance may be used to define the vertical extent of the biologically active zone. These species can include endemic and keystone animals, plants, or other species. Abiotic factors such as groundwater upwelling, salt wedges, water temperature, dissolved oxygen, and hyporheic flow can affect the vertical distribution of organisms in the biologically active zone.
- (5) "Cleanup action" means any remedial action, except an interim action, taken at a sediment site or sediment cleanup unit to eliminate, render less toxic, stabilize, contain, immobilize, isolate, treat, destroy, or remove contaminants that complies with sediment cleanup standards and other applicable laws. A remedial action that does not comply with sediment cleanup standards and other applicable laws is an interim action.
- (6) "Cleanup screening level" means the maximum allowed concentration of any contaminant and level of biological effects permissible at the site or sediment cleanup unit per procedures in WAC 173-204-560(4) after completion of the cleanup action. Cleanup screening levels are also used to identify and assess the hazard of sites under WAC 173-204-510 and 173-204-520.
- (7) "Contaminant" means any hazardous substance that does not occur naturally or occurs at greater than natural background levels.
- (8) "Enhanced natural recovery" means a cleanup action that uses human intervention to accelerate the process of nat-

Permanent [22]

ural recovery. An example of enhanced natural recovery is the placement of a thin clean layer of sediment over an area of contaminated sediment to naturally mix with the contaminated sediment and reduce the contaminant concentrations or toxicity followed by a period of monitoring to determine the effectiveness.

- (9) "Include" means included, but not limited to.
- (10) "Monitored natural recovery" means a cleanup action that is a form of natural recovery that includes regular monitoring of sediment quality, tissue, benthic infauna, and/or biota as appropriate to assess the effectiveness of natural recovery to restore sediment quality.
- (11) "Natural background" means the concentration of a hazardous substance consistently present in the environment that has not been influenced by localized human activities. For example, several metals and radionuclides naturally occur in the bedrock, sediment, and soil of Washington state due solely to the geologic processes that formed these materials and the concentration of these hazardous substances would be considered natural background. Also, low concentrations of some particularly persistent organic compounds such as polychlorinated biphenyls (PCBs) can be found in surficial soils and sediment throughout much of the state due to global distribution of these hazardous substances. These low concentrations would be considered natural background. Similarly, concentrations of various radionuclides that are present at low concentrations throughout the state due to global distribution of fallout from bomb testing and nuclear accidents would be considered natural background.
- (12) "Natural recovery" means physical, chemical or biological processes that act, without human intervention, to reduce the toxicity or concentration of contaminated sediment. An example of natural recovery is the natural deposition of a layer of clean sediment over an area of contaminated sediment resulting in burial over time of contaminated sediment below the biologically active zone. The natural process of sediment mixing, and degradation of some contaminants, such as polycyclic aromatic hydrocarbons, can also contribute to natural recovery.
- (13) "Point of compliance" means the locations within a site or sediment cleanup unit where sediment cleanup levels must be met.
- (14) "Practicable" means capable of being designed, constructed and implemented in a reliable and effective manner including consideration of cost. When considering cost under this analysis, an alternative shall not be considered practicable if the incremental costs of the alternative are disproportionate to the incremental degree of benefits provided by the alternative over other lower cost alternatives.
- (15) "Practical quantitation limit" means the lowest concentration that can be reliably measured within specified limits of precision, accuracy, representativeness, completeness, and comparability during routine laboratory operating conditions, using department approved methods. When the limit for an analytical method is higher than the concentrations based on protection of human health or the environment, the department may require the use of another method to lower the practical quantitation limit.
- (16) "Regional background" means the concentration of a contaminant within a department-defined geographic area

- that is primarily attributable to diffuse sources, such as atmospheric deposition or storm water, not attributable to a specific source or release. See WAC 173-204-560(5) for the procedures and requirements for establishing regional background.
- (17) "Sediment cleanup level" means the concentration or level of biological effects for a contaminant in sediment that must be achieved and is determined by the department to be protective of human health and the environment under the authority of chapter 70.105D RCW. The sediment cleanup level can be established between the sediment cleanup objective and cleanup screening level in accordance with the requirements in WAC 173-204-560(2).
- (18) "Sediment cleanup objective" means the goal for protection of human health and the environment and is established under the authority of chapter 70.105D RCW. The sediment cleanup objective is established in accordance with the requirements in WAC 173-204-560(3). Sediment cleanup objectives are also used to identify and assess the hazard of sites under WAC 173-204-510 and 173-204-520.
- (19) "Sediment cleanup standard" means the standards adopted under RCW 70.105D.030 (2)(e). Establishing sediment cleanup standards requires specification of the following:
- (a) The chemical concentration or level of biological effects for a contaminant in sediment that is determined by the department to be protective of human health and the environment (sediment cleanup level);
- (b) The location at the site or sediment cleanup unit where those sediment cleanup levels must be achieved (point of compliance); and
- (c) Additional regulatory requirements that apply to a cleanup action because of the type of action and/or the location of the site. These requirements are specified in applicable laws and are generally established in conjunction with the selection of a specific cleanup action.
- (20) "Sediment cleanup unit" means a discrete subdivision of a sediment site designated by the department for the purpose of expediting cleanups. A sediment cleanup unit may be established based on unique chemical concentrations or parameters, regional background, environmental, spatial, or contaminant source characteristics, or other methods determined appropriate by the department, e.g., development-related cleanups, cleanup under piers, cleanup in eelgrass beds, and cleanup in navigational lanes.
- (21) "Sediment recovery zone" means an area authorized by the department within a site or sediment cleanup unit where the department has determined the cleanup action cannot achieve the applicable sediment cleanup standards within ten years after completion of construction of the active components of the cleanup action. Sediment recovery zones must meet the requirements in WAC 173-204-590 and be authorized by the department under WAC 173-204-575.
- (22) "Surface sediment" or "sediment" means settled particulate matter located at or below the ordinary high water mark, where the water is present for a minimum of six consecutive weeks, to which biota (including benthic infauna) or humans may potentially be exposed, including that exposed by human activity (e.g., dredging).

(23) "Technically possible" means capable of being designed, constructed and implemented in a reliable and effective manner, regardless of cost.

AMENDATORY SECTION (Amending WSR 96-02-058, filed 12/29/95, effective 1/29/96)

- WAC 173-204-510 ((Sereening)) Identifying sediment station clusters of potential concern. (1) ((Using the sediment quality standards inventory of WAC 173-204-350,)) Data analysis. The department shall analyze ((the)) sediment sampling data to identify station clusters of potential concern and station clusters of low concern ((per the standards of this section)). Station clusters of potential concern shall be further evaluated using the hazard assessment standards of WAC ((173-204-530)) 173-204-520. Station clusters of low concern shall remain on the inventory and no further cleanup action determinations shall be ((taken)) made by the department until the stations are reexamined per subsection (5) of this section.
- (2) **Station clusters.** A station cluster is defined as any number of stations ((from the inventory of WAC 173-204-350)) that are determined by the department to be spatially and chemically similar. For the purpose of identifying a station cluster of potential concern ((per the procedures of this subsection)), three stations with the highest ((eontaminant)) <u>chemical</u> concentration for any particular ((contaminant)) chemical or the highest degree of biological effects as identified in WAC ((173-204-520)) <u>173-204-562 or 173-204-563</u>, as applicable are selected from a station cluster. This procedure may be repeated for multiple chemicals ((identified in WAC 173-204-520)), recognizing that the three stations with the highest concentration for each particular ((eontaminant)) chemical may be different and the respective areas for all chemicals may overlap. The department shall ((review the inventory of WAC 173-204-350 to)) identify station clusters of potential concern ((via the following)) using the process((÷)) specified in this subsection.
- (a) Identify if available, the three stations within a station cluster with the highest concentration of each chemical ((eontaminant)) identified in WAC ((173-204-520, Cleanup screening levels criteria; and)) 173-204-562 or 173-204-563, as applicable.
- (((b))) (i) For each ((eontaminant)) chemical identified in (a) of this subsection, determine the average concentration for the ((eontaminant)) chemical at the three stations identified ((in (a) of this subsection; and)).
- (((e) Identify if available, three stations within the station eluster with the highest level of biological effects for the biological tests identified in WAC 173-204-315(1); and
- (d))) (ii) If the average ((eontaminant)) chemical concentration for any three stations identified in (a) of this subsection(($\frac{1}{5}$)) exceeds the applicable cleanup screening level in WAC (($\frac{173-204-520}{520}$)) $\frac{173-204-562}{520}$ or $\frac{173-204-563}{520}$, then the station cluster (($\frac{1}{5}$)) shall be defined as a station cluster of potential concern(($\frac{1}{5}$)).
- (((e))) (b) Identify, if available, three stations within the station cluster with the highest level of biological effects for the biological tests identified in WAC 173-204-562 or 173-204-563, as applicable. If the level of biological effects at

- each of the three stations from $(((e) \circ f))$ this subsection exceeds the <u>applicable</u> cleanup screening level in WAC $((\frac{173-204-520}{520}))$ $\frac{173-204-562}{520}$ or $\frac{173-204-563}{520}$, then the station cluster $((\frac{is}{5}))$ shall be defined as a station cluster of potential concern $((\frac{is}{5}))$.
- (((f) If neither of the conditions of (d) or (e) of this subsection apply, then the station cluster is defined as a station cluster of low concern; and
- (g))) (c) If the department determines that ((any)) each of three stations within a station cluster exceed the ((sediment eleanup screening)) following criteria, then the station cluster shall be defined as a station cluster of potential concern:
- (i) The applicable human health and regional background cleanup screening levels ((human health criteria or)) in WAC 173-204-560(4);
- (ii) The other toxic, radioactive, biological, or deleterious substances criteria in WAC 173-204-562 or 173-204-563, as applicable; or
- (iii) The nonanthropogenically affected criteria of WAC ((173-204-520, then the station cluster is defined as a station cluster of potential concern)) 173-204-562 or 173-204-563, as applicable.
- (d) If none of the conditions of (a) through (c) of this subsection apply, then the station cluster shall be defined as a station cluster of low concern.
- (3) **Notification.** When a station cluster of potential concern has been identified, the department shall issue notification, as appropriate, to the landowners, lessees, onsite dischargers, adjacent dischargers, and other persons determined appropriate by the department ((prior to)) if the ((department's conducting a)) hazard assessment as defined in WAC 173-204-530(3) results in identification of a cleanup site.
- (4) No further cleanup action. No further cleanup action determinations shall be taken with station clusters of low concern until ((the inventory of WAC 173-204-350 is updated)) new information is available and the stations reexamined per subsection (5) of this section. Station clusters of low concern shall receive no further consideration for active cleanup, unless new information indicates an increase of chemical contamination at the stations in question. Station clusters of low concern shall be evaluated by the department for improved source control and/or monitoring requirements of this ((chapter)) part.
- (5) **Reevaluation.** The department may at any time reexamine a station or group of stations to reevaluate and identify station clusters of potential concern following the procedures of subsection (2) of this section when new information demonstrates to the department's satisfaction that reexamination actions are necessary to fulfill the purposes of WAC 173-204-500 through 173-204-590.

<u>AMENDATORY SECTION</u> (Amending WSR 96-02-058, filed 12/29/95, effective 1/29/96)

- WAC 173-204-520 ((Cleanup sereening levels eriteria.)) Sediment cleanup levels based on protection of the benthic community in marine and low salinity sediment. (1) Applicability.
- (((a) The marine sediment eleanup screening levels chemical criteria, and the marine sediment biological effects

Permanent [24]

- eriteria, and the marine sediment other toxie, radioactive, biological, or deleterious substance criteria, and the marine sediment nonanthropogenically affected criteria of this section)) This section defines sediment cleanup objectives and cleanup screening levels for contaminants based on protection of the benthic community in marine and low salinity sediment. They are used to:
- (a) Identify and assess the hazard of sites under WAC 173-204-510 and 173-204-520;
- (b) Establish sediment cleanup levels for sites and sediment cleanup units under WAC 173-204-560.
- (2) Marine sediment Chemical criteria. The chemical concentration criteria in Table III establish the sediment cleanup objectives and cleanup screening levels chemical criteria for marine sediment. The criteria of this section shall apply to marine sediments ((within Puget Sound)) for toxicity to the benthic community.
- (a) The sediment cleanup objectives of this section establish a no adverse effects level, including no acute or chronic adverse effects, to the benthic community. Chemical concentrations at or below the sediment cleanup objectives correspond to sediment quality that results in no adverse effects to the benthic community.
- (b) The cleanup screening levels of this section establish a minor adverse effects level, including acute or chronic effects, to the benthic community. Chemical concentrations at or below the cleanup screening level but greater than the sediment cleanup objective correspond to sediment quality that results in minor adverse effects to the benthic community. The marine chemical and biological cleanup screening levels establish minor adverse effects as the level above which station clusters of potential concern are defined and may be defined as potential cleanup sites for benthic community toxicity, and at or below which station clusters of low concern are defined, per the procedures identified in WAC 173-204-510(((2))) and 173-204-520. ((The cleanup screening levels also establish the levels above which station clusters of potential concern are defined as cleanup sites, per the procedures identified in WAC 173-204-530, Hazard assessment. The criteria in Table III and this section also establish minor adverse effects as the Puget Sound marine sediment minimum cleanup level to be used in evaluation of cleanup alternatives per the procedures of WAC 173-204-560, and selection of a site cleanup standard(s) per the procedures of WAC 173-204-570.
- (b) Non-Puget Sound marine sediment cleanup screening levels and minimum cleanup levels criteria. Reserved: The department shall determine on a case-by-case basis the criteria, methods, and procedures necessary to meet the intent of this chapter.))
- (c) The cleanup screening level chemical criteria is exceeded when the sediment chemical concentration for an individual chemical is above the cleanup screening level in Table III.
- (d) The sediment cleanup objective chemical criteria is exceeded when the sediment chemical concentration for one or more chemicals is above the sediment cleanup objective in Table III.
- (e) Low salinity sediment cleanup screening levels ((and minimum eleanup levels)) criteria. Reserved: The depart-

- ment shall determine on a case-by-case basis the criteria, methods, and procedures necessary to meet the intent of this ((ehapter)) part.
- (((d) Freshwater sediment cleanup screening levels and minimum cleanup levels criteria. Reserved: The department shall determine on a case-by-case basis the criteria, methods, and procedures necessary to meet the intent of this chapter.
- (2) Puget Sound marine sediment cleanup screening levels and minimum cleanup levels chemical criteria. The chemical concentration criteria in Table III establish the Puget Sound marine sediment cleanup screening levels and minimum cleanup levels chemical criteria.
- (a)) (f) For purposes of this section, where ((laboratory analysis)) chemical analyses indicates a chemical is not detected in a ((sediment)) sample, the method detection limit and the practical quantitation limit shall be reported and shall be at or below the ((Marine)) sediment ((Quality Standards)) cleanup objectives chemical criteria ((value set)) in ((WAC 173-204-320(2))) Table III.
- (((b))) (g) Where chemical criteria in ((this)) <u>Table III</u> represent the sum of individual compounds or isomers, the following methods shall be applied:
- (i) Where chemical analyses identify an undetected value for every individual compound/isomer, then the single highest detection limit shall represent the sum of the respective compounds/isomers; and
- (ii) Where chemical analyses detect one or more individual compound/isomers, only the detected concentrations will be added to represent the group sum.
- $((\frac{e}{e}))$ (h) For some chemical criteria in Table III, the listed ((ehemical parameter)) criteria represent concentrations in parts per million(($\frac{1}{2}$)) "normalized(($\frac{1}{2}$))" or expressed(($\frac{1}{2}$)) on a total organic carbon basis. To normalize to total organic carbon, the dry weight concentration for each parameter is divided by the decimal fraction representing the percent total organic carbon content (e.g., 0.01 means 1 percent) of the sediment per the equation: ppm OC = (ppb dry weight)/(percent total organic carbon x 1000).
- (((d))) (i) The LPAH criterion in Table III represents the sum of the following "low molecular weight ((polynuclear)) polycyclic aromatic hydrocarbon" compounds: Naphthalene, Acenaphthylene, Acenaphthene, Fluorene, Phenanthrene, and Anthracene. The LPAH criterion is not the sum of the criteria values for the individual LPAH compounds as listed.
- (((e))) (j) The HPAH criterion in Table III represents the sum of the following "high molecular weight ((polynuclear)) polycyclic aromatic hydrocarbon" compounds: Fluoranthene, Pyrene, Benz(a)anthracene, Chrysene, Total Benzofluoranthenes, Benzo(a)pyrene, Indeno(1,2,3,-c,d)pyrene, Dibenzo(a,h)anthracene, and Benzo(g,h,i)perylene. The HPAH criterion is not the sum of the criteria values for the individual HPAH compounds as listed.
- (((f))) (k) The ((TOTAL BENZOFLUORANTHENES)) total benzofluoranthenes criterion in Table III represents the sum of the concentrations of the "B," "J," and "K" isomers.

Table III
((Puget Sound)) Marine Sediment
Sediment Cleanup Objectives and
Cleanup Screening Levels
((and Minimum Cleanup Levels—))
Chemical Criteria

((CHEMICAL	MG/KG DRY WEIGHT
PARAMETER	(PARTS PER MILLION (PPM) DRY)
ARSENIC	93
CADMIUM	6.7
CHROMIUM	270
COPPER	390
LEAD	530
MERCURY	0.59
SILVER	6.1
ZINC	960
CHEMICAL	MG/KG ORGANIC CARBON (PPM-
PARAMETER	CARBON)
LPAH	780
NAPHTHALENE	170
ACENAPHTHYLENE	66
ACENAPHTHENE	57
FLUORENE	79
PHENANTHRENE	4 80
ANTHRACENE	1200
2-METHYLNAPHTHALENE	64
HPAH	5300
FLUORANTHENE	1200
PYRENE	1400
BENZ(A)ANTHRACENE	270
CHRYSENE	460
TOTAL BENZOFLUORANTHEN	ES 450
BENZO(A)PYRENE	210
INDENO (1,2,3,-C,D) PYRENE	88
DIBENZO (A,H) ANTHRACENE	33
BENZO(G,H,I)PERYLENE	78
1,2-DICHLOROBENZENE	2.3
1,4-DICHLOROBENZENE	9
1,2,4-TRICHLOROBENZENE	1.8
HEXACHLOROBENZENE	2.3
DIMETHYL PHTHALATE	53
DIETHYL PHTHALATE	110
DI-N-BUTYL PHTHALATE	1700
BUTYL BENZYL PHTHALATE	64
BIS (2-ETHYLHEXYL) PHTHAL	
DI-N-OCTYL PHTHALATE	4 500
DIBENZOFURAN	58
HEXACHLOROBUTADIENE	6.2
N-NITROSODIPHENYLAMINE	11
TOTAL PCB'S	65
CHEMICAL	UG/KG DRY WEIGHT
PARAMETER	(PARTS PER BILLION (PPB) DRY)
PHENOL	1200
2-METHYLPHENOL	63
4-METHYLPHENOL	670
2,4-DIMETHYL PHENOL	29

CHEMICAL	UG/KG DRY WEIGHT		
PARAMETER	(PARTS PER BILLION (PPB) DRY)		
PENTACHLOROPHENOL	690		
BENZYL ALCOHOL	73		
BENZOIC ACID	650))		

Chemical Parameter	mg/kg Dry Weight (Parts per Million (ppm) Dry Weight)	mg/kg Dry Weight (Parts per Million (ppm) Dry Weight)
	Sediment Cleanup	Cleanup Screening
	Objective	<u>Level</u>
<u>Arsenic</u>	<u>57</u>	<u>93</u>
<u>Cadmium</u>	<u>5.1</u>	<u>6.7</u>
<u>Chromium</u>	<u>260</u>	<u>270</u>
<u>Copper</u>	<u>390</u>	<u>390</u>
<u>Lead</u>	<u>450</u>	<u>530</u>
<u>Mercury</u>	<u>0.41</u>	<u>0.59</u>
Silver	<u>6.1</u>	<u>6.1</u>
<u>Zinc</u>	<u>410</u>	<u>960</u>

<u>Chemical</u> Parameter	mg/kg Organic Carbon (ppm carbon)	mg/kg Organic Carbon (ppm carbon)	
<u> </u>	Sediment Cleanup	Cleanup Screening	
	<u>Objective</u>	Level	
<u>LPAH</u>	370	<u>780</u>	
Naphthalene	<u>99</u>	<u>170</u>	
Acenaphthylene	<u>66</u>	<u>66</u>	
Acenaphthene	<u>16</u>	<u>57</u>	
Fluorene	<u>23</u>	<u>79</u>	
<u>Phenanthrene</u>	<u>100</u>	<u>480</u>	
<u>Anthracene</u>	220	<u>1200</u>	
2-Methylnaphthalene	<u>38</u>	<u>64</u>	
<u>HPAH</u>	<u>960</u>	<u>5300</u>	
<u>Fluoranthene</u>	<u>160</u>	<u>1200</u>	
<u>Pyrene</u>	<u>1000</u>	<u>1400</u>	
Benz(a)anthracene	<u>110</u>	<u>270</u>	
<u>Chrysene</u>	<u>110</u>	<u>460</u>	
Total Benzofluoranthenes	<u>230</u>	<u>450</u>	
Benzo(a)pyrene	<u>99</u>	<u>210</u>	
Indeno(1,2,3 c,d) Pyrene	<u>34</u>	<u>88</u>	
Dibenzo (a,h) Anthracene	<u>12</u>	<u>33</u>	
Benzo (g,h,i) Perylene	<u>31</u>	<u>78</u>	
1,2 Dichlorobenzene	<u>2.3</u>	<u>2.3</u>	
1,4 Dichlorobenzene	<u>3.1</u>	<u>9</u>	
1,2,4 Trichlorobenzene	<u>0.81</u>	<u>1.8</u>	
<u>Hexachlorobenzene</u>	<u>0.38</u>	<u>2.3</u>	
Dimethyl Phthalate	<u>53</u>	<u>53</u>	
<u>Diethyl Phthalate</u>	<u>61</u>	<u>110</u>	
Di-n-butyl Phthalate	<u>220</u>	<u>1700</u>	
Butyl Benzyl Phthalate	<u>4.9</u>	<u>64</u>	
Bis (2-ethylhexyl) Phthal-	<u>47</u>	<u>78</u>	
ate			
<u>Di-n-octyl Phthalate</u>	<u>58</u>	<u>4500</u>	
<u>Dibenzofuran</u>	<u>15</u>	<u>58</u>	
<u>Hexachlorobutadiene</u>	<u>3.9</u>	<u>6.2</u>	
N-Nitrosodiphenylamine	<u>11</u>	<u>11</u>	
Total PCBs	<u>12</u>	<u>65</u>	

Permanent [26]

	ug/kg Dry Weight (Parts per Billion (ppb) Dry Weight)	ug/kg Dry Weight (Parts per Billion (ppb) Dry Weight)
<u>Phenol</u>	<u>420</u>	<u>1200</u>
2-Methylphenol	<u>63</u>	<u>63</u>
4-Methylphenol	<u>670</u>	<u>670</u>
2,4 Dimethyl Phenol	<u>29</u>	<u>29</u>
Pentachlorophenol	<u>360</u>	<u>690</u>
Benzyl Alcohol	<u>57</u>	<u>73</u>
Benzoic Acid	<u>650</u>	<u>650</u>

- (3) ((Puget Sound)) Marine sediment ((eleanup sereening levels and minimum eleanup level)) Biological criteria. The biological effects criteria ((of this subsection)) in Table IV establish the ((Puget Sound)) marine sediment cleanup objectives and cleanup screening ((level, and the Puget Sound marine sediment minimum cleanup level criteria.
- (a) The acute and chronic effects biological tests of WAC 173-204-315(1) shall be used to:
- (i) Identify the Puget Sound marine sediment cleanup screening level for the purpose of screening sediment station elusters of potential concern using the procedures of WAC 173-204-510(2); and
- (ii) Identify the Puget Sound marine sediment cleanup screening level for the purpose of identifying station clusters of low concern and/or cleanup sites using the hazard assessment procedures of WAC 173-204-530(4); and/or
- (iii) Identify the Puget Sound marine sediment minimum eleanup level to confirm minimum cleanup level determinations using the procedures of WAC 173-204-570(3).
- (b) When using biological testing to determine if station clusters exceed the cleanup screening level or to identify the minimum cleanup level for a contaminated site, test results from at least two acute effects tests and one chronic effects test shall be evaluated.
- (c) The biological tests shall not be considered valid unless test results for the appropriate control and reference sediment samples meet the performance standards described in WAC 173-204-315(2).
- (d))) levels. The criteria of this section shall apply to marine sediments for toxicity to the benthic invertebrate community.
- (a) The sediment cleanup objectives of this section establish a no adverse effects level, including acute or chronic adverse effects, to the benthic community. The sediment cleanup objective biological criteria for a sampling station is exceeded when one of the biological test results is above the sediment cleanup objective as described in Table IV.
- (b) The cleanup screening levels of this section establish a minor adverse effects level, including acute or chronic adverse effects, to the benthic community. The cleanup screening level ((and minimum cleanup level)) biological criteria for a sampling station is exceeded when:
- (i) Any two of the biological test((s)) results for a sampling station exceed the ((eriteria of WAC 173-204-320(3); or one of the following test determinations is made:
- (i) Amphipod: The test sediment has a higher (statistically significant, t test, p≤0.05) mean mortality than the reference sediment and the test sediment mean mortality is greater

- than a value represented by the reference sediment mean mortality plus thirty percent.
- (ii) Larval: The test sediment has a mean survivorship of normal larvae that is less (statistically significant, t test, p≤0.05) than the mean normal survivorship in the reference sediment and the test sediment mean normal survivorship is less than seventy percent of the mean normal survivorship in the reference sediment (i.e., the test sediment has a mean combined abnormality and mortality that is greater than thirty percent relative to time-final in the reference sediment).
- (iii) Benthic abundance: The test sediment has less than fifty percent of the reference sediment mean abundance of any two of the following major taxa: Class Crustacea, Phylum Mollusca or Class Polychaeta and the test sample abundances are statistically different (t test, p≤0.05) from the reference abundances.
- (iv) Juvenile polychaete: The test sediment has a mean individual growth rate of less than fifty percent of the reference sediment mean individual growth rate and the test sediment mean individual growth rate is statistically different (t test, p≤0.05) from the reference sediment mean individual growth rate.
- (4) Puget Sound marine sediment cleanup screening levels and minimum cleanup levels human health criteria. Reserved: The department may determine on a case-by-case basis the criteria, methods, and procedures necessary to meet the intent of this chapter.
- (5) Puget Sound marine sediment cleanup screening levels and minimum cleanup levels)) sediment cleanup objective in Table IV; or
- (ii) One of the biological test results for a sampling station exceeds the cleanup screening level in Table IV.
- (c) The acute and chronic effects biological tests of Table V shall be used to:
- (i) Confirm designation of marine sediments for benthic community toxicity. The department may require, or any person may perform, biological testing to confirm the designation of marine sediment which either passes or fails the chemical criteria established in subsection (2) of this section. If required, the sediment shall be tested using the procedures in (d) of this subsection; and
- (ii) Establish the marine sediment cleanup objective and cleanup screening level for identifying sediment station clusters of potential concern for benthic community toxicity using the procedures of WAC 173-204-510(2); and
- (iii) Establish the marine sediment cleanup objective or cleanup screening level for identifying station clusters of low concern using the procedures of WAC 173-204-510(2).
- (d) To designate sediment quality using biological criteria, a minimum of the following shall be included in the suite of biological tests for each sediment sample as described in Table V:
 - (i) Two acute effects tests; and
 - (ii) One chronic test.
- (e) The appropriate control and reference sediment samples shall meet the performance standards described in Table IV. Selection and use of reference sediment must be approved by the department. The department may approve a different performance standard based on latest scientific knowledge.

- (f) Use of alternate biological tests may be required by the department and shall be subject to the review and approval of the department under WAC 173-204-130(4).
- (g) Any person who designates test sediments using the procedures of this section shall meet the sampling and testing plan requirements of WAC 173-204-600 and records management requirements of WAC 173-204-610. Test sediments designated using the procedures of this section shall be sampled and analyzed using methods approved by the department, and shall use an appropriate quality assurance/quality control program, as determined by the department.
- (4) Marine sediment Other toxic, radioactive, biological, or deleterious substances criteria. "Other toxic, radioactive, biological, or deleterious substances" means substances not specified in Table III, that are in, or on, sediments. They shall be at or below levels which cause minor adverse effects in marine biological resources((, or which correspond to a significant health risk to humans, as deter-

mined by the department)). The department shall determine on a case-by-case basis ((the)) other criteria, methods, and procedures, such as using the biological criteria of subsection (3)(a) through (g) of this section, necessary to meet the intent of this ((chapter)) part.

(((6) Puget Sound marine sediment cleanup screening levels and minimum cleanup levels nonanthropogenically affected sediment criteria. Whenever the nonanthropogenically affected sediment quality is of a lower quality (i.e., higher chemical concentrations, higher levels of adverse biological response, or posing a higher threat to human health) than the applicable cleanup screening levels or minimum cleanup levels criteria established under this section, the existing sediment chemical and biological quality shall be identified on an area-wide basis as determined by the department, and used in place of the standards of WAC 173-204-520.))

<u>Table IV</u>

<u>Marine Sediment Cleanup Objectives and Cleanup Screening Levels Biological Criteria</u>

Diological Tost/Endneint	Performance Standard	Performance Standard	Sediment Cleanup Objective for each biological test	Cleanup Screening Level
Biological Test/Endpoint	<u>Control</u>	<u>Reference</u>	ior each biological test	for each biological test
<u>Amphipod</u>		<u></u>		
10-day Mortality	$\underline{M_{\underline{C}}} \le 10\%$	$\underline{M_R} \le 25\%$	$M_{\underline{T}} > 25\%$ Absolute and $M_{\underline{T}}$	$M_{T} - M_{R} \ge 30\%$
			$vs M_R SD (p \le 0.05)$	<u>and</u>
				$\underline{M_T \text{ vs } M_R \text{ SD } (p \le 0.05)}$
Larval	1			
Bivalve or Echinoderm	$\underline{N_C / I \ge 0.70}$	$N_R/N_C \ge 0.65$	$(N_R - N_T)/N_C > 0.15$	$(N_R - N_T)/N_C > 0.30$
Abnormality/Mortality	_	= =	and	and
			$N_T/N_C \text{ vs } N_R/N_C \text{SD}$	N_T/N_C vs N_R/N_C SD
			$(p \le 0.10)$	$(p \le 0.10)$
			4	*
Juvenile Polychaete				
Neanthes 20-day Growth	<u>M_C < 10%</u>	MIG _R /MIG _C	$MIG_T/MIG_R < 0.70$	$\underline{\text{MIG}}_{\underline{\text{T}}}/\underline{\text{MIG}}_{\underline{\text{R}}} < 0.50$
	<u>and</u>	<u>> 0.80</u>	<u>and</u>	<u>and</u>
	$MIG_C > 0.72$ mg/individ-		MIG_T vs MIG_R SD $(p \le 0.05)$	MIG _T vs MIG _R SD
	ual/day			$(p \le 0.05)$
	(or case-by-case)			*
<u>Microtox</u>				
Microtox Decreased	case-by-case	case-by-case	$\underline{ML_T/ML_R} < 0.80$	
Luminescence			<u>and</u>	
			$\underline{ML_T \text{ vs } ML_R \text{ SD } (p = 0.05)}$	
Benthic Abundance				
Benthic Abundance	See Table I	IV legend	$A_{T}/A_{R} < 0.50$	$A_{T}/A_{R} < 0.50$
			For any one of three major	For any two of three major
			<u>taxa</u>	<u>taxa</u>
			Class Crustacea, Phylum	Class Crustacea, Phylum
			Mollusca or Class	Mollusca or Class
			<u>Polychaeta</u>	<u>Polychaeta</u>

Table IV Explanatory Notes:

A = Abundance;

AFDW = Ash free dry weight;

C = Control;

R = Reference;

T = Test;

<u>I = Initial count;</u>

M = Mortality;

N = Normal survivorship expressed as actual counts;

MIG = Mean individual growth rate expressed in mg/ind/day AFDW;

ML = Mean light output;

<u>SD</u> = <u>Statistically significant difference</u>;

An exceedance of the criteria requires a statistically significant difference at $p \le 0.05$ for Amphipod, Juvenile Polychaete, Microtox tests:

An exceedance of the criteria requires a statistically significant difference at $p \le 0.10$ for the Larval tests.

Benthic Abundance: The reference benthic macroinvertebrate assemblage should be representative of areas removed from significant sources of contaminants and, to the extent possible, have the following characteristics:

(1) The taxonomic richness of benthic macroinvertebrates and the abundances of higher taxonomic groups that reflect seasonality

Permanent [28]

- and natural, physical, and chemical conditions (e.g., grain size composition, salinity of sediments, water depth) in a reference area and not be obviously depressed as a result of chemical toxicity.
- (2) Normally abundant species that are known to be sensitive to chemical contaminants are present;
- (3) Normally rare species that are known to become abundant only under chemically disturbed conditions are rare or absent; and
- (4) The abundances of normally rare species that control benthic community structure through physical modification of the sediment are similar to those observed at the test sediment site.

Types of Marine Sediment Biological Tests, Species, and
Applicable Endpoints.

Species/Class, biological test, and endpoint	Acute effects biological test	Chronic effects biological test
Amphipod: Rhepoxynius abronius, Ampelisca abdita, Eohaustorius estuarius		
10-day Mortality	<u>X</u>	
Larval: Crassostrea gigas (Pacific oyster), Mytilus (edulis) galloprovincialis (Blue mussel), Strongylocentrotus purpuratus (Purple sea urchin), Dendraster excentricus (Sand dollar)		
Mortality/Abnormality	<u>X</u>	
Juvenile Polychaete:		
Neanthes arenaceodentata		
20-day Growth		<u>X</u>
Microtox: Vibrio fisheri		
15-minute exposure; Decreased luminescence		X
Benthic Infauna: Class Crustacea, Polychaeta, Phylum Mollusca		X

(5) Low salinity sediment cleanup screening levels criteria. Reserved: The department shall determine on a case-by-case basis the criteria, methods, and procedures necessary to meet the intent of this part.

AMENDATORY SECTION (Amending WSR 96-02-058, filed 12/29/95, effective 1/29/96)

- WAC 173-204-530 Hazard assessment and site identification. (1) Purpose. A hazard assessment shall be performed to gather existing and available information to further characterize each station cluster of potential concern identified per WAC 173-204-510.
- (2) Hazard assessment requirements. ((Onsite)) Onsite dischargers, lessees, landowners, and adjacent dischargers shall submit, upon the department's request, all existing and available information or, if determined necessary by the department, shall perform sampling for a known or suspected release that would enable the department to:
- (a) Determine the concentration and/or areal extent and depth of sediment contamination at the station cluster of potential concern by:

- (i) Identifying the contaminants exceeding the applicable sediment ((quality standards)) cleanup objectives of WAC ((173-204-320 through 173-204-340)) 173-204-562 or 173-204-563;
- (ii) Identifying individual stations within the station cluster of potential concern ((which exceed)) exceeding the applicable sediment cleanup screening levels ((eriteria)) of WAC ((173-204-520)) 173-204-562 or 173-204-563;
- (iii) Identifying the level of toxicity to the applicable biological test organisms of WAC ((173-204-320 through 173-204-340)) 173-204-562 or 173-204-563;
- (iv) Determining where the applicable sediment ((quality standards)) cleanup objectives of WAC ((173-204-320 through 173-204-340)) 173-204-562 or 173-204-563, for any given ((eontaminant)) chemical, is met;
- (v) Determining if concentrations of chemicals exist that ((potentially present a significant threat to human health)) exceed applicable cleanup screening levels of WAC 173-204-560; and
- (vi) Defining the location where the ((minimum eleanup)) cleanup screening level as defined in WAC ((173-204-570)) 173-204-560 is not met.
- (b) Identify and characterize the present and historic source or sources of the contamination((-1)).
- (c) Identify the location of sediment impact zones authorized under WAC 173-204-415((-));
- (d) Identify sensitive resources in the vicinity of the station cluster of potential concern((-));
- (e) ((Provide)) Compile other information as determined necessary by the department for ((ranking)) evaluating sites under WAC ((173-204-540.
 - (3) The department shall also)) 173-204-530; and
- (f) Compile existing and available information from other federal, state, and local governments ((that pertain to the topics in subsection (2) of this section)).
- (((4+))) (3) Identification of cleanup sites. To identify cleanup sites, the department shall use all available information of acceptable quality gathered from the hazard assessment to evaluate station clusters of potential concern identified pursuant to WAC 173-204-510(2). For the purpose of identifying a cleanup site per the procedures of this subsection, three stations with the highest ((contaminant)) chemical concentration for any particular ((eontaminant)) chemical or the highest degree of biological effects as identified in WAC $((\frac{173-204-520}{173-204-562}))$ 173-204-562 or 173-204-563, as applicable, are selected from a station cluster of potential concern. This procedure may be repeated for multiple chemicals ((identified in WAC 173 204 520,)) recognizing that the three stations with the highest concentration for each particular ((eontaminant)) chemical may be different and the respective areas for all chemicals may overlap. The department shall review the list of station clusters of potential concern to identify cleanup sites via the following process:
- (a) ((Identify if available, three stations within the station cluster of potential concern with the highest level of biological effects for the biological tests identified in WAC 173-204-315(1).
- (b))) Station clusters of potential concern ((where the level of biological effects for any three stations within the station cluster of potential concern exceeds the cleanup screen-

[29] Permanent

- ing levels of WAC 173-204-520(3))) that meet the conditions in WAC 173-204-510 (2)(a)(ii) or (b) shall be defined as cleanup sites((-
- (c) Identify if available, the three stations within a station eluster of potential concern with the highest concentration of each chemical contaminant identified in WAC 173-204-520, Cleanup screening levels criteria.)) if concentrations are above the regional background cleanup screening level in WAC 173-204-560(4), as applicable;
- (b) For the purpose of identifying a cleanup site per the procedures of this subsection, stations that meet the biological standards of WAC ((173 204 520(3))) 173-204-562(3) or 173-204-563(3), as applicable, shall not be included in the evaluation of chemical contaminant concentrations((-
- (d) For each contaminant identified in (e) of this subsection, determine the average concentration for the contaminant at the three stations identified in (e) of this subsection.
- (e) Station clusters of potential concern for which any average chemical concentration identified in (d) of this subsection exceeds the cleanup screening level chemical criteria of Table III shall be defined as cleanup sites.
 - (f))) for benthic community toxicity;
- (c) After completion of the hazard assessment, if ((neither of)) the conditions of (a) or (b) ((or (e))) of this subsection do not apply, then the station cluster is defined as a station cluster of low concern((-
- (g) Station clusters of potential concern where)) for benthic community toxicity; and
- (d) If the department determines that ((any)) each of three stations within the station cluster of potential concern exceed any one of the ((sediment cleanup screening levels human health criteria or)) following criteria, then the station cluster of potential concern may be defined as a cleanup site or area for potential further investigation:
- (i) The applicable human health and regional background cleanup screening levels in WAC 173-204-560(4);
- (ii) The other toxic, radioactive, biological, or deleterious substances criteria in WAC 173-204-562 or 173-204-563, as applicable; or
- (iii) The nonanthropogenically affected criteria of WAC ((173-204-520, shall be defined as cleanup sites)) 173-204-562 or 173-204-563, as applicable.

<u>AMENDATORY SECTION</u> (Amending Order 90-41, filed 3/27/91, effective 4/27/91)

- WAC 173-204-540 ((Ranking)) Evaluation and ((list)) listing of sites. (1) Purpose. The department shall prepare and maintain a list of contaminated sediment sites in the order of their relative ((hazard ranking)) risk to human health and the environment. From this list, the department shall select sites where action shall be taken.
- (2) Site ((ranking)) evaluation. The department shall evaluate each sediment cleanup site identified by the procedures in WAC ((173-204-530)) 173-204-520 on a consistent basis using ((the procedure described in Sediment Ranking System ("SEDRANK"), January 1990, and all additions and revisions thereto or other)) procedures approved by the department. The purpose of ((ranking)) the evaluation is to estimate, based on technical information compiled during the

- hazard assessment procedures in WAC ((173-204-530)) 173-204-520, the relative potential risk posed by the site to human health and the environment. Information obtained during the hazard assessment, ((plus any additional data specified in "SEDRANK,")) shall be included in the site ((hazard ranking)) evaluation.
- (3) Considerations in ((ranking)) site evaluation. In conducting sediment site ((ranking)) evaluations, the department shall assess both human health hazard and ecological hazard, and consider chemical toxicity, affected resources, and site characteristics for both types of hazards. The department shall also use best professional judgment and other information as necessary on a case-by-case basis to conduct site ((ranking)) evaluations.
- (4) **Site** ((reranking)) reevaluations. The department may, at its discretion, ((rerank)) reevaluate a site. To ((rerank)) reevaluate a site, the department shall use any additional information within the scope of the ((hazard ranking)) evaluation criteria and best professional judgment to establish that a significant change ((in rank)) should result.
 - (5) ((List)) Listing of ((ranked)) sites.
- (a) Contaminated sediment sites ((that are ranked via "SEDRANK")) shall be placed on a list ((in the order of their relative hazard ranking)). The list shall describe the current status of cleanup action at each site ((and be updated on an annual basis. The department may change a site's status to reflect current conditions on a more frequent basis. The status for each site shall be identified as one or more of the following:
 - (i) Sites awaiting cleanup action;
- (ii) Sites where voluntary, incidental, partial or department initiated cleanup actions, as defined in WAC 173-204-550, are in progress;
- (iii) Sites where a cleanup action has been completed and confirmational monitoring is underway;
- (iv) Sites with sediment recovery zones authorized under WAC 173-204-590; and/or
 - (v) Other categories established by the department)).
- (b) The department shall routinely publish and make the list available to be used in conjunction with a review of ongoing and proposed regulatory actions to determine where and when a cleanup action should be taken. The department shall also make the list available to landowners and dischargers at or near listed sites, and to the public.
 - (6) Site delisting.
- (a) The department may remove a site from the list only after it has determined that:
- (i) All cleanup actions, except confirmational monitoring ((have been completed and compliance with the site eleanup study and report)) and all other actions required in the cleanup action plan or equivalent document under WAC 173-204-575, have been completed and all sediment cleanup ((standard(s) has)) standards have been achieved; or
 - (ii) The listing of the site was erroneous.
- (b) A site owner or operator may request that a site be removed from the list by submitting a petition to the department. The petition shall state the reason for the site delisting request, and as determined appropriate by the department, shall include thorough documentation of all investigations performed, all cleanup actions taken, and all compliance

Permanent [30]

- monitoring data and results to demonstrate to the department's satisfaction that the ((site)) sediment cleanup standards have been achieved. The department may require payment of costs incurred((, including an advance deposit,)) for review and verification of the work performed. The department shall review such petitions, however the timing of the review shall be at its discretion and as resources may allow.
- (c) The department shall maintain a record of sites that have been removed from the list under (a) of this subsection. This record shall be made available to the public on request.
- (d) The department shall provide public notice and an opportunity to comment when the department proposes to remove a site from the list.
- (7) <u>Site relisting ((of sites)</u>). The department may relist a site which has previously been removed if it determines that the site requires further cleanup action.
- (8) ((Delisting notice: The department shall provide public notice and an opportunity to comment when the department proposes to remove a site from the list.
- (9))) Relationship to hazardous sites list. The department may additionally evaluate cleanup sites on the site list developed under subsection (5) of this section for possible inclusion on the hazardous sites list published under WAC 173-340-330.

<u>AMENDATORY SECTION</u> (Amending Order 90-41, filed 3/27/91, effective 4/27/91)

- WAC 173-204-550 Types of cleanup and authority.

 (1) Purpose. ((The department acknowledges that cleanups of contaminated sediment sites can occur under the authority of chapter 90.48 or 70.105D RCW. Sediment cleanups may also be initiated by the federal government pursuant to the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). This section describes the department's role in department initiated and other cleanup actions.)) This section describes the authorities and administrative options that may be used to address a release or threatened release of a contaminant to sediment that may pose a threat to human health or the environment. This section also describes the process for selecting an appropriate authority and administrative option.
- (2) Authority. This part shall apply to a release or threatened release of a contaminant to sediment that may pose a threat to human health or the environment. The department recognizes that such a release may also be addressed under other authorities. The department shall use best professional judgment ((and other information as necessary)) on a case-by-case basis to determine the appropriate ((administrative)) authority for ((eonducting, or requiring contaminated sediment cleanup actions based on, but not limited to,)) addressing such a release. The department may initiate remedial actions under this part or may determine that another authority is more appropriate. When determining the appropriate authority, the department's decision may include the following considerations:
- (a) Source of contaminants requiring cleanup including spills, dredging actions, and wastewater and/or storm water discharges;

- (b) Significance of contamination threat to human health and the environment including the degree of contamination and types and number of contaminants;
- (c) Public ((perception)) comments received concerning the contaminant threat to human health and the environment;
- (d) ((Personal or corporate financial status of the landowner(s) and/or discharger(s);
- (e))) Enforcement compliance history of the land-owner(s) and/or discharger(s);
- (((f))) (<u>e</u>) Status of existing or pending federal, state, or local legal orders or administrative actions; and
- $((\frac{g}{g}))$ (f) Size of cleanup action proposed or determined necessary.
- (3) ((The types of cleanup actions below establish seenarios recognized by the department which may occur to effect cleanup of contaminated sediment sites. All of these types of cleanup actions shall be subject to administrative review and approval of the department under chapters 90.48 and/or 70.105D RCW.
- (a) Department initiated cleanup. Department initiated eleanup actions occur when the department uses its authority under chapter 90.48 and/or 70.105D RCW to conduct or require and/or otherwise effect cleanup to meet the intent of this chapter.
- (b) Voluntary eleanup. Voluntary cleanup actions are initiated by parties other than the department. The department shall encourage voluntary eleanup actions whenever possible, and as early as possible, to meet the intent of this chapter.
- (c) Incidental cleanup. Incidental cleanup actions are conducted when other state or federally permitted activities are ongoing in and/or around the contaminated sediment site. Early coordination of incidental cleanup actions with the department is encouraged to meet the intent of this chapter, chapter 70.105D RCW, and chapter 90.48 RCW, as appropriate.
- (d) Partial cleanup. Partial cleanup actions may be conducted when completion of cleanup study requirements under WAC 173-204-560 has identified and proposed discrete site units and cleanup standards, the department has approved the selection of the partial cleanup alternative per the standards of WAC 173-204-580, and the department has determined that awaiting action or decision on conducting a complete site cleanup would have a net detrimental effect on the environment or human health.
- (e) CERCLA eleanup. Pursuant to the federal Comprehensive Environmental Response, Compensation and Liability Act, the department may identify chapter 173-204 WAC as an applicable state requirement for cleanup actions conducted by the federal government.)) Administrative options. Administrative options used to conduct remedial actions at sites and sediment cleanup units include:
- (a) Department-conducted or supervised remedial actions. The department may conduct or require others to conduct remedial actions at sites or sediment cleanup units under chapter 70.105D RCW;
- (b) Federal-conducted or supervised remedial actions. The federal government may conduct or require others to conduct remedial actions at sites or sediment cleanup units pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (42 U.S.C. Sec.

- 9601 et seq.). When evaluating federal remedial actions, the department shall consider all requirements in this part to be legally applicable requirements under 42 U.S.C. Sec. 9621(d). Federal remedial actions may be considered by the department to meet the requirements of this part provided:
- (i) The remedial actions are consistent with the requirements in this part;
 - (ii) The state has concurred with the remedial action; and (iii) An opportunity was provided for the public to com-
- (iii) An opportunity was provided for the public to comment on the remedial action.
- (c) Incidental remedial actions. Incidental remedial actions may be conducted when other state or federally permitted activities are ongoing in and/or around the site. Early coordination of incidental remedial actions with the department is encouraged to ensure such actions meet the requirements in this part and chapter 70.105D RCW.

AMENDATORY SECTION (Amending WSR 96-02-058, filed 12/29/95, effective 1/29/96)

- WAC 173-204-560 ((Cleanup)) Remedial investigation and feasibility study. (1) Purpose. ((This section describes cleanup study plan and report standards which meet the intent of cleanup actions required under authority of chapter 90.48 and/or 70.105D RCW, and/or this chapter. Cleanup actions required under authority of chapter 70.105D RCW shall also meet all standards of chapter 173-340 WAC, the Model Toxics Control Act cleanup regulation. The eleanup study plan and report standards in this chapter include activities to collect, develop, and evaluate sufficient information to enable consideration of cleanup alternatives and selection of a site-specific sediment cleanup standard prior to making a cleanup decision. Each person performing a cleanup action to meet the intent of this chapter shall submit a cleanup study plan and cleanup study report to the department for review and written approval prior to implementation of the cleanup action. The department may approve the eleanup study plan as submitted, may approve the eleanup study plan with appropriate changes or additions, or may require preparation of a new cleanup study plan.)) The purpose of a remedial investigation/feasibility study is to collect, develop, and evaluate sufficient information regarding a site or sediment cleanup unit for the department to establish sediment cleanup standards and select a cleanup action under this
- (2) Scope ((of eleanup study plan)). The scope of a ((eleanup study plan shall)) remedial investigation/feasibility study depends on ((the specific site informational needs, the site hazard,)) many factors, including the nature and extent of contamination, the exposure pathways of concern, the natural resources potentially impacted by the contamination, the characteristics of the site or sediment cleanup unit, and the type of cleanup action ((proposed, and the authority cited by the department to require cleanup. In establishing the necessary scope of the cleanup study plan, the department may eonsider cost mitigation factors, such as the financial resources of the person(s) responsible for the cleanup action) alternatives likely to be evaluated under WAC 173-204-570 through 173-204-575. In all cases, sufficient information must be collected, developed, and evaluated to enable the

((appropriate selection of a)) department to establish sediment cleanup standards ((under WAC 173-204-570 and a eleanup action decision under WAC 173-204-580. The sediment cleanup study plan shall address:)) and select cleanup actions under this part.

(3) Administrative requirements.

- (a) Unless otherwise directed by the department, a remedial investigation/feasibility study must be completed before a cleanup action is selected under WAC 173-204-570 and 173-204-575.
- (b) Before conducting a remedial investigation, a work plan must be submitted to and approved by the department.
- (c) As directed by the department, a remedial investigation and a feasibility study may be conducted as separate steps in the cleanup process and submitted as separate reports or combined into a single step and report.
- (d) Remedial investigation and feasibility study reports must be submitted to the department for review and approval.
- (4) Remedial investigation work plan. The remedial investigation work plan shall include the following:
 - (a) Public ((information/education)) participation plan;
- (b) ((Site investigation and eleanup alternatives evaluation:
- (e))) A summary of available information regarding the site and data gaps needing to be addressed by the remedial investigation;
- (c) A conceptual site model, including current and potential human and ecological receptors and exposure pathways;
- (d) Cleanup action alternatives that are likely to be considered in the feasibility study;
- (e) Sampling plan and recordkeeping in compliance with WAC 173-204-600 through 173-204-610. Analytical methods and limits shall be sufficiently sensitive to measure concentrations at levels of potential regulatory concern. Proposed sampling locations should consider the movement and deposition patterns of sediments; ((and
 - (d))) (f) Site safety((-
- (3) Cleanup study plan public information/education requirements)) plan to meet the requirements of the Occupational Safety and Health Act of 1970 (29 U.S.C. Sec. 651 et seq.) and the Washington Industrial Safety and Health Act (chapter 49.17 RCW), and regulations promulgated pursuant thereto. These requirements are subject to enforcement by the designated federal and state agencies. Actions taken by the department under this part do not constitute an exercise of statutory authority within the meaning of section (4)(b)(1) of the Occupational Safety and Health Act;
- (g) A proposed schedule for completion of the remedial investigation/feasibility study; and
 - (h) Other information as required by the department.
- (5) <u>Public participation plan requirements</u>. The ((eleanup study)) <u>public participation</u> plan shall encourage <u>early</u>, coordinated, and effective public involvement commensurate with the nature of the proposed cleanup action, the level of public concern, and the existence of, or potential for, adverse effects on biological resources and/or a threat to human health. The ((eleanup study)) plan shall ((address proposed activities for)) be consistent with WAC 173-340-600 and include the following ((subjects)) information:

Permanent [32]

- (a) When public notice will occur, the length of the comment periods accompanying each notice, the potentially affected vicinity, and any other areas to be provided notice;
- (b) Where public information ((repositories)) will be located to provide ((site)) information ((to the publie)) about the site;
- (c) Methods for identifying the public's concerns((; e.g.,)) such as interviews, questionnaires, and community group meetings((; etc.));
- (d) Methods for providing information to the public((; e.g.,)) such as press releases, public meetings, fact sheets, ((etc.)) and listservs;
- (e) Coordination of public participation requirements mandated by other ((federal, state, or local)) applicable laws;
- (f) Amendments to the planned public involvement activities; and
- (g) Any other ((elements that)) information required by the department ((determines to be appropriate for inclusion in the cleanup study plan)).
- (((4) Cleanup study plan site investigation and cleanup alternatives evaluation requirements. The content of the cleanup study plan for the site investigation and cleanup alternatives evaluation is determined by the type of cleanup action selected as defined under WAC 173-204-550. As determined by the department, the cleanup study plan shall address the following subjects:)) (6) Remedial investigation report. The remedial investigation report shall include the following as appropriate:
- (a) General site information. General information, including: Project title; name, address, and phone number of project coordinator; legal description of the cleanup site; area and volume dimensions of the site; present and past owners and operators; present owners and operators of contaminant source discharges to the site((; chronological listing of past owners and operators of contaminant source discharges to the site)) and their respective operational history; and other pertinent information ((determined)) required by the department((τ));
- (b) <u>Sediment cleanup unit</u>. <u>If applicable, the proposed sediment cleanup unit boundary and basis for the boundary;</u>
- (c) Sediment cleanup standards. For each contaminant, identify the following and the basis for the proposed values:
 - (i) The proposed sediment cleanup objective;
 - (ii) The proposed cleanup screening level;
- (iii) The proposed sediment cleanup standard including the sediment cleanup level and point of compliance;
- (d) Site conditions map. An existing site conditions map which illustrates site features as follows:
 - (i) Property boundaries((-));
- (ii) The site boundary <u>as</u> defined by the individual contaminants exceeding the ((applicable)) <u>proposed</u> sediment ((quality)) <u>cleanup</u> standards ((of)) <u>as specified in</u> WAC ((173-204-320 through 173-204-340)) <u>173-204-560</u>. <u>Delineations shall be made</u> at the point where the concentration of the contaminants would meet the((÷
 - (A) Cleanup objective; and
 - (B) Minimum cleanup level; and
- (C) Recommended cleanup standards.)) criteria in (c) of this subsection;

- (iii) <u>Proposed sediment cleanup unit boundary, if applicable;</u>
 - (iv) Surface and subsurface structures topography((-
 - (iv) Surface and subsurface structures.));
 - (v) Utility lines((\cdot)):
 - (vi) Navigation lanes((-
 - (vii) Current and ongoing sediment sources.

(viii)); and

(vii) Other pertinent information determined by the department((-

(c) Site));

- (e) Investigation. Sufficient investigation to characterize the distribution of sediment contamination ((present at the site,)) and the threat or potential threat to human health and the environment. Where applicable ((to the site)), these investigations shall address the following:
- (i) Surface water and sediments. Investigations of <u>sediment</u>, surface water hydrodynamics, and sediment transport mechanisms to characterize significant hydrologic features such as:
- ((Site)) (A) Surface water drainage patterns, quantities and flow rates((z));
- (B) Areas of sediment erosion and deposition including estimates of sedimentation rates((, and actual or potential));
- (C) Contaminant migration routes ((to and from the site and within the site. Sufficient surface water and sediment sampling shall be performed to adequately characterize the));
- (D) Areal and vertical distribution and concentrations of contaminants((-)) in sediment; and
- (E) Recontamination potential of sediments which are likely to influence the type and rate of contaminant migration, or are likely to affect the ability to implement alternative cleanup actions ((shall be characterized));
- (ii) Geology and groundwater system characteristics. Investigations of ((site)) the geology and hydrogeology to ((adequately)) characterize the physical properties and distribution of sediment types, and the characteristics of groundwater flow rate, groundwater gradient, groundwater discharge areas, and groundwater quality data which may affect ((site)) cleanup action alternatives evaluations;
- (iii) Climate. Information regarding local and regional climatological characteristics which are likely to affect surface water hydrodynamics, groundwater flow characteristics, and migration of sediment contaminants such as: Seasonal patterns of rainfall; the magnitude and frequency of significant storm events; and prevailing wind direction and velocity;
- (iv) Land use. Information characterizing human populations exposed or potentially exposed to sediment contaminants ((released from the site and)), the present and proposed uses ((and)) of the land, zoning for contiguous shoreline areas ((contiguous with the site)), and the aquatic state land use classification under chapter 332-30 WAC; and
- (v) Natural resources and ((ecology)) <u>habitat</u>. Information to determine the impact or potential impact of sediment contaminants ((from the site)) on <u>ecological receptors</u>, natural resources and ((ecology)) <u>sensitive habitat</u> of the area such as((: Sensitive environment, local and regional habitat,)) <u>spawning areas</u>, nursery grounds, shellfish or eelgrass beds

and other plant and animal species((, and other environmental receptors.

(d) Sediment));

- (f) Confirmed and suspected contaminant sources. A description of the confirmed and suspected sources, including the location((5)) and quantity, ((areal and vertical extent, concentration and sources of)) as well as any active and inactive waste disposal ((and other sediment contaminant discharge sources which affect or potentially affect the site)) facilities. Where determined relevant by the department, the following information shall be obtained by the department from the responsible discharger:
- (i) The physical and chemical characteristics((;)) and the biological effects of ((site)) sediment contaminant sources;
- (ii) The status of source control actions for permitted and unpermitted ((site sediment)) contaminant sources; and
- (iii) ((A recommended)) Existing compliance time frames for ((known)) permitted ((and unpermitted site sediment)) contaminant sources which affect or potentially affect implementation of the timing and scope of the ((site)) cleanup action alternatives((-

(e)));

- (g) Human health risk assessment. The current and potential <u>significant</u> threats to human health ((that may be)) posed by sediment ((site)) contamination shall be evaluated ((using a risk assessment procedure approved by the department.
- (f) Cleanup action alternatives.)) under WAC 173-204-561; and
 - (h) Any other information required by the department.
- (7) **Feasibility study report.** The feasibility study report shall include the following as appropriate:
- (a) If the feasibility study is not combined with the remedial investigation in one report, a summary of the remedial investigation results including:
- (i) Conceptual site model to provide the basis from which cleanup action alternatives are developed and evaluated;
- (ii) If applicable, the proposed sediment cleanup unit boundary and the basis for the boundary;
- (iii) The proposed biologically active zone and the basis for the zone;
- (iv) For each contaminant, the proposed sediment cleanup standard, including sediment cleanup level and point of compliance, and basis for the standard; and
- (v) Maps, cross-sections, and calculations illustrating the location, estimated amount and concentration distribution of contaminants above proposed sediment cleanup levels and the proposed sediment cleanup objectives and cleanup screening levels;
- (b) Results of any additional investigations or technology evaluations conducted after completion of the remedial investigation report:
- (c) Each ((eleanup)) <u>feasibility</u> study ((plan)) shall include an evaluation of alternative cleanup actions that protect human health and the environment by eliminating, reducing, or otherwise controlling risks posed through each exposure pathway and migration route. The number and types of alternatives to be evaluated shall take into account the characteristics and complexity of the site((-

- (i) The proposed site cleanup alternatives may include establishment of site units, as defined in WAC 173-204-200(24), with individual cleanup standards within the range required by WAC 173-204-570, based on site physical characteristics and complexity, and cleanup standard alternatives established on consideration of cost, technical feasibility, and net environmental impact.
- (ii) The proposed site cleanup alternatives may include establishment)) and be evaluated using the requirements in WAC 173-204-570;
- (d) Identification and evaluation of a reasonable number and type of alternatives;
- (e) Identification of alternatives eliminated that do not meet the requirements in WAC 173-204-570;
- (f) Documentation of the alternatives evaluation process. For each alternative evaluated include the following:
- (i) The location and estimated amount of each contaminant to be removed or treated by the alternative and the estimated time frame in which removal or treatment will occur; and
- (ii) The location, estimated amount, and projected concentration distribution of each contaminant remaining above proposed sediment cleanup levels after implementation of the alternative;
 - (g) The preferred remedy and the basis for selection;
- (h) Applicable laws specific to the proposed preferred remedy, including a description of permit/approval conditions identified in consultation with the permitting agencies;
- (i) Identification of ((a)) any proposed sediment recovery zone ((as authorized)) and justification for this zone under WAC 173-204-590((, Sediment recovery zones. Establishment or expansion of a sediment recovery zone shall not be used as a substitute for active cleanup actions, when such actions are practicable and meet the standards of WAC 173-204-580. The cleanup study plan shall include the following information for evaluation of sediment recovery zone alternatives:
- (A) The time period during which a sediment recovery zone is projected to be necessary based on source loading and net environmental recovery processes determined by application of the department's sediment recovery zone computer models "CORMIX," "PLUMES," and/or "WASP," or an alternate sediment recovery zone model(s) approved by the department under WAC 173-204-130(4) as limited by the standards of this section and the department's best professional judgment;
- (B) The legal location and landowner(s) of property proposed as a sediment recovery zone;
- (C) Operational terms and conditions including, but not limited to proposed confirmational monitoring actions for discharge effluent and/or receiving water column and/or sediment chemical monitoring studies and/or bioassays to evaluate ongoing water quality, sediment quality, and biological conditions within and adjacent to the proposed or authorized sediment recovery zone to confirm source loading and recovery rates in the proposed sediment recovery zone.
- (D) Potential risks posed by the proposed sediment recovery zone to human health and the environment;
- (E) The technical practicability of elimination or reduction of the size and/or degree of chemical contamination

Permanent [34]

and/or level of biological effects within the proposed sediment recovery zone; and

- (F) Current and potential use of the sediment recovery zone, surrounding areas, and associated resources that are, or may be, affected by releases from the zone.
- (G) The need for institutional controls or other site use restrictions to reduce site contamination risks to human health.
- (iii) A phased approach for evaluation of alternatives may be required for certain sites, including an initial screening of alternatives to reduce the number of potential remedies for the final detailed evaluation. The final evaluation of cleanup action alternatives that pass the initial screening shall consider the following factors:
- (A) Overall protection of human health and the environment, time required to attain the cleanup standard(s), and onsite and offsite environmental impacts and risks to human health resulting from implementing the cleanup alternatives;
- (B) Attainment of the cleanup standard(s) and compliance with applicable federal, state, and local laws;
- (C) Short-term effectiveness, including protection of human health and the environment during construction and implementation of the alternative; and
- (D) Long-term effectiveness, including degree of certainty that the alternative will be successful, long-term reliability, magnitude of residual, biological and human health risk, and effectiveness of controls for ongoing discharges and/or controls required to manage treatment residues or remaining wastes cleanup and/or disposal site risks;
- (g) Ability to be implemented. The ability to be implemented including the potential for landowner cooperation, consideration of technical feasibility, availability of needed offsite facilities, services and materials, administrative and regulatory requirements, scheduling, monitoring requirements, access for construction, operations and monitoring, and integration with existing facility operations and other current or potential cleanup actions;
- (h) Cost, including consideration of present and future direct and indirect capital, operation, and maintenance costs and other foreseeable costs;
- (i) The degree to which community concerns are addressed;
- (j) The degree to which recycling, reuse, and waste minimization are employed; and

(k))))

- (j) Proposed monitoring plan during and after cleanup consistent with the provisions in WAC 173-204-600;
- (k) Environmental impact. Sufficient information shall be provided to fulfill the requirements of chapter 43.21C RCW, the State Environmental Policy Act, for the proposed preferred remedy. Discussions of significant short-term and long-term environmental impacts, significant irrevocable commitments of natural resources, significant alternatives including mitigation measures, and significant environmental impacts which cannot be mitigated shall be included((-
- (5) Cleanup study plan sampling plan and recordkeeping requirements. The cleanup study plan shall address proposed sampling and recordkeeping activities to meet the standards of WAC 173-204-600, Sampling and testing plan

- standards, and WAC 173-204-610, Records management, and the standards of this section.
- (6) Cleanup study plan site safety requirements. The eleanup study plan shall address proposed activities to meet the requirements of the Occupational Safety and Health Act of 1970 (29 U.S.C. Sec. 651 et seq.) and the Washington Industrial Safety and Health Act (chapter 49.17 RCW), and regulations promulgated pursuant thereto. These requirements are subject to enforcement by the designated federal and state agencies. Actions taken by the department under this chapter do not constitute an exercise of statutory authority within the meaning of section (4)(b)(1) of the Occupational Safety and Health Act.
- (7) Cleanup study report. Each person performing a eleanup action to meet the intent of this chapter shall submit a cleanup study report to the department for review and written approval of a cleanup decision prior to implementation of the cleanup action. The sediment cleanup study report shall include the results of cleanup study site investigations conducted pursuant to subsection (4) of this section, and preferred and alternate cleanup action proposals based on the results of the approved cleanup study plan.
- (8) Sampling access. In cases where the person(s) responsible for cleanup is not able to secure access to sample sediments on lands subject to a cleanup study plan approved by the department, the department may facilitate negotiations or other proceedings to secure access to the lands. Requests for department facilitation of land access for sampling shall be submitted to the department in writing by the person(s) responsible for the cleanup action study plan.)); and
 - (1) Any other information required by the department.
- (8) Sampling access. In cases where the person(s) responsible for cleanup is not able to secure access to sample sediment on lands subject to a remedial investigation and feasibility study required by the department, the department may facilitate negotiations or other proceedings to secure access to the lands. Requests for department facilitation of land access for sampling shall be submitted to the department in writing by the person(s) responsible for the remedial investigation and feasibility study.

NEW SECTION

- WAC 173-204-561 Sediment cleanup levels based on protection of human health. (1) Applicability. This section defines sediment cleanup objectives and cleanup screening levels for contaminants based on protection of human health. They are used to:
- (a) Identify and assess the hazard of sites under WAC 173-204-510 and 173-204-520; and
- (b) Establish sediment cleanup levels for sites and sediment cleanup units under WAC 173-204-560.
- (2) **Sediment cleanup objectives.** Sediment cleanup objectives based on protection of human health shall be calculated using the following:
- (a) Target risk levels. Sediment cleanup objectives based on protection of human health shall be at least as protective as the following sediment concentrations:
- (i) Noncarcinogens. For noncarcinogens, sediment concentrations that are estimated to result in no acute or chronic

toxic effects to human health as determined using a hazard quotient of one. If there are multiple noncarcinogens and/or exposure pathways at the site and the hazard index for the site exceeds one, then the sediment cleanup objectives shall be adjusted downward in accordance with WAC 173-340-708 or other methods approved by the department; and

- (ii) Carcinogens. For known or suspected carcinogens, sediment concentrations for which the upper bound on the estimated lifetime excess cancer risk for individual carcinogens is less than or equal to one in one million (1 x 10-6). If there are multiple carcinogens and/or exposure pathways at the site and the total lifetime excess cancer risk for the site exceeds one in one hundred thousand (1 x 10-5), then the sediment cleanup objectives shall be adjusted downward in accordance with WAC 173-340-708 or other methods approved by the department;
- (b) Reasonable maximum exposure. Sediment cleanup objectives and cleanup screening levels for contaminants based on protection of human health shall be calculated using reasonable maximum exposure scenarios that reflect the highest exposure that is reasonably expected to occur under current and potential future site use conditions;
- (i) Default scenario. Except as provided under (b)(ii) of this subsection, the reasonable maximum exposure scenario for a site shall be tribal consumption of fish and shellfish. The department shall consider, as appropriate, the following information on a site-specific basis when selecting or approving the exposure parameters used to represent the reasonable maximum exposure scenario:
- (A) Historic, current, and potential future tribal use of fish and shellfish from the general vicinity of the site;
- (B) Relevant studies and best available science related to fish consumption rates;
- (C) The total fish and shellfish in an individual's diet that is obtained, or has the potential to be obtained, from the general vicinity of the site. This value depends on the ability of the aquatic habitat within the general vicinity of the site to support a department approved fish and shellfish consumption rate under current and potential future site use conditions;
- (D) The fish and shellfish contaminant body burden acquired, or potentially acquired, from the general vicinity of the site; and
- (E) Other information determined by the department to be relevant;
- (ii) Site-specific scenario. The department may approve an alternate reasonable maximum exposure scenario for the site in accordance with WAC 173-340-708 (3) and (10) and 173-340-702 (14) through (16);
- (c) Toxicity parameters. For toxicological parameters, values established by the United States Environmental Protection Agency (USEPA) and available through the Integrated Risk Information System (IRIS) data base shall be used. If the value for a toxicological parameter is not available through IRIS, other sources shall be used. When evaluating the appropriateness of using other sources, the department may use the hierarchy in the following document: USEPA, Office of Solid Waste and Emergency Response, Directive 9285.7-53, "Human Health Toxicity Values in Superfund Risk Assessments."

(3) Cleanup screening levels.

- (a) General. Cleanup screening levels based on protection of human health shall be calculated using the factors in (b) of this subsection and in subsection (2)(b) through (c) of this section.
- (b) Target risk levels. Cleanup screening levels based on protection of human health shall be at least as protective as the following sediment concentrations:
- (i) Noncarcinogens. For noncarcinogens, sediment concentrations that are estimated to result in no acute or chronic toxic effects to human health as determined using a hazard quotient of one. If there are multiple noncarcinogens and/or exposure pathways at the site and the hazard index for the site exceeds one, then the cleanup screening levels shall be adjusted downward in accordance with WAC 173-340-708 or other methods approved by the department; and
- (ii) Carcinogens. For known or suspected carcinogens, sediment concentrations for which the upper bound on the estimated lifetime excess cancer risk for individual carcinogens is less than or equal to one in one hundred thousand (1 x 10^{-5}). If there are multiple carcinogens and/or exposure pathways at the site and the total lifetime excess cancer risk for the site exceeds one in one hundred thousand (1 x 10^{-5}), then the cleanup screening levels shall be adjusted downward in accordance with WAC 173-340-708 or other methods approved by the department.

NEW SECTION

- WAC 173-204-563 Sediment cleanup levels based on protection of the benthic community in freshwater sediment. (1) Applicability. This section defines sediment cleanup objectives and cleanup screening levels for contaminants based on protection of the benthic community in freshwater sediment. They are used to:
- (a) Identify and assess the hazard of sites under WAC 173-204-510 and 173-204-520; and
- (b) Establish sediment cleanup levels for sites and sediment cleanup units under WAC 173-204-560.
- (2) Freshwater sediment Chemical criteria. The chemical concentration criteria in Table VI establish the sediment cleanup objectives and cleanup screening levels chemical criteria for freshwater sediment. The criteria of this section shall apply to freshwater sediments for toxicity to the benthic community.
- (a) The sediment cleanup objectives of this section establish a no adverse effects level, including no acute or chronic adverse effects, to the benthic community. Chemical concentrations at or below the sediment cleanup objectives correspond to sediment quality that results in no adverse effects to the benthic community.
- (b) The cleanup screening levels of this section establish a minor adverse effects level, including acute or chronic effects, to the benthic community. Chemical concentrations at or below the cleanup screening level but greater than the sediment cleanup objective correspond to sediment quality that results in minor adverse effects to the benthic community. The freshwater chemical and biological cleanup screening levels establish minor adverse effects as the level above which station clusters of potential concern are defined and

Permanent [36]

may be defined as potential cleanup sites for benthic community toxicity, and at or below which station clusters of low concern are defined, per the procedures identified in WAC 173-204-510 and 173-204-520.

- (c) The cleanup screening level chemical criteria is exceeded when the sediment chemical concentration for an individual chemical is above the cleanup screening level in Table VI.
- (d) The sediment cleanup objective chemical criteria is exceeded when the sediment chemical concentration for an individual chemical is above the sediment cleanup objective in Table VI.
- (e) For purposes of this section, where chemical analyses indicate a chemical is not detected in a sediment sample, the method detection limit and the practical quantitation limit shall be reported and shall be at or below the freshwater sediment cleanup objectives chemical criteria value in Table VI.
- (f) Where chemical criteria in Table VI represent the sum of individual compounds or isomers, the following methods shall be applied:
- (i) Where chemical analyses identify an undetected value for every individual compound/isomer, then the single highest detection limit shall represent the sum of the respective compounds/isomers; and
- (ii) Where chemical analyses detect one or more individual compound/isomers, only the detected concentrations will be added to represent the group sum.
- (g) The chemical criteria in Table VI represent concentrations as dry weight.
- (h) The total polycyclic aromatic hydrocarbon (PAH) criterion in Table VI represents the sum of the following polycyclic aromatic hydrocarbon compounds: 1-methylnaphthalene, 2-methylnaphthalene, acenaphthene, acenaphthylene, anthracene, benz(a)anthracene, benzo(a)pyrene, benzo(ghi)perylene, chrysene, dibenz(ah)anthracene, fluoranthene, fluorene, indeno(123-cd)pyrene, naphthalene, phenanthrene, pyrene, total benzofluoranthenes (b+k+j).
- (i) The total benzofluoranthenes criterion in Table VI represents the sum of the concentrations of the "B," "J," and "K" isomers.
- (j) The total dichlorodiphenyldichloroethane (DDDs) criterion in Table VI represents the sum of the following DDD isomers: o,p'-DDD and p,p'-DDD.
- (k) The total dichlorodiphenyldichloroethylene (DDEs) criterion in Table VI represents the sum of the following DDE isomers: o,p'-DDE and p,p'-DDE.
- (l) The total dichlorodiphenyltrichloroethane (DDTs) criterion in Table VI represents the sum of the following DDT isomers: o,p'-DDT, p,p'-DDT.
- (m) The total polychlorinated biphenyl (PCB) Aroclors criterion in Table VI represents the sum of the following Aroclors: 1016, 1221, 1242, 1248, 1254, 1260, 1268.
- (n) When the listed chemical criteria in Table VI have a ">" (greater than) value for the cleanup screening level, the cleanup screening level is unknown but is above the concentration shown. If test results show concentrations above this cleanup screening level, bioassays shall be conducted to evaluate potential benthic community toxicity.
- (o) The department recognizes that, in the following types of freshwater sediment environments, the chemical cri-

- teria in Table VI may not reliably predict benthic community toxicity:
- (i) Sediment with unusual geochemical or biochemical characteristics influencing toxicity (release or bioavailability of contaminants) including total organic carbon in environments such as bogs and alpine wetlands;
- (ii) Sediment with pore water or overlying water that has unusual geochemical or biochemical characteristics influencing toxicity (release or bioavailability of contaminants) including pH or hardness;
- (iii) Sediment impacted by metals mining, metals milling, or metals smelting; and
- (iv) Sediment impacted by other toxic, radioactive, biological, or deleterious substances as specified in subsection (4) of this section.
- (p) At a site where the freshwater sediment environment meets the categories specified in (o)(i) or (ii) of this subsection, the department may require alternative methods for characterizing benthic community toxicity. At a site where the freshwater sediment environment meets the categories specified in (o)(iii) or (iv) of this subsection, an alternative method for characterizing benthic community toxicity shall be required. The alternative method used shall be the biological criteria of subsection (3)(a) through (h) of this section, unless the department determines one of the following methods are consistent with the provisions in subsection (3)(a) through (h) of this section:
- (i) Establishing site-specific chemical criteria using site chemistry and the biological criteria of subsection (3)(a) through (h) of this section;
- (ii) Other biological methods approved by the department; or
- (iii) Other approaches in accordance with WAC 173-204-130.

Table VI
Freshwater Sediment Cleanup Objectives and Cleanup
Screening Levels Chemical Criteria

Chemical Parameter	Dry Weight	Dry Weight
	Sediment Cleanup Objective	Cleanup Screening Level
Conventional chemicals (mg/kg)		
Ammonia	230	300
Total sulfides	39	61
Metals (mg/kg)		
Arsenic	14	120
Cadmium	2.1	5.4
Chromium	72	88
Copper	400	1200
Lead	360	> 1300
Mercury	0.66	0.8
Nickel	26	110
Selenium	11	> 20

Permanent

Chemical	Dwy Woight	Dw. Waight
Parameter	Dry Weight Sediment	Dry Weight Cleanup
	Cleanup Objective	Screening Level
Silver	Objective 0.57	1.7
Zinc	3200	> 4200
Organic chemicals	3200	7 4200
(μg/kg)		
4-Methylphenol	260	2000
Benzoic acid	2900	3800
Beta-Hexachlorocy-	7.2	11
clohexane	1.2	11
Bis(2-ethylhexyl)	500	22000
phthalate		
Carbazole	900	1100
Dibenzofuran	200	680
Dibutyltin	910	130000
Dieldrin	4.9	9.3
Di-n-butyl phthalate	380	1000
Di-n-octyl phthalate	39	> 1100
Endrin Ketone	8.5	> 8.5
Monobutyltin	540	> 4800
Pentachlorophenol	1200	> 1200
Phenol	120	210
Tetrabutyltin	97	> 97
Total PCB Aroclors	110	2500
Total DDDs	310	860
Total DDEs	21	33
Total DDTs	100	8100
Total PAHs	17000	30000
Tributyltin	47	320
Bulk Petroleum		
Hydrocarbons		
(mg/kg)		
Total Petroleum	340	510
Hydrocarbon (TPH)- Diesel		
Total Petroleum	3600	4400
Hydrocarbon (TPH)-	3000	4400
Residual		

- (3) Freshwater sediment Biological criteria. The biological effects criteria in Table VII establish the sediment cleanup objectives and cleanup screening levels biological criteria for freshwater sediment. The criteria of this section shall apply to freshwater sediments for toxicity to the benthic invertebrate community.
- (a) The sediment cleanup objectives of this section establish a no adverse effects level, including no acute or chronic adverse effects, to the benthic community. The sediment cleanup objective biological criteria for a sampling station is

- exceeded when one of the biological test results is above the sediment cleanup objective as described in Table VII.
- (b) The cleanup screening levels of this section establish a minor adverse effects level, including acute or chronic effects, to the benthic community. The cleanup screening level biological criteria for a sampling station is exceeded when:
- (i) Any two of the biological test results for a sampling station are above the sediment cleanup objective in Table VII: or
- (ii) One of the biological test results for a sampling station is above the cleanup screening level as described in Table VII.
- (c) The acute and chronic effects biological tests of Table VIII shall be used to:
- (i) Confirm designation of freshwater sediment for benthic toxicity. The department may require, or any person may perform, biological testing to confirm the designation of freshwater sediment which either passes or fails the chemical criteria in subsection (2) of this section. The sediment shall be tested using the procedures in (d) of this subsection;
- (ii) Evaluate the freshwater sediment cleanup objective and cleanup screening level for identifying sediment station clusters of potential concern for benthic community toxicity using the procedures in WAC 173-204-510(2); and
- (iii) Establish the freshwater sediment cleanup objective or cleanup screening level for identifying station clusters of low concern for benthic community toxicity using the procedures in WAC 173-204-510(2).
- (d) To designate sediment quality using biological criteria, a minimum of the following shall be included in the suite of biological tests for each sediment sample as described in Table VIII:
 - (i) Two different species;
 - (ii) Three endpoints;
 - (iii) One chronic test; and
 - (iv) One sublethal endpoint.
- (e) The appropriate control and reference sediment samples shall meet the performance standards described in Table VII. Selection and use of reference sediment must be approved by the department and shall meet the performance standards of Table VII. The department may approve a different performance standard based on latest scientific knowledge.
- (f) When sediment is collected to conduct the biological tests in Table VIII or other biological tests approved by the department, the overlying site water shall be collected and analyzed for pH, hardness, and temperature.
- (g) Use of alternate biological tests may be required by the department and shall be subject to the review and approval of the department using the procedures of WAC 173-204-130(4).
- (h) Any person who designates test sediments using the procedures of this section shall meet the sampling and testing plan requirements of WAC 173-204-600 and records management requirements of WAC 173-204-610. Test sediments designated using the procedures of this section shall be sampled and analyzed using methods approved by the department, and shall use an appropriate quality assurance/quality control program, as determined by the department.

Permanent [38]

(4) Freshwater sediment - Other toxic, radioactive, biological, or deleterious substances criteria. "Other toxic, radioactive, biological, or deleterious substances" means substances not specified in Table VI that are in, or on, sediments and cause minor adverse effects to biological resources, as determined in subsection (3) of this section. The department shall determine on a case-by-case basis other criteria, methods, and procedures, such as those listed in subsection (2)(p) of this section, necessary to meet the criteria in subsection (3) of this section.

Table VII Freshwater Sediment Cleanup Objectives and Cleanup Screening Levels Biological Criteria

Biological Test/		rmance ndard*	Sediment Cleanup Objective	Cleanup Screening Level for each
Endpoint*	Control*	Reference	for each biological test	biological test
Hyalella azteca				
10-day mortality	$M_C \le 20\%$	$M_R \le 25\%$	$\begin{aligned} \mathbf{M_T} &- \mathbf{M_C} > 15\% \\ \text{and} \\ \mathbf{M_T} & \text{vs } \mathbf{M_C} \text{ SD } (\mathbf{p} \leq 0.05) \end{aligned}$	$\begin{aligned} \mathbf{M_T} &- \mathbf{M_C} > 25\% \\ \text{and} \\ \mathbf{M_T} & \text{vs } \mathbf{M_C} \text{ SD } (\mathbf{p} \leq 0.05) \end{aligned}$
28-day mortality	$M_C \le 20\%$	$M_R \le 30\%$	$M_{T} - M_{C} > 10\%$ and $M_{T} \text{ vs } M_{C} \text{ SD } (p \le 0.05)$	M_T - M_C > 25% and M_T vs M_C SD (p \leq 0.05)
28-day growth	$MIG_C \ge 0.15 \text{ mg/individual}$	$MIG_R \ge 0.15 \text{ mg/individual}$	$\begin{aligned} &(MIG_C - MIG_T)/MIG_C > 0.25\\ &\text{and}\\ &MIG_T \text{ vs } MIG_C \text{ SD } (p \leq 0.05) \end{aligned}$	$(MIG_C - MIG_T)/MIG_C > 0.40$ and MIG_T vs MIG_C SD $(p \le 0.05)$
Chironomus dilutus				
10-day mortality	M _C ≤ 30%	$M_R \le 30\%$	$M_{T} - M_{C} > 20\%$ and $M_{T} \text{ vs } M_{C} \text{ SD } (p \le 0.05)$	$M_{T} - M_{C} > 30\%$ and $M_{T} \text{ vs } M_{C} \text{ SD } (p \le 0.05)$
10-day growth	$MIG_C \ge 0.48 \text{ mg/individual}$	$MIG_R/MIG_C \ge 0.8$	$\begin{aligned} &(MIG_C - MIG_T)/MIG_C > 0.20 \\ &\text{and} \\ &MIG_T \text{ vs } MIG_C \text{ SD } (p \leq 0.05) \end{aligned}$	$\begin{aligned} &(MIG_C - \\ &MIG_T)/MIG_C > 0.30 \\ &\text{and} \\ &MIG_T \text{ vs } MIG_C \text{ SD} \\ &(p \leq 0.05) \end{aligned}$
20-day mortality	M _C ≤ 32%	$M_R \le 35\%$	$M_{T} - M_{C} > 15\%$ and $M_{T} \text{ vs } M_{C} \text{ SD } (p \le 0.05)$	$\begin{aligned} &M_{\rm T} - M_{\rm C} > 25\%\\ &\text{and}\\ &M_{\rm T} \text{ vs } M_{\rm C} \text{ SD } (\text{p} \leq 0.05) \end{aligned}$
20-day growth	$MIG_C > 0.60 \text{ mg/individual}$	$MIG_R/MIG_C \ge 0.8$	$\begin{aligned} &(MIG_C - MIG_T)/MIG_C > 0.25\\ ∧\\ &MIG_T \ vs \ MIG_C \ SD \ (p \leq 0.05) \end{aligned}$	$\begin{aligned} &(MIG_C - \\ &MIG_T)/MIG_C > 0.40 \\ &\text{and} \\ &MIG_T \text{ vs } MIG_C \text{ SD} \\ &(p \leq 0.05) \end{aligned}$

Table VII Explanatory Notes:

C = Control;

MIG = Mean individual growth at time final;

SD = Statistically significant difference;

R = Reference;

T = Test.

An exceedance of the sediment cleanup objective and cleanup screening level requires a statistically significant difference at $p \le 0.05$. Reference performance standards are provided for sites where the department has approved a freshwater reference sediment site(s) and reference results will be substituted for control in comparing test sediments to criteria.

*The department shall use the most updated American Society for Testing and Materials and EPA protocols and performance standards.

Table VIII Types of Freshwater Sediment Biological Tests, Species, and Applicable Endpoints

Species, Biological Test, and Endpoint	Acute Effects Biological Test	Chronic Effects Biological Test	Lethal Effects Biological Test	Sublethal Effects Biological Test
Amphipod				
Hyalella azteca				
10-day Mortality	X		X	
28-day Mortality		X	X	

[39] Permanent

Species, Biological Test, and Endpoint	Acute Effects Biological Test	Chronic Effects Biological Test	Lethal Effects Biological Test	Sublethal Effects Biological Test
28-day Growth		X		X
Midge				
Chironomus dilutus				
10-day Mortality	X		X	
10-day Growth	X			X
20-day Mortality		X	X	
20-day Growth		X		X

Table VIII Explanatory Notes:

The department shall use the most current American Society for Testing and Materials and EPA protocols for establishing appropriate biological tests.

NEW SECTION

WAC 173-204-564 Sediment cleanup levels based on protection of higher trophic level species. (1) Applicability. This section defines sediment cleanup objectives and cleanup screening levels for contaminants based on protection of species at trophic levels not addressed in WAC 173-204-562 and 173-204-563 (hereafter called "higher trophic level species"). They are used to establish sediment cleanup levels for sites and sediment cleanup units under WAC 173-204-560.

- (2) **Requirements.** Sediment cleanup objectives and cleanup screening levels based on protection of higher trophic level species shall be established at concentrations that have no adverse effects. To establish such concentrations, a site-specific ecological risk assessment meeting the requirements of this subsection must be performed.
- (a) Approval by the department. Prior to performing the assessment, the department must approve the criteria, methods, and procedures to be used in the assessment.
- (b) Species evaluated. The assessment must evaluate higher trophic level species that currently utilize, may potentially inhabit, or have historically inhabited the site.
- (c) Factors considered. The assessment must consider factors such as:
- (i) Effects that impair the higher trophic level species reproduction, growth, or survival;
- (ii) The species life history, feeding and reproductive strategy, population numbers, home range, and the potential for recruitment or immigration of individuals to the site; and
- (iii) The potential for the contaminant to bioaccumulate or biomagnify through the food chain. A contaminant will be presumed to have this potential if any of the following conditions are met:
- (A) The contaminant is listed as a persistent, bioaccumulative, or toxic (PBT) contaminant on the department's PBT list in WAC 173-333-310; or
- (B) The log of the contaminant's octonal-water partitioning coefficient is greater than 3.5 (log $K_{ow} > 3.5$);
- (iv) Whether contaminants are present at the site at concentrations that are known or suspected to cause adverse or minor adverse effects on higher trophic level species.
- (d) Coordination. Coordination with the appropriate state and federal agencies should be conducted if species protected under the federal Endangered Species Act (16 U.S.C. 1531 et seq.), Title 77 or 79 RCW are present at the site or the site is within the critical habitat of a protected species.

AMENDATORY SECTION (Amending Order 90-41, filed 3/27/91, effective 4/27/91)

WAC 173-204-570 Sediment cleanup standards—General requirements. (1) Applicability and purpose. This section ((establishes the)) specifies the methods for establishing sediment cleanup standards ((requirements for eleanup actions required)) under ((authority of)) chapter ((90.48 and/or)) 70.105D RCW((, and/or this chapter, and describes the process to determine site-specific eleanup standards)) for sites where there has been a release or threatened release of contaminants to sediment.

- (2) <u>Sediment cleanup levels.</u> The sediment cleanup level is the concentration or level of biological effects of a contaminant in sediment determined by the department to be protective of human health and the environment.
- (a) Method for establishing sediment cleanup levels. The sediment cleanup level shall be established in accordance with the following requirements:
- (i) **Initial level.** The sediment cleanup level shall initially be established at the sediment cleanup objective;
- (ii) **Upward adjustments.** The sediment cleanup level may be adjusted upward from the sediment cleanup objective based on the following site-specific factors:
- (A) Whether it is technically possible to achieve the sediment cleanup level at the applicable point of compliance within the site or sediment cleanup unit; and
- (B) Whether meeting the sediment cleanup level will have a net adverse environmental impact on the aquatic environment, taking into account the short- and long-term positive effects on natural resources, habitat restoration, and habitat enhancement and the short- and long-term adverse impacts on natural resources and habitat caused by cleanup actions;
- (iii) Limit on upward adjustments. A sediment cleanup level may not be adjusted upward above the cleanup screening level.
- (b) Establishment of more stringent sediment cleanup levels. The department may establish sediment cleanup levels more stringent than those established under (a) of this subsection when, based on a site-specific evaluation, the department determines that such levels are necessary to protect human health and the environment. The sediment cleanup level may not be established below the sediment cleanup objective.

Permanent [40]

- (3) <u>Sediment cleanup objectives</u>. ((The sediment eleanup objective shall be to eliminate adverse effects on biological resources and significant health threats to humans from sediment contamination. The sediment cleanup objective for all eleanup actions shall be the sediment quality standards as defined in WAC 173-204-320 through 173-204-340, as applicable. The sediment cleanup objective identifies sediments that have no acute or chronic adverse effects on biological resources, and which correspond to no significant health risk to humans, as defined in this chapter.
- (3) Minimum cleanup)) The sediment cleanup objective for a contaminant shall be established as the highest of the following levels:
 - (a) The lowest of the following risk-based levels:
- (i) The concentration of the contaminant based on protection of human health as specified in WAC 173-204-561(2);
- (ii) The concentration or level of biological effects of the contaminant based on benthic toxicity as specified in WAC 173-204-562 or 173-204-563, as applicable;
- (iii) The concentration or level of biological effects of the contaminant estimated to result in no adverse effects to higher trophic level species as specified in WAC 173-204-564; and
 - (iv) Requirements in other applicable laws;
 - (b) Natural background; and
 - (c) Practical quantitation limit.
- (4) Cleanup screening levels. The ((minimum cleanup level is the maximum allowed chemical concentration and level of biological effects permissible at the cleanup site to be achieved by year ten after completion of the active cleanup action.
- (a) The minimum cleanup levels criteria of WAC 173-204-520 shall be used in evaluation of cleanup alternatives per the procedures of WAC 173-204-560, and selection of a site cleanup standard(s) per the procedures of this section.
- (b) The Puget Sound marine sediment minimum cleanup level is established by the following:
- (i) Sediments with chemical concentrations at or below the chemical criteria of Table III shall be determined to meet the minimum cleanup level, except as provided in (b)(iv) of this subsection; and
- (ii) Sediments with chemical concentrations that are higher than the chemical criteria of Table III shall be determined to exceed the minimum cleanup level, except as provided in (b)(iii) of this subsection; and
- (iii) Sediments with biological effects that do not exceed the levels of WAC 173-204-520(3) shall be determined to meet the minimum cleanup level; and
- (iv) Sediments with biological effects that exceed the levels of WAC 173 204 520(3) shall be determined to exceed the minimum cleanup level; and
- (v) Sediments which exceed the sediment minimum eleanup level human health criteria or the other toxic, radio-active, biological, or deleterious substances criteria or the nonanthropogenically affected criteria of WAC 173-204-520 as determined by the department, shall be determined to exceed the minimum cleanup level.
- (4) Sediment cleanup standard. The sediment cleanup standards are established on a site-specific basis within an

- allowable range of contamination. The lower end of the range is the sediment cleanup objective as defined in subsection (2) of this section. The upper end of the range is the minimum cleanup level as defined in subsection (3) of this section. The site specific cleanup standards shall be as close as practicable to the cleanup objective but in no case shall exceed the minimum cleanup level. For any given cleanup action, either a site-specific sediment cleanup standard shall be defined, or multiple site unit sediment cleanup standards shall be defined in consideration of the net environmental effects (including the potential for natural recovery of the sediments over time), cost and engineering feasibility of different cleanup alternatives, as determined through the cleanup study plan and report standards of WAC 173-204-560.
- (5) All cleanup standards must ensure protection of human health and the environment, and must meet all legally applicable federal, state, and local requirements.)) cleanup screening level for a contaminant shall be established as the highest of the following levels:
 - (a) The lowest of the following risk-based levels:
- (i) The concentration of the contaminant based on protection of human health as specified in WAC 173-204-561(3);
- (ii) The concentration or level of biological effects of the contaminant based on benthic toxicity as specified in WAC 173-204-562 or 173-204-563, as applicable;
- (iii) The concentration or level of biological effects of the contaminant estimated to result in no adverse effects to higher trophic level species as specified in WAC 173-204-564; and
 - (iv) Requirements in other applicable laws;
- (b) Regional background as defined in subsection (5) of this section; and
 - (c) Practical quantitation limit.
- (5) **Regional background.** Regional background for a contaminant shall be established by the department in accordance with the requirements of this subsection.
- (a) The department will determine the geographic area for establishing regional background for a contaminant.
- (b) If a site or sediment cleanup unit is located within a geographic area where regional background for a contaminant has not been established, the department may:
- (i) Compile and collect sufficient sampling data to establish regional background;
- (ii) Require any potentially liable person to compile and collect sufficient sampling data, as determined by the department, to establish regional background; or
- (iii) If there is currently insufficient sampling data to establish regional background, after consulting with any potentially liable person, establish regional background at natural background.
- (c) The department expects that regional background will usually be greater than natural background. If the department determines, based on sampling data, that regional background is not greater than natural background, the department will establish regional background at natural background.
- (d) Calculation of regional background for a contaminant must exclude samples from areas with an elevated level

[41] Permanent

- of contamination due to the direct impact of known or suspected contaminant sources, including areas within a sediment cleanup unit or depositional zone of a discharge.
- (e) The department will determine the appropriate statistical analyses, number and type of samples, and analytical methods to establish a regional background on a case-by-case basis.
- (f) If a water body is not beyond the direct influence of a significant contaminant source, the department may use alternative geographic approaches to determine regional background for a contaminant. Several factors must be evaluated when determining an alternate geographic approach including:
 - (i) Proximity of sampling locations to the site;
 - (ii) Similar geologic origins as the site sediment;
- (iii) Similar fate and transport and biological activities as the site; and
 - (iv) Chemical similarity with the site.
- (6) Point of compliance. The point of compliance shall be established at a location that is protective of both aquatic life and human health. To protect aquatic life, the point of compliance shall be established within the biologically active zone. If that location is not sufficient to protect human health, then the point of compliance shall be established at a different location that is also protective of human health.
 - (7) Compliance monitoring.
- (a) General. The methods used to determine compliance with sediment cleanup standards shall be determined by the department on a site-specific basis.
- (b) Use of tissue analysis. At the department's discretion, and when determined to provide appropriate protection for human health or the environment, contaminants in tissue may be used to identify and screen chemicals of concern in sediment during the remedial investigation/feasibility study and to evaluate compliance with sediment cleanup standards.
- (i) Risk assessment requirements. Assessments of risk to human health or the environment from tissue chemical concentrations must be consistent with the procedures of WAC 173-204-560, 173-204-561, and 173-204-564.
- (ii) Species and tissue type selection. The methods and procedures used to select the appropriate species and tissue types shall be determined by the department on a site-specific basis.
- (c) Monitoring approaches. For sediment cleanup standards based on the benthic criteria in WAC 173-204-562 or 173-204-563, as applicable, the department will determine compliance on an individual station by station approach. For sediment cleanup standards based on other criteria, the department will determine compliance by area weighted or other averaging approach, individual station by station approach, or a combination of both. The department will determine the most appropriate monitoring approach based on exposure pathways and receptors.
- (8) **Data reporting.** Any person who samples sediment and/or tissue to assess compliance with this part shall comply with the following conditions:
- (a) Where analytical results indicate a chemical is not detected in a sample, the data shall be reported as "non detect" at the method detection limit and the method detection limit reported; and

(b) Where analytical results indicate a chemical is detected between the method detection limit and the practical quantitation limit in a sample, the data shall be reported and qualified as "estimated."

NEW SECTION

- WAC 173-204-575 Cleanup action decisions. (1) Purpose. The department shall use the remedial investigation/feasibility study report and other appropriate information to establish sediment cleanup standards and select cleanup actions for a site or sediment cleanup unit. These decisions must be consistent with this part and chapter 70.105D RCW.
- (2) **State cleanup sites.** For sites or sediment cleanup units being cleaned up under the authority of chapter 70.105D RCW, the department shall prepare a cleanup action plan documenting its cleanup decisions. The cleanup action plan shall be prepared consistent with the pertinent requirements and procedures specified in WAC 173-340-380. The decisions in the cleanup action plan shall be incorporated into any enforcement order, agreed order, consent decree, or other binding legal document issued under chapter 70.105D RCW. The public review process for the department's decisions shall comply with the requirements and procedures in chapter 173-340 WAC.
- (3) Federal cleanup sites. For sites or sediment cleanup units being cleaned up under the authority of the federal Comprehensive Environmental Response, Compensation and Liability Act (42 U.S.C. Sec. 9601 et seq.), a record of decision, administrative order, consent decree, or other binding legal document issued under the federal cleanup law may be used by the department to meet the requirements of this section provided:
- (a) The remedial action is consistent with the requirements in this part;
 - (b) The state has concurred with the remedial action; and
- (c) An opportunity was provided for the public to comment on the remedial action.
- (4) Other authorities. For sites or sediment cleanup units being cleaned up under other authorities, the department expects that cleanup decisions will be incorporated into the permit, administrative order, or other appropriate binding legal document. The public review process, and documentation for the department's decisions, shall be consistent with the requirements and procedures for the underlying administrative authority.
- (5) **Public involvement.** The department shall provide public notice and an opportunity for review and comment on its sediment cleanup decisions under this part.
- (a) Where the underlying administrative authority used to implement the remedial action provides an adequate public notice and comment opportunity prior to implementation of the remedial action, separate public notice and comment is not required under this part.
- (b) If the underlying administrative authority does not provide adequate public notice and comment opportunity, then the department shall provide for this prior to implementation of the remedial action.

Permanent [42]

(c) Where more than one public notice and comment period is needed to fulfill the requirements of this part and those in other laws, the department may combine public notice and comment periods, hearings, and other public involvement opportunities to streamline the public review process.

<u>AMENDATORY SECTION</u> (Amending Order 90-41, filed 3/27/91, effective 4/27/91)

- WAC 173-204-580 Selection of cleanup actions ((decision)). (((1) Each person performing a cleanup action to meet the intent of this chapter shall comply with the standards of WAC 173-204-560(7), Cleanup study report. Except for cleanups conducted under chapter 70.105D RCW, the department shall review each cleanup study report and issue a written approval of one or more of the cleanup action alternatives described in the cleanup study report, or issue a written disapproval of all alternatives described in the cleanup study report. The department's approval of one or more eleanup study report eleanup action alternatives shall constitute the cleanup decision and shall be referenced in one or more permit or administrative authorities established under chapter 90.48 or 70.105D RCW, Section 401 of the federal Clean Water Act, chapter 173-225 WAC, establishment of implementation procedures of application for certification, or other administrative authorities available to the department. The department may approve the cleanup alternative recommended in the cleanup study report, may approve a different alternative discussed in the report, or may approve an alternative(s) with appropriate conditions. The department's disapproval of all cleanup study report cleanup action alternatives shall be issued by certified mail, return receipt requested, to the cleanup action proponent(s). The procedures for department review of the cleanup study report and selection of a cleanup action under chapter 70.105D RCW shall be in accordance with the procedures of chapter 173-340 WAC.
- (2) All cleanup actions conducted under this chapter shall meet the following requirements:
- (a) Receive department review and written approval of the preferred and/or alternate cleanup actions and necessary sediment recovery zones proposed in the cleanup study report prior to implementing a cleanup action(s);
- (b) Achieve a degree of cleanup that is protective of human health and the environment:
- (e) Achieve compliance with applicable state, federal, and local laws;
 - (d) Achieve compliance with site cleanup standards;
- (e) Achieve compliance with sediment source control requirements pursuant to WAC 173-204-400 through 173-204-420, if necessary;
- (f) Provide for landowner review of the cleanup study plan and report, and consider public concerns raised during review of the draft cleanup report; and
- (g) Provide adequate monitoring to ensure the effectiveness of the cleanup action.
 - (3) Cleanup time frame.
- (a) The cleanup action selected shall provide for a reasonable time frame for completion of the cleanup action, based on consideration of the following factors:

- (i) Potential risks posed by the site to biological resources and human health;
- (ii) Practicability of achieving the site cleanup standards in less than a ten-year period;
- (iii) Current use of the site, surrounding areas, and associated resources that are, or may be, affected by the site contamination;
- (iv) Potential future use of the site, surrounding areas, and associated resources that are, or may be, affected by the site contamination;
- (v) Likely effectiveness and reliability of institutional controls;
- (vi) Degree of, and ability to control and monitor, migration of contamination from the site; and
- (vii) Natural recovery processes which are expected to occur at the site that will reduce concentrations of contaminants.
- (b) The department may authorize cleanup time frames that exceed the ten-year period used in deriving the site cleanup standards of WAC 173-204-570(4) where cleanup actions are not practicable to accomplish within a ten-year period.
- (4) In evaluating eleanup action alternatives, the department shall consider:
- (a) The net environmental effects of the alternatives, including consideration of residual effects, recovery rates, and any adverse effects of cleanup construction or disposal activities:
- (b) The relative cost-effectiveness of the alternatives in achieving the approved site cleanup standards; and
- (c) The technical effectiveness and reliability of the alternatives:
- (5) Public participation. The department shall provide opportunity for public review and comment on all cleanup action study plans, reports, and decisions reviewed and approved by the department, for cleanup actions conducted under this chapter.
- (6) Land access. In cases where the person(s) responsible for cleanup is not able to secure access to lands subject to a cleanup action decision made pursuant to this section, the department may facilitate negotiations or other proceedings to secure access to the lands. Requests for department facilitation of land access shall be submitted to the department in writing by the person(s) named in the cleanup action approval.)) (1) Purpose. This section establishes the minimum requirements and criteria for selecting sediment cleanup actions under chapter 70.105D RCW. This section applies both to sediment-only cleanup sites and to the sediment portion of any combined upland and sediment cleanup site.
- (2) General requirements. The department shall review and provide written approval of cleanup actions and sediment recovery zones under WAC 173-204-575 prior to implementation of a cleanup action.
- (3) Minimum requirements for sediment cleanup actions. The requirements in this subsection and the requirements for establishing sediment cleanup standards under WAC 173-204-560 shall be considered concurrently. All sediment cleanup actions shall meet the following minimum requirements:

Permanent

- (a) Protect human health and the environment;
- (b) Comply with all applicable laws;
- (c) Comply with the sediment cleanup standards specified in WAC 173-204-560 through 173-204-564;
- (d) Use permanent solutions to the maximum extent practicable, as specified in subsection (4) of this section;
- (e) Provide for a reasonable restoration time frame as specified in subsection (5) of this section. Preference shall be given to alternatives with a shorter restoration time frame;
- (f) Where source control measures are necessary as part of a cleanup action, preference shall be given to alternatives that include source control measures that are more effective in minimizing the accumulation of contaminants in sediment caused by discharges;
- (g) If a sediment recovery zone is necessary as part of the cleanup action, meet the requirements in WAC 173-204-590;
- (h) Cleanup actions for a site shall not rely exclusively on monitored natural recovery or institutional controls and monitoring where it is technically possible to implement a more permanent cleanup action. Where institutional controls are used, they must comply with WAC 173-340-440 and the department shall, as appropriate, consider any aquatic state land use classification under chapter 332-30 WAC. Preference shall be given to institutional controls with a demonstrated ability to control exposures and ensure the integrity of the cleanup action;
- (i) Provide an opportunity for review and comment by affected landowners and the general public, consistent with the public participation plan, and consider concerns identified in these comments;
- (j) Provide adequate monitoring to ensure the effectiveness of the cleanup action. Preference will be given to alternatives with a greater ability to monitor the effectiveness of the cleanup action; and
- (k) Provide for periodic review to determine the effectiveness and protectiveness of cleanup actions that utilize containment, enhanced natural recovery, monitored natural recovery, institutional controls, sediment cleanup levels based on practical quantitation limits, or a sediment recovery zone. When required by this provision, the periodic review shall follow the process and requirements specified in WAC 173-340-420.

(4) <u>Using permanent solutions to the maximum extent practicable.</u>

- (a) This subsection specifies the requirements for determining whether a cleanup action consists of permanent solutions to the maximum extent practicable, as required under subsection (3)(d) of this section. When making this determination, the process and criteria in WAC 173-340-360(3) shall be used, except as provided in (b) of this subsection.
- (b) The evaluation of cleanup action alternatives under WAC 173-340-360(3) requires consideration of several criteria. One of those criteria is long-term effectiveness. Cleanup actions may consist of a combination of cleanup action components. When assessing the relative degree of long-term effectiveness of cleanup action components, the following types of components may be used as a guide, in descending order, in place of the components listed in WAC 173-340-360 (3)(f)(iv):

- (i) Source controls in combination with other cleanup technologies;
 - (ii) Beneficial reuse of the sediments;
- (iii) Treatment to immobilize, destroy, or detoxify contaminants;
- (iv) Dredging and disposal in an upland engineered facility that minimizes subsequent releases and exposures to contaminants:
- (v) Dredging and disposal in a nearshore, in-water, confined aquatic disposal facility;
- (vi) Containment of contaminated sediments in-place with an engineered cap;
- (vii) Dredging and disposal at an open water disposal site approved by applicable state and federal agencies;
 - (viii) Enhanced natural recovery;
 - (ix) Monitored natural recovery; and
 - (x) Institutional controls and monitoring.
- (5) Providing a reasonable restoration time frame. This subsection specifies the requirements and procedures for determining whether a cleanup action provides for a reasonable restoration time frame, as required under subsection (3)(e) of this section.
- (a) **Presumption.** Unless otherwise determined by the department, cleanup actions that achieve compliance with the sediment cleanup standards at the site or sediment cleanup unit within ten years of completion of construction of the active components of the cleanup action shall be presumed to have a reasonable restoration time frame.
- (b) Relationship to sediment recovery zone. If the restoration time frame for a cleanup action is longer than ten years after completion of construction of the active components of the cleanup action, then a sediment recovery zone must be established as part of a cleanup action in accordance with WAC 173-204-590.
- (c) Factors. When determining whether a cleanup action provides a reasonable restoration time frame, the following factors shall be considered:
- (i) The length of time it will take for the cleanup action to achieve the sediment cleanup standards at the site or sediment cleanup unit. Preference shall be given to alternatives that achieve sediment cleanup standards at the site or sediment cleanup unit sooner;
- (ii) Potential risks posed by the site or sediment cleanup unit to biological resources and human health;
- (iii) Practicability of achieving the site or sediment cleanup unit-specific cleanup standards in less than a ten-year period;
- (iv) Current use of the site or sediment cleanup unit, surrounding areas, and associated resources that are, or may be, affected by residual contamination;
- (v) The aquatic state land use classification under chapter 332-30 WAC of the lands encompassing the site or sediment cleanup unit;
- (vi) Potential future use of the site or sediment cleanup unit, surrounding areas, and associated resources that are, or may be, affected by residual contamination;
- (vii) Likely effectiveness of source control measures to reduce the time to achieve cleanup standards;
- (viii) Likely effectiveness and reliability of institutional controls;

Permanent [44]

- (ix) Degree of, and ability to, control and monitor migration of residual contamination; and
- (x) The degree to which natural recovery processes are expected to reduce contamination.

AMENDATORY SECTION (Amending WSR 96-02-058, filed 12/29/95, effective 1/29/96)

WAC 173-204-590 Sediment recovery zones. (1) <u>Applicability.</u> ((The purpose of this section is to set forth the requirements for establishment and monitoring of sediment recovery zones to meet the intent of sediment quality dilution zones authorized pursuant to RCW 90.48.520.

The standards of this section are applicable to cleanup action decisions made pursuant to WAC 173-204-580 where selected actions leave in place marine, low salinity, or freshwater sediments that exceed the applicable sediment quality standards of WAC 173-204-320 through 173-204-340-)) This section specifies requirements governing the establishment and monitoring of sediment recovery zones. Sediment recovery zones are required at sites and sediment cleanup units where:

- (a) The department has determined under WAC 173-204-570 that the selected cleanup actions cannot achieve sediment cleanup standards within ten years after completion of construction of the active components of the cleanup action; and
- (b) Performance monitoring or a periodic review indicates a cleanup action has not achieved, or is projected to not achieve, sediment cleanup standards within ten years after completion of construction of the active components of the cleanup action.
- (2) General requirements. ((Authorization of)) A sediment recovery zone ((by the department)) shall ((require empliance)) comply with the following general requirements:
- (a) ((The sediment recovery zone shall be determined by application of the department's sediment recovery zone computer models "CORMIX," "PLUMES," and/or "WASP," or an alternate sediment recovery zone model(s) approved by the department under WAC 173-204-130(4) as limited by the standards of this section and the department's best professional judgment.
- (b) The department shall provide specific authorization for a sediment recovery zone within the written approval of the cleanup study report and cleanup decision required under WAC 173 204 580.
- (e) The time period during which a sediment recovery zone is authorized by the department shall be so stated in the department's written approval of the cleanup study report and cleanup decision.
- (d) The department's written sediment recovery zone)) When the department determines during the remedy selection process under WAC 173-204-570 that a sediment recovery zone is necessary, the sediment recovery zone shall be described in the cleanup action plan or other decision document issued under WAC 173-204-575;
- (b) When the department determines that a sediment recovery zone is necessary as a result of performance monitoring or a periodic review, the sediment recovery zone shall

- be described in a new or amended decision document issued under WAC 173-204-575;
- (c) Once established, the duration or boundary of a sediment recovery zone may only be adjusted during the periodic review process under WAC 173-204-570(3) or during the renewal of the sediment recovery zone. Any change in the duration or boundary of a sediment recovery zone is subject to public involvement under subsection (7) of this section;
- (d) Specific authorization for the sediment recovery zone, any extension, or change to the duration or boundary of that zone, must be provided in an enforceable document (permit, order, consent decree, etc.);
- (e) Establishment or expansion of a sediment recovery zone shall not be used as a substitute for active cleanup actions, when such actions are determined to be practicable under WAC 173-204-570;
- (f) The areal extent of the sediment recovery zone shall be as small as practicable, as determined under WAC 173-204-570;
- (g) The chemical concentrations within the sediment recovery zone shall be as close to the sediment cleanup standard as practicable, as determined under WAC 173-204-570;
- (h) Appropriate source control measures shall be implemented to minimize contaminant loading on the sediment recovery zone from ongoing discharges; and
- (i) Any authorization <u>for a sediment recovery zone</u> shall identify the legal location and landowners of property proposed as a sediment recovery zone.
- (((e) Operational terms and conditions for the authorized sediment recovery zone pursuant to subsection (5) of this section shall be maintained at all times.
- (f) Where cleanup is not practicable pursuant to the analysis under WAC 173-204-570(4), sediment recovery zones)) (3) Criteria. When considering whether to authorize, extend or change a sediment recovery zone, the department shall consider the criteria in subsection (2) of this section and the following factors:
- (a) Limitation of any modeling used to project the areal extent and time period needed for the sediment recovery zone;
- (b) Potential risks posed by the sediment recovery zone to human health and the environment;
- (c) The technical practicability of eliminating or reducing the size and degree of chemical contamination or level of biological and human health effects within the proposed sediment recovery zone as determined under WAC 173-204-570;
- (d) Current and potential future use of the sediment recovery zone, surrounding areas, and associate resources that are, or may be, affected by releases from the zone including any aquatic state land use classification under chapter 332-30 WAC; and
- (e) The need for institutional controls or other site use restrictions to reduce risks to human health while the sediment recovery zone is in place.
- (4) **Duration.** The department may ((be authorized)) authorize a sediment recovery zone for ((periods in excess)) an initial duration of up to ten years and, upon application by a potentially liable person, authorize extensions in increments not to exceed ten years. When a potentially liable per-

Permanent

- son has made timely and sufficient application, as specified in the authorizing document, for the renewal of a sediment recovery zone, the expiring authorization remains in effect and enforceable until the department either denies the application or reauthorizes the sediment recovery zone.
- (((3))) The areal extent and time period during which a sediment recovery zone is projected to be necessary will be based on the source loading rate and the recovery rate. The source loading rate and recovery rate shall be determined by application of the department's models "CORMIX," "PLUMES," and/or "WASP," or an alternate method approved by the department under WAC 173-204-130(4), as limited by the requirements of this section and the department's best professional judgment.
- (5) Operational terms and conditions. Operational terms and conditions for the authorized sediment recovery zone shall be maintained at all times. These terms and conditions may include:
- (a) Chemical, bioassay, benthic infauna, or tissue monitoring of discharges, receiving water column, organisms, and sediment:
- (b) Confirmation of sediment source(s) loading rates, chemical quality and biological toxicity;
 - (c) Monitoring contaminant bioaccumulation; and
- (d) Ongoing evaluation of the water quality, sediment quality, biological conditions, and human health impacts within and adjacent to the proposed or authorized sediment recovery zone.
- (6) Trespass not authorized. A sediment recovery zone authorization issued by the department under the authority of chapter ((90.48 or)) 70.105D RCW((, or other administrative means available to the department,)) does not constitute authorization to trespass on lands not owned by the applicant. These requirements do not address, and in no way alter, the legal rights, responsibilities, or liabilities of the permittee or landowner of the sediment recovery zone for any applicable requirements of proprietary, real estate, tort, and/or other laws not directly expressed as a requirement of this ((ehapter)) part.
- (((4))) (7) Public involvement. Prior to authorization, the department shall make a reasonable effort to identify and notify all landowners affected by the proposed sediment recovery zone. The department shall issue a sediment recovery zone notification letter to any person it believes to be a potentially affected landowner, the Washington state department of natural resources, the U.S. Army Corps of Engineers, affected port districts, affected tribes, local governments with land use planning authority for the area, and other parties determined appropriate by the department. The notification letter shall be sent by certified mail, return receipt requested, or by personal service. The notification letter shall provide:
- (a) The name of the person the department believes to be the affected landowner; ((and))
- (b) The names of other affected landowners to whom the department has sent a proposed sediment recovery zone notification letter; ((and))
- (c) The name of the sediment recovery zone applicant; ((and))

- (d) A general description of the proposed sediment recovery zone, including the chemical(s) of concern by name and concentration, and the area of affected sediment; ((and))
- (e) The determination of the department concerning whether the proposed sediment recovery zone application meets the ((standards)) requirements of this section; ((and))
- (f) The intention of the department whether to authorize the proposed sediment recovery zone; and
- (g) ((Notification that the affected landowner may)) Invite comments on the proposed sediment recovery zone. Any landowner comments shall be submitted in writing to the department within thirty days from the date of receipt of the notification letter, unless the department provides an extension.
- (((5) As determined necessary by the department, operational terms and conditions for the sediment recovery zone may include completion and submittal to the department of discharge effluent and/or receiving water column and/or sediment chemical monitoring studies and/or bioassays to evaluate ongoing water quality, sediment quality, and biological conditions within and adjacent to the proposed or authorized sediment recovery zone.
- (6))) (8) Enforcement. The department shall review all data or studies conducted ((in accordance with)) under a sediment recovery zone authorization to ensure compliance with the terms and conditions of the authorization and the ((standards)) requirements of this section. Whenever, in the opinion of the department, the ((operational)) terms and conditions of a sediment recovery zone or the ((standards)) requirements of this section are violated or there is a potential to violate the sediment recovery zone authorization or the ((standards)) requirements of this section, or new information or a reexamination of existing information indicates the sediment recovery zone is no longer appropriate, the department may at its discretion:
- (a) Require additional chemical or biological monitoring as necessary;
- (b) Revise the sediment recovery zone authorization as necessary to meet the ((standards)) requirements of this section;
- (c) Require active contaminated sediment maintenance actions, including additional cleanup in accordance with the standards of WAC 173-204-500 through ((173-204-580)) 173-204-575; and/or
- (d) Withdraw the department's authorization of the sediment recovery zone.

NEW SECTION

The following section of the Washington Administrative Code is decodified as follows:

Old WAC Number	New WAC Number
173-204-520	173-204-562
173-204-530	173-204-520
173-204-540	173-204-530
173-204-550	173-204-540
173-204-560	173-204-550

Permanent [46]

Old WAC Number New WAC Number 173-204-570 173-204-560 173-204-580 173-204-570

WSR 13-06-015 PERMANENT RULES DEPARTMENT OF REVENUE

[Filed February 25, 2013, 3:13 p.m., effective March 28, 2013]

Effective Date of Rule: Thirty-one days after filing.

Purpose: The department engaged in this rule making to amend Rule 15501, adopt two new rules (Rules 15502 and 15503), and repeal Rule 155 to explain the impacts of the 2009 and 2010 legislation, and to address other tax issues related to computer hardware, computer software, and computer services described below.

- Chapter 535, Laws of 2009 (ESHB 2075), made major changes to the taxation of certain products and services provided or furnished electronically (commonly referred to as "digital products"). This legislation specifically imposed sales and use tax on digital products such as: Digital goods, including digital audio works, digital audio-visual works, and digital books; digital automated services; digital codes used to obtain digital goods or digital automated services; and remote-access software. The legislation also provided a number of sales and use tax exemptions.
- Chapter 111, Laws of 2010 (SHB 2620), clarified ambiguities and corrected unintended consequences related to the 2009 legislation.

Citation of Existing Rules Affected by this Order: Repealing WAC 458-20-155 Information and computer services; and amending WAC 458-20-15501 Taxation of computer systems and hardware.

Statutory Authority for Adoption: RCW 82.32.200 and 82.01.060.

Adopted under notice filed as WSR 12-17-161 on August 22, 2012.

Changes Other than Editing from Proposed to Adopted Version:

Rule 155 and 15501:

None.

Rule 15502:

- Added subsection (2)(e) to clarify that certain examples assume nexus, are only a general guide, and stand on their own unless otherwise indicated.
- Added language in subsection (3)(b) to clarify that prewritten software remained taxable regardless of method of delivery.
- Added language in subsection (10) to clarify that the sale of remote access prewritten software was subject to service and other B&O prior to July 26, 2009.
- Added subsection (10)(a) to clarify that remote access to software is a general term that may include

- custom software which is not subject to retail sales tax.
- Added language to subsection (11)(b) to clarify what exemption certificate should be used.
- Added example 35 to clarify the benefits of the multiple points of use to purchasers.

Rule 15503:

- Added language in the introduction to the rule to clarify how the rule is supposed to be used similar to a "decision tree."
- Added language to most examples clarifying tax conclusions for the facts in the example.
- Reordered some existing examples to fit better within the structure of the rule.
- Added language in subsection (302)(d)(i) to clarify that end user transactions involving photography are subject to retail sales tax, and certain other photography transactions remain subject to royalties B&O.
- Added and deleted language in subsection (303)(a) addressing the primarily human effort exclusion in order to simplify and streamline the analysis. We reduced the number of factors to consider to two (time and cost only), clarified that cost includes direct costs only, and also provided for an alternative method for doing the analysis in certain situations. We also deleted previous examples and provided a more simplified example.
- Added language to subsection (401) to clarify that sales sourced outside Washington are not subject to Washington sales tax.
- Added language to subsection (505) to clarify that the solely for a business purpose exemption is only available when the buyer provides the seller an exemption certificate.
- Added example 39 to clarify that certain photography transactions remain subject to royalties B&O tax.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 2, Amended 1, Repealed 1.

Number of Sections Adopted at Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's Own Initiative: New 2, Amended 1, Repealed 1.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted Using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 0, Repealed 0.

Date Adopted: February 25, 2013.

Alan R. Lynn Rules Coordinator

[47] Permanent

AMENDATORY SECTION (Amending WSR 09-01-088, filed 12/16/08, effective 1/16/09)

WAC 458-20-15501 ((Computer hardware, computer software, information service, and computer services.)) Taxation of computer systems and hardware. (((1) Introduction. This section explains the business and occupation (B&O), retail sales, and use tax treatment of activities related to computer hardware, computer software, information service, and computer services. Such activities include, but are not limited to, selling, leasing, manufacturing, installing, repairing, and maintaining computer hardware and software, as well as developing, duplicating, configuring, licensing, downloading, and accessing computer software.

This section contains examples that identify a number of facts and then state a conclusion. The examples should be used only as a general guide. The tax results in all situations must be determined after a review of all facts and circumstances.

The information provided in this section is divided into five parts:

- (a) Part I provides information on taxation of computer systems.
- (b) Part II provides information on taxation of computer hardware.
- (e) Part III provides information on taxation of computer software.
- (d) Part IV provides information on taxation of information services and computer services.
- (e) Part V provides reference to WAC 458-20-155 (Information and computer services) on the distinction between sales of products and sales of services.

PART I - TAXATION OF COMPUTER SYSTEM

(101)) (1) Taxation of computer systems.

- (a) What is a computer? A "computer" is an electronic device that accepts information in digital or similar form and manipulates it for a result based on a sequence of instructions. RCW 82.04.215. Examples of a computer include, but are not limited to, mainframe computer, laptop, workstation, and desktop computer. "Computer" also includes automatic data processing equipment, which is a computer used for data processing purposes. "Computer" does not include any computer software or peripheral devices.
- (b) Computer systems and computer networks distinguished. A "computer system" is a functional unit, consisting of one computer and associated computer software, whereas a computer network is two or more computers and associated computer software that uses common storage. A computer system may or may not include peripheral devices.
- (c) Wholesale sale of computer systems. Gross proceeds of sales of computer systems to persons other than consumers (e.g., sales for resale without intervening use) are subject to B&O tax under the wholesaling classification. To verify the wholesale nature of the sale, the seller should obtain a ((resale certificate)) reseller permit from the buyer as provided by WAC 458-20-102 (((Resale certificates))) (Reseller permits).
- (d) **Retail sale of computer systems.** Gross proceeds of sales of computer systems to consumers are subject to B&O tax under the retailing classification. Persons making retail

- sales are responsible for collecting retail sales tax at the time of sale and remitting the tax to the department, unless the sale is specifically exempt by law. If the seller is required to collect Washington sales tax (such as in the case of the seller having nexus with Washington), but does not collect Washington sales tax, the buyer is responsible for remitting retail sales tax (commonly referred to as deferred sales tax), unless the sale is specifically exempt by law. If the seller is not required to collect Washington sales tax, then the buyer is responsible for remitting use tax, unless the transaction is specifically exempt by law. Separately stated charges for custom software sold with the computer system are subject to service B&O tax. ((See subsection (302) of this section))
- (e) Manufacturing of computer systems. Persons manufacturing computer systems are subject to manufacturing B&O tax upon the value of the products. See WAC 458-20-112 (Value of products) and 458-20-136 (Manufacturing, processing for hire, fabricating). Manufacturers of computer systems who sell their products at retail or wholesale are also subject to either the retailing or wholesaling B&O tax, as the case may be. In such cases the manufacturer must report under both the "production" (manufacturing) and "selling" (wholesaling or retailing) B&O tax classifications and may claim a multiple activities tax credit (MATC). See WAC 458-20-19301 (Multiple activities tax credits) for detailed information about the MATC.
- (i) Separately stated charges for custom programming sold with the computer system are not subject to manufacturing B&O tax, but are subject to service B&O tax. ((See subsection (302) of this section.))
- (ii) Separately stated charges for computer software sold and installed after the sale of a computer system are not subject to manufacturing B&O tax.
- (iii) The combining of a computer system with certain peripheral devices is considered a packaging activity not subject to manufacturing B&O tax, when the following occurs:
- (A) The peripheral devices remain in the original packaging;
- (B) The person does not attach its own label to the peripheral devices;
- (C) The person maintains a separate inventory of the peripheral devices for sale apart from the sale of the computer system; and
- (D) The charge for the sale of peripheral devices is separately stated from the charge for the sale of computer systems.

$((\frac{102}{102}))$ (2) Examples.

- (a) ABC Computers, Inc., an in-state manufacturer, manufactures and sells at retail computer systems. ABC sells a computer system to Steve for one flat charge. The computer system includes a disk drive, memory, CPU, keyboard, mouse, monitor, and bundled prewritten computer software. ABC is subject to retailing B&O tax and must collect retail sales tax on the sale to Steve. In addition, ABC is subject to manufacturing B&O tax on the value of the product sold (which is generally the sales price). ABC is entitled to claim a multiple activities tax credit.
- (b) ADE Computers, Inc., manufactures and sells computer systems at retail to customers. ADE sells to Julie a computer system with certain peripheral devices at separate

Permanent [48]

charges. The computer system without the peripheral devices consists of a disk drive, memory, CPU, and bundled prewritten computer software. The peripheral devices include a keyboard, mouse, and monitor. All peripheral devices remain in the original packaging of the manufacturers. ADE does not attach its own label to the peripheral devices. Finally, ADE maintains a separate inventory of the peripheral devices for sale apart from the sale of ADE's computer systems. ADE is subject to retailing B&O tax and must collect retail sales tax from Julie on the sales of the computer system including the peripheral devices. ADE is subject to manufacturing B&O tax on the value of the computer system excluding the peripheral devices. ADE is entitled to claim a multiple activities tax credit. ADE is not subject to manufacturing B&O tax on the value of the peripheral devices($(\frac{1}{2})$) because the combining of a computer system with the peripheral devices in this case constitutes packaging activities.

- (c) AFG Computers, Inc., an in-state company, manufactures and sells at retail computer systems. AFG sells a computer system to Joe for a lump sum. Joe purchases from AFG, as part of the sales package, prewritten computer software developed by a third-party software developer. AFG installs the prewritten computer software to Joe's computer. AFG is subject to retailing B&O tax and must collect retail sales tax from Joe on the sale of the computer system, including the bundled prewritten computer software. Also, AFG is subject to manufacturing B&O tax on the value of the computer system, including the value of the prewritten computer software. AFG is entitled to claim a multiple activities tax credit.
- (d) Same facts as (c) of this subsection, except that AFG sells and installs the prewritten computer software after Joe purchases and takes possession of the computer system. AFG is subject to retailing B&O tax and must collect retail sales tax from Joe on the sale of the computer system and the prewritten computer software. Also, AFG is subject to manufacturing B&O tax on the value of the computer system. AFG is entitled to claim a multiple activities tax credit. AFG is not subject to manufacturing B&O tax on the value of the prewritten computer software((-,)) because the installation of the software by AFG is not a part of AFG's manufacturing activity.

((PART II - TAXATION OF COMPUTER HARD-WADE

(201))) (3) Taxation of computer hardware, both internal and external peripheral devices.

- (a) What is computer hardware? For purposes of this section, "computer hardware" includes, but is not limited to, the mechanical, magnetic, electronic, or electrical components of a computer system such as towers, motherboards, central processing units (CPU), hard disk drives, memory, as well as internal and external peripheral devices such as compact disk read-only memory (CD-ROM) drives, compact disk ((rewriteable)) rewritable (CD-RW) drives, zip drives, internal and external modems, wireless fidelity (Wi-Fi) devices, floppy disks, compact disks (CDs), digital versatile disks (DVDs), cables, mice, keyboards, printers, monitors, scanners, web cameras, speakers, and microphones.
- (b) Wholesale sale of computer hardware. Gross proceeds of sales of computer hardware to persons other than

- consumers (e.g., sales for resale without intervening use) are subject to B&O tax under the wholesaling classification. To verify the wholesale nature of the sale, the seller should obtain a ((resale certificate)) reseller permit from the buyer as provided by WAC 458-20-102 (((Resale certificates))) (Reseller permits).
- (c) **Retail sale of computer hardware.** Gross proceeds of sales of computer hardware to consumers are subject to B&O tax under the retailing classification. Persons making retail sales are responsible for collecting retail sales tax at the time of sale and remitting the tax to the department, unless the sale is specifically exempt by law.
- (d) Manufacturing of computer hardware. Persons manufacturing computer hardware are subject to manufacturing B&O tax upon the value of the products. See WAC 458-20-112 (Value of products) and 458-20-136 (Manufacturing, processing for hire, fabricating). Manufacturers of computer hardware who sell their products at retail or wholesale are also subject to either the retailing or wholesaling B&O tax, as the case may be. In such cases the manufacturer must report under both the "production" (manufacturing) and "selling" (wholesaling or retailing) B&O tax classifications and may claim a multiple activities tax credit (MATC). See WAC 458-20-19301 (Multiple activities tax credits) for detailed information about the MATC.

$((\frac{(202)}{(202)}))$ (4) Examples.

- (a) ALM Computers, Inc., purchases used computers. ALM replaces a built-in CD-ROM drive with a CD-RW drive and adds a zip drive, additional memory, and an upgraded CPU. ALM is engaged in manufacturing activity subject to manufacturing B&O tax with respect to that computer.
- (b) AJK Computers, Inc., acquires damaged computers for refurbishment and sale. AJK removes damaged hardware components and replaces them with new components without upgrading these components. Refurbishing computers in this manner is not a manufacturing activity. Retail sales of such refurbished computers are subject to retailing B&O tax and retail sales tax.
- (c) APQ Computers, Inc., purchases computers for refurbishment and sale. APQ replaces the failed zip drive on one of the computers with an upgraded zip drive because the upgrade is the nearest version of the failed component that is available. The manufacturer has discontinued manufacturing the original version of the zip drive because of a flaw in the design. APQ is not engaged in manufacturing activity with respect to that computer. Retail sale of that refurbished computer is subject to retailing B&O tax and retail sales tax.
- (d) ATV Computers, Inc., is hired by a call center company to repair damaged computers. ATV removes damaged hardware components and replaces them with new components without upgrading these components. Refurbishing computers in this manner is not a manufacturing activity; however, it is a retail service. Refurbishing computers in this manner is subject to retailing B&O tax and retail sales tax must be collected. See WAC 458-20-173 (((services on tangible personal property)) Installing, cleaning, repairing or otherwise altering or improving personal property of consumers) for more information on repairs and maintenance.

Permanent

- $((\frac{(203)}{)}))$ (5) Taxation of other activities associated with computer hardware.
- (a) **Installing computer hardware.** Gross proceeds of sales for installing computer hardware are subject to whole-saling or retailing B&O tax, as the case may be. Installation of computer hardware for consumers is subject to retail sales tax. See ((WAC 458-20-145)) RCW 82.32.730 (sourcing) for more information on sourcing retail sales of computer services. See WAC 458-20-173 (((services on tangible personal property)) Installing, cleaning, repairing or otherwise altering or improving personal property of consumers) for more information on installations.
- (b) Repairing or maintaining computer hardware. Gross proceeds of sales for repair or maintenance of computer hardware are subject to wholesaling or retailing B&O tax. Repair of computer hardware for consumers is subject to retail sales tax. See ((WAC 458 20 145 (sourcing))) RCW 82.32.730 for more information on sourcing ((retail sales)). See WAC 458-20-173 (((services on tangible personal property)) Installing, cleaning, repairing or otherwise altering or improving personal property of consumers) for more information on repairs and maintenance. Also, see WAC 458-20-257 (Warranties and maintenance agreements) for information about repair performed as part of a warranty or maintenance agreement.

((PART III - TAXATION OF COMPUTER SOFT-WARE

- (301) What is computer software? RCW 82.04.215 provides that "computer software" is a set of coded instructions designed to cause a computer or automatic data processing equipment to perform a task. All software is classified as either prewritten or custom. "Computer software" includes only those sets of coded instructions intended for use by an end user and specifically excludes retained rights in software and master copies of software. Computer software does not include data.
- (a) How is computer software delivered? Computer software may be delivered either by intangible means such as electronically or by tangible means such as tangible storage media.
- (b) What is automatic data processing equipment? "Automatic data processing equipment" includes computers used for data processing purposes and their peripheral equipment.
- (c) What are retained rights? "Retained rights" means any and all rights, including intellectual property rights such as those rights arising from copyrights, patents, and trade secret laws, that are owned or are held under contract or license by a software developer, author, inventor, publisher, licensor, sublicensor, or distributor. RCW 82.04.215.
- (d) What are master copies of software? "Master copies" of software means copies of software from which a software developer, author, inventor, publisher, licensor, sublicensor, or distributor makes copies for sale or license. RCW 82.04.215.
- (i) Development of a master copy of software. Development of a master copy of software by a software developer, or a third party hired by the software developer, that is used to produce copies of software for sale or commercial or

- industrial use, is not a manufacturing activity. A third-party charge for development of a master copy of software is a charge for custom software development and is subject to service and other activities B&O tax.
- (ii) Use of prewritten computer software developer. The internal use of prewritten computer software by the developer of that software is not subject to use tax because the software developer is not an end user of its own internally developed software. For example, VV Software, Inc., an in-state software developer, creates accounting software generally used by small businesses. VV plans to sell its newly created software to other companies. VV also plans to make a copy of this software and use it for its accounting operation. The copy of software used by VV for its accounting operation is not subject to use tax.
- (302) What is custom software? "Custom software" is software created for a single person. RCW 82.04.215. The use of library files in software development does not preclude such software from being characterized as custom software, as long as the software is created for a single person. The nature of custom software does not change when ownership is transferred to a person with no rights retained by the transferor.

For purposes of this section, "library files" are a collection of precompiled and frequently used routines that a software developer can use in developing the software.

- (a) Creation of custom software. Gross income received for creating custom software is subject to service and other activities B&O tax.
- (b) **Duplication of custom software.** Duplication of custom software for the same person, or by the same person for the person's own use, does not change the character of the custom software. RCW 82.04.29001. Duplication of custom software for the same person, or by the same person for its own use, is not subject to manufacturing B&O tax.
- If a person duplicates custom software for sale to or use by another person other than the original purchaser, the software becomes prewritten computer software as defined in subsection (303) of this section and is subject to manufacturing B&O tax if the prewritten computer software is delivered by tangible storage media.
- (c) Sale of custom software. If custom software is sold to another person other than the original purchaser, the software loses its character as custom software and becomes prewritten computer software as defined in subsection (303) of this section.
- (d) Use of custom software. Use of custom software is not subject to use tax.
- (e) Example: PFC, Inc., offers data base management software on-line to its client through remote access for a monthly fee. PFC developed its software for the specific client and stored the software on its server. PFC is not subject to manufacturing B&O tax or use tax because the data base management software is custom software. PFC's income from the sale of the custom software to the one specific client is subject to service and other activities B&O tax. Additionally, income received for client access and use of the software is subject to service and other activities B&O tax. PFC is hosting its own software for client access and use. See subsection (401)(g) of this section for treatment of gross income

Permanent [50]

received for providing remote access to software applications such as an ASP provides.

(303) What is prewritten computer software? RCW 82.04.215 provides that "prewritten computer software" is computer software, including prewritten upgrades, that is not designed and developed by the author or other creator to the specifications of a specific purchaser.

The combining of two or more prewritten computer software programs or prewritten portions thereof does not result in custom software. Configuration of prewritten computer software to work with other computer software does constitute customization of prewritten computer software.

Prewritten computer software includes software designed and developed by the author or other creator to the specifications of a specific purchaser when it is sold to a person other than such purchaser.

Where a person, who is not the author or creator, modifies or enhances prewritten computer software, that person is deemed to be the author or creator only of the modifications or enhancements made. Prewritten computer software, or a portion thereof, that is modified or enhanced to any degree, remains prewritten computer software, even though the modification or enhancement is designed and developed to the specifications of a specific purchaser. Where there is a reasonable, separately stated charge or an invoice or other statement of the price given to the purchaser for the modification or enhancement, the modification or enhancement will not be considered prewritten computer software.

- (a) Wholesale sales of prewritten computer software. Gross proceeds from sales of prewritten computer software to persons other than consumers (e.g., sales for resale without intervening use) are subject to B&O tax under the wholesaling classification, whether or not ownership or title passes to the buyer, and regardless of any express or implied restrictions upon the buyer. The method of delivery of prewritten computer software does not alter the wholesale nature of the transaction, whether it is through tangible storage media or any electronic means. Delivery of software manuals and backup copies of prewritten computer software does not alter the delivery of the actual copy of prewritten computer software to be used by the buyer in determining when and where the sale takes place. To verify the wholesale nature of the sale, the seller obtains a resale certificate from the buyer as provided by WAC 458-20-102 (Resale certificates).
- (i) Distinction between wholesale sales of prewritten computer software and royalties received for the licensing of prewritten computer software. Sales of prewritten computer software constitute wholesale sales if the reseller, who has no right to reproduce the software for further sales, sells the same software to its customers. The true object of the sale to the reseller is the sale of the software. On the other hand, income received for granting an intangible right to reproduce and distribute copies of prewritten computer software for sale constitutes royalties. The true object of the transaction that generates royalty income is the right to reproduce and relicense the software. See subsection (308) of this section for more information on royalties.
- (ii) Examples. The examples presume sellers have nexus with Washington.

- (A) UM Computers, Inc., is a software developer that develops engineering software. UM sells the prewritten computer software at wholesale to OX Computers, Inc., in shrink-wrapped packages. UM delivers the software to OX. OX then resells the software to customers in the same shrink-wrapped packages. Sales of prewritten computer software by UM are subject to wholesaling B&O tax. Sales by OX to consumers are retail sales subject to retailing B&O tax and retail sales tax.
- (B) GB Computers, Inc., is a software developer that develops engineering software. GB grants SE Computers, Inc., the right to reproduce and distribute copies of the pre-written computer software for sale. GB retains all of its ownership rights to the software and delivers one copy of the software to SE to reproduce. Amounts received from GB granting the right to reproduce and distribute prewritten computer software to SE are subject to royalties B&O tax. Sales by SE to consumers are retail sales subject to retailing B&O tax and retail sales tax.
- (C) DH Computers, Inc., is a software developer that develops engineering software. DH grants the right to sell its engineering prewritten computer software to WK Computers, Inc. DH delivers the software electronically to WK. WK then sells the software to its customers, who download the software from WK. Income to DH is subject to royalties B&O tax. Sales of prewritten computer software by WK to its customers are retail sales subject to retail sales tax.
- (D) AJ Soft, Inc., is a software developer of architectural drafting software. AJ Soft enters into an agreement with DJ Sales, Inc., to sell AJ Soft's drafting software. DJ Sales must pay a fee for each copy DJ Sales sells through its web site. AJ Soft does not allow DJ Sales to reproduce the drafting software. Customers download the software, but are unaware the software is downloaded directly from AJ Soft. AJ Soft is making a wholesale sale of software to DJ Sales subject to wholesaling B&O tax. DJ Sales is making a retail sale to its Washington customers subject to retail sales tax.
- (b) Retail sales of prewritten computer software. Gross proceeds of sales of prewritten computer software to consumers are subject to B&O tax under the retailing classification, whether or not ownership or title passes to the buyer, and regardless of any express or implied restrictions upon the buyer. The method of delivery of prewritten computer software does not alter the retail nature of the transaction, whether it is through tangible storage media or any electronic means. Delivery of software manuals and backup copies of prewritten computer software does not alter the delivery of the actual copy of prewritten computer software to be used by the buyer in determining when and where the sale takes place. Persons making retail sales are responsible for collecting retail sales tax at the time of sale and remitting the tax to the department, unless the sale is specifically exempt by law.
- (e) Use of prewritten computer software. Prewritten computer software, regardless of the method of delivery, is generally subject to use tax upon use in this state if Washington retail sales tax was not previously paid. However, use of prewritten computer software is not taxable, if it is provided free of charge, or if it is provided for temporary use in viewing information, or both. RCW 82.12.020. This exception from use tax is limited to prewritten computer software pro-

[51] Permanent

vided free of charge or for temporary use in viewing information, such as free promotional software, donated software, free download of software, and software provided in beta testing to a third party free of charge.

For purposes of this use tax exception, "beta testing" means the last stage of testing for prewritten computer software prior to its commercial release including the release to manufacturing (RTM). Beta testing may involve sending the software to a third party for the use of the third party. Beta testing is often preceded by a round of testing called alpha testing.

- (i) Example: DS Computers, Inc., is a software developer. In order to perform beta testing of its new accounting software prior to commercial release, DS sends a copy of the software free of charge to KG Technologies, Inc. DS is not subject to use tax for the release of the beta software to KG. KG is not subject to use tax for the use of beta software free of charge.
- (ii) **Example.** DH, Inc., provides free card games online to its customers. The customers, however, must download DH's free software in order to be able to play card games on-line at DH's web site. Wendy downloads the software free of charge. Wendy is not subject to use tax for the use of the software.
- (iii) **Example.** DW, Inc., provides free software to the public for anyone to watch videos on line. Roger downloads the software free of charge. Roger is not subject to use tax for the use of the software.
- (d) Manufacturing of prewritten computer software. Persons engaged in manufacturing prewritten computer software are subject to manufacturing B&O tax upon the value of the products. See WAC 458-20-112 (Value of products) and WAC 458-20-136 (Manufacturing, processing for hire, fabricating). Manufacturers of prewritten computer software who sell their products at retail or wholesale are also subject to either the retailing or wholesaling B&O tax, as the ease may be. In such cases the manufacturer must report under both the "production" (manufacturing) and "selling" (wholesaling or retailing) B&O tax classifications and may claim a multiple activities tax credit (MATC). See WAC 458-20-19301 (Multiple activities tax credits) for detailed information about the MATC.
- (e) **Duplication of prewritten computer software.**Duplication of prewritten computer software for sales to or use by more than one person is subject to manufacturing B&O tax upon the value of products. Duplication of prewritten computer software outside this state is not subject to manufacturing B&O tax regardless of where software development takes place.

Duplication of prewritten computer software is a manufacturing activity only if the prewritten computer software is delivered from the seller to the purchaser by means of tangible storage media which is retained by the purchaser. RCW 82.04.120.

When a software developer contracts with a third party to duplicate prewritten computer software, the parties must take into account the value of all tangible and intangible materials or ingredients, including the software code, when determining the relative value of all materials or ingredients furnished by each party. If the third party furnishes less than twenty percent of the total value of all materials or ingredients that become a part of the produced product, then the third party is presumed to be a processor for hire and the software developer is presumed to be a manufacturer. See WAC 458-20-136 (Manufacturing, processing for hire, fabricating) for more information.

- (304) Site license of prewritten computer software. A site license provides a consumer acquiring prewritten computer software with the right to duplicate prewritten computer software for use on its own computers, based on the number of computers, the number of workers using the computers, or some other criteria. A site license agreement may cover one site or multiple sites of a purchaser.
- (a) Retail sales of a site license. Gross proceeds of sales of a site license to a consumer are subject to B&O tax under the retailing classification, whether or not ownership or title passes to the consumer, and regardless of any express or implied restrictions upon the consumer. Delivery occurs when and where the prewritten computer software subject to the site license is received by the consumer, whether it is through tangible storage media or any electronic means, regardless of the method of delivery. See WAC 458-20-145 (sourcing) for more information on sourcing prewritten computer software. See also WAC 458 20 197 (When tax liability arises) and WAC 458-20-199 (Accounting methods) for details regarding reporting procedures and revenue recognition of retail sales of a site license. Delivery of software manuals and backup copies of prewritten computer software does not alter the delivery of the actual copy of prewritten computer software to be used by the consumer in determining when and where the sale takes place. Persons making retail sales are responsible for collecting retail sales tax at the time of sale and remitting the tax to the department, unless the sale is specifically exempt by law.

If the prewritten software is hosted by the licensor or a third party for remote access by the licensee (e.g., an Application Service Provider (ASP)), then see subsection (401)(g) of this section.

- (b) Duplication of prewritten computer software by a person under a site license. A seller of a site license is subject to manufacturing B&O tax for its own duplication of prewritten computer software. Duplication of prewritten computer software is subject to manufacturing B&O tax only if the prewritten computer software is delivered from the seller to the purchaser by means of tangible storage media which is retained by the purchaser. RCW 82.04.120. Purchaser of a site license is not subject to manufacturing B&O tax for the duplication of prewritten computer software for its own use, pursuant to a site license agreement with the seller.
- (c) Use of a site license partly in this state and partly outside this state. Where the use of a site license is partly in this state and partly outside this state, the part of the site license used by the person in this state is subject to use tax, provided Washington state sales tax was not previously paid. For example, a person purchases and takes delivery of a site license in California. Pursuant to the multiple site license agreement, this person is licensed to use one thousand copies of prewritten computer software, of which four hundred copies will be used in Washington. Use tax is due on the four hundred copies of prewritten computer software used in this

Permanent [52]

state. If the prewritten software purchased by the licensee is delivered in Washington, then the entire charge for the site license is subject to retail sales tax if purchased from a seller responsible for collecting Washington's sales tax.

(d) Sales and use of additional copies of prewritten computer software under the same site license. In some cases, the buyer of a site license may subsequently purchase additional copies of prewritten computer software under the same site license agreement. The seller may or may not deliver any additional copy of the software to the buyer, because the original copy of the software has already been delivered.

(i) Retail sales of additional copies of prewritten computer software under the same site license. Retail sales of the additional copies of software occurs when and where the seller delivers any additional copy of prewritten computer software to the buyer, whether it is through tangible storage media or any electronic means, regardless of the method of delivery. See WAC 458-20-145 (sourcing) for more information on sourcing retail sales of prewritten computer software. If the seller does not deliver any additional copy of the software to the buyer, then the sales occur when the sales agreements are made to purchase the additional copies and where the original copy or copies of prewritten computer software was delivered. If the original sale of the site license was subject to manufacturing B&O tax, then the sale of additional licenses are also subject to manufacturing B&O tax.

Delivery of software manuals and backup copies of prewritten computer software does not alter the delivery of the actual copy of prewritten computer software to be used by the buyer in determining when and where the sale takes place.

(ii) Use of additional copies of prewritten computer software under the same site license. Where the use of the additional copies of software is partly in this state and partly outside this state and was not previously subject to Washington sales tax, the part of the additional copies of software used by the person in this state is subject to use tax.

(e) Examples.

(i) DEF Computers, Inc., is located in Washington and sells in this state at retail a multiple site license of its prewritten computer software to P's Design, Inc. A copy of the prewritten computer software is electronically delivered to P's Design in Washington. P's Design then electronically duplicates the software and distributes the software in Washington and several other states for its use. Neither DEF nor P's Design is subject to manufacturing B&O tax. DEF, however, is subject to retailing B&O tax, and it must collect retail sales tax from P's Design for the entire sale of the software.

(ii) Same facts as (e)(i) of this subsection, except that in addition, DEF delivers a backup copy of the software to P's Design outside Washington. The backup copy of the software is for disaster recovery purposes and is not downloaded to any of P's Design's computers for use. There is no separate charge for the delivery of the backup software. The software manuals are mailed to P's Design in Washington. DEF is still subject to retailing B&O tax, and it must collect retail sales tax from P's Design for the entire sale of the software. Delivery of the software manuals and the backup copy of the software are not relevant in determining when and where the sale

takes place. This transaction is not subject to manufacturing B&O tax.

(iii) Same facts as (e)(i) of this subsection, except that in addition, P's Design subsequently purchases 50 additional copies of the software from DEF under the same site license agreement. P's Design merges with another company, and the additional copies are needed for the use of its new employees. No additional copy of the software is delivered to P's Design in fulfilling this new agreement. Neither DEF nor P's Design is subject to manufacturing B&O tax. DEF, however, is subject to retailing B&O tax, and it must collect retail sales tax from P's Design for the subsequent sale of the 50 additional copies of software because the original copy of the software was delivered in Washington. However, if the original sale of the license had included delivery of the prewritten software by a tangible storage device (and was therefore subject to manufacturing B&O tax), then the licensor is also subject to manufacturing B&O tax based on the value of the additional

(iv) GH Computers, Inc., sells at retail a multiple site license of its prewritten computer software to Quick, Inc. GH is located outside Washington, while Quick is located in Washington and in other states and outside the U.S. The desktop software is licensed on an unlimited basis, which means that there are no restrictions of its use by Quick. The software is delivered to Quick outside Washington. Quick then electronically duplicates the software and distributes the software to all of its 500 employees, of which 100 employees are located in Washington. The software is electronically downloaded into the desktop computers of all employees and is immediately put into use. Use tax is due on the value of the 100 copies of prewritten computer software used in Washington.

(v) Same facts as (e)(iv) of this subsection, except that under the original site license agreement, Quick is entitled to reproduce, distribute, and use up to 500 copies of the desktop software. Then Quick merges with another company, and additional copies are needed for the use of its new employees. Quick, therefore, subsequently purchases 100 additional copies of the software from GH under the same site license agreement. No additional copy of the software is delivered to Quick in fulfilling this new agreement. Quick distributes the additional copies of the software to its 100 new employees, of which 50 employees are located in Washington. Use tax is due on the value of the 50 additional copies of prewritten computer software used in Washington.

(vi) JJ Computers, Inc., sells at retail a multiple site license of its prewritten computer (server) software to Rest, Inc. JJ is located outside Washington, but Rest is located in Washington and in other states. The server software is delivered to Rest outside Washington. Rest then electronically duplicates the software and distributes the software to its three servers for immediate use. One of the servers is located in Washington, and the other two servers are located outside Washington. Use tax is due on the value of the copy of the prewritten computer (server) software on the server in Washington.

(305) Key to activate computer software. A key, or an enabling or activating code, may be required in some instances to activate computer software and put the software

Permanent

into use, and the key may be delivered to a purchaser after the software is already delivered and in possession of the same purchaser. In such instances, the entire sale of computer software occurs when both the key and the software are delivered to the purchaser. The sale takes place where the software is received by the purchaser in accordance with RCW 82.32.730. However, if the receiving location for the software is unavailable to the vendor because the software was delivered by a third party, then the sale takes place where the key is received in accordance with RCW 82.32.730. There is no separate sale of the key from the software, regardless of how such sale may be characterized by the vendor or by the purchaser.

See subsection (304) of this section for more information if a site license of prewritten computer software is involved. If the sale of the prewritten software is subject to manufacturing B&O tax, then the sale of the key required by that prewritten software is also subject to manufacturing B&O tax. The income from the sale of a key is part of a sale of prewritten computer software, whether the sales transactions are together or separate.

- (a) Example. JKL Computers, Inc., an in-state business, sells at retail prewritten computer software to Rebecca. JKL delivers the software to Rebecca in this state. The prewritten computer software, however, cannot be activated without a key. JKL subsequently delivers the key in this state to Rebecca for a separate price. JKL is subject to retailing B&O tax, and it must collect retail sales tax from Rebecca on the entire sale of the software including the separate charge for the key. The entire sale takes place in this state (where the software is delivered) when both the software and the key are delivered to Rebecca. There is no separate sale of the key, regardless of the fact that JKL delivers the key to Rebecca for a separate charge.
- (b) Example: Same facts as (a) of this subsection, except that JKL subsequently delivers the key outside this state to Rebecca for a separate price. JKL is subject to retailing B&O tax, and it must collect retail sales tax from Rebecca on the entire sale of the software including the separate charge for the key. The entire sale takes place in this state (where the software is delivered) when both the software and the key are delivered to Rebecca. There is no separate sale of the key, regardless of the fact that JKL delivers the key to Rebecca for a separate charge.
- (e) Example: MNO Computers, Inc., is an in-state software developer. TKO Computers, Inc., an out-of-state original equipment manufacturer (OEM), agrees in contract with MNO to distribute MNO's prewritten computer software. TKO delivers MNO's inoperable software to Sally as part of the sale of the computer system. Sally, however, must purchase a key directly from MNO in order to activate and use the software. MNO has no knowledge of where the software was initially delivered to Sally, but MNO knows that the key is delivered to Sally in this state. MNO is subject to retailing B&O tax, and it must collect retail sales tax from Sally on the entire sale of the key and the inoperable software. The entire sale takes place in this state because the key is delivered in this state and MNO has no knowledge of where the inoperable software was initially delivered by TKO. Assuming TKO delivers MNO's software to Sally electronically, then dupli-

eation of the key would not be subject to manufacturing B&O tax. If TKO delivers the software on tangible storage media, then the key would be subject to manufacturing B&O tax.

(306) Client access license and server license for the server software. A server license, paid for at the time the server software is purchased, grants the buyer the right to install the server software on the buyer's server. A client access license (CAL) grants the buyer the right to access the server software. The CAL is not computer software and is not downloaded into the buyer's computer.

Charges for server licenses and CAL are a part of the sale of the server software, even if the charges are separately stated. The sales take place where the server software is delivered to the buyer.

In cases where server software is delivered to the buyer and used in multiple locations, see subsection (304) of this section on site licenses for more information.

- (a) Example: ZZ Computers, Inc., an in-state business, sells at retail server software to Jack. ZZ delivers the server software to Jack in Washington. ZZ also provides Jack with client access licenses allowing Jack the right to access the server software from his personal computers. The sale of server software to Jack is subject to retailing B&O tax, and ZZ must collect retail sales tax from Jack for the same sale.
- (b) Example. Same facts as (a) of this subsection, except that ZZ makes two separate sales at retail of two types of prewritten computer software to Jack. One is server software, and the other is client software (which is different from elient access licenses). ZZ delivers the server software to Jack in Washington where Jack's server is located. ZZ delivers the client software to Jack outside Washington where all of Jack's personal computers are located. Only the sale of server software to Jack is subject to retailing B&O tax, and ZZ must collect retail sales tax from Jack for the same sale.
- (307) Other activities associated with computer soft-
- (a) Customizing prewritten computer software. Gross income received for customizing prewritten computer software is subject to service and other activities B&O tax. RCW 82.04.29001.
- (i) What is customizing prewritten computer software? RCW 82.04.215 provides that "customization of prewritten computer software" is any alteration, modification, or development of applications using or incorporating prewritten computer software for a specific person.

"Customization of prewritten computer software" includes individualized configuration of software to work with other software and computer hardware but does not include routine installation. Customization of prewritten computer software does not change the underlying character or taxability of the original prewritten computer software.

- (ii) Combined charge for prewritten computer software, customization, and routine installation. If a lump-sum charge is made for a sale of prewritten computer software, customization of prewritten computer software, and routine installation, the entire charge is considered to be a sale of prewritten computer software. See (a)(iv) of this subsection for more information on routine installation.
- (iii) Separately stated charge for customization of prewritten computer software. Where there is a reasonable

Permanent [54]

separately stated charge on an invoice or other statement of the price given to the purchaser for customization of prewritten computer software (including installation that is not routine, see (a)(i) of this subsection), such customization is subject to service and other activities B&O tax. If a charge for customization of prewritten computer software is not separately stated from a sale of prewritten computer software, the entire charge is considered a sale of prewritten computer software.

- (iv) Customization of prewritten computer software versus routine installation. Customization of prewritten computer software does not include routine installation. "Routine installation" means the process of loading program files and installation files onto a computer. Routine installation does not include installation of the customized elements of prewritten computer software.
- (v) Separately stated charge for routine installation from customization of prewritten computer software. Where there is a separately stated charge on an invoice or other statement of the price given to the purchaser for routine installation from customization of prewritten computer software, routine installation is subject to retailing B&O tax and retail sales tax. If a charge for routine installation is not separately stated from customization of prewritten computer software, the predominant nature of the transaction determines taxability.

(vi) Examples.

- (A) Tee, Inc., is in need of financial modeling software that can tie into most of its existing computer systems. Because of its unique business, however, Tee needs the industry-wide computer software offered by PQR Computers, Inc., that is modified to meet the needs of Tee. Both Tee and PQR are in-state corporations, and the software is delivered in this state. PQR provides a separately stated charge to Tee for customization of prewritten computer software performed in this state that is supported by the terms of the sales agreement. PQR is subject to retailing B&O tax, and it must collect retail sales tax from Tee for the sale of prewritten computer software in Washington. PQR, in addition, is subject to service and other activities B&O tax for the customization of prewritten computer software in Washington.
- (B) Same facts as (a)(vi)(A) of this subsection, except that, in addition, PQR provides a separately stated charge to Tee for routine installation of prewritten computer software in this state. This charge represents installation of only the prewritten portion of the software. In addition to the tax treatments in (a)(vi)(A) of this subsection, PQR is subject to retailing B&O tax and it must collect retail sales tax from Tee for the routine installation in Washington.

(b) Installing or uninstalling computer software.

- (i) Gross income received from installing or uninstalling custom software is subject to service and other activities B&O tax.
- (ii) Gross proceeds of sales for routine installation of prewritten computer software are subject to retailing B&O tax and retail sales tax. See (a)(iv) of this subsection for more information on routine installation. See WAC 458-20-145 (sourcing) for more information on sourcing retail sales of prewritten software and routine installation. Routine installation of prewritten computer software includes charges for

labor and services in respect to the installation, such as travel costs for the routine installation of the software. As of July 1, 2008, if the routine installation occurs through remote access by someone outside the state of Washington, then the installation is sourced to where first use occurs. For example, XYZ Computers, Inc., is hired by Dan for routine installation of prewritten software onto Dan's computers. XYZ's out-of-state employee remotely accesses Dan's computers in Washington to install the prewritten software on his computers. If XYZ has nexus with Washington, then it must collect and remit the sales tax. If XYZ does not have nexus, then Dan must pay use tax.

Gross proceeds of sales of uninstalling prewritten computer software are subject to retailing B&O tax and retail sales tax.

For example, XYZ Computers, Inc., is hired by Dan to remove spy ware from his computers. Spy ware is prewritten computer software. Removal of spy ware requires uninstalling the spy ware from the computer. XYZ sends an employee to Dan's location to remove spy ware from its computers. Charges for removal of spy ware are subject to retailing B&O tax and retail sales tax.

(c) Repairing, altering, or modifying computer software. Repair of prewritten computer software for more than one person may be distributed as a fix or patch by tangible storage media or electronically in the nature of software upgrades and updates. The sale of prewritten computer software upgrades and updates is a sale of prewritten computer software subject to retailing B&O tax and retail sales tax. See WAC 458-20-145 (sourcing) for more information on sourcing retail sales of computer services.

Alteration or modification of prewritten computer software performed for a specific person is subject to the service and other activities B&O tax. Such alteration or modification of prewritten computer software for a specific person constitutes customization of prewritten computer software. See RCW 82.04.215.

Alteration or modification of custom software is subject to service and other activities B&O tax.

- (i) Example. STU Computers, Inc., a Washington company, is hired by Betty to perform repairs via remote access on her prewritten computer software in Washington. STU is performing alteration or modification of prewritten computer software for a specific person and is subject to service and other activities B&O tax.
- (ii) **Example.** VW Computers, Inc., an out-of-state service provider, is hired by Clyde to perform alterations or modifications via remote access on his prewritten computer software located in this state. VW's facility is located outside this state. VW may be subject to service and other activities B&O tax if it has nexus with Washington. See WAC 458-20-194 (Apportionment).
- (d) Maintaining computer software. Computer software maintenance agreements typically include, but are not limited to, support activities such as telephone consulting, help desk services, remote diagnostic services, and software upgrades and updates.
- (i) Tax treatment of computer software maintenance agreements in general. Sales of stand-alone computer software maintenance agreements that include telephone consult-

[55] Permanent

ing, help desk services, remote diagnostic services, and other professional services are taxable under the service and other activities B&O tax. However, if the services are part of a sale of an extended warranty on or after July 1, 2005, then the sale is subject to retailing B&O tax and retail sales tax. See WAC 458-20-257 (Warranties and maintenance agreements) for information about extended warranties.

Stand-alone sales of updates or upgrades to prewritten computer software are retail sales of tangible personal property subject to retailing B&O tax and retail sales tax.

(ii) Prewritten computer software maintenance agreement with mixed elements. The sale of a prewritten computer software maintenance agreement that includes professional service components such as telephone consulting and retail components such as upgrades and updates of prewritten computer software is a retail sale subject to retailing B&O tax and retail sales tax.

In cases where the charges for the professional service component(s) and the retail component(s) are separately stated within a prewritten computer software maintenance agreement and invoice, then each activity is taxed according to the nature of the activity.

(iii) Duplication of prewritten computer software upgrades and updates. Duplication of prewritten computer software upgrades and updates is subject to manufacturing B&O tax upon the value of products, if the software upgrades and updates are delivered by means of tangible storage media which is retained by the purchaser. This is the case regardless of any maintenance agreement with mixed elements involved. The measure of tax is presumed to be the contract price of the maintenance agreement, unless the person can prove otherwise. See WAC 458 20 112 (Value of products) for more information.

If the software upgrades and updates are delivered from the seller by means other than tangible storage media which is retained by the purchaser, then the software upgrades and updates are not subject to manufacturing B&O tax.

(iv) Maintenance agreement on custom software and customized elements of prewritten computer software. Sales of maintenance or support services relating to custom software or the customized elements of prewritten computer software are subject to the service and other activities B&O tax. Such services, including upgrades and updates, are rendered in respect to the custom or customized software and take on the underlying character and taxability of the custom or customized software.

(v) Examples.

(A) On December 15, 2005, CBA Computers, Inc., sells at retail a prewritten computer software maintenance agreement to Frank for his software. The software maintenance agreement includes an extended warranty for the software, software upgrades and updates, and telephone consulting services. CBA delivers the software upgrades and updates electronically, as well as provides the maintenance services to Frank at one charge. CBA is subject to retailing B&O tax, and it must collect retail sales tax from Frank for the sale of the mixed agreement.

(B) Same facts as (d)(v)(A) of this subsection, except that CBA delivers the software upgrades and updates on compact disks. CBA is subject to retailing B&O tax, and it

must collect retail sales tax from Frank for the sale of the mixed agreement. In addition, CBA is subject to manufacturing B&O tax on duplication of software upgrades and updates. The measure of tax is presumed to be the contract price of the maintenance agreement, unless CBA can prove otherwise.

(C) Same facts as (d)(v)(A) of this subsection, except that CBA provides a separately stated charge for each component of the maintenance agreement. CBA is subject to retailing B&O tax, and it must collect retail sales tax from Frank for the charges on software upgrades and updates and on the extended warranty purchased after July 1, 2005. CBA is subject to service and other activities B&O tax for the charge on telephone consulting services.

(D) FED Computers, Inc., sells at retail a computer software maintenance agreement to Greta for her software. The maintenance agreement covers only software upgrades and updates. Greta's software is prewritten computer software with customized elements. FED provides the maintenance services to Greta at one charge. FED is subject to retailing B&O tax, and it must collect retail sales tax from Greta for the sale of the entire maintenance agreement of the prewritten computer software.

(E) Same facts as (d)(v)(D) of this subsection, except that FED provides a separately stated charge for maintaining the customized elements. FED is subject to service and other activities B&O tax for the charge on maintaining the customized elements. FED is subject to retailing B&O tax, and it must collect retail sales tax from Greta for the charge on maintaining prewritten computer software.

- (e) Computer software training. Gross income received for training on the use of custom software is subject to service and other activities B&O tax. Gross income received for training on the use of prewritten computer software is subject to service and other activities B&O tax, if the charge for such training is separately stated from the sale of prewritten computer software. If the charge for software training is not separately stated from the sale of prewritten computer software, the entire charge is considered to be a sale of prewritten computer software subject to retailing B&O tax and retail sales tax.
- (308) Licensing computer software royalties. Income received from charges in the nature of royalties for the licensing of computer software is taxable under the royalties B&O tax classification.
- (a) What are royalties? RCW 82.04.2907 provides that "royalties" is compensation for the use of intangible property, such as copyrights, patents, licenses, franchises, trademarks, trade names, and similar items. The true object of a transaction involving royalties is to grant an intangible right to reproduce and distribute copies of computer software for sale. It does not, however, include compensation for the licensing of prewritten computer software to the end user. The manner in which computer software is sold (e.g., volume of transactions, subscription license, term license, or perpetual license) or the manner in which payment amount is determined (e.g., fixed fee per copy, percentage of receipts, lump sum, etc.) does not alter the royalty nature of the transaction.
- (b) Royalties versus site license. Regarding royalties, the true object of the transaction is to grant an intangible right

Permanent [56]

to reproduce and distribute copies of computer software for sale. In contrast, the true object of a site license is the sale to an end user of prewritten computer software for use on its computers. See subsection (304) of this section for more information on site licenses.

(c) Royalties versus wholesale sales of prewritten computer software. See subsection (303)(a) of this section for more information.

(d) Examples.

(i) HG Computers, Inc., an original equipment manufacturer (OEM), acquires prewritten computer software from LL Software, Inc., under a license to reproduce and distribute the prewritten computer software as part of a bundled computer hardware and software package HG sells to end users. LL retains all of its ownership rights to the software. The gross income received by LL from granting intangible rights to reproduce and distribute prewritten computer software to HG is subject to royalties B&O tax.

(ii) Same facts as (d)(i) of this subsection, except that, in addition, HG acquires a site license from LL for the purposes of using the prewritten computer software as an end user. LL delivers the software to HG. Amounts received by LL for the sale of a site license are subject to retailing B&O tax and retail sales tax.

(309) Special use tax exemption for computer hardware and computer software donated to certain schools or colleges. Use tax does not apply to the use of computer hardware and computer software irrevocably donated to any public or private nonprofit school or college, as defined under chapter 84.36 RCW, RCW 82.12.0284.

PART IV TAXATION OF INFORMATION SER-VICES AND COMPUTER SERVICES

(401) Activities associated with information services and computer services. For services described below that are subject to service and other activities B&O tax, see WAC 458-20-194 (Doing business inside and outside the state) for more information on the apportionment of service and other activities B&O tax for taxpayers who maintain places of business both within and without the state that contribute to the rendition of the services.

(a) Sales of information services. Gross income received for information services is subject to service and other activities B&O tax.

(i) What are information services? "Information services" means every business activity, process, or function by which a person transfers, transmits, or conveys data, facts, knowledge, procedures, and the like to any user of such information through any tangible or intangible medium. "Information services" does not include transfers of tangible personal property such as computer hardware or standard prewritten software programs. Neither does "information services" include telecommunication services defined under RCW 82.04.065.

Effective August 1, 2007, and in accordance with RCW 82.08.705 and 82.12.705, a sales and use tax exemption is provided for sales of electronically delivered standard financial information, if the sale is to an investment management company or a financial institution. Standard financial information is defined as "any collection of financial data or facts,"

not compiled for a specific consumer, including financial market data, bond ratings, credit ratings, and deposit, loan, or mortgage reports." See RCW 82.08.705.

(ii) Examples.

(A) XX Statistical Data, Inc., sells statistical data at the specific request of each customer. XX does not compile such statistical information to be available for all customers. Instead, each customer submits its own request of the statistical information based on its needs. XX compiles, analyzes, and summarizes the statistical information it gathers and sends the information to customers in a tangible medium. XX is subject to service and other activities B&O tax for the sales of statistical information, because XX is providing an information service at the specific request of each customer.

(B) ZZ Statistical Data, Inc., allows its customers to perform on-line research of statistical information through its data base. ZZ bills its customers a monthly fee for having online access to the data base for research. Its customers do not download any information onto their computers. ZZ is subject to service and other activities B&O tax for providing information services to its customers.

(C) WW Travel, Inc., bills its customers a monthly fee for having access to a travel reservation system that includes a charge for dedicated telephone lines. WW is subject to service and other activities B&O tax for providing information services, rather than a telecommunications service. The provider of dedicated telephone lines to WW must collect retail sales tax from WW on the sale of telecommunications service. WW is the consumer of telecommunications service.

(D) VV Telephone, Inc., provides a satellite-based tracking and communications system that includes instant messaging between vehicles in transit and dispatch centers. Both the vehicles and the dispatch centers are operated by its customers, and information is both generated and received by the customers. This is not a sale of information service. The true object of the transaction is the transmission of data between the vehicles and the dispatch centers through VV's communications system. VV is providing telecommunications services subject to retailing B&O tax, and it must collect retail sales tax on the sale of telecommunications services. See RCW 82.32.520 for sourcing of telecommunications services.

(E) AA Data, Inc., provides a daily report of bond ratings for electronic download by its investment management company consumers. Each investment management company downloads the same report. As of August 1, 2007, AA provides standard financial information that falls within the exemption found in RCW 82.08.705 and 82.12.705. Therefore, AA does not collect or remit retail sales tax.

(b) Sales of data processing services. Gross income received for data processing services is subject to service and other activities B&O tax.

"Data processing services" includes, but is not limited to, word processing, data entry, data retrieval, data search, information compilation, payroll processing, business accounts processing, data production, and other computerized data and information storage or manipulation. "Data processing services" also includes the use of a computer or computer time for data processing whether the processing is performed by the provider of the computer or by the purchaser or other beneficiary of the service.

[57] Permanent

- (i) **Example.** JK Processing, Inc., provides payroll processing services to other businesses. JK is subject to service and other activities B&O tax for providing data processing services.
- (ii) Example. KL Processing, Inc., processes payroll data related to its employees. KL is not subject to manufacturing B&O tax or use tax for the electronic processing of its own data.
- (c) Sales of internet services. Gross income received for internet services are subject to service and other activities B&O tax.
- (i) What is the internet? "Internet" means the international computer network of both federal and nonfederal interoperable packet switched data networks, including the graphical subnetwork called the world wide web. RCW 82.04.297.
- (ii) What are internet services? "Internet service" is a service furnished by an internet service provider (ISP) that allows users access to the internet. The ISP must provide the service through use of computer processing applications that either provide the user with additional or restructured information or permit the user to interact with stored information through the internet or a proprietary subscriber network. "Internet service" includes the following services furnished by the ISP:
 - Provision of internet electronic mail:
 - Access to the internet for information retrieval; and
 - Hosting of information for retrieval over the internet.
- "Internet service" does not include telecommunications service as defined in RCW 82 04 065
- (iii) What is a proprietary subscriber network? "Proprietary subscriber network" means proprietarily or privately owned network in which its services are available to the public for fees. Proprietary subscriber network does not include intranets.

(iv) Examples.

- (A) ISP, Inc., is an internet service provider that provides customers with access to the internet. ISP does not furnish any telephone lines to its customers in providing this access. ISP maintains its operation in Washington. Amelia is charged a monthly internet access fee from ISP for access to the internet in Washington. ISP is subject to service and other activities B&O tax for the monthly internet access fee charged to Amelia.
- (B) Same facts as (e)(iv)(A) of this subsection, except that ISP provides customers with access to the internet along with telephone lines used to provide that access. Amelia is charged a combined monthly fee for access to the internet in Washington using the telephone lines. ISP is subject to service and other activities B&O tax for the combined fee, because the true object of the transaction is to provide access to the internet, rather than to provide telecommunications service.
- (C) Telecomm Co. provides customers with telephone lines for telecommunications, including long distance service, and for access to the internet (internet services). Zoe is charged a combined monthly fee for access to the internet and for communication services in Washington using the telephone lines. Telecomm Co. is subject to retailing B&O tax for the combined fee because the primary purpose of the

- transaction is to provide telecommunications service, rather than to provide access to the internet. However, if Telecomm Co. separately states or can reasonably identify from its books and records the fees for telecommunications service and internet access, then Telecomm Co. will be subject to retail and service classifications respectively.
- (D) DD Computers, Inc., provides access to information through its web site for which it charges its users a fee. DD charges Stan, an out-of-state customer, a transaction fee to use DD's web site to search and retrieve real estate appraisal information. DD is not providing internet service because DD is not an ISP and does not provide customers with access to the internet. DD, however, is providing Stan access to its web site for informational search and retrieval which is subject to service and other activities B&O tax.
- (d) Sales of intranet services. Gross proceeds of sales of intranet services are sales of telecommunications service defined under RCW 82.04.065 and are subject to retailing B&O tax and retail sales tax.

"Intranet service" means the service of providing a private or intracompany network used by a person to facilitate the sharing or accessing of internal information by the person's employees or other authorized parties.

- (c) Sales of Voice over Internet Protocol (VoIP) services. "VoIP service" is a service that enables subscribers to use the internet as the transmission medium for telephone calls by sending voice data in packets in internet protocol. Gross proceeds of sales of VoIP services are sales of telecommunications service defined under RCW 82.04.065 subject to retailing B&O tax and retail sales tax.
- (f) Sales of network system support services. Gross income received for network system support services is subject to service and other activities B&O tax. "Network system support" activities include analyzing and interpreting problems using diagnostic software, monitoring network to ensure network availability to users, and performing network system configurations. Network system support activities may be performed through remote telephone support or onsite consulting.
- (g) Sales of remote access to prewritten software. Le., application service providers (ASPs) or software as a service (SAAS). Gross income received for providing remote access to applications on the host's servers are subject to service and other activities B&O tax, when the service is performed in Washington. Sellers of remote access to applications (e.g., ASPs) may be able to apportion income if they perform activities in multiple states (i.e., servers used in multiple states to host the software). See WAC 458-20-194 (apportionment).
- "ASP" means a provider that generally offers customers with electronic access to applications on the ASP's server. ASP generally does not provide computer software for customers to download. ASP, however, may provide downloadable codes in order for customers to access its applications on its server that are only incidental to the services provided to customers.
- (i) Example. BE Software, Inc., offers a variety of prewritten software products on-line, but not for download, to its eustomers for a monthly subscription fee. BE Software is

Permanent [58]

subject to service and other activities B&O tax for its subscription fees received.

- (ii) Example. Same facts as (g)(i) of this subsection, except that, in addition, BE provides computer software for customers to download before the on-line software can be used. The downloaded software does not provide any function other than confirm registration and provide access codes necessary for a customer to be able to use the on-line software. The downloaded software is provided as part of the monthly subscription fee. Once the subscription ends, the access software the customers downloaded will not perform any function. BE Software is subject to service and other activities B&O tax for its subscription fees received, because the true object of the transaction is to provide on-line software to its customers.
- (iii) Example: Same facts as (g)(i) of this subsection, except that, in addition, BE offers an option to allow its customers to download a limited number of software applications for an additional fee. Kelly purchases and downloads a number of additional prewritten software packages from BE in this state. BE is subject to retailing B&O tax, and BE must collect retail sales tax from Kelly on the additional fee for the sale of downloaded software.
- (h) Sales of web site development or hosting services. Gross income received for web site development or hosting services are subject to service and other activities B&O tax.

"Web site development service" means the design and development of a web site provided by a web site developer to a customer. "Web site hosting service" means providing server space to host a customer's web site.

(i) Sales of on-line advertising services. Gross income received for on-line advertising services are subject to service and other activities B&O tax. See RCW 82.04.280 and 82.04.214 for tax treatment of the electronic form of a printed newspaper.

For example, BB.com sells souvenir items through the internet. BB.com provides on-line advertising services for third parties. Income received for on-line advertising services is subject to service and other activities B&O tax.

- (j) Sales of data warehousing services. Gross income received for data warehousing services is subject to service and other activities B&O tax. "Data warehousing service" means the service of a provider offering server space for a customer to store its data and to access, retrieve, or use the data as needed.
- (i) Example: HH Recovery, Inc., provides substitute computer systems so that its customers may access its computer facilities for disaster recovery purposes, if such customers experience unplanned computer system failures. Lance pays a monthly subscription fee for this service. HH is subject to service and other activities B&O tax for the sale of data warehousing services to Lance.
- (ii) **Example.** Same facts as (j)(i) of this subsection, except that, in addition, HH performs "live" data backup for disaster recovery purposes. HH purchases prewritten computer software to perform "live" backup of data. HH is subject to use tax for the use of prewritten computer software to perform "live" backup of data.

PART V - DISTINCTION BETWEEN SALES AND SERVICES

(501) Current WAC 458-20-155 makes a distinction between sales and services. Liability for sales or use tax depends upon whether the subject of the sale is a product or a service. Professional and personal services rendered to a client are not generally subject to retail sales or use tax. If the consumer's true object of the transaction is obtaining professional or personal services, similar to those performed by a public accountant, architect, lawyer, etc., then the retail sales or use tax is not applicable. The retail sales and use tax is not applicable because these services are performed to meet a consumer's specific needs and any property transferred in the transaction is considered the medium in or on which those services are rendered and is merely the tangible evidence of a professional service rendered.

If the true object of the transaction is a product made available to any consumer and not created to meet the particular needs of a specific consumer, regardless of the method of delivery, then the transaction is taxable under the retailing B&O tax classification and taxable as a retail sale. The term "product" includes tangible personal property, such as prewritten software. This is no different from a usual inventory of tangible personal property held for sale or lease, and the sale or lease of such products is a sale at retail subject to retail sales tax or use tax.

Please see WAC 458-20-155 for more information.))

NEW SECTION

- WAC 458-20-15502 Taxation of computer software. (1) What is computer software? RCW 82.04.215 provides that "computer software" is a set of coded instructions designed to cause a computer or automatic data processing equipment to perform a task. All software is classified as either prewritten or custom. "Computer software" includes only those sets of coded instructions intended for use by an end user and specifically excludes retained rights in software and master copies of software. Computer software does not include data.
- (a) **How is computer software delivered?** Computer software may be delivered either by intangible means such as electronically downloaded or by tangible means such as tangible storage media.
- (b) What is automatic data processing equipment? "Automatic data processing equipment" includes computers used for data processing purposes and their peripheral equipment.
- (c) What are retained rights? "Retained rights" means any and all rights, including intellectual property rights such as those rights arising from copyrights, patents, and trade secret laws, that are owned or are held under contract or license by a software developer, author, inventor, publisher, licensor, sublicensor, or distributor. RCW 82.04.215.
- (d) What are master copies of software? "Master copies" of software means copies of software from which a software developer, author, inventor, publisher, licensor, sublicensor, or distributor makes copies for sale or license. RCW 82.04.215.

[59] Permanent

- (i) **Development of a master copy of software.** Development of a master copy of software by a software developer, or a third party hired by the software developer, that is used to produce copies of software for sale or commercial or industrial use, is not a manufacturing activity. A third-party charge for development of a master copy of software is a charge for custom software development and is subject to service and other activities B&O tax.
- (ii) Use of prewritten computer software by software developer. The internal use of prewritten computer software by the developer of that software is not subject to use tax because the software developer is not an end user of its own internally developed software. For example, VV Software, Inc., an in-state software developer, creates accounting software generally used by small businesses. VV plans to sell its newly created software to other companies. VV also plans to make a copy of this software and use it for its accounting operation. The copy of software used by VV for its accounting operation is not subject to use tax.
- (2) What is custom software? "Custom software" is computer software created for a single person. RCW 82.04.-215. The use of library files in software development does not preclude the developed software from being characterized as custom software, as long as the software is created for a single person. The nature of custom software does not change when ownership is transferred to a person with no rights retained by the transferor.

For purposes of this section, "library files" are a collection of precompiled and frequently used routines that a software developer can use in developing the software. The purchase or use of such "library files" may be subject to retail sales or use tax as the sale of prewritten software.

- (a) Creation of custom software. Gross income received for creating custom software is subject to service and other activities B&O tax.
- (b) **Duplication of custom software.** Duplication of custom software for the same person, or by the same person for the person's own use, does not change the character of the custom software. RCW 82.04.29001. Duplication of custom software for the same person, or by the same person for its own use, is not subject to manufacturing B&O tax.

If a person duplicates custom software for sale to or use by another person other than the original purchaser, the software becomes prewritten computer software as defined in subsection (3) of this section and is subject to manufacturing B&O tax if the prewritten computer software is delivered by tangible storage media.

- (c) **Sale of custom software.** If custom software is sold to another person other than the original purchaser, the software loses its character as custom software and becomes prewritten computer software as defined in subsection (3) of this section.
- (d) Use of custom software. Use of custom software is not subject to use tax.
- (e) The examples included in this rule identify a number of facts and then state a general conclusion; they should be used only as a general guide. Additionally, each fact pattern in each example is self contained (e.g., "stands on its own") unless otherwise indicated by reference to another example. The tax consequences of all situations must be determined

- after a review of all the facts and circumstances. Examples requiring that sales tax be collected by the seller assume that the seller has "tax nexus" with Washington and no exclusions or exemptions apply and the sale is sourced to Washington.
- (f) **Example 1.** PFC, Inc., develops software for its client. PFC is not subject to manufacturing B&O tax because the software is custom software. PFC's income from the sale of the custom software to the one specific client is subject to service and other activities B&O tax.
- (3) What is prewritten computer software? RCW 82.04.215 provides that "prewritten computer software" is computer software, including prewritten upgrades, patches, fixes, etc., that is not designed and developed by the author or other creator to the specifications of a specific purchaser.

The combining of two or more prewritten computer software programs or prewritten portions thereof does not result in custom software. Configuration of prewritten computer software to work with other computer software does constitute customization of prewritten computer software.

Prewritten computer software includes software designed and developed by the author or other creator to the specifications of a specific purchaser when it is sold to a person other than such purchaser.

Where a person, who is not the author or creator, modifies or enhances prewritten computer software, that person is deemed to be the author or creator only of the modifications or enhancements made. Prewritten computer software, or a portion thereof, that is modified or enhanced to any degree, remains prewritten computer software, even though the modification or enhancement is designed and developed to the specifications of a specific purchaser. Where there is a reasonable, separately stated charge or an invoice or other statement of the price given to the purchaser for the modification or enhancement, the modification or enhancement will not be considered prewritten computer software.

- (a) Wholesale sales of prewritten computer software. Gross proceeds from sales of prewritten computer software to persons other than consumers (e.g., sales for resale without intervening use) are subject to B&O tax under the wholesaling classification, whether or not ownership or title passes to the buyer, and regardless of any express or implied restrictions upon the buyer. The method of delivery of prewritten computer software does not alter the wholesale nature of the transaction, whether it is through tangible storage media or any electronic means. Delivery of software manuals and backup copies of prewritten computer software does not alter the delivery of the actual copy of prewritten computer software to be used by the buyer in determining when and where the sale takes place. To verify the wholesale nature of the sale, the seller obtains a reseller permit from the buyer as provided by WAC 458-20-102 (Reseller permits).
- (i) Distinction between wholesale sales of prewritten computer software and royalties received for the licensing of prewritten computer software. Sales of prewritten computer software constitute wholesale sales if the reseller, who has no right to reproduce the software for further sales, sells the same software to its customers. The true object of the sale to the reseller is the sale of the software. On the other hand, income received for granting an intangible right to reproduce and distribute copies of prewritten computer software for sale

Permanent [60]

constitutes royalties. The true object of the transaction that generates royalty income is the right to reproduce and relicense the software. See subsection (8) of this section for more information on royalties.

(ii) Examples.

- (A) Example 2. UM Computers, Inc., develops engineering software. UM sells the prewritten computer software at wholesale to OX Computers, Inc., in shrink-wrapped packages. UM delivers the software to OX. OX then resells the software to customers in the same shrink-wrapped packages. Sales of prewritten computer software by UM are subject to wholesaling B&O tax. Sales by OX to consumers are retail sales subject to retailing B&O tax and retail sales tax.
- (B) Example 3. GB Computers, Inc., develops engineering software. GB grants SE Computers, Inc., the right to reproduce and distribute copies of the prewritten computer software for sale to end users. GB retains all of its ownership rights to the software and delivers one copy of the software to SE to reproduce and sell. Amounts received by GB from SE for granting the right to reproduce and distribute prewritten computer software are subject to royalties B&O tax. Sales by SE to consumers are retail sales subject to retailing B&O tax and retail sales tax.
- (C) Example 4. DH Computers, Inc., develops engineering software. DH grants to WK Computers, Inc., the right to copy and redistribute its prewritten computer software. DH delivers the software electronically to WK. WK then sells the software to its customers, who download a copy of the software from WK. Income to DH from WK is subject to royalties B&O tax. Sales of prewritten computer software by WK to its customers are retail sales subject to retail sales
- (D) Example 5. AJ Soft, Inc., is a software developer of architectural drafting software. AJ Soft enters into an agreement with DJ Sales, Inc., to sell AJ Soft's drafting software. DJ Sales must pay a fee for each copy DJ Sales sells through its web site. AJ Soft does not allow DJ Sales to reproduce the drafting software. Customers download the software, but are unaware the software is downloaded directly from AJ Soft. AJ Soft is making a wholesale sale of software to DJ Sales subject to wholesaling B&O tax. DJ Sales is making a retail sale to its Washington customers subject to retail sales tax.
- (E) **Example 6.** Same facts as Example 5, however, instead of customers downloading the prewritten software, DJ Sales' customers access the prewritten software remotely on AJ Soft's servers. AJ Soft is still making a wholesale sale of remotely accessed prewritten software to DJ Sales subject to wholesaling B&O tax. DJ Sales is making a retail sale of remotely accessed prewritten software to its Washington customers subject to retail sales tax.
- (b) Retail sales of prewritten computer software. Gross proceeds of sales of prewritten computer software to consumers are subject to B&O tax under the retailing classification, whether or not ownership or title passes to the buyer, and regardless of any express or implied restrictions upon the buyer. Regardless of the method of delivery, whether through tangible media or electronic means, prewritten computer software remains subject to retail sales tax and retailing B&O tax. Delivery of software manuals and backup copies of prewritten computer software does not alter the delivery of

the actual copy of prewritten computer software to be used by the buyer in determining when and where the sale takes place. Persons making retail sales are responsible for collecting retail sales tax at the time of sale and remitting the tax to the department, unless the sale is specifically exempt by law.

(c) Use of prewritten computer software. Prewritten computer software, regardless of the method of delivery, is generally subject to use tax upon use in this state if Washington retail sales tax was not previously paid. However, use of prewritten computer software is not taxable, if it is provided free of charge, or if it is provided for temporary use in viewing information, or both. RCW 82.12.020. This exception from use tax is limited to prewritten computer software provided free of charge or for temporary use in viewing information, such as free promotional software, donated software, free download of software, and software provided in beta testing to a third-party free of charge.

For purposes of this use tax exception, "beta testing" means the last stage of testing for prewritten computer software prior to its commercial release including the release to manufacturing (RTM). Beta testing may involve sending the software to a third party for the use of the third party. Beta testing is often preceded by a round of testing called alpha testing.

- (i) **Example 7.** DS Computers, Inc., is a software developer. In order to perform beta testing of its new accounting software prior to commercial release, DS sends a copy of the software free of charge to KG Technologies, Inc. DS is not subject to use tax for the release of the beta software to KG. KG is not subject to use tax for the use of beta software free of charge.
- (ii) **Example 8.** DH, Inc., provides free card games online to its customers. The customers, however, must download DH's free software in order to be able to play card games on-line at DH's web site. Wendy downloads the software free of charge. Wendy is not subject to use tax for the use of the software.
- (iii) **Example 9.** DW, Inc., provides free software to the public for anyone to watch videos on-line. Roger downloads the software free of charge. Roger is not subject to use tax for the use of the software.
- (d) Manufacturing of prewritten computer software. Persons engaged in manufacturing prewritten computer software on tangible storage media are subject to manufacturing B&O tax upon the value of the products. See WAC 458-20-112 (Value of products) and WAC 458-20-136 (Manufacturing, processing for hire, fabricating). Manufacturers of prewritten computer software who sell their products at retail or wholesale are also subject to either the retailing or wholesaling B&O tax, as the case may be. In such cases the manufacturer must report under both the "production" (manufacturing) and "selling" (wholesaling or retailing) B&O tax classifications and may claim a multiple activities tax credit (MATC). See WAC 458-20-19301 (Multiple activities tax credits) for detailed information about the MATC. Income from the sale of prewritten software electronically delivered or transferred is not subject to manufacturing B&O tax.
- (e) **Duplication of prewritten computer software.** Duplication of prewritten computer software on tangible media for sales to or use by more than one person is subject

[61] Permanent

to manufacturing B&O tax upon the value of products which includes both the value of the tangible media and the software. Duplication of prewritten computer software on tangible media outside this state is not subject to manufacturing B&O tax regardless of where software development takes place.

Duplication of prewritten computer software is a manufacturing activity only if the prewritten computer software is delivered from the seller to the purchaser by means of tangible storage media which is retained by the purchaser. RCW 82.04.120.

When a software developer contracts with a third party to duplicate prewritten computer software, the parties must take into account the value of all tangible and intangible materials or ingredients, including the software code, when determining the relative value of all materials or ingredients furnished by each party. If the third party furnishes less than twenty percent of the total value of all materials or ingredients that become a part of the produced product, then the third party is presumed to be a processor for hire and the software developer is presumed to be a manufacturer. See WAC 458-20-136 (Manufacturing, processing for hire, fabricating) for more information.

- (4) Site license of prewritten computer software. A site license provides a consumer acquiring prewritten computer software with the right to duplicate prewritten computer software for use on its own computers, based on the number of computers, the number of workers using the computers, or some other criteria. A site license agreement may cover one site or multiple sites of a purchaser.
- (a) **Retail sales of a site license.** Gross proceeds of sales of a site license to a consumer are subject to B&O tax under the retailing classification, whether or not ownership or title passes to the consumer, and regardless of any express or implied restrictions upon the consumer. Delivery occurs when and where the prewritten computer software subject to the site license is received by the consumer, whether it is through tangible storage media or any electronic means, regardless of the method of delivery. See RCW 82.32.730 for more information on sourcing prewritten computer software. Delivery of software manuals and backup copies of prewritten computer software does not alter the delivery of the actual copy of prewritten computer software to be used by the consumer in determining when and where the sale takes place. Persons making retail sales are responsible for collecting retail sales tax at the time of sale and remitting the tax to the department, unless the sale is specifically exempt by law.

If the prewritten software is hosted by the licensor or a third party for remote access by the licensee, then see subsection (10) of this section.

(b) **Duplication of prewritten computer software by a person under a site license.** A seller of a site license is subject to manufacturing B&O tax for its own duplication of prewritten computer software. Duplication of prewritten computer software is subject to manufacturing B&O tax only if the prewritten computer software is delivered from the seller to the purchaser by means of tangible storage media which is retained by the purchaser. RCW 82.04.120. Purchaser of a site license is not subject to manufacturing B&O tax for the

duplication of prewritten computer software for its own use, pursuant to a site license agreement with the seller.

- (c) Use of a site license partly in this state and partly outside this state. The part of the site license used by the person in this state is subject to use tax, provided Washington state sales tax was not previously paid. For example, a person purchases and takes delivery of a site license in California. Pursuant to the multiple site license agreement, this person is licensed to use one thousand copies of prewritten computer software, of which four hundred copies will be used in Washington. Use tax is due on the four hundred copies of prewritten computer software used in this state. If the prewritten software purchased by the licensee is delivered in Washington, then the entire charge for the site license is subject to retail sales tax if purchased from a seller responsible for collecting Washington's sales tax. However, a purchaser can issue a multiple points of use exemption certificate under certain circumstances to minimize Washington tax as discussed below in subsection (11) of this section.
- (d) Sales and use of additional copies of prewritten computer software under the same site license. In some cases, the buyer of a site license may subsequently purchase additional copies of prewritten computer software under the same site license agreement. The seller may or may not deliver any additional copy of the software to the buyer, because the original copy of the software has already been delivered.
- (i) Retail sales of additional copies of prewritten computer software under the same site license. Retail sales of the additional copies of software occurs when and where the seller delivers any additional copy of prewritten computer software to the buyer, whether it is through tangible storage media or any electronic means, regardless of the method of delivery. If the seller does not deliver any additional copy of the software to the buyer, then the sales occur when the sales agreements are made to purchase the additional copies and where the original copy or copies of prewritten computer software was delivered. If the original sale of the site license was subject to manufacturing B&O tax, then the sale of additional licenses are also subject to manufacturing B&O tax.

Delivery of software manuals and backup copies of prewritten computer software does not alter the delivery of the actual copy of prewritten computer software to be used by the buyer in determining when and where the sale takes place.

- (ii) Use of additional copies of prewritten computer software under the same site license. Where the use of the additional copies of software is partly in this state and partly outside this state and was not previously subject to Washington sales tax, the part of the additional copies of software used by the person in this state is subject to use tax.
 - (e) Examples.
- (i) **Example 10.** DEF Computers, Inc., is located in Washington and sells in this state, at retail, a multiple site license of its prewritten computer software to P's Design, Inc. A copy of the prewritten computer software is electronically delivered to P's Design in Washington. P's Design then electronically duplicates the software and distributes the software in Washington and several other states for its use. Neither DEF nor P's Design is subject to manufacturing B&O tax. DEF, however, is subject to retailing B&O tax, and it must

Permanent [62]

collect retail sales tax from P's Design for the entire sale of the software unless P's Design provides DEF with a multiple points of use exemption certificate as discussed in subsection (11) of this section.

- (ii) **Example 11.** Same facts as Example 10, except that in addition, DEF delivers a backup copy of the software to P's Design outside Washington. The backup copy of the software is for disaster recovery purposes and is not downloaded to any of P's Design's computers for use. There is no separate charge for the delivery of the backup prewritten software. The software manuals are mailed to P's Design in Washington. DEF is still subject to retailing B&O tax, and it must collect retail sales tax from P's Design for the entire sale of the software unless P's Design provides DEF with a multiple points of use exemption certificate as discussed in subsection (11) of this section. Delivery of the software manuals and the backup copy of the software are not relevant in determining when and where the sale takes place. This transaction is not subject to manufacturing B&O tax.
- (iii) Example 12. Same facts as Example 10 of this subsection, except that in addition, P's Design subsequently purchases 50 additional copies of the software from DEF under the same site license agreement. P's Design merges with another company, and the additional copies are needed for the use of its new employees. No additional copy of the software is delivered to P's Design in fulfilling this new agreement. Neither DEF nor P's Design is subject to manufacturing B&O tax. DEF, however, is subject to retailing B&O tax, and it must collect retail sales tax from P's Design for the subsequent sale of the 50 additional copies of software because the original copy of the software was delivered in Washington unless P's Design provides DEF with a multiple points of use exemption certificate as discussed in subsection (11) of this section. However, if the original sale of the license had included delivery of the prewritten software by a tangible storage device (and was therefore subject to manufacturing B&O tax), then the licensor is also subject to manufacturing B&O tax based on the value of the additional licenses.
- (iv) **Example 13.** GH Computers, Inc., sells at retail a multiple site license of its prewritten computer software to Quick, Inc. GH is located outside Washington, while Quick is located in Washington, other states and other countries. The desktop software is licensed on an unlimited basis, which means that there are no restrictions of its use by Quick. The software is delivered to Quick outside Washington. Quick then electronically duplicates the software and distributes the software to all of its 500 employees, of which 100 employees are located in Washington. The software is electronically downloaded into the desktop computers of all employees and is immediately put into use. Use tax is due on the value of the 100 copies of prewritten computer software used in Washington
- (v) **Example 14.** Same facts as Example 13 of this subsection, except that under the original site license agreement, Quick is entitled to reproduce, distribute, and use up to 500 copies of the desktop software. Then Quick merges with another company, and additional copies are needed for the use of its new employees. Quick, therefore, subsequently purchases 100 additional copies of the software from GH under the same site license agreement. No additional copy of

the software is delivered to Quick in fulfilling this new agreement. Quick distributes the additional copies of the software to its 100 new employees, of which 50 employees are located in Washington. Use tax is due on the value of the 50 additional copies of prewritten computer software used in Washington.

(5) **Key to activate computer software.** A key, or an enabling or activating code, may be required in some instances to activate computer software and put the software into use, and the key may be delivered to a purchaser after the software is already delivered and in possession of the same purchaser. In such instances, the sale of computer software occurs when both the key and the software are delivered to the purchaser. The sale takes place where the software is received by the purchaser in accordance with RCW 82.32.-730. However, if the place of receipt for the software is unavailable to the vendor because the software was delivered by a third party, then the sale takes place where the key is received in accordance with RCW 82.32.730. There is no separate sale of the key from the software, regardless of how such sale may be characterized by the vendor or by the purchaser.

See subsection (4) of this section for more information if a site license of prewritten computer software is involved. If the sale of the prewritten software is subject to manufacturing B&O tax, then the sale of the key required by that prewritten software is also subject to manufacturing B&O tax. The income from the sale of a key is part of a sale of prewritten computer software, whether the sales transactions are together or separate.

- (a) Example 15. JKL Computers, Inc., an in-state business, sells at retail prewritten computer software to Rebecca. JKL delivers the software to Rebecca in this state. The prewritten computer software, however, cannot be activated without a key. JKL subsequently delivers the key in this state to Rebecca for a separate price. JKL is subject to retailing B&O tax, and it must collect retail sales tax from Rebecca on the entire sale of the software including the separate charge for the key. The entire sale takes place in this state (where the software is delivered) when both the software and the key are delivered to Rebecca. There is no separate sale of the key, regardless of the fact that JKL delivers the key to Rebecca for a separate charge.
- (b) **Example 16.** Same facts as Example 15 of this subsection, except that JKL subsequently delivers the key outside this state to Rebecca for a separate price. JKL is subject to retailing B&O tax, and it must collect retail sales tax from Rebecca on the entire sale of the software including the separate charge for the key. The entire sale takes place in this state (where the software is delivered) when both the software and the key are delivered to Rebecca. There is no separate sale of the key, regardless of the fact that JKL delivers the key to Rebecca for a separate charge.
- (c) Example 17. MNO Computers, Inc., is an in-state software developer. TKO Computers, Inc., an out-of-state original equipment manufacturer of computers (OEM), agrees in contract with MNO to distribute MNO's prewritten computer software on its computers. TKO delivers MNO's inoperable software to Sally as part of the sale of the computer system. Sally, however, must purchase a key directly

Permanent

from MNO in order to activate and use the software. MNO has no knowledge of where the software was initially delivered to Sally, but MNO knows that the key is delivered to Sally in this state. MNO is subject to retailing B&O tax, and it must collect retail sales tax from Sally on the entire sale of the key and the inoperable software. The entire sale takes place in this state because the key is delivered in this state and MNO has no knowledge of where the inoperable software was initially delivered by TKO.

(6) Client access license and server license for the server software. A server license, paid for at the time the server software is purchased, grants the buyer the right to install the server software on the buyer's server. A client access license (CAL) grants the buyer the right to access the server software.

Charges for server licenses and CAL are a part of the sale of the server software, even if the charges are separately stated. The sales take place where the server software is delivered to the buyer.

In cases where server software is delivered to the buyer and used in multiple locations, see subsection (4) of this section on site licenses for more information.

- (a) **Example 18.** ZZ Computers, Inc., an in-state business, sells at retail server software to Jack. ZZ delivers the server software to Jack in Washington. ZZ also provides Jack with client access licenses for free allowing Jack the right to access the server software from his personal computers. The sale of server software to Jack is subject to retailing B&O tax, and ZZ must collect retail sales tax from Jack for the same sale.
- (b) Example 19. Same facts as Example 18 of this subsection, except that ZZ makes two separate sales at retail of two types of prewritten computer software to Jack. One is server software, and the other is client software (which is different from client access licenses). ZZ delivers the server software to Jack in Washington where Jack's server is located. ZZ delivers the client software to Jack outside Washington where all of Jack's personal computers are located. Only the sale of server software to Jack is subject to retailing B&O tax, and ZZ must collect retail sales tax from Jack for the same sale. Jack may use a multiple points of use exemption certificate for the server software. See subsection (11) of this section for more detail on multiple points of use.
- (7) Other activities associated with computer software.
- (a) Customizing prewritten computer software. Gross income received for customizing prewritten computer software is subject to service and other activities B&O tax. RCW 82.04.29001.
- (i) What is customizing prewritten computer software? RCW 82.04.215 provides that "customization of prewritten computer software" is any alteration, modification, or development of applications using or incorporating prewritten computer software for a specific person.

"Customization of prewritten computer software" includes individualized configuration of software to work with other software and computer hardware but does not include routine installation. Customization of prewritten computer software does not change the underlying character or taxability of the original prewritten computer software.

- (ii) One nonitemized price for prewritten computer software, customization, and routine installation. If prewritten computer software, customization of prewritten computer software, and routine installation are sold for a one nonitemized price, the entire charge is considered to be subject to retail sales tax. See (a)(iv) of this subsection for more information on routine installation.
- (iii) Separately stated charge for customization of prewritten computer software. Where there is a reasonable separately stated charge on an invoice or other statement of the price given to the purchaser for customization of prewritten computer software (including installation that is not routine, see (a)(i) of this subsection), such customization is subject to service and other activities B&O tax. If a charge for customization of prewritten computer software is not separately stated from a sale of prewritten computer software, the entire charge is considered a retail sale subject to retail sales tax.
- (iv) Customization of prewritten computer software versus routine installation. Customization of prewritten computer software includes custom installations but does not include routine installation. "Routine installation" means the process of loading program files and installation files onto a computer. Routine installation includes the process of "clicking through" dialog boxes to install prewritten software. Routine installation does not require any specialized knowledge or skills. Custom installation generally requires programming by a programmer to integrate customized elements of prewritten computer software.
- (v) Separately stated charge for routine installation from customization of prewritten computer software. Where there is a reasonable separately stated charge on an invoice or other statement of the price given to the purchaser for routine installation from customization of prewritten computer software, routine installation is subject to retailing B&O tax and retail sales tax. If a charge for routine installation is not separately stated from customization of prewritten computer software and is de minimis, the transaction would not be subject to retail sales tax, but instead subject to service and other activities B&O tax.
 - (vi) Examples.
- (A) Example 20. Tee, Inc., needs financial modeling software that can tie into its existing computer systems. Because of its unique business, however, Tee needs the industry-wide computer software offered by PQR Computers, Inc., to be modified to meet the needs of Tee. Both Tee and PQR are in-state corporations, and the software is delivered in this state. PQR provides a separately stated charge to Tee for customization of prewritten computer software performed in this state that is supported by the terms of the sales agreement. PQR is subject to retailing B&O tax, and it must collect retail sales tax from Tee for the sale of prewritten computer software in Washington. PQR, in addition, is subject to service and other activities B&O tax for the customization of prewritten computer software in Washington.
- (B) **Example 21.** Same facts as Example 20 of this subsection, except that, in addition, PQR provides a separately stated charge to Tee for routine installation of prewritten computer software in this state. This charge represents installation of only the prewritten portion of the software. In addi-

Permanent [64]

tion to the tax treatments in Example 20 of this subsection, PQR is subject to retailing B&O tax and it must collect retail sales tax from Tee for the routine installation in Washington.

- (b) Installing or uninstalling computer software.
- (i) Gross income received from installing or uninstalling custom software is subject to service and other activities B&O tax.
- (ii) Gross proceeds of sales for routine installation of prewritten computer software are subject to retailing B&O tax and retail sales tax. See (a)(iv) of this subsection for more information on routine installation. Routine installation of prewritten computer software includes charges for labor and services in respect to the installation, such as travel costs for the routine installation of the software. As of July 1, 2008, if the routine installation occurs through remote access by someone outside the state of Washington, then the installation is sourced pursuant to RCW 82.32.730.

Example 22. XYZ Computers, Inc., is hired by Dan for routine installation of prewritten software onto Dan's computers. XYZ's out-of-state employee remotely accesses Dan's computers in Washington to install the prewritten software on his computers. If XYZ has nexus with Washington, then it must collect and remit the sales tax. If XYZ does not have nexus, then Dan must pay use tax.

Gross proceeds of sales from uninstalling prewritten computer software are subject to retailing B&O tax and retail sales tax.

- **Example 23.** XYZ Computers, Inc., is hired by Dan to remove prewritten computer software from his computers. Removal of the prewritten computer software requires uninstalling the software from the computer. XYZ sends an employee to Dan's location to remove the software from his computers. Charges for removal of the prewritten computer software are subject to retailing B&O tax and retail sales tax.
- (c) Repairing, altering, or modifying computer software. Repair of prewritten computer software for more than one person may be distributed as a fix or patch by tangible storage media or electronically in the nature of software upgrades and updates. The sale of prewritten computer software upgrades and updates is a sale of prewritten computer software subject to retailing B&O tax and retail sales tax.

Alteration or modification of prewritten computer software performed for a specific person is subject to the service and other activities B&O tax. Such alteration or modification of prewritten computer software for a specific person constitutes customization of prewritten computer software. See RCW 82.04.215.

- (i) **Example 24.** STU Computers, Inc., a Washington company, is hired by Betty to perform repairs (using primarily human effort) via remote access on her prewritten computer software in Washington. STU is performing alteration or modification of prewritten computer software for a specific person and is subject to service and other activities B&O tax
- (ii) **Example 25.** VW Computers, Inc., an out-of-state service provider, is hired by Clyde to perform alterations or modifications (using primarily human effort) via remote access on his prewritten computer software located in this state. VW's facility is located outside this state. VW may be

subject to service and other activities B&O tax if it has nexus with Washington.

- (d) Maintaining computer software. Computer software maintenance agreements typically include, but are not limited to, support activities such as telephone consulting, help desk services, remote diagnostic services, and software upgrades and updates.
- (i) Tax treatment of computer software maintenance agreements in general. Sales of stand-alone computer software maintenance agreements that include telephone consulting, help desk services, remote diagnostic services, and other professional services only, are taxable under the service and other activities B&O tax. However, if the services are part of a sale of an extended warranty on or after July 1, 2005, then the sale is subject to retailing B&O tax and retail sales tax. See WAC 458-20-257 (Warranties and maintenance agreements) for information about extended warranties.

Stand-alone sales of updates or upgrades to prewritten computer software are retail sales of tangible personal property subject to retailing B&O tax and retail sales tax.

(ii) Prewritten computer software maintenance agreement with mixed elements. The sale of a prewritten computer software maintenance agreement for a single non-itemized price that includes professional service components such as telephone consulting and retail components such as upgrades and updates of prewritten computer software is generally considered a retail sale subject to retailing B&O tax and retail sales tax unless charges for the upgrades and updates are de minimis.

In cases where the charges for the professional service component(s) and the retail component(s) are separately stated within a prewritten computer software maintenance agreement and invoice, then each activity is taxed according to the nature of the activity.

(iii) **Duplication of prewritten computer software upgrades and updates.** Duplication of prewritten computer software upgrades and updates is subject to manufacturing B&O tax upon the value of products, if the software upgrades and updates are delivered by means of tangible storage media which is retained by the purchaser. This is the case regardless of any maintenance agreement with mixed elements involved. The measure of tax is presumed to be the contract price of the maintenance agreement, unless the person can prove otherwise. See WAC 458-20-112 (Value of products) for more information.

If the software upgrades and updates are delivered from the seller by means other than tangible storage media which is retained by the purchaser, then the software upgrades and updates are not subject to manufacturing B&O tax.

- (iv) Maintenance agreement on custom software and customized elements of prewritten computer software. Sales of maintenance or support services relating to custom software or the customized elements of prewritten computer software are subject to the service and other activities B&O tax. Such services, including upgrades and updates, are rendered in respect to the custom or customized software and take on the underlying character and taxability of the custom or customized software.
 - (v) Examples.

Permanent

- (A) Example 26. On December 15, 2005, CBA Computers, Inc., sells at retail a prewritten computer software maintenance agreement to Frank for his prewritten software. The software maintenance agreement includes an extended warranty for the software, software upgrades and updates, and telephone consulting services for a single nonitemized price. The consulting services are not offered exclusively in connection with the software, nor are they essential to use of the software. CBA delivers the software upgrades and updates electronically. CBA is subject to retailing B&O tax, and it must collect retail sales tax from Frank for the sale of the mixed agreement.
- (B) **Example 27.** Same facts as Example 26 of this subsection, except that CBA delivers the software upgrades and updates on compact disks. CBA is subject to retailing B&O tax, and it must collect retail sales tax from Frank for the sale of the mixed agreement. In addition, CBA is subject to manufacturing B&O tax on duplication of software upgrades and updates. The measure of tax is presumed to be the contract price of the maintenance agreement, unless CBA can prove otherwise.
- (C) Example 28. Same facts as Example 26 of this subsection, except that CBA provides a separately stated charge for each component of the maintenance agreement. CBA is subject to retailing B&O tax, and it must collect retail sales tax from Frank for the charges on prewritten software upgrades and updates and on the extended warranty purchased after July 1, 2005. CBA is subject to service and other activities B&O tax for the charge on telephone consulting services.
- (D) Example 29. FED Computers, Inc., sells at retail a computer software maintenance agreement to Greta for her software. The maintenance agreement covers only software upgrades and updates. Greta's software is prewritten computer software with customized elements. FED provides the maintenance services to Greta at one nonitemized charge. FED is subject to retailing B&O tax, and it must collect retail sales tax from Greta for the sale of the entire maintenance agreement of the prewritten computer software.
- (E) **Example 30.** Same facts as Example 29 of this subsection, except that FED provides a separately stated charge for maintaining the customized elements. FED is subject to service and other activities B&O tax on the charges for maintaining the customized elements. FED is subject to retailing B&O tax, and it must collect retail sales tax from Greta for the charge on maintaining prewritten computer software.
- (e) Computer software training. Gross income received for training on the use of custom software is subject to service and other activities B&O tax. Gross income received for training on the use of prewritten computer software is subject to service and other activities B&O tax, if the charge for such training is separately stated from the sale of prewritten computer software. If the charge for software training is not separately stated from the sale of prewritten computer software and the prewritten software value is more than de minimis, the entire charge is considered to be a retail sale subject to retailing B&O tax and retail sales tax.
- (8) Licensing computer software Royalties. Income received from charges in the nature of royalties for certain

- licensing of computer software is taxable under the royalties B&O tax classification.
- (a) What are royalties? RCW 82.04.2907 provides that "royalties" means compensation for the use of intangible property, such as copyrights, patents, licenses, franchises, trademarks, trade names, and similar items. The true object of a transaction involving royalties is to grant an intangible right to reproduce and distribute copies of computer software for sale. It does not, however, include compensation for the licensing of prewritten computer software to the end user. The manner in which computer software is sold (e.g., volume of transactions, subscription license, term license, or perpetual license) or the manner in which payment amount is determined (e.g., fixed fee per copy, percentage of receipts, lump sum, etc.) does not alter the royalty nature of the transaction.
- (b) **Royalties versus site license.** Regarding royalties, the true object of the transaction is to grant an intangible right to reproduce and distribute copies of computer software for sale. In contrast, the true object of a site license is the sale to an end user of prewritten computer software for use on its computers. See subsection (4) of this section for more information on site licenses.
- (c) Royalties versus wholesale sales of prewritten computer software. See subsection (3)(a) of this section for more information.
 - (d) Examples.
- (i) **Example 31.** HG Computers, Inc., an original equipment manufacturer (OEM), acquires prewritten computer software from LL Software, Inc., under a license to reproduce and distribute the prewritten computer software as part of a bundled computer hardware and software package HG sells to end users. LL retains all of its ownership rights to the software. The gross income received by LL from granting intangible rights to reproduce and distribute prewritten computer software to HG is subject to royalties B&O tax.
- (ii) **Example 32.** Same facts as Example 31 of this subsection, except that, in addition, HG acquires a site license from LL for the purposes of copying and using the prewritten computer software as an end user. LL delivers the software to HG. Amounts received by LL for the sale of a site license are subject to retailing B&O tax and retail sales tax.
- (9) Special use tax exemption for computer hardware and computer software donated to certain schools or colleges. Use tax does not apply to the use of computer hardware and prewritten software irrevocably donated to any public or private nonprofit school or college, as defined under chapter 84.36 RCW. RCW 82.12.0284.
 - (10) Sales of remote access software.
- (a) **Remote access custom software.** Sales of remote access custom software on the seller's (or a third-party's) servers are subject to service and other B&O tax.
- (b) Remote access prewritten software. Sales of remote access prewritten software on the seller's (or a third-party's) servers are subject to retail sales tax, when the sale is sourced to Washington pursuant to RCW 82.32.730. Sale of remote access prewritten software prior to July 26, 2009, were subject to service and other activities B&O tax.

Example 33. BE Software, Inc., a Washington corporation, offers a variety of prewritten software products on-line, but not for download, to its customers for a monthly subscrip-

Permanent [66]

tion fee. BE Software must charge Washington customers retail sales tax and is subject to retailing B&O tax for the subscription fees received from its Washington customers.

- (c) Exemptions from retail sales or use tax for remote access prewritten software. The following exemptions only apply to remote access prewritten software, and not other types of prewritten software sold.
- (i) **Offered free.** Purchases of prewritten software that will be offered remotely by the purchaser to its own customers is exempt from retail sales tax. RCW 82.04.190 (2)(f). The purchaser of the prewritten software must provide an exemption certificate to the seller in order to receive the exemption. The income from the sale of the prewritten software is subject to retailing B&O tax.
- **Example 34.** BE Software, a Washington company, purchases prewritten software from Joe's Software Developer Co., that BE will provide remotely to its customers. BE provides an exemption certificate to Joe's for the purchase of prewritten software. Joe's does not collect or remit retail sales tax, but does pay retailing B&O tax on the income from the sale. BE would generally charge and collect retail sales tax and pay retailing B&O tax on income received from the sale of the prewritten software remotely accessed by consumers.
- (ii) Made available free to the general public. Retail sales and use taxes do not apply to the purchase or use by a business or other organization of remote access prewritten software in order to make that remote access prewritten software available free of charge for the use or enjoyment of the general public. Buyers claiming this exemption must provide the seller with a properly completed "Digital Products and Remote Access Software Exemption Certificate" or other exemption certificate acceptable to the department.
- (A) Available for free. In order to qualify, the remote access prewritten software purchased must be made available for free. In this context, "free" means that the recipient of the remote access prewritten software does not need to provide anything of significant value. If the purchaser requires something of significant value from the recipient in exchange for the remote access prewritten software, it is not given away for free.
- (B) "General public" means all persons and is not limited or restricted to a particular class of persons, except that the general public includes:
- (I) Certain classes of persons defined by their residency or ownership: The general public includes a class of persons residing or owning property within the boundaries of any state (e.g., Washington), political subdivision of a state (e.g., King County), or a municipal corporation (e.g., Seattle).
- (II) Library customers. With respect to libraries, the term general public includes authorized library patrons.
- (C) Purchaser must have the legal rights to provide the remote access prewritten software to the general public: The exemption provided in subsection (3) of this section does not apply unless the purchaser has the legal right to broadcast, rebroadcast, transmit, retransmit, license, relicense, distribute, redistribute, or exhibit the remote access prewritten software, in whole or in part, to the general public.
 - (11) Multiple points of use (MPU) exemptions.
- (a) The retail sales tax does not apply to the sale of prewritten computer software or remote access prewritten soft-

- ware if the buyer correctly provides the seller with an exemption certificate claiming multiple points of use.
- (b) If the sale of the prewritten software or the remote access prewritten software (including retail sales of licenses to prewritten software and remote access prewritten software) is sourced to Washington and the purchaser does not provide an exemption certificate, then the entire charge is subject to retail sales tax. Buyers may use the department's "Digital Products and Remote Access Software Exemption Certificate" to claim this exemption.
- (i) **Requirements.** A buyer is entitled to use an exemption certificate claiming MPU only if the buyer is a business or other organization and the prewritten software or remote access prewritten software purchased will be concurrently available for use within and outside Washington. A buyer is not entitled to use an exemption certificate claiming MPU for prewritten software purchased for personal use.
- (ii) **Concurrently available.** "Concurrently for use within and outside this state" means that employees or other agents of the buyer may use the prewritten software or remote access prewritten software simultaneously from one or more locations within this state and one or more locations outside this state.
- (iii) **Apportionment (allocation) of use tax.** For purposes of this subsection on MPU, "allocation" and "apportionment" will have the same meaning. A business or other organization subject to use tax on prewritten software or remote access prewritten software that is concurrently available for use within and outside this state is entitled to apportion the amount of tax due this state based on users in this state compared to users everywhere. Additionally, the department may authorize or require an alternative method of apportionment supported by the taxpayer's records that fairly reflects the proportion of in-state to out-of-state use by the taxpayer.
- (c) **Records requirement.** No allocation under this section is allowed unless the allocation method is supported by the taxpayer's records kept in the ordinary course of business.
- (i) "User" means an employee or agent of the taxpayer who is authorized by the taxpayer to use the prewritten software or remote access prewritten software purchased in the performance of his or her duties as an employee or other agent of the taxpayer.
- (ii) **Example 35.** Neymar operates an accounting firm headquartered in Seattle. Neymar purchases from Lionel prewritten software which Neymar installs on a server in Seattle. The software is accessed and used concurrently by 5 employees at his Seattle office and 5 employees at his California office. Neymar provides Lionel with a sales tax exemption certificate claiming multiple points of use. Neymar is only required to pay use tax for the value attributed to his employee's use at the Seattle office (i.e., 50%). Neymar does not pay use tax to Washington for the value of the software used in his California offices even though the software resides on servers in Seattle.

NEW SECTION

WAC 458-20-15503 Digital products. This rule provides a structured approach for determining tax liability for

[67] Permanent

digital products and digital codes. For purposes of this rule, a digital product includes digital goods or digital automated services, which are described in detail below. The sale or use of digital products and digital codes is generally subject to retail sales or use tax unless purchased for resale or some other exemption applies.

This rule is organized into six parts. Each part addresses a question or topic relevant to the determination of whether a person is selling or purchasing a digital product or digital code and, if so, what are the tax consequences that follow from such activity. In this respect this rule is intended to function similar to the decision tree provided in ETA 9003.2010.

- 1. Part 1: Are the products or services transferred electronically? If yes, go to Part 2.
- 2. Part 2: Does the product or service meet the general definitions of digital product or digital code? If yes, go to Part 3.
- 3. Part 3: Are there applicable exclusions from the general definitions of the digital product or digital code? If no, go to Part 4.
- 4. Part 4: Are the sales of the digital product or digital code sourced to Washington? If yes, go to Part 5.
- 5. Part 5: Are there applicable retail sales or use tax exemptions for the purchase or use of the digital product or digital code? If no, the transaction is likely taxable in Washington.
 - 6. Part 6: Miscellaneous provisions.

Examples included in this rule identify a number of facts and then state a general conclusion; they should be used only as a general guide. The tax consequences of all situations must be determined after a review of all the facts and circumstances. Additionally, each fact pattern in each example is self contained (e.g., "stands on its own") unless otherwise indicated by reference to another example. Examples concluding that sales tax applies to the transaction assume that no exclusions or exemptions apply, and the sale is sourced to Washington.

Part 1. Are the Products or Services Transferred Electronically?

- (101) **Introduction.** Products or services must be transferred electronically in order to be digital products. If a product is transferred by means of a tangible storage media (e.g., compact disc, magnetic tape, hard drive, etc.), it is not a digital product. Digital codes need not be transferred electronically in order to be digital codes, but may be obtained by any means, including tangible storage media.
- (102) **Transferred electronically.** Means the purchaser obtains the product by means other than tangible storage media. Generally, this means the product is transferred using the public internet, a private network, or some combination. However, it is not necessary that the product be delivered to the purchaser. As long as the purchaser may access the product, it will be considered to have been electronically transferred to the purchaser. For example, whether a digital movie is downloaded by the user or streamed by the user, it is considered to be "transferred electronically." Alternatively, the same movie purchased on tangible media (e.g., DVD, etc.) is the purchase of tangible personal property and is not consid-

ered to be either the sale of a digital product or transferred electronically.

Part 2. Does the Product or Service Meet the General Definition of Digital Product or Digital Code?

- (201) **Introduction.** The term "digital product" means (1) digital goods and (2) digital automated services. Digital products transferred to an end user are generally subject to retail sales or use tax regardless of whether the purchaser's right of use is permanent, less than permanent (e.g., 24-hour period), or the purchaser is obligated to make continued payments as a condition of the sale (e.g., "subscriptions").
- (202) **Digital goods.** Means sounds, images, data, facts, or information, or any combination thereof, transferred electronically, with certain exclusions discussed in Part 3 of this rule. The term "digital goods" includes within it the specific term "specified digital products" (as required by the Streamline Sales and Use Tax Agreement). The sale of a digital good is generally subject to retail sales tax and retailing business and occupation (B&O) tax.
- (a) **Specified digital products.** Means electronically transferred digital audio-visual works, digital audio works, and digital books.
- (i) **Digital audio works.** These are products that result from the fixation of a series of musical, spoken, or other sounds. Digital audio works include ringtones, recorded or live music, readings of books or other written materials, speeches, and other sound recordings. For example, a music file in MP3 format accessed or downloaded through the internet is a digital audio work.
- (1) A "ringtone" is a digitized sound file that is downloaded onto a communication device (e.g., mobile phone) and may be used to alert the user to an incoming communication such as a call or text message.
- (2) A ringtone does not include "ring-back tones" or other digital audio files that are not stored on the purchaser's communication device. In other words a ring-back tone is not a "specified digital product." A ring-back tone may be a digital automated service or a digital good depending on the facts. See analysis for digital automated services in subsection (203) of this section.
- (ii) **Digital audio visual works.** These products are a series of related images which, when shown in succession, impart an impression of motion, together with accompanying sounds, if any. Digital audio visual works include movies, music videos, videos of live events, and news and entertainment programs. For example, a movie downloaded or accessed via the internet is a digital audio visual work.
- (iii) **Digital books.** These are books in a digital format that are generally recognized in the ordinary and usual sense as books. A digital book does not include periodicals, magazines, newspapers, chat rooms, or weblogs. For example, a cookbook in a PDF format downloaded or accessed through the internet is a digital book.
- (b) **Other digital goods.** The following list illustrates the types of products that are also digital goods in addition to the subclass of "specified digital products" discussed above. This list is merely illustrative and not exhaustive:
- (1) A digital schematic of a lawnmower engine transferred electronically.

Permanent [68]

- (2) A digital car history report transferred electronically.
- (3) A digital picture transferred electronically.
- (4) Digital periodicals or magazines transferred electronically.
- (5) A digital presentation that includes still photos and accompanying audio content transferred electronically.
- (c) **Digital goods prior to July 26, 2009.** The mere accessing or streaming of a digital good was not a retail sale before July 26, 2009. Instead, accessing or streaming a digital good was subject to the service and other activities B&O tax. The sale of a digital good to a customer who downloaded the digital good was a retail sale. See Part 6, subsection (604) of this section for a discussion of tax amnesty for past periods.
- (203) **Digital automated services.** Means services transferred electronically that use one or more software applications. The sale of a digital automated service is generally subject to retail sales tax and retailing B&O tax.
- (a) **Digital automated services may include.** One or more software applications either prewritten or custom, as well as components that are similar to stand-alone digital goods. For example, an online information service may contain data, facts, or information the use of which is facilitated by one or more software applications that provide search capabilities and other functionality. Thus, digital automated services will include software and may include elements similar to stand alone digital goods, which operate together in an integrated fashion to provide an electronically transferred service.
- **Example 1.** BFC provides an online service that facilitates apartment building management. The online service lists and advertises apartment vacancies, screens applicants, routes maintenance requests, and accepts and processes rental payments. In this example the software based service facilitates and automates various administrative functions and coordinates third-party services for apartment renting. The service is a digital automated service the sale of which is generally subject to retail sales tax and retailing B&O tax.
- **Example 2.** QPR provides a service that uses one or more software applications to "crawl the internet" in order to identify, gather, and categorize digital information according to specified criteria. In this example software facilitates the gathering, identifying and categorizing of information acquired from the internet. The service is a digital automated service the sale of which is generally subject to retail sales tax and retailing B&O tax.
- (i) **Distinguishing a digital good from digital automated services.** A digital good is not a service involving one or more software applications. A digital good consists solely of images, sounds, data, facts, information or any combination thereof. Clear examples of digital goods are digital books, digital music, digital video files, and raw data.
- **Example 3.** XYZ provides an online service that uses one or more software applications to facilitate the use of news and information with features such as: Research history, natural and boolean searching, industry chat forums, chart creation, document and word flagging, and information organizing folders. In this example software features facilitate the search of the news or information. XYZ's service is a digital

automated service the sale of which is subject to retail sales tax and retailing B&O tax.

- **Example 4.** Company sells digital music files (i.e., digital goods) on its web site. In order to locate specific digital music files customers may use a free software based search function that is integrated into Company's web site. Customers may also find the digital music file they are seeking by clicking on a series of links to get to the desired music file. Company's software based search function associated with the sale of the digital music file does not transform the sale of the digital music file into a digital automated service. Company is selling a digital good (i.e., music file) subject to retail sales tax and retailing B&O tax.
- (ii) **Distinguishing remote access prewritten software from digital automated services.** Remote access prewritten software (defined in RCW 82.04.050 (6)(b)) is solely prewritten software that is made remotely accessible from the vendor's server or other third-party server for a customer. To the extent that components similar to digital goods and/or additional services are supplied with the prewritten software the sale may be the sale of a digital automated service (see also Part 3, subsection (303)(h) of this section).
- **Example 5.** CFC provides an online gaming service that allows subscribers to play a game with other subscribers in a real time multiplayer environment using software accessed via the internet. In this example the gaming software is combined with additional capabilities that enable a real time multiplayer environment that is not otherwise available. The service is a digital automated service, the sale of which is generally subject to retail sales tax and retailing B&O tax.
- **Example 6.** Company sells prewritten word processing software that is accessed by customers but hosted on Company's computers. The software includes access to clip-art image files that can be inserted into documents created with the remotely accessed prewritten word processing software. Company is selling remote access prewritten software and not a digital automated service or digital goods. The clip art made available with the software does not transform the remotely accessed prewritten software into a digital automated service or a digital good. Company is selling remote access prewritten software subject to retail sales tax and retailing B&O tax.
- (b) **Digital automated service prior to July 26, 2009.** The sale of a digital automated service to consumers was not a retail sale before July 26, 2009. Generally, income earned from such sales was subject to B&O tax under the service and other activities classification.
- (204) **Digital codes.** These are codes that provide a purchaser with the right to obtain one or more digital products, if all of the digital products to be obtained through the use of the code have the same retail sales and use tax treatment. A digital code may be obtained by any means, including e-mail or by tangible media regardless of its designation as song code, video code, book code, or some other term. For example, a digital code includes the sale of an alphanumeric code that, when entered online at a web site, provides the customer with a digital music file for download.
- (a) **Products with mixed tax treatment.** Codes that provide the right to obtain one or more products that do not

[69] Permanent

have the same retail sales and use tax treatment are not digital codes

(b) Codes that represent a stored monetary value, redeemable cards, gift cards, or gift certificates. Codes that represent a stored monetary value that is deducted from a total as it is used by the purchaser or that represent a redeemable card, gift card, or gift certificate that entitles the holder to select digital products of an indicated cash value, are not digital codes.

Example 7. Calvin purchases a code at his local grocery store for use on Joe Seller's (JS) web site. At check out, Calvin tells the grocery store clerk to put \$25.00 in value on the plastic card containing the code. Calvin then goes to JS's web site and inputs the code from the card. The \$25.00 value of the card is stored in Calvin's "account" and can be used on any purchase by Calvin from JS's web site. Calvin then purchases five digital songs for \$5.00 from JS. At check-out from JS's web site, \$5.00 is deducted from Calvin's account to pay for the songs. When the transaction is complete, Calvin has a \$20.00 balance remaining in his account on JS's web site. Because the code represents a stored monetary value it is not a digital code and the sale of the code is not subject to retail sales tax or retailing B&O tax.

Part 3. Are There Applicable Exclusions from the General Definitions of Digital Product and Digital Code?

(301) **Introduction.** For certain products or services transferred electronically that otherwise meet the definition of digital good or digital automated service (as discussed in Part 2) there may be a specific exclusion from the applicable definition. If an exclusion applies, then the product or service will generally not be considered a digital good or digital automated service for retail sales and use tax purposes. For example, a service that is transferred electronically and that uses one or more software applications will generally be subject to retail sales tax as a digital automated service. However, if the service is an advertising service, then an exclusion applies, and the service will not be a digital automated service subject to retail sales tax; however, the service may still be subject to B&O tax. An excluded service may also still be subject to retail sales tax under certain circumstances. For example, telecommunications services are excluded from the definition of digital automated services, but remain subject to retail sales tax under their own separate definition of retail sale.

(302) Exclusions from the definition of digital good are:

- (a) **Telecommunications and ancillary services** as defined in RCW 82.04.065. These services may be used to distribute digital goods, digital automated services, and digital codes, but are not themselves any of these products.
- (b) **Computer software** as defined in RCW 82.04.215 and WAC 458-20-15502. These are coded instructions designed to cause a computer or automatic data processing equipment to perform a task.
- (c) **The internet and internet access** as defined in RCW 82.04.297.
- (d) **Professional or personal services** represented in electronic form are not a digital good. This exclusion applies where the service primarily involves the application of human effort by the service provider, and the human effort

- originated after the customer requested the service. For example, an electronic engineering report created at the customer's request that reflects an engineer's professional analysis, calculations, and judgment, which is sent to the customer electronically, is considered evidence of a professional service and not a digital good.
- (i) **Photography.** This exclusion for professional or personal services does not apply to photographers in respect to amounts received for the taking of digital photographs that are transferred electronically to the end user/customer as defined in RCW 82.04.190(11). See Example 39 for an example of a nonend user transaction involving photography that is subject to royalties B&O tax.
- (e) Exclusions listed directly below for digital automated services are also exclusions from the definition of digital good.
- (303) Exclusions from the definition of digital automated service are:
- (a) Services that require primarily human effort by the seller and the human effort originated after the customer requested the service. In this context, "primarily" means greater than fifty percent of the effort to perform the service involved human labor. To determine whether the fifty percent or greater threshold is satisfied, the average of the time and cost factors is considered. The time factor is determined by dividing the time spent to perform the human effort portion for customers by the total time spent performing the service. The cost factor is determined by dividing the direct costs incurred to perform the human effort portion for customers by the total direct costs incurred to perform the service. Direct costs of the human effort component include salaries, employee benefits and similar direct costs. Direct costs of the automated component include the cost of software, computers, hosting services and other similar direct costs. If the average of the time and cost factors is greater than fifty percent then the service requires primarily human effort and is not a digital automated service in which case the service will generally be subject to service and other activities B&O tax

Example 8. RepuCo.com performs a reputation monitoring service on the internet for its clients. The service utilizes software and other technology that searches the internet for web sites that allow posting of information that may be harmful to RepuCo.com's client's reputation ("the automated component"). If the automated component finds a web site that is posting erroneous or harmful information about one of RepuCo.com's clients, then a RepuCo.com employee will contact the owner of the web site by phone or e-mail and work with the owner and the client to resolve the matter to the satisfaction of the client ("the human effort component"). If the human effort time factor is 20% and the human effort direct cost factor is 60%, then the average of the two factors is 40% (80%/2 = 40%). Accordingly, the service is performed using 40% human effort which is less than 50% and therefore the service does not require primarily human effort and is subject to retail sales tax as a digital automated service.

Alternative methods. If the time and cost factors in this rule do not fairly represent the extent to which the service is performed using primarily human effort, the taxpayer may ask in writing for, or the department may require, the employ-

Permanent [70]

ment of another reasonable method to equitably determine whether the service is performed using primarily human effort

- (b) Loaning or transferring money or the purchase, sale, or transfer of financial instruments. For purposes of this section, "financial instruments" include cash, accounts receivable and payable, loans and notes receivable and payable, debt securities, equity securities, as well as derivative contracts such as forward contracts, swap contracts, and options. For example, the electronic transfer of money from a savings account to a checking account, whether done for the customer by a bank teller or by an ATM machine, is excluded from the definition of digital automated service.
- (c) Dispensing cash or other physical items from a machine. Includes an ATM that dispenses cash to users.
- (d) **Payment processing services**, including services such as electronic credit card processing activities conducted online or in physical retail stores via electronic transmission.
- (e) **Parimutuel wagering and handicapping contests** as authorized by chapter 67.16 RCW.
- (f) **Telecommunications services and ancillary services** as those terms are defined in RCW 82.04.065. For additional information, refer to the discussion above concerning the comparable exclusion from the definition of digital goods (see Part 3, subsection (302)(a) of this section).
- (g) **The internet and internet access** as those terms are defined in RCW 82.04.297.
- (h) **Remote access prewritten software.** Remote access prewritten software (defined in RCW 82.04.050 (6)(b)) provided on a standalone basis is excluded from the definition of digital automated service. However, software that is used in connection with a service that is transferred electronically would generally be included in the definition of a digital automated service.

Example 9. Company sells prewritten gaming software that is identical in all substantive respects to the same software available in stores for individual use and installation on home computers except that it is hosted on Company's servers and accessed by customers. Company's sales to consumers would be treated as a sale of remote access prewritten software and therefore is excluded from the definition of digital automated services and generally subject to retail sales tax and retailing B&O tax.

Example 10. Same facts as Example 9 except that Company uses the remote access prewritten software to provide a monthly subscription service that provides a real item multiplayer environment. Company is selling a digital automated service. In this case the customers are not merely receiving the individual use of software, but instead an online gaming service facilitated by the software. Thus, the monthly subscription service is not excluded from the definition of digital automated service and is subject to retail sales tax and retailing B&O tax.

- (i) **Online education programs** provided by the following:
 - (i) Public or private elementary or secondary schools; or
- (ii) An institution of higher education as defined in Sections 1001 or 1002 of the federal Higher Education Act of 1965 (Title 20 U.S.C. Sections 1001 and 1002), as existing on July 1, 2009. This would include most colleges and universi-

ties. For the purposes of this section, an online educational program must be encompassed within the institution's accreditation.

Example 11. ABC University, a qualifying institution of higher education under the federal Higher Education Act of 1965, provides an accredited online Spanish course for which it charges a quarterly access and use fee to students. The course is remotely accessed by students logging into a web site and accessing a fully interactive program that includes components of video, text, and audio, as well as extensive software code. This service would generally be considered a digital automated service. However, it is specifically excluded from the definition of digital automated service as an online educational program and would generally be subject to service and other activities B&O tax.

(j) **Live presentations** such as lectures, seminars, workshops, or courses, where participants are connected to other participants and presenters via the internet or other networks, allowing the participants and the presenters to provide, receive, and discuss information together in real time.

Example 12. Company provides an online seminar service for Customer. Company provides a panel of live speakers that make a presentation to Customer's employees listening to and viewing the seminar through an internet connection supplied by a third-party service provider. The seminar allows Customer's employees and panelists to ask and answer questions on a real time basis. Company's online seminar service is transferred electronically and uses one or more software applications and therefore would generally be considered a digital automated service. However, this type of service allowing live interaction is specifically excluded from the definition of digital automated service and would generally be subject to service and other activities B&O tax.

Example 13. Same facts as Example 12 except that Company records the seminar and charges other individuals a fee for accessing the seminar from Company's web site. The recorded presentation allows these customers to watch the presentation but it does not allow them to ask questions on a real time basis. Because the presentation was prerecorded there is no live interaction contemporaneous with the presentation and therefore Company is selling a digital good generally subject to retail sales tax and retailing B&O tax.

Example 14. Company provides online training courses to Steve for a fee. The training courses provide key interactive elements such as study guides, knowledge testing, and automated help, all facilitated by one or more software applications. Such courses are not live presentations and do not provide human interaction. Accordingly, Company is selling a digital automated service generally subject to retail sales tax and retailing B&O tax.

- (k) **Travel agent services**, including online travel services, and automated systems used by travel agents to book reservations.
- (l) **Online marketplace related activities,** which are services that allow the person receiving the services to make online sales of products or services, digital or otherwise, using either:
 - (i) The service provider's web site; or
- (ii) The service recipient's web site, but only when the service provider's technology is used either to:

[71] Permanent

- (1) Create or host the service recipient's web site; or
- (2) Process orders from customers using the service recipient's web site.

Example 15. Company provides an "electronic marketplace" service to Holcomb that allows Holcomb to list and sell his coffee mugs on the internet using Company's web site. This online marketplace service is excluded from the definition of digital automated services and charges for the service would generally be subject to service and other activities B&O tax.

Example 16. Same facts as Example 15, except that now Holcomb decides he no longer wants to be just another seller on Company's web site. Instead, Holcomb wants his own "retailing presence" on the internet so Holcomb contracts with Company to create and host Holcomb's new coffee mug web site, "HolcombsCoffeeWorld.com." This is still an online marketplace service that is excluded from the definition of digital automated services and charges for the service would generally be subject to service and other activities B&O tax.

- (iii) Exclusion limitation. The services described in this subsection do not include the underlying sale of the products or services, digital or otherwise, by the person receiving the service. For instance, in Examples 15 and 16, the sale by Holcomb of coffee mugs would still generally be subject to retail sales tax and retailing B&O tax as the sale of tangible personal property.
- (m) Advertising services means all services directly related to the creation, preparation, production, or the dissemination of advertisements. Advertising services include: Layout, art direction, graphic design, mechanical preparation, production supervision, placement, and rendering advice to a client concerning the best methods of advertising that client's products or services. Advertising services also include online referrals, search engine marketing and lead generation optimization, web campaign planning, the acquisition of advertising space in the internet media, and the monitoring and evaluation of web site traffic for purposes of determining the effectiveness of an advertising campaign. Advertising services do not include web hosting services and domain name registration.

Example 17. Company provides marketing services to customers wishing to promote their products using the internet. Amy sells widgets on the internet and hires Company to market her products. Company consults with Amy on her marketing needs and then creates a marketing plan for her business. Company also creates and distributes online banners, links, and targeted "e-mail blasts" that promote Amy's business. All of the services provided by Company are advertising services excluded from the definition of digital automated services and would generally be subject to service and other activities B&O tax.

Example 18. RVP, Inc. creates "sponsored links" on its web site that drive customer traffic to Amy's web site. RVP is paid by Amy for each click on a sponsored link on RVP's web site. The services provided by RVP are advertising services excluded from the definition of digital automated services and charges for such would generally be subject to service and other activities B&O tax.

(n) **Storage, hosting, and back-up.** The mere storage of digital products, digital codes, computer software, or master copies of software is excluded from the definition of digital automated services. This exclusion includes providing space on a server for web hosting or backing-up data or other information.

Example 19. Company charges Rowe a fee for 25 terabytes of storage space under its "basic storage service" offering. Company also charges Rowe an additional and optional fee for its "premium service" package offering, which involves services beyond mere storage. The "basic storage" services are mere storage services and excluded from the definition of digital automated services. These services would generally be subject to service and other activities B&O tax. However, the charges for the optional premium services are more than mere storage or hosting services. As such, the premium services are not excluded from the definition of digital automated services and would generally be subject to retail sales tax and retailing B&O tax.

(o) **Data processing services** means a primarily automated service provided to a business or other organization where the primary object of the service is the systematic performance of operations by the service provider on data supplied in whole or in part by the customer to: (1) extract the required information in an appropriate form, or (2) to convert the data to usable information. Data processing services include check processing, image processing, form processing, survey processing, payroll processing, claim processing, and similar activities. Data processing does not include remote access prewritten software used by the customer to process their own data.

Example 20. Bango Corp., in preparation for litigation, hires Company to use its automated technology to search Bango's computers and gather documents relevant to the lawsuit. Company's service also provides software tools that allow Bango to categorize, copy, store, and notate the gathered documents. Company's service is not data processing. The services performed primarily involve gathering data, and providing software tools that allow the customer to categorize, copy, store and notate documents in preparation for litigation. Accordingly, Company is selling a digital automated service generally subject to retail sales tax and retailing B&O tax

Example 21: Company provides check processing services to Wallo Corp., a bank operating in Washington. Company accepts scanned checks provided by Wallo and then uses its software and technology to extract the check dollar amount, account number, and verify the check has been signed. Company then provides this extracted and reformatted data back to Wallo allowing it to reconcile its customer's accounts. Company provides data processing services which are excluded from the definition of digital automated services. These services would generally be subject to service and other activities B&O tax.

Example 22. Same facts as Example 21, except that Company accepts checks provided directly by Wallo's customers. Thus, check images come from both Wallo and Wallo's customers. The services provided by Company are still data processing services excluded from the definition of digital automated services even though the data does not

Permanent [72]

come exclusively from Wallo. These services would generally be subject to service and other activities B&O tax.

Part 4. Are the Sales of the Digital Product or Digital Code Sourced to Washington?

(401) **Introduction.** Once it is determined that a transaction involves the sale of a digital product or digital code, the sale must be sourced to Washington in order to be subject to Washington's retail sales tax and B&O tax. If the sale is sourced outside Washington it is not subject to Washington sales tax or B&O tax. Sales of digital products are sourced using the same statute that applies to other retail sales, RCW 82.32.730 as outlined below.

(402) Sourcing retail sales.

(a) **Business location.** When a digital product or digital code is received by the buyer at a business location of the seller, the sale is sourced to that business location.

Example 23. Frank goes to BigBox brick-and-mortar store in Washington and purchases a music file from an electronic kiosk in the store. Frank purchases and downloads the music file inside BigBox's store by connecting his digital music player to the kiosk in the store. The sale of the music file is sourced to BigBox's store location in Washington and is generally subject to retail sales tax and retailing B&O tax.

- (b) **Place of receipt.** If the first sourcing rule explained above in (a) of this subsection does not apply, the sale is sourced to the location where receipt takes place.
- (i) The digital product or digital code may be received by the buyer at the buyer's location or by the buyer's donee (e.g., a gift recipient) at the donee's location.
- (ii) In the context of digital products and digital codes, "receive" and "receipt" means: (i) Making first use of digital automated services; or (ii) taking possession or making first use of digital goods or digital codes, whichever comes first.

Example 24. Drogba Inc., located in Olympia, Washington, purchases a digital automated service generally subject to retail sales tax from Company. Drogba's employees access and make first use of the service at their computer workstations located in Olympia. Company knows that the digital automated service is received in Olympia and therefore will source the sale of the digital automated service to that location.

(c) Address in records. If the first two sourcing rules explained above in (a) and (b) of this subsection do not apply, the sale is sourced to the location indicated by an address for the buyer that is available from the seller's business records maintained in the ordinary course of business, so long as use of this address does not constitute bad faith. For example, any address of the buyer held by the seller that reasonably estimates the receipt location will be sufficient, including an address contained in a relevant service contract or an address used for accounts receivable purpose.

Example 25. Nani Corp., located in California, purchases a digital automated service generally subject to retail sales tax and retailing B&O tax from Company located in Washington. The purchase contract between Nani and Company provides that Nani may have 5 users access the digital automated service. Company does not know where the digital automated service is actually received. However, Company has Nani's California address in its business records and

will therefore source the sale to Nani's California address. Because the sale is sourced outside Washington, it is not subject to Washington's retail sales tax or retailing B&O tax. Note, to the extent that Nani Corp., receives the service at locations in Washington, it may have a use tax liability. See subsection (403) of this section for more on use tax.

- (d) Address obtained during sale. If the first three sourcing rules explained above in (a), (b), and (c) of this subsection do not apply, the sale is sourced to the location indicated by an address for the buyer obtained during the consummation of the sale. For example, an address obtained during consummation of the sale would include the address of a buyer's payment instrument (e.g., billing address for a credit card), if no other address is available, so long as use of this address does not constitute bad faith.
- (i) **Internet protocol (IP) address.** The buyer's IP address is acceptable location information obtained at the time of sale if an address cannot otherwise be obtained during consummation of the sale.
- (e) **Origin.** If the first four sourcing rules explained above in (a), (b), (c), or (d) of this subsection do not apply, including the circumstance where the seller is without sufficient information to apply those provisions, then the sale must be sourced to the location determined by the address from which the digital good or digital code was first available for transmission by the seller, or from which the digital automated service was provided. Any location that merely provided the digital transfer of the product sold shall be disregarded.
- (403) **Sourcing for use tax purposes.** The sales sourcing rules above in subsection (402) of this section are for sourcing sales subject to retail sales tax under RCW 82.08.020 and RCW 82.32.730. What follows below is a discussion of use tax reporting obligations with respect to digital goods, digital automated services, and digital codes. Generally, use tax applies to the use of a digital product or digital code in Washington if retail sales tax has not already been paid and no exemption otherwise applies.
- (a) **Digital good or digital code.** "Use" means the first act within this state by which the taxpayer, as a consumer, views, accesses, downloads, possesses, stores, opens, manipulates, or otherwise uses or enjoys the digital good or digital code.
- (b) **Digital automated service.** "Use" means the first act within this state by which the taxpayer, as a consumer, uses, enjoys, or otherwise receives the benefit of the service.

Example 26. Company, located in New York, sells a digital automated service generally subject to retail sales tax and retailing B&O tax to Lampard Inc., located in Washington. Lampard's employees in Washington use the internet to access Company's services using an internet web browser. However, Company does not have nexus with Washington and is therefore not required to charge and collect retail sales tax on the sale of its service to Lampard. Lampard has a use tax reporting obligation because it uses, enjoys, or otherwise receives the benefit of Company's digital automated service at its location in Washington.

Permanent

Part 5. Are there Applicable Retail Sales or Use Tax Exemptions for the Purchase or Use of the Digital Product or Digital Code?

- (501) **Introduction.** After determining that a digital product or digital code has been sold or used and the sale or use is sourced to Washington, exemptions from retail sales or use tax should be examined. What follows is not an exhaustive list of exemptions but instead an explanation of the most common exemptions for digital products. Some exemptions may apply only with respect to certain digital products (e.g., some exemptions apply only to digital goods, not digital automated services). Exemptions may also require an exemption certificate or reseller permit.
- (502) **Resale.** The purchase of a digital product or digital code for resale with no intervening use is not subject to retail sales or use tax. Sellers should obtain from buyers a copy of the buyer's reseller permit, a properly completed "Digital Products and Remote Access Software Exemption Certificate," or otherwise comply with RCW 82.04.470 to substantiate the wholesale nature of the sale. See RCW 82.32.780.
- (503) Component of a new product. Generally, purchasing, acquiring, owning, holding, or using any digital product or digital code for purposes of incorporating it into a new product for sale will not be subject to retail sales tax. The digital product or digital code must become a component of the new product for sale. A digital code becomes a component of a new product if the digital good or digital automated service acquired through the use of the digital code becomes incorporated into a new product. RCW 82.04.190 (11). This is also discussed in subsection (602) of this section in the context of wholesale sales.
- (a) **Product.** For purposes of this subsection, "product" means a digital product, an article of tangible personal property, or remote access prewritten software as defined in RCW 82.04.050 (6)(b). For example, an industrial drill manufacturer and seller combines hardware, software, and data to create a new product, a "smart drill." Software embedded in the drill uses the variance data (also embedded in the drill) to control the hardware during drill operations. The data is a digital good purchased for use as a component of a new product for sale (i.e., the drill). Sellers should obtain from buyers a copy of the buyer's reseller permit, a properly completed "Digital Products and Remote Access Software Exemption Certificate," or otherwise comply with RCW 82.04.470 to substantiate the wholesale nature of the sale.
- (504) Made available free to the general public. Retail sales and use tax does not apply to the purchase or use by a business or other organization of a digital product (including a digital product acquired through the use of a digital code) in order to make that digital product (1) available free of charge for the use or enjoyment of (2) the general public. Buyers claiming this exemption must provide the seller with a properly completed "Digital Products and Remote Access Software Exemption Certificate" or other exemption certificate acceptable to the department. See RCW 82.08.02082.
- (a) **Available for free.** In order to qualify, the digital product purchased must be made available for free. In this context, "free" means that the recipient of the digital product

does not need to provide anything of significant value. If the purchaser requires something of significant value from the recipient in exchange for the digital product, it is not given away for free.

Example 27. Mauro purchases 1,000 digital music files from Company to be used for a "give away" to the first 1,000 people to visit Mauro's web site. When people visit Mauro's web site they are required to fill out a marketing survey before they may receive a digital music file. The information gathered from the marketing survey is then sold to a marketing company by Mauro. Thus, Mauro has required that recipients provide something of significant value in exchange for the digital music file. This is not a "free" transaction and therefore, Mauro's purchase of the digital music from Company does not qualify for the exemption and would be subject to retail sales tax and retailing B&O tax. (See also Example 29.)

- (b) "General public" means all persons and is not limited or restricted to a particular class of persons, except that the general public includes:
- (i) Certain classes of persons defined by their residency or property ownership. The general public includes a class of persons residing or owning property within the boundaries of any state (e.g., Washington), political subdivision of a state (e.g., King County), or a municipal corporation (e.g., Seattle).

Example 28. The City of Evergreen (a municipal corporation) makes satellite images of land parcels available for free only to persons residing in Evergreen. Residents are required to enter their zip code prior to accessing the images and certify that they are a resident of the City. Accordingly, the City of Evergreen can purchase the satellite images exempt from retail sales tax.

- (ii) **Library customers.** With respect to libraries, the term general public includes authorized library patrons.
- (c) Buyer must have the legal rights to provide the digital product to the general public. The exemption provided in this subsection does not apply unless the purchaser has the legal right to broadcast, rebroadcast, transmit, retransmit, license, relicense, distribute, redistribute, or exhibit the digital product, in whole or in part, to the general public.

Example 29. Same facts as Example 27, except this time visitors to Mauro's web site are provided free access to the digital music files and no survey information is required in exchange. Additionally, Mauro purchased the digital music files from Company with the right to distribute them to the general public. Mauro also provided the seller with an exemption certificate. Accordingly, Mauro's purchase from Company qualifies for the exemption because he has made the digital audio files available free of charge to the general public pursuant to a contract that gives him rights of distribution. Mauro only purchased 1,000 files and therefore must limit the distribution to the first 1,000 people. Most "giveaways" will have similar quantity limitations but this fact alone will not disqualify such transactions under the "general public" requirement.

(505) Purchased solely for business purpose.

(a) **Introduction.** Retail sales and use tax does not apply to the sale to or use by a business of digital goods and services rendered in respect to those digital goods, where the

Permanent [74]

digital goods and services rendered in respect to digital goods are purchased solely for business purposes. This exemption only applies to purchases of digital goods and does not apply to the purchase of digital automated services, prewritten software, or remote access prewritten software. The exemption is only available when the buyer provides the seller with an exemption certificate. Buyers may use the department's "Digital Products and Remote Access Software Exemption Certificate" to claim this exemption. See RCW 82.08.02087.

- (b) **Digital codes.** This exemption also applies to the sale to or use by a business of a digital code if all of the digital goods to be obtained through the use of the code will be used solely for business purposes. If the digital code purchased by a business for a business purpose provides access to both digital goods and digital automated services, the purchase of the digital code does not qualify for this exemption.
- (c) "Business purposes" means the digital good is relevant to the buyer's business needs.
- (d) **Personal or household purpose.** This exemption does not apply to the purchase for personal or household purposes.
- (e) **Government entities.** This exemption does not apply to purchases by a governmental entity.
- (f) **Prior periods.** For the period July 26, 2009, through June 30, 2010, the "business purpose" exemption applied only to "standard digital information." Standard digital information is a subset of digital goods.
- (i) **Standard digital information** is a digital good that consists primarily of data, facts, and/or information that is not generated or compiled for a specific client or customer. Standard digital information does not include a digital good that is comprised primarily of sounds or images.
- (506) **Multiple points of use (MPU).** Retail sales tax does not apply to the sale of digital products or digital codes concurrently available for use within and outside this state. See RCW 82.12.02088 and 82.08.02088. Note that Washington use tax still applies to the use of the digital product or digital code used in Washington.
- (a) **Requirements.** A buyer is entitled to claim the MPU exemption only if:
 - (i) The buyer is a business or other organization.
- (ii) The digital product purchased (or obtained by using the digital code purchased) will be concurrently available for use within and outside this state (not for personal use).
- (iii) The buyer provides the seller with a valid exemption certificate acceptable to the department claiming the MPU exemption. Buyers may use the department's "Digital Products and Remote Access Software Exemption Certificate" to claim this exemption.
- (b) **Concurrently available.** "Concurrently available for use within and outside this state" means that employees or other agents of the buyer may use the digital product simultaneously from one or more locations within this state and one or more locations outside this state.

Example 30. Company sells an online patent searching service to Iniesta Corp., for simultaneous use at Iniesta's headquarters in Washington and its research and development facility in California. This service would generally be considered the sale of a digital automated service subject to retail sales tax and retailing B&O tax. In this case, the digital

automated service is concurrently available for use by Iniesta's employees both within Washington and outside Washington, and therefore Iniesta may claim the MPU exemption from retail sales tax for its purchase of the digital automated service from Company. See (c) of this subsection directly below for an explanation of how to apportion the use tax in this example.

- (c) Apportionment (allocation) of use tax. For purposes of this subsection on multiple points of use, "allocation" and "apportionment" have the same meaning. A business or other organization subject to use tax on digital products or digital codes that are concurrently available for use within and outside this state is entitled to apportion the amount of tax due this state based on users in this state compared to users everywhere. For example, in the case of Iniesta in Example 30, if we assume Iniesta had five employees in California and five employees in Washington using the service concurrently, Iniesta would allocate one-half of the purchase price to Washington because five of its ten users are in Washington (e.g., 5/10 = 50%). Thus Iniesta would pay use tax to Washington based on fifty percent of the value of the digital automated service. Additionally, the department may authorize or require an alternative method of allocation supported by the taxpayer's records that fairly reflects the proportion of in-state to out-of-state use by the taxpayer.
- (i) **Records requirement.** No allocation under this section is allowed unless the allocation method is supported by the taxpayer's records kept in the ordinary course of business.
- (ii) "User" means an employee or agent of the taxpayer who is authorized by the taxpayer to use the digital product purchased in the performance of his or her duties as an employee or other agent of the taxpayer.
- (d) **Application to digital codes.** A digital code is concurrently available for use within and outside this state if users may use the digital goods or digital automated services to be obtained by the code simultaneously at one or more locations within this state and one or more locations outside this state.
- (e) **Reporting.** A buyer claiming an exemption under this section must report and pay state and local use tax directly to the department. As explained above in (c) of this subsection, use tax may be reported and paid on an apportioned basis if supported by the buyer's records.
- (507) Machinery and equipment. Generally retail sales and use tax does not apply to sales to or use by a manufacturer or processor for hire of certain machinery and equipment used directly in a manufacturing or research and development operation. This exemption is commonly referred to as the M&E exemption. (See RCW 82.08.02565 and 82.12.02565 and WAC 458-20-13601 for information regarding the M&E exemption.) Included within the definition of "machinery and equipment" for purposes of the M&E exemption are digital goods. Accordingly, digital goods acquired by manufacturers and processors for hire and used directly in a manufacturing or research and development operation are exempt from retail sales and use tax, provided all of the requirements for the M&E exemption are met.
- (508) **Audio or video programming.** Income received from the sale of regular audio or video programming by a radio or television broadcaster is generally subject to service

Permanent

and other B&O tax and therefore not subject to retail sales tax. However, the sale of audio or video programming sold on a pay per program or subscription on-demand basis is generally subject to retail sales and use tax except as provided in (d) and (e) of this subsection.

- (a) "Radio and television broadcasters" include satellite radio providers, satellite television providers, cable television providers, and providers of subscription internet television.
- (b) "Pay per program or subscription on-demand basis" means programming that the buyer pays for on a per program basis or a service that allows the buyer to access a library of programs at any time for a specific charge.
- (c) "Regular programming" is scheduled programming. The person watching cannot stop, pause, rewind, or otherwise control the broadcast of the scheduled programming, including the time that the scheduled program is broadcast.
- (i) The fact that a customer uses a recording device, such as a VCR or DVR, does not result in the broadcaster's programming being characterized as a digital good.
- (d) Cable television providers paying franchise fees. Cable television providers' sales of programming to consumers on a pay-per-program or subscription on-demand basis are not subject to retail sales and use tax if the cable television provider is subject to a franchise fee (under the authority of Title 47 U.S.C. Sec. 542(a)) on the gross revenue received from such sales. If the cable television provider is not subject to a franchise fee on the income from the sale of programming on a pay-per-program or subscription on-demand basis, then the exemption does not apply and the cable television provider must collect and remit retail sales tax on the retail sale of such programming.

Example 31. XYZ sells video programming to customers using cable technology. XYZ does not pay a franchise fee. Customers of XYZ are charged a monthly subscription fee to receive video programming. Customers are charged additional fees to view selected movies. XYZ must charge and collect retail sales tax on the additional fees charged to view the selected movies, but not on the monthly subscription fee which would generally be subject to service and other activities B&O tax.

- (e) Satellite television providers do not generally pay franchise fees and therefore do not qualify for the retail sales and use tax exemption based on payment of franchise fees as described in (d) of this subsection.
- (509) **Newspapers.** Generally, retail sales and use tax does not apply to sales of newspapers transferred electronically, provided that the electronic version has a printed counterpart, and the electronic version:
 - (a) Shares content with the printed newspaper; and
- (b) Is prominently identified by the same name as the printed newspaper or otherwise conspicuously indicates that it is a complement to the printed newspaper.
- (c) "Printed newspaper" means a publication issued regularly at stated intervals at least twice a month and printed on newsprint in tabloid or broadsheet format folded loosely together without stapling, glue, or any other binding of any kind, including any supplement of a printed newspaper.

- (510) **Received for free by end user.** Digital products and digital codes obtained by the end user for free are not subject to use tax.
- (a) For example, a person's use of a free search engine is not subject to use tax.
- (b) For example, a person reading an online article or viewing an online picture for free is not subject to use tax.
- (511) **Other use tax exemptions.** Use tax does not apply to the use of digital goods that are:
- (a) Noncommercial in nature, such as personal e-mail communications;
 - (b) Created solely for an internal audience; or
- (c) Created solely for the business needs of the person who created the digital good and is not the type of digital good that is offered for sale, including business e-mail communications.

Example 32. Gary, an employee of Kadabbera Corp., creates a digital audio-visual presentation using presentation authoring software and his innate creative capacity. Gary distributes the presentation internally to various divisions within Kadabbera in order to train employees on changes to company policies. Gary has created and distributed an item that meets the definition of "digital good." However, the distribution and use of this digital good is not subject to use tax as long as it is used solely internally or solely for the business needs of Kadabbera.

Part 6. Miscellaneous Provisions

(601) **Retail services.** Washington imposes retail sales and use tax on certain enumerated services under RCW 82.04.050 ("retail services"). For example, the sale of credit bureau services is subject to retail sales tax. However, when a retail service is transferred electronically and also meets the definition of digital automated service or digital good, such service will be treated as a digital product and is eligible for all applicable digital products retail sales and use tax exemptions as described above in Part 5 of this rule. Retail services that are not transferred electronically or those retail services that are excluded from the definitions of digital good or digital automated service (e.g., telecommunications services and ancillary services) continue to be taxed as retail services.

Example 33. ABC creates a "canned" digital report on Company X's creditworthiness prepared prior to a customer request for the report. The report may be a credit bureau service and/or a digital good (if transferred electronically). The "canned" report is listed for sale on ABC's web site. An employee of InvestCo, Inc. purchases and downloads a digital copy of the "canned" credit report from ABC's web site for InvestCo's business purpose. ABC is selling a digital good generally subject to retail sales tax. However, the "canned" report is purchased by InvestCo solely for a business purpose and therefore exempt from retail sales tax (see subsection (505) of this section for more on this exemption).

Example 34. Company sells credit reports and credit research services. EPD Corp., requests that Company prepare a credit report for EPD's specialized business purposes. After receiving the request, Company's employee researches, analyzes and generates information from various digital sources to prepare the credit report for EPD. Company then sends the report electronically as a digital file to EPD. Com-

Permanent [76]

pany is not selling a digital good because the digital item supplied to EPD is merely a representation of a professional service performed by EPD's employee. Therefore, Company's services are not a "digital product." However, Company is still required to charge and collect retail sales tax because Company is still providing credit bureau services, a retail service, subject to retail sales tax.

Example 35. Company sells an online credit reporting service. The service includes access to searchable data bases, digital data analysis, and digital data reporting tools. ManageCo investigates the credit worthiness of individuals and therefore purchases access to Company's online service. Company is selling a digital automated service to be used solely for a business purpose by ManageCo. However, the "used solely for a business purpose" exemption is limited to digital goods and is not applicable to digital automated services. As such, Company is required to charge and collect retail sales tax on its sale of the digital automated service to ManageCo.

(602) Royalties and wholesaling B&O tax on digital products. The sale of digital products to "nonend users" may be subject to royalties or wholesaling B&O tax depending on the type of transaction and the intangible rights provided to the purchaser. Transactions which provide the right to resell digital products (no copying rights) to consumers will generally be treated as wholesale sales. Additionally, transactions which allow the purchaser the right to incorporate a digital product into a new product for sale will also be treated as wholesale sales. See also subsection (503) of this section. Other nonend user transactions involving digital products or digital codes will generally be treated as royalties transactions.

Example 36. Media Corp., licenses to Rerun Inc., the right to further broadcast a digital movie file on Rerun's web site for a specified period of time. In this case Media Corp. provides Rerun with the right by contract to further commercially broadcast or exhibit a digital movie to its subscribers. This is a nonend user transaction subject to royalties B&O tax. Media Corp. would report its gross receipts from this transaction under the royalties B&O tax classification and not charge and collect retail sales tax on the transaction with Rerun. Rerun's charges for the subscription service provided to consumers are generally subject to retail sales tax and retailing B&O tax.

Example 37. Same facts as Example 36 except Rerun purchases individual digital movie files from Media Corp. with the right to resell those individual files to end users at retail instead of rebroadcasting or exhibiting to the public. In this case Media Corp. has provided Rerun with the right to resell individual digital movie files to end users. Media Corp. would report its gross receipts from this transaction under the wholesaling B&O tax classification and not charge and collect retail sales tax on the transaction with Rerun. Rerun's charges to consumers for the movie files are generally subject to retail sales tax and retailing B&O tax.

Example 38. Same facts as Example 37 except that Rerun purchases a single digital movie file with the right provided by contract to duplicate and sell that movie file. In this case Media Corp. has provided Rerun with the right to duplicate and sell individual digital movie files. Media Corp.

would report its gross receipts from this transaction under the royalties B&O tax classification. Media Corp. would not need to charge and collect retail sales or use tax from Rerun. Rerun's charges to consumers for the movie files are generally subject to retail sales tax and retailing B&O tax.

Example 39. Jack is a photographer who creates a digital picture of Mt. Rainier. Jack licenses, by contract, to Cashman the right to duplicate and sell copies of the Mt. Rainier picture in retail stores. Cashman's payment to Jack is for the grant of an intangible right and subject to royalties B&O tax. Cashman's sale of the picture at retail to customers is subject to retail sales tax and retailing B&O tax.

(603) **Substantial nexus** is not established in Washington if a business's only contact with the state of Washington is ownership of, or rights in, computer software as defined in RCW 82.04.215, including computer software used in providing a digital automated service; master copies of software; a digital goods or digital codes residing on servers in Washington. For purposes of this section, "substantial nexus" means the requisite connection that a person must have with a state to allow the state to subject the person to the state's taxing authority, consistent with the commerce clause of the United States Constitution.

(604) **Amnesty.** Before July 26, 2009, retail sales of downloaded digital goods on a permanent or nonpermanent basis were subject to retail sales tax. This did not include accessed or streamed digital goods. However, amnesty is available to those who did not collect or pay retail sales or use tax on digital goods and digital codes during that time. Sales of digital automated services and accessed or streamed digital goods were subject to service and other B&O tax before July 26, 2009, and amnesty does not extend to these transactions because they were not subject to retail sales tax during that time period.

- (a) Refunds and credits of retail sales or use tax. No refund or credit will be given for state and local retail sales and use taxes properly paid on the sale or use, before July 26, 2009, of digital goods or of installing, repairing, altering, or improving digital goods.
- (b) No B&O tax refund or credit unless sales tax was paid. If a taxpayer paid B&O tax under the service and other activities classification prior to July 26, 2009, on income received from retail sales of digital products or digital codes, the taxpayer may not receive a refund or credit for the difference between the B&O tax actually paid and the B&O tax that should have been paid under the retailing classification unless the taxpayer has remitted the retail sales tax for those sales.
- (605) **Bundled transactions.** A "bundled transaction" is the retail sale of two or more products, which are distinct and identifiable for one nonitemized price. Because retail sales of digital products and digital codes are subject to retail sales tax, the general rules on the taxation of bundled transactions may apply to certain transactions involving digital products and digital codes. See RCW 82.08.190 and 82.08.195 for more information on the tax treatment of bundled transactions
- (606) **Property tax.** The excise tax laws relating to digital products and digital codes do not have any impact in the characterization of digital goods and digital codes as tangible

[77] Permanent

or intangible personal property for purposes of property taxation and may not be used in any way in construing Title 84 RCW. See section 1201, chapter 535, Laws of 2009.

REPEALER

The following section of the Washington Administrative Code is repealed:

WAC 458-20-155

Information and computer services.

WSR 13-06-022 PERMANENT RULES DEPARTMENT OF FINANCIAL INSTITUTIONS

(Division of Consumer Services) [Filed February 27, 2013, 11:34 a.m., effective April 1, 2013]

Effective Date of Rule: April 1, 2013.

Purpose: To increase the number of required prelicensing education hours specific to Washington law. On April 1, 2013, a uniform state test section will be added to the national SAFE test. The Washington specific component test will be phased out. An increase in the number of Washington specific prelicensing education hours will ensure mortgage loan originator applicants have knowledge of Washington law prior to licensing.

The rule making was proposed under OFM Guideline 3.d.

Citation of Existing Rules Affected by this Order: Amending WAC 208-660-355 and 208-660-360.

Statutory Authority for Adoption: Chapter 43.320 RCW, RCW 19.146.223.

Adopted under notice filed as WSR 13-01-086 on December 18, 2012.

Changes Other than Editing from Proposed to Adopted Version: WAC 208-660-355(1): Insert "(a)" in front of "Yes." Then insert a new subsection (b) as follows: "(b) You will receive credit for having completed the SAFE required prelicensing education for every state once you have successfully completed the SAFE required prelicensing education requirements approved by the NMLS for any state." Adding this language clarifies that the mortgage loan originator (MLO) requirement in the Mortgage Broker Practices Act is consistent with the same MLO requirement in the Consumer Loan Act.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's Own Initiative: New 0, Amended 2, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted Using Negotiated Rule Making: New 0, Amended 2, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 0, Repealed 0.

Date Adopted: February 27, 2013.

Deborah Bortner, Director Division of Consumer Services

AMENDATORY SECTION (Amending WSR 12-18-048, filed 8/29/12, effective 11/1/12)

WAC 208-660-355 Loan originators—Prelicensing education. (1)(a) Must I obtain prelicensing education before I will be given a license? Yes. You must ((take 20)) complete at least twenty-two hours of prelicensing education from an NMLS approved provider. The prelicensing education must include at least three hours of federal law and regulations; three hours of ethics, which must include instruction on fraud, consumer protection, and fair lending issues; two hours related to lending standards for the nontraditional mortgage product marketplace; and at least ((two)) four hours of training specifically related to Washington law.

- (b) You will receive credit for having completed the SAFE required prelicensing education for every state once you have successfully completed the SAFE required prelicensing education requirements approved by the NMLS for any state.
- (2) **Who provides prelicensing education?** The NMLS approves course providers and courses for prelicensing education. See the NMLS Resource Center for a list of approved providers and courses.
- (3) Must I ((take)) complete continuing education in the year I complete the prelicensing education? No. You will not have a continuing education requirement in the year in which you complete the core twenty hours of prelicensing education.

AMENDATORY SECTION (Amending WSR 12-18-048, filed 8/29/12, effective 11/1/12)

WAC 208-660-360 Loan originators—Testing. (1) Must I pass a test prior to becoming a loan originator? Yes. You must take and pass the NMLS ((national and state tests prior to becoming a)) sponsored loan originator test. The test has two parts; one on federal law and regulation and one on uniform state law and regulation. You must receive a score of seventy-five percent or higher to pass the test.

- (2) Where may I find information about the loan originator test? The NMLS contracts for its test provider. You will find information on the test provider on the NMLS web site at www.stateregulatoryregistry.org.
- (3) How much does the loan originator test cost? Testing costs are set by contract between the test provider and the NMLS and may be modified from time to time. The department will publish the current testing fee on its web site or you may find it on the NMLS web site at www.stateregulatoryregistry.org.
- (4) **How do I register to take the loan originator test?** The department will provide a link to the NMLS test provider on its web site.

Permanent [78]

- (5) What topics may be covered in the loan originator test? At a minimum, the test topics will include ethics, federal and state law and regulation pertaining to mortgage origination, federal and state law and regulation on fraud, consumer protection, nontraditional mortgage products, and fair lending.
- (6) After passing the loan originator test, will I have to take it again? You must retake the loan originator test if you have not been a loan originator within the past five years.
- (7) How soon after failing the loan originator test may I take it again? You may retake a test three consecutive times with each consecutive taking occurring at least thirty days after the preceding test. After failing three consecutive tests, you must wait at least six months before taking the test again.

WSR 13-06-023 PERMANENT RULES OFFICE OF INSURANCE COMMISSIONER

[Insurance Commissioner Matter No. R 2012-26—Filed February 27, 2013, 2:20 p.m., effective July 1, 2013]

Effective Date of Rule: July 1, 2013.

Purpose: This new rule brings the agency in line with the uniform limited line travel licensing guidelines adopted by the National Association of Insurance Commissioners.

Citation of Existing Rules Affected by this Order: Amending WAC 284-17-001 and 284-17-011.

Statutory Authority for Adoption: RCW 48.17.005.

Adopted under notice filed as WSR 13-02-089 on January 2, 2013.

Changes Other than Editing from Proposed to Adopted Version: WAC 284-17-011(1) "or as set forth in subsection (2) of this section" was included.

- (3) "the travel insurance producer" was included.
- (4) "Employer" was deleted and replaced with "tax."
- (4)(e) "of the travel retailer" was included after "employee."

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's Own Initiative: New 0, Amended 2, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted Using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 2, Repealed 0.

Date Adopted: February 27, 2013.

Mike Kreidler Insurance Commissioner

- AMENDATORY SECTION (Amending Matter No. R 2012-23, filed 10/29/12, effective 11/29/12)
- WAC 284-17-001 Definitions. For purposes of this chapter, unless the context requires otherwise:
- (1) "Affiliation" is a type of appointment whereby a business entity authorizes an individual insurance producer or surplus line broker to represent it when conducting insurance business.
- (2) "Business entity" has the meaning set forth in RCW 48.17.010(2) and includes a sole proprietorship having associated licensees authorized to act on its behalf in the business or trade name of the sole proprietorship.
- (3) "Days" means calendar days including Saturday and Sunday and holidays, unless otherwise specified.
- (4) "Electronic submission" or "submitted electronically" means submission of a licensing process by an applicant, licensee, insurer, or education provider by means of the commissioner's web site or a third-party licensing provider or other state agency.
- (5) "File" means a record in any retrievable format, and unless otherwise specified, includes paper and electronic formats
- (6) "Home state" has the meaning set forth in RCW 48.17.010(4).
- (7) "Insurer" has the meaning set forth in RCW 48.17.-010(7).
- (8) "Licensee" means a person licensed by the commissioner under Title 48 RCW to sell, solicit or negotiate insurance and includes adjusters and surplus line brokers.
- (9) "Line of authority" means a license issued in one or more lines of insurance listed in RCW 48.17.170.
- (10) "NAIC" means the National Association of Insurance Commissioners.
- (11) "Third-party licensing provider" is designated on the commissioner's web site at: www.insurance.wa.gov.
- (12) "Reinstatement" means the reissuance by the commissioner of a license that was not renewed more than sixty days but fewer than twelve months after its expiration date.
- (13) "Resident" means a person who has elected to make Washington his or her home state, or, in the case of a business entity, has a place of business in this state.
- (14) "Sending written notice" or "sending a copy of the written notice" means transmitting the required information in writing and, where required, on forms designated by the commissioner for that purpose, via first class mail, commercial parcel delivery company, telefacsimile, or electronic transmission, unless a specific method of transmission is specified.
- (15) "Surety" means that limited line of authority of insurance or bond that covers obligations to pay the debts of, or answer for the default of another, including faithlessness in a position of public or private trust.
- (16) "Travel insurance" means ((that limited line of authority of insurance coverage for trip cancellation, trip interruption, baggage, life, sickness and accident, disability, and personal effects when limited to a specific trip and sold in connection with transportation provided by a common carrier.
- (17))) insurance coverage for personal risks incident to planned travel including, but not limited to:

Permanent

- (a) Interruption or cancellation of trip or event;
- (b) Loss of baggage or personal effects;
- (c) Damages to accommodations or rental vehicles; or
- (d) Sickness, accident, disability, or death occurring during limited duration travel.

Travel insurance does not include major medical plans, which provide comprehensive medical protection for travelers with trips lasting six months or longer, including those working overseas as an expatriate or military personnel being deployed.

- (17) "Travel insurance producer" means a licensed limited lines producer of travel insurance.
- (18) "Travel retailer" means a business entity that offers and disseminates travel insurance on behalf of and under the direction and supervision of a licensed travel insurance producer.
- (19) "Written" or "in writing" means any retrievable method of recording an agreement or document, and, unless otherwise specified, includes paper and electronic formats.

AMENDATORY SECTION (Amending Matter No. R 2011-12, filed 9/13/11, effective 10/14/11)

WAC 284-17-011 Limited line of travel insurance. (1) Travel insurance is a limited line of authority ((and is defined in WAC 284-17-001(16).

- (1) Insurers must ensure that their licensed and appointed insurance producers who transact the limited line of travel insurance are qualified by education or experience to offer their travel insurance products)). A person must not sell, solicit, or negotiate travel insurance in this state unless that person is licensed as an insurance producer with the travel limited line of authority or as set forth in subsection (2) of this section.
- (2) A business entity acting as a travel insurance producer is required to:
- (a) Be licensed as a producer with the travel limited line of authority; and
- (b) Designate an individual licensed as a producer with the travel limited line of authority to act as a designated licensed responsible person (DLRP) who is responsible for the business entity's compliance with the laws of this state.
- $(((\frac{2}{2})))$ (3) The requirements of this chapter for passing an insurance producer examination and for prelicensing and continuing insurance education do not apply to insurance producers that transact only the limited line of travel insurance
- (4) A travel retailer may offer and disseminate travel insurance on behalf of and under a travel insurance producer business entity license only if the travel insurance producer holds a business entity license, and the travel insurance producer:
- (a) Clearly identifies the licensed business entity as the licensed producer on marketing materials and fulfillment packages distributed by travel retailers to customers, identification shall include the entity's name and contact information;
- (b) Keeps a register of each travel retailer that offers travel insurance on the licensed business entity's behalf. The register must include the name and contact information of the

- travel retailer and an officer or person who directs or controls the travel retailer's operations, and the travel retailer's federal tax identification number. The licensed business entity must also certify that the travel retailer registered complies with United States Code, Title 18, section 1033. The licensed business entity must submit the register within thirty days upon request by the commissioner;
- (c) Complies with the fingerprinting requirements applicable to insurance producers in the resident state of the business entity;
- (d) Has paid all applicable insurance producer licensing fees as set forth in Washington state law; and
- (e) Requires each employee of the travel retailer whose duties include offering and disseminating travel insurance to receive a program of instruction or training, which is subject to review by the commissioner.
- (5) An employee of a travel retailer may sell or offer travel insurance without being individually licensed as an insurance producer if the travel retailer is licensed and acting in compliance with this chapter, and the employees are under the supervision of a licensed travel producer.
- (6) A travel retailer whose activities, and those of its employees, are limited to offering and disseminating travel insurance on behalf of and under the direction of a licensed business entity meeting the conditions stated in this section, is authorized to do so, upon registration by the licensed business entity.
- (7) As the insurer designee, the travel insurance producer is responsible for the acts and supervision of the travel retailer.

WSR 13-06-024 PERMANENT RULES LIQUOR CONTROL BOARD

[Filed February 27, 2013, 2:28 p.m., effective March 30, 2013]

Effective Date of Rule: Thirty-one days after filing.

Purpose: This rule making was requested by stakeholders to lessen the difficulties of operating a business during the current economy. Currently the rules require a restaurant licensee to be open a minimum of five days a week. Many licensees have found that five days a week is difficult during the current economy. Rather than the licensee having to request an exception due to hardship, stakeholders have requested the board amend the rules to require a restaurant licensee be open a minimum of three days a week and remove the hardship exception.

Citation of Existing Rules Affected by this Order: Amending WAC 314-02-015 and 314-02-045.

Statutory Authority for Adoption: RCW 66.08.030.

Adopted under notice filed as WSR 13-01-040 on December 12, 2012.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at Request of a Nongovernmental Entity: New 0, Amended 2, Repealed 0.

Permanent [80]

Number of Sections Adopted on the Agency's Own Initiative: New 0, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted Using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 0, Repealed 0.

Date Adopted: February 27, 2012 [2013].

Sharon Foster Chairman

AMENDATORY SECTION (Amending WSR 11-23-045, filed 11/9/11, effective 12/10/11)

- WAC 314-02-015 What is a spirits, beer, and wine restaurant license? (1) Per RCW 66.24.400, this license allows a restaurant to:
- (a) Serve spirits by the individual glass for on-premises consumption;
- (b) Serve beer by the bottle or can or by tap for on-premises consumption;
 - (c) Serve wine for on-premises consumption;
- (d) Allow patrons to remove recorked wine from the licensed premises;
- (e) Sell wine by the bottle for off-premises consumption with the appropriate endorsement; and
- (f) Sell kegs of malt liquor with the appropriate endorsement. This endorsement also allows the sale of beer to a purchaser in a sanitary container brought to the premises by the purchaser or furnished by the licensee and filled at the tap by the retailer at the time of sale.
- (2) To obtain and maintain a spirits, beer, and wine restaurant license, the restaurant must be open to the public at least five hours a day during the hours of 8:00 a.m. and 11:00 p.m., ((five)) three days a week. ((The board may consider written requests for exceptions to this requirement due to demonstrated hardship, and may grant an exception under such terms and conditions as the board determines are in the best interests of the public.))
- (3) All applicants for a spirits, beer, and wine license must establish, to the satisfaction of the board, that the premises will operate as a bona fide restaurant. The term "bona fide restaurant" is defined in RCW 66.24.410(2).

<u>AMENDATORY SECTION</u> (Amending WSR 11-23-045, filed 11/9/11, effective 12/10/11)

WAC 314-02-045 What is a beer and/or wine restaurant license? (1) Per RCW 66.24.320 and 66.24.354, this license allows a restaurant to:

Privilege	Annual fee
(a) Serve beer by the bottle or can or	\$200
by tap for on-premises consumption.	
(b) Serve wine for on-premises con-	\$200
sumption (see RCW 66.24.320	
regarding patrons removing recorked	
wine from the premises).	

Privilege	Annual fee
(c) Sell beer and/or wine in the original, unopened containers for off-premises consumption.	\$120
(d) Sell tap beer for off-premises consumption in a sanitary container holding less than four gallons of beer, and brought to the premises by the purchaser.	In conjunction with off-premises privilege outlined in subsection (c).
(e) Sell beer in kegs or other containers holding at least four gallons of beer (see WAC 314-02-115 regarding the requirements for registering kegs).	In conjunction with off-premises privilege outlined in subsection (c).

- (2) All applicants for a beer and/or wine restaurant license must establish, to the satisfaction of the board, that the premises will operate as a bona fide restaurant, as defined in RCW 66.04.010(30).
- (a) Minimum food service is required, as defined in WAC 314-02-010.
- (b) To obtain and maintain a beer and/or wine restaurant license, the restaurant must be open to the public at least five hours a day, ((five)) three days a week. ((The board may consider written requests to this requirement due to demonstrated hardship, and may grant an exception under such terms and conditions as the board determines are in the best interests of the public.))
- (3) If a beer and/or wine restaurant's dedicated dining area comprises less than fifteen percent of the total customer service area, the premises must maintain a tavern license (see WAC 314-02-070 regarding the tavern license).

WSR 13-06-025 PERMANENT RULES DEPARTMENT OF RETIREMENT SYSTEMS

[Filed February 27, 2013, 2:52 p.m., effective April 1, 2013]

Effective Date of Rule: April 1, 2013.

Purpose: Corrects the administration of retirement benefits when a retiree who has purchased additional service credits returns to work and exceeds the hours limit for continuing pension payments. Retirees who exceed the return-to-work limits will have their retirement benefit suspended, including any portion that is attributable to purchased service credit.

Citation of Existing Rules Affected by this Order: Amending WAC 415-02-177 May I purchase additional service credit?

Statutory Authority for Adoption: RCW 415.50.050(5) [41.50.050(5)].

Adopted under notice filed as WSR 13-03-154 on January 23, 2013.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or

[81] Permanent

Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's Own Initiative: New 0, Amended 1, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted Using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 0, Repealed 0.

Date Adopted: February 27, 2013.

Marcie Frost Director

AMENDATORY SECTION (Amending WSR 10-16-086, filed 7/30/10, effective 9/1/10)

WAC 415-02-177 May I purchase additional service credit? (1) What is the option for purchasing additional service credit? The following statutes provide an option for eligible members to purchase additional service credit that provides a guaranteed, lifetime increase to their monthly retirement benefit:

- (a) RCW 41.26.199 for LEOFF Plan 1 members;
- (b) RCW 41.26.432 for LEOFF Plan 2 members;
- (c) RCW 41.40.034 for PERS Plan 1, 2, and 3 members;
- (d) RCW 41.37.265 for PSERS Plan 2 members;
- (e) RCW 41.35.183 for SERS Plan 2 and 3 members;
- (f) RCW 41.32.066 for TRS Plan 1, 2, and 3 members; and
 - (g) RCW 43.43.233 for WSPRS Plan 1 and 2 members.
- (2) Am I eligible to purchase additional service credit?
- (a) You may purchase additional service credit if you are eligible to retire from one or more of the following plans and you elect a monthly benefit rather than a lump sum payment:

Additional service credit: $60 \text{ months} \div 12 = 5 \text{ years}$ Early retirement factor (WAC 415-02-320(5)): .7240000

- (i) LEOFF Plan 1 or 2 under RCW 41.26.090 or 41.26.-
- (ii) PERS Plan 1, 2 or 3 under RCW 41.40.180, 41.40.-630, or 41.40.820;
 - (iii) PSERS Plan 2 under RCW 41.37.210;
- (iv) SERS Plan 2 or 3 under RCW 41.35.420 or 41.35.-680;
- (v) TRS Plan 1, 2, or 3 under RCW 41.32.480, 41.32.765, or 41.32.875; or
 - (vi) WSPRS Plan 1 or 2 under RCW 43.43.250.
- (b) If you retire as a result of a disability, you may purchase additional service credit if you meet the requirements in (a) of this section.
- (3) **How much additional service credit may I purchase?** If you are eligible, you may purchase from one to sixty months of additional service credit in whole month increments.
- (4) May I use the additional purchased service credit to qualify for normal retirement or an early retirement? No. You may not use the purchased service credit to qualify for normal retirement or to qualify for an early retirement.
- (5) When must I apply to purchase additional service credit? You must submit your request to purchase additional service credit to the department at the same time you submit your application for retirement.
- (6) How much will my monthly retirement benefit increase if I purchase additional service credit? The increase in your monthly retirement benefit will be calculated using the benefit formula for your system and plan, with a reduction for early retirement, if applicable.

Example 1 (PERS Plan 2): John is a member of PERS Plan 2. He applies for retirement, effective the first month after his 62nd birthday. His AFC is \$4000 per month. If he purchases sixty months of additional service credit, his monthly retirement benefit will increase by \$289.60 per month, calculated as follows:

Amount of increase = 2% x additional service credit years x AFC x early retirement factor

= 2% x 5 years x \$4000 x .7240000

= \$289.60

Example 2 (TRS Plan 3): Jane is a member of TRS Plan 3. She applies for retirement, effective the first month after her 62nd birthday. Her AFC is \$4000 per month. If she purchases sixty months of additional service credit, her monthly retirement benefit will increase by \$144.80 per month, calculated as follows:

Additional service credit: $60 \text{ months} \div 12 = 5 \text{ years}$ Early retirement factor (WAC 415-02-320(5)): .7240000

Amount of increase = 1% x additional service credit years x AFC x early retirement factor

= 1% x 5 years x \$4000 x .7240000

= \$144.80

Example 3 (LEOFF Plan 2): Jim is a member of LEOFF Plan 2. He applies for retirement, effective the first month after his 53rd birthday. His FAS is \$4000 per month. If he purchases sixty months of additional service credit, his monthly retirement benefit will increase by \$400 per month, calculated as follows:

Permanent [82]

Additional service credit: $60 \text{ months} \div 12 = 5 \text{ years}$

Amount of increase = 2% x additional service credit years x FAS

= 2% x 5 years x \$4000

= \$400

(7) **How is the cost of the additional purchased service credit calculated?** The cost to purchase additional service credit is calculated by dividing the amount of the increase in subsection (6) of this section by the age-based annuity factor in WAC 415-02-340.

Example. In subsection (6) of this section, Example 1, it was determined that John's retirement benefit would increase by \$289.60 per month. The cost to purchase the five years of additional service credit would be \$44,542.88, calculated as follows:

Age-based annuity factor (WAC 415-02-340): .0065016

 $Cost = Amount of increase \div age-based annuity factor$

= \$289.60 \div .0065016

= \$44,542.88

- (8) How and when do I pay for the additional service credit? The department will generate a bill to you for the cost of the additional service credit.
- (a) Payment may be made with an eligible rollover, a direct rollover or a trustee-to-trustee transfer, if allowed by the transferring plan. Payment may also be made with after-tax dollars, such as money from a personal savings account. However, IRS regulations limit the amount of after-tax dollars you may use to purchase additional service credit.
- (b) Payment must be made in full within ninety days after the bill issue date.
- (9) If I choose a benefit option with a survivor feature, will my survivor beneficiary's monthly benefit reflect the additional purchased service credit? Yes. Depending upon the rules for your retirement system and plan and the benefit option you choose at retirement, your survivor beneficiary's monthly benefit will be a percentage of the gross monthly retirement benefit you were receiving at the time of your death. If you choose a benefit option with a survivor feature and your survivor beneficiary dies before you, your monthly retirement benefit will increase to the amount it would have been had you not selected a survivor option.
- (10) Will I receive a cost of living adjustment (COLA) on the portion of my benefit that is based on the additional purchased service credit?
- (a) For all systems and plans, except as noted in (b) of this subsection, your COLA will be based on your gross monthly retirement benefit, including the increase due to the purchased service credit.
- (b) If you retire from PERS Plan 1 or TRS Plan 1 and you do not elect the optional auto COLA, you will not receive a COLA on the additional purchased service credit amount.
- (11) If I purchase additional service credit and then return to work, how will my retirement benefit be affected?
- (a) If you return to work with an employer that participates with the department:
- (i) Elect to return to membership Your entire retirement benefit is suspended, including the portion of your retirement benefit attributable to service credit purchased under this section.
- (ii) Do not elect to return to membership If your retirement benefit is suspended due to working over the hours

- allowed annually, the portion of your retirement benefit attributable to service credit purchased under this section will ((not)) be suspended.
- (b) If you return to work with an employer that does not participate with the department, your retirement benefit and the portion of your retirement benefit attributable to service credit purchased under this section will not be suspended.
- (12) If I retire and purchase less than sixty months of additional service credit, may I purchase more at a later time? If you retire and purchase less than sixty months of additional service credit, you may not purchase additional months of service credit from the same plan unless you return to membership and reretire from the same system and plan. You must meet the eligibility requirements provided in subsection (2) of this section at the time you reretire. You may not purchase more than a total of sixty months of service credit regardless of how many times you reretire from the same system and plan.
- (13) May I purchase service credit from more than one retirement plan?
- (a) If you are a dual member under chapter 415-113 WAC, Portability of public employment benefits, and you combine service credit to retire as a dual member, you may purchase up to sixty months of additional service credit from each of your dual member plans.
- (b) If you retire from more than one plan, but are not a dual member under chapter 415-113 WAC, you may purchase up to sixty months of additional service credit from each plan in which you meet the eligibility requirements in subsection (2) of this section.
- (14) How are the funds I paid to purchase the additional service credit treated upon my death (and the death of my survivor beneficiary, if applicable)?
- (a) Plans 1 and 2. The amount paid to purchase the additional service credit is credited to your individual account as part of your accumulated contributions. Distribution of accumulated contributions after your death (and the death of your survivor beneficiary, if any) is governed by the statutes and rules applicable to your plan. See:
 - (i) WAC 415-108-326 for PERS Plan 1 and 2;
 - (ii) WAC 415-112-504(((8))) <u>(9)</u> for TRS Plan 1;
 - (iii) WAC 415-112-505(7) for TRS Plan 2;
 - (iv) WAC 415-110-610(7) for SERS Plan 2;
 - (v) WAC 415-106-600(7) for PSERS Plan 2;

[83] Permanent

- (vi) WAC 415-103-215 for WSPRS Plan 1;
- (vii) WAC 415-103-225(7) for WSPRS Plan 2;
- (viii) WAC 415-104-202 for LEOFF Plan 1; or
- (ix) WAC 415-104-215(7) for LEOFF Plan 2.
- (b) Plan 3. The amount paid to purchase the additional service credit is credited to the Plan 3 trust fund and not to your member account. There are no circumstances under which the amount will be distributed upon your death.

WSR 13-06-029 PERMANENT RULES DEPARTMENT OF FISH AND WILDLIFE

[Order 13-26—Filed February 28, 2013, 11:48 a.m., effective March 31, 2013]

Effective Date of Rule: Thirty-one days after filing.

Purpose: The Pacific halibut fishery is jointly managed by the Washington department of fish and wildlife (WDFW), the National Marine Fisheries Service, and the International Pacific Halibut Commission. The purpose of this proposal is to adopt and incorporate the federal regulations on Pacific halibut imposed by the Code of Federal Regulations (C.F.R.) in 50 C.F.R. § 300.60-300.67 and the Federal Register.

Having state regulations that conform to regulations adopted by the International Pacific Halibut Commission and implemented into federal regulation by the National Marine Fisheries Service provides consistency for stakeholders and strengthens WDFW's enforcement staff's ability to enforce regulations pertaining to commercial Pacific halibut fishing.

Statutory Authority for Adoption: RCW 77.04.020, 77.12.045, and 77.12.047.

Other Authority: 50 C.F.R. § 300.60-300.67.

Adopted under notice filed as WSR 13-01-082 on December 18, 2012.

Number of Sections Adopted in Order to Comply with Federal Statute: New 1, Amended 0, Repealed 0; Federal Rules or Standards: New 1, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's Own Initiative: New 1, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted Using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 0, Repealed 0.

Date Adopted: February 28, 2013.

Philip Anderson Director

NEW SECTION

WAC 220-20-130 Commercial Pacific halibut fishery—Seasons, gear, possession, and landing require-

- ments. (1) The commercial Pacific halibut fishery is jointly managed by the Washington department of fish and wildlife (WDFW), the National Marine Fisheries Service (NMFS), and the International Pacific Halibut Commission (IPHC). The Code of Federal Regulations (C.F.R.) 50 C.F.R. § 300.60-300.67 and related appendices in Subpart E provide federal requirements for this fishery including, but not limited to, the time, place, and manner of taking Pacific halibut. This section adopts the federal regulations on Pacific halibut imposed by 50 C.F.R. § 300.60-300.67 and the Federal Register, and it incorporates those federal regulations by reference. A copy of the federal regulations may be obtained by contacting the department at 360-902-2200, or accessing a copy on-line at www.pcouncil.org.
- (a) It is unlawful to take, fish for, possess, transport through the waters of the state, or land in any Washington state port Pacific halibut taken for commercial purposes in violation of the requirements published in 50 C.F.R. § 300.60-300.67, Subpart E.
- (b) Where the federal regulations refer to the fishery management area, that area is extended to include Washington state waters adjacent to the Exclusive Economic Zone.
- (c) If state rules are more restrictive than federal regulations, the Washington Administrative Code takes precedence over the federal regulations.
- (d) Additional regulations on Pacific halibut may be listed in the Federal Register. Other regulations on Pacific halibut in the Federal Register take precedence over the Pacific halibut fishery regulations in 50 C.F.R. § 300.60-300.67 if the regulations conflict. The department recommends that a person consult the Federal Register and the C.F.R. prior to participating in the commercial Pacific halibut fishery.
- (2) Violation of reporting requirements under this section is punishable under RCW 77.15.280.
- (3) Violation of possession requirements under this section is punishable under RCW 77.15.550.
- (4) Violation of gear requirements under this section is punishable under RCW 77.15.520.

WSR 13-06-034 PERMANENT RULES DEPARTMENT OF FISH AND WILDLIFE

[Order 13-44—Filed March 1, 2013, 8:26 a.m., effective April 1, 2013]

Effective Date of Rule: Thirty-one days after filing.

Purpose: The purpose of this proposal is to change the state's recreational clam and oyster seasons on selected public beaches, based on abundance and usage surveys and agreements with comanagers and other state agencies.

Reasons Supporting Proposal: This rule change proposal was discussed during the fish and wildlife commission meeting and public hearing on February 8, 2013. The proposed changes were adopted by the commission during its February 15, 2013, conference call. The changes will allow recreational clam and oyster seasons to be opened or extended on some public beaches and closed on other

Permanent [84]

beaches to achieve maximum recreational opportunity while conserving shellfish resources.

Citation of Existing Rules Affected by this Order: Amending WAC 220-56-350 and 220-56-380.

Statutory Authority for Adoption: RCW 77.04.020 and 77.12.047.

Adopted under notice filed as WSR 12-24-069 on December 4, 2012.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's Own Initiative: New 0, Amended 2, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted Using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 0, Repealed 0.

Date Adopted: March 1, 2013.

Miranda Wecker, Chair Fish and Wildlife Commission

<u>AMENDATORY SECTION</u> (Amending Order 12-31, filed 3/12/12, effective 4/12/12)

WAC 220-56-350 Clams other than razor clams, mussels—Areas and seasons. A person can take, dig for, and possess clams and mussels for personal use on Puget Sound the entire year except from public tidelands at the beaches listed below, which are closed unless otherwise provided.

- (1) Ala Spit: Open May 1 through May 31.
- (2) Alki Park: Closed the entire year.
- (3) Alki Point: Closed the entire year.
- (4) Bay View State Park: Closed the entire year.
- (5) Belfair State Park: Open ((January)) <u>April</u> 1 through ((December 31)) <u>April</u> 30.
 - (6) Brown's Point Lighthouse: Closed the entire year.
 - (7) Cama Beach State Park: Closed the entire year.
 - (8) Camano Island State Park: Closed the entire year.
 - (9) Chuckanut Bay: Closed the entire year.
 - (10) Coupeville: Closed the entire year.
 - (11) Dash Point State Park: Closed the entire year.
 - (12) Dave Mackie County Park: Closed the entire year.
 - (13) Des Moines City Park: Closed the entire year.
 - (14) Discovery Park: Closed the entire year.
 - (15) DNR-79: Closed the entire year.
 - (16) DNR-142: Closed the entire year.
 - (17) DNR-144 (Sleeper): Closed the entire year.
 - (18) Dockton County Park: Closed the entire year.
- (19) Dosewallips State Park: Open ((March)) April 1 through ((October 31)) August 15 only in area defined by boundary markers and signs posted on the beach.

- (20) Dungeness Spit and Dungeness National Wildlife Refuge Tidelands Open May 15 through September 30.
 - (21) Eagle Creek: Open July 1 through July 31.
- (22) East San de Fuca: Closed the entire year <u>east of the Rolling Hills Glencairn Community dock</u>.
- (23) Fort Flagler State Park including that portion of the spit west of the park boundary (Rat Island): Open May 15 through ((September 30)) October 31.
 - (24) Fort Ward State Park: Closed the entire year.
 - (25) Freeland County Park: Closed the entire year.
- (26) Frye Cove County Park: Open January 1 through May 15.
- (27) Garrison Bay: Tidelands at Guss Island and those tidelands at British camp between the National Park Service dinghy dock at the north end and the park boundary at the south end are closed the entire year.
- (28) Gertrude Island All tidelands at Gertrude Island closed the entire year.
 - (29) Golden Gardens: Closed the entire year.
 - (30) Graveyard Spit: Closed the entire year.
 - (31) Harrington Beach: Closed the entire year.
- (32) Hoodsport: Tidelands at Hoodsport Salmon Hatchery are closed the entire year.
- (33) Hope Island State Park (South Puget Sound): Open May 1 through May 31.
 - (34) Howarth Park: Closed the entire year.
 - (35) Illahee State Park: Open April 1 through July 31.
 - (36) Kayak Point County Park: Closed the entire year.
 - (37) Kitsap Memorial State Park: Closed the entire year.
- (38) Kopachuck State Park: Open June 1 through July 31.
- (39) Liberty Bay All state-owned tidelands in Liberty Bay north and west of the Keyport Naval Supply Center are closed to the harvest of clams the entire year.
 - (40) Lincoln Park: Closed the entire year.
 - (41) Lions Park (Bremerton): Closed the entire year.
 - (42) Little Clam Bay: Closed the entire year.
 - (43) Lower Roto Vista Park: Closed the entire year.
 - (44) Manchester State Park: Closed the entire year.
- (45) McNeil Island All tidelands on McNeil Island are closed the entire year.
 - (46) Meadowdale County Park: Closed the entire year.
 - (47) Mee-Kwa-Mooks Park: Closed the entire year.
 - (48) Monroe Landing: Closed the entire year.
 - (49) Mukilteo State Park Closed the entire year.
- (50) Mystery Bay State Park: Open October 1 through April 30.
- (51) Nisqually National Wildlife Refuge: Closed the entire year.
 - (52) North Beach County Park: Closed the entire year.
 - (53) North Fort Lewis: Closed the entire year.
 - (54) North Point Hudson: Closed the entire year.
 - (55) Northeast Cultus Bay: Closed the entire year.
- (56) Oak Bay County Park: Open ((May)) April 1 through July 31.
 - (57) Oak Harbor City Park: Closed the entire year.
 - (58) Old Man House State Park: Closed the entire year.
 - (59) Olympia Shoal: Closed the entire year.

[85] Permanent

- (60) Oyster Reserves: Puget Sound and Willapa Bay state oyster reserves are closed the entire year except as follows:
- (a) North Bay: State-owned oyster reserves open ((the entire year)) April 1 through September 15.
- (b) Oakland Bay: State-owned oyster reserves open the entire year except in areas defined by boundary markers and signs posted on the beach.
- (c) Willapa Bay Long Island oyster reserve: Northwest side of Long Island between reserve monuments 39 and 41 and southwest side of Long Island between reserve monuments 58 and 59.
- (61) Penrose Point State Park: Open March 1 through May 15.
 - (62) Picnic Point County Park: Closed the entire year.
 - (63) Pitship Point: Closed the entire year.
- (64) Pitt Island All tidelands on Pitt Island are closed the entire year.
 - (65) Pleasant Harbor State Park: Closed the entire year.
 - (66) Point Defiance: Closed the entire year.
- (67) Point Whitney (excluding Point Whitney Lagoon): Open March ((+)) 15 through March 31.
- $((\frac{(67)}{)}))$ (68) Point Whitney Lagoon: Open April 1 through April 30.
- (((68))) (<u>69</u>) Port Angeles Coast Guard: Closed the entire year.
- (((69))) (70) Port Angeles Harbor: Closed the entire year.
 - (((70))) Port Gardner: Closed the entire year.
- $((\frac{71}{1}))$ Port Townsend Ship Canal/Portage Canal: Open January 1 through $(\frac{1}{1})$ June 30.
 - (((72))) (73) Post Point: Closed the entire year.
- (((73))) <u>(74)</u> Potlatch DNR tidelands: Open April 1 through June 30.
- (((74))) (75) Potlatch State Park: Open April 1 through June 30.
- (((75))) (76) Priest Point County Park: Closed the entire year.
- $((\frac{76}{1}))$ Purdy Spit County Park: The southern shore of the spit from the boat ramp to the bridge is closed the entire year.
- (((77))) (78) Quilcene Bay Tidelands All state-owned tidelands in Quilcene Bay north of a line drawn from the Quilcene Boat Haven to Fisherman's Point are closed to the harvest of clams the entire year, except those state-owned tidelands on the west side of the bay north of the Quilcene Boat Haven are open April 1 through December 31, daily from official sunrise to official sunset only.
- (((78))) (79) Reid Harbor South Beach: Closed the entire year.
 - (((79))) (80) Retsil: Closed the entire year.
- $((\frac{(80)}{)})$ (81) Richmond Beach Saltwater Park: Closed the entire year.
- (((81))) (82) Saltwater State Park: Closed the entire year.
 - (((82))) (83) Samish Beach: Closed the entire year.
- (((83))) (84) Scenic Beach State Park: Closed the entire year.
- (((84))) (85) Seahurst County Park: Closed the entire year.

- (((85))) (86) Semiahmoo: Closed the entire year.
- (((86))) (87) Semiahmoo County Park: Closed the entire year.
- (((87))) (88) Sequim Bay State Park Open May 1 through June 30.
- (((88))) (<u>89</u>) Shine Tidelands State Park: Open January 1 through May 15.
- (((89))) (<u>90)</u> Silverdale Waterfront Park: Closed the entire year.
 - (((90))) (91) Sinclair Inlet: Closed the entire year.
- (((91))) (92) Skagit Wildlife Area: Closed the entire year.
 - (((92))) <u>(93)</u> South Carkeek Park: Closed the entire year.
 - (((93))) <u>(94)</u> South Gordon Point: Closed the entire year.
- (((94))) (<u>95)</u> South Indian Island County Park: Open ((May 15)) <u>April 1</u> through ((August 31)) <u>June 15</u>.
- (((95))) <u>(96)</u> South Mukilteo Park: Closed the entire year.
 - (((96))) (97) South Oro Bay: Closed the entire year.
- (((97))) (98) South Point Wilson (Port Townsend): Closed the entire year.
- (((98))) (99) Southworth Ferry Dock: Closed the entire year.
- (((99))) (100) Spencer Spit State Park: Open March 1 through July 31.
- $((\frac{(100)}{100}))$ (101) Suquamish (Old Man House): Closed the entire year.
 - (((101))) (102) Taylor Bay: Closed the entire year.
- (((102))) (103) Triton Cove Tidelands: Open ((June)) <u>July</u> 1 through August 31.
- $((\frac{(103)}{)})$ (104) Twanoh State Park: Open August 1 through September $((\frac{30}{)})$ 15.
- (((104))) (105) Walker County Park: Closed the entire year.
- (((105))) (106) West Dewatto: DNR Beach 44A open ((August)) July 1 through September 30.
- (((106))) (107) West Pass Access: Closed the entire year.
- (((107))) (108) Willapa Bay: State-owned tidelands east of the department Willapa Bay Field Station and Nahcotta Tidelands Interpretive Site are closed year-round.
- (((108))) (109) Wolfe Property State Park: Open January 1 through May 15.
 - (((109))) (110) Woodard Bay: Closed the entire year.

A person can take, dig for, and possess clams, cockles, borers, and mussels, not including razor clams, for personal use in Grays Harbor and Willapa Harbor the entire year, except from state oyster reserves, which are closed to clam digging the entire year.

A person can take, dig for, and possess clams, cockles, borers, and mussels, not including razor clams, for personal use from the Pacific Ocean beaches from November 1 through March 31.

<u>AMENDATORY SECTION</u> (Amending Order 12-31, filed 3/12/12, effective 4/12/12)

WAC 220-56-380 Oysters—Areas and seasons. A person can take and possess oysters for personal use from public tidelands the entire year except from public tidelands

Permanent [86]

at the beaches listed below, which are closed unless otherwise provided.

- (1) Ala Spit: Open May 1 through May 31.
- (2) Alki Park: Closed the entire year.
- (3) Alki Point: Closed the entire year.
- (4) Bangor: Closed the entire year.
- (5) Bay View State Park: Closed the entire year.
- (6) Brown's Point Lighthouse: Closed the entire year.
- (7) Cama Beach State Park: Closed the entire year.
- (8) Camano Island State Park: Closed the entire year.
- (9) Chuckanut: Closed the entire year.
- (10) Coupeville: Closed the entire year.
- (11) Dash Point State Park: Closed the entire year.
- (12) Dave Mackie County Park: Closed the entire year.
- (13) Des Moines City Park: Closed the entire year.
- (14) Discovery Park: Closed the entire year.
- (15) DNR-79: Closed the entire year.
- (16) DNR-142: Closed the entire year.
- (17) DNR 144 (Sleeper): Closed the entire year.
- (18) Dockton County Park: Closed the entire year.
- (19) Dungeness Spit/National Wildlife Refuge: Open May 15 September 30.
- (20) East San de Fuca: Closed the entire year <u>east of the Rolling Hills Glencairn Community dock</u>.
- (21) Fort Flagler State Park including that portion of the spit west of the park boundary (Rat Island): Open May 15 through ((September 30)) October 31.
 - (22) Fort Ward State Park: Closed the entire year.
 - (23) Freeland County Park: Closed the entire year.
- (24) Frye Cove County Park: Open January 1 through May 15.
 - (25) Golden Gardens: Closed the entire year.
 - (26) Graveyard Spit: Closed the entire year.
 - (27) Harrington Beach: Closed the entire year.
- (28) Hoodsport: Tidelands at the Hoodsport Salmon Hatchery are closed the entire year.
- (29) Hope Island State Park (South Puget Sound): Open May 1 through May 31.
 - (30) Howarth Park: Closed the entire year.
 - (31) Illahee State Park: Open April 1 through July 31.
 - (32) Kayak Point County Park: Closed the entire year.
 - (33) Kitsap Memorial State Park: Closed the entire year.
- (34) Kopachuck State Park: Open March 1 through July 31.
- (35) Liberty Bay All state-owned tidelands in Liberty Bay north and west of the Keyport Naval Supply Center are closed to the harvest of oysters the entire year.
 - (36) Lincoln Park: Closed the entire year.
 - (37) Lions Park (Bremerton): Closed the entire year.
 - (38) Little Clam Bay: Closed the entire year.
 - (39) Lower Roto Vista Park: Closed the entire year.
 - (40) Manchester State Park: Closed the entire year.
 - (41) Meadowdale County Park: Closed the entire year.
 - (42) Mee-Kwa-Mooks Park: Closed the entire year.
 - (43) Monroe Landing: Closed the entire year.
 - (44) Mukilteo State Park: Closed the entire year.
- (45) Mystery Bay State Park: Open October 1 through April 30.
- (46) Nisqually National Wildlife Refuge: Closed the entire year.

- (47) North Beach County Park: Closed the entire year.
- (48) North Fort Lewis: Closed the entire year.
- (49) North Point Hudson: Closed the entire year.
- (50) Northeast Cultus Bay: Closed the entire year.
- (51) Oak Bay County Park: Open ((May)) April 1 through July 31.
 - (52) Oak Harbor Beach Park: Closed the entire year.
 - (53) Oak Harbor City Park: Closed the entire year.
 - (54) Old Man House State Park: Closed the entire year.
 - (55) Olympia Shoal: Closed the entire year.
- (56) Oyster Reserves: Puget Sound and Willapa Bay oyster reserves are closed the entire year except the following are open the entire year:
- (a) Oakland Bay State-owned oyster reserves open the entire years except in areas defined by boundary markers and signs posted on the beach.
- (b) North Bay State-owned reserves open ((the entire year)) April 1 through September 15.
- (c) Willapa Bay Long Island oyster reserve: Northwest side of Long Island between reserve monuments 39 and 41 and southwest side of Long Island between reserve monuments 58 and 59.
- (57) Penrose Point State Park: Open March 1 through May 15.
 - (58) Picnic Point: Closed the entire year.
 - (59) Pitt Island: Closed the entire year.
 - (60) Pleasant Harbor State Park: Closed the entire year.
 - (61) Point Defiance: Closed the entire year.
- (62) Point Whitney tidelands (excluding Point Whitney Lagoon): Open January 1 through June 30.
- (((62))) (63) Port Angeles Coast Guard: Closed the entire year.
- (((63))) <u>(64)</u> Port Angeles Harbor: Closed the entire year.
 - (((64))) (65) Port Gardner: Closed the entire year.
- (((65))) (<u>66)</u> Port Townsend Ship Canal/Portage Canal: Open January 1 through ((July 31)) <u>June 30</u>.
 - (((66))) (67) Post Point: Closed the entire year.
- (((67))) (68) Potlatch DNR Tidelands: Open April 1 through June 30.
- (((68))) <u>(69)</u> Potlatch State Park: Open April 1 through June 30.
- (((69))) Priest Point County Park: Closed the entire year.
- $(((\frac{70}{10})))$ (71) Purdy Spit County Park: The southern shore of the spit from the boat ramp to the bridge is closed the entire year.
- (((71))) (72) Quilcene Bay Tidelands All state-owned tidelands in Quilcene Bay north of a line drawn from the Quilcene Boat Haven to Fisherman's Point are closed except those state-owned tidelands on the west side of the bay north of the Quilcene Boat Haven are open April 1 through December 31, daily from official sunrise to official sunset, only.
- $((\frac{72}{12}))$ (73) Reid Harbor South Beach: Closed the entire year
 - (((73))) (74) Retsil: Closed the entire year.
- $((\frac{74}{1}))$ (75) Richmond Beach Saltwater Park: Closed the entire year.
- (((75))) (76) Saltwater State Park: Closed the entire year.

[87] Permanent

(((76))) (77) Samish Beach: Closed the entire year.

(((777))) (78) Seahurst County Park: Closed the entire year.

(((78))) (79) Scenic Beach State Park: Closed the entire year.

(((79))) (80) Semiahmoo: Closed the entire year.

(((80))) (81) Semiahmoo County Park: Closed the entire year.

 $((\frac{(81)}{)})$ (82) Shine Tidelands State Park: Open January 1 through May 15.

(((82))) (83) Silverdale Waterfront Park: Closed the entire year.

((83)) (84) Sinclair Inlet: Closed the entire year.

(((84))) (85) Skagit Wildlife Area: Closed the entire year.

(((85))) (86) South Carkeek Park: Closed the entire year.

(((86))) (87) South Gordon Point: Closed the entire year.

(((87))) (88) South Indian Island County Park: Open ((May 15)) April 1 through ((August 31)) June 15.

(((88))) (<u>89)</u> South Mukilteo Park: Closed the entire year.

((89))) (90) South Oro Bay: Closed the entire year.

(((99))) (91) South Point Wilson (Port Townsend): Closed the entire year.

(((91))) (92) Southworth Ferry Dock: Closed the entire year.

(((92))) (93) Spencer Spit State Park: Open March 1 through July 31.

(((93))) (94) Suquamish (Old Man House): Closed the entire year.

(((94))) (95) Taylor Bay: Closed the entire year.

(((95))) (96) Walker County Park: Closed the entire year.

(((96))) (97) West Pass Access: Closed the entire year.

(((97))) (98) Willapa Bay: State-owned tidelands east of the department Willapa Bay Field Station and the Nahcotta Tidelands Interpretive Site are open only between boundary markers and posted signs.

(((98))) (99) Woodard Bay: Closed the entire year.

(((99))) (100) Wolfe Property State Park: Open January 1 through May 15.

WSR 13-06-041 PERMANENT RULES OFFICE OF INSURANCE COMMISSIONER

[Insurance Commissioner Matter No. R 2012-30—Filed March 4, 2013, 9:43 a.m., effective July 1, 2013]

Effective Date of Rule: July 1, 2013.

Purpose: The purpose of this new rule is to provide uniformity in the application of NAIC model 830.

Statutory Authority for Adoption: RCW 48.02.060 and 48.74.020.

Adopted under notice filed as WSR 13-03-139 on January 23, 2013.

A final cost-benefit analysis is available by contacting Kacy Scott, [P.O. Box] 40255, Olympia, WA 98504-0255,

phone (360) 725-7041, fax (360) 586-3109, e-mail kacys@oic.wa.gov.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's Own Initiative: New 1, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted Using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 1, Amended 0, Repealed 0.

Date Adopted: March 4, 2013.

Mike Kreidler Insurance Commissioner

NEW SECTION

WAC 284-74-365 Implementation of WAC 284-74-360. (1) Insurers will fully apply NAIC Actuarial Guideline XXXVIII, as adopted on September 12, 2012, to properly and uniformly implement WAC 284-74-360.

(2) NAIC Actuarial Guideline XXXVIII will be effective July 1, 2013.

WSR 13-06-050 PERMANENT RULES DEPARTMENT OF LABOR AND INDUSTRIES

[Filed March 5, 2013, 8:55 a.m., effective April 15, 2013]

Effective Date of Rule: April 15, 2013.

Effective Completion		
Date	Requirement(s)	Who
June 1, 2014	Train employees on the new label elements and safety data sheet (SDS) format.	Employers.
June 1, 2015	Compliance with all provisions of the WAC 296-901-140 final rule, except as listed below:	Chemical manufactures, importers, distributors, and employers.
June 1, 2016	Update alternative workplace labeling and hazard communication program as necessary, and provide additional employee training for newly identified physical or health hazards.	Employers.
December 1, 2015	The distributor must not ship containers labeled by the chemical manufacturer or importer unless it is a GHS label.	Distributors.

Permanent [88]

		ı
Effective		
Completion		
Date	Requirement(s)	Who
Transition period	May comply with the applicable	Chemical manu-
to the effective	requirements in the following	facturers,
completion dates	rules:	importer[s], dis-
noted above.	• WAC 296-800-170	tributors, and
	Employer chemical hazard	employers.
	communication (core rules).	
	 Chapter 296-307 WAC, Part 	
	Y-1, Employer chemical	
	hazard communication	
	(agriculture).	
	 Chapter 296-839 WAC, 	
	Content and distribution of	
	material safety data sheets	
	(MSDS) and label informa-	
	tion.	
	Chapter 296-307 WAC, Part	
	Y-2, Material safety data	
	sheets and label preparation	
	(agriculture).	
	• Chapter 296-816 WAC, Pro-	
	tecting trade secrets.	
	Chapter 296-62 WAC, Part	
	B-1, Trade secrets (applies	
	only to agriculture).	
	Or the requirements in the new	
	hazard communication standard in	
	WAC 296-901-140, or both.	

Purpose: The Occupational Safety and Health Administration (OSHA) adopted the final rules updating its hazard communication standard into alignment with the globally harmonized system of classification and labeling of chemicals (GHS). The department is required to update our rules to be at-least-as-effective-as OSHA. The scope of OSHA's hazard communication standard includes requirements for employers as well as chemical manufacturers, importers, and distributors, and the department's comparable requirements are in separate rules at this time. This rule making created a new rule, WAC 296-901-140, incorporating all the elements of the existing department rules into one rule to be consistent with OSHA's hazard communication standard. The effective dates of the new rule will be delayed and phased in. During the transition period, there is the option to comply with the applicable requirements in the existing rules or the requirements in the new rule or both. Upon completion of the transition period, the existing standards will be repealed.

The effective dates of OSHA's rule are delayed and phased in. The department is required to update our rules to be at-least-as-effective-as OSHA. The scope of OSHA's hazard communication standard includes requirements for employers as well as chemical manufacturers, importers, and distributors. The department's comparable requirements are in separate rules, as follows:

Employer Requirements: WAC 296-800-170 Employer chemical hazard communication (core rules) and chapter 296-307 WAC, Part Y-1, Employer chemical hazard communication (agriculture).

Chemical Manufacturer, Importer, and Distributor Requirements: Chapter 296-839 WAC, Content and distribu-

tion of material safety data sheets (MSDS) and label information and chapter 296-307 WAC, Part Y-2, Material safety data sheets and label preparation (agriculture).

Trade Secrets: Chapter 296-816 WAC, Protecting trade secrets and chapter 296-62 WAC, Part B-1, Trade secrets (applies only to agriculture).

In addition, other department rules specific to activities and workplaces reference the requirements in WAC 296-800-170.

This rule making created a new rule, WAC 296-901-140, incorporating all the elements of the existing department rules into one rule to be consistent with OSHA's hazard communication standard. In part, OSHA's new standard has lengthy mandatory appendices that make it infeasible to split the rule into separate sections. During the transition period, there is the option to comply with the applicable requirements in the existing rules or the requirements in the new rule or both (see Table 1). Upon completion of the transition period, the existing standards will be repealed (see Table 2).

OSHA's rule also modified other existing OSHA standards that contain hazard classification and communication provisions to be internally consistent and aligned with the GHS modifications to the hazard communication standard. It is anticipated that the department's rule making to modify other existing standards to align with the GHS changes as required by OSHA's rule will be done in a subsequent rule making (see Table 2).

Table 1 Effective Dates

See Effective Date above.

Table 2
Proposed Schedule for Related Rule Changes

Rule Change	Proposed Schedule
Adopt WAC 296-901-140 Hazard	Adoption proposed
communication.	in March 2013.
Amend other existing DOSH rules to align with the GHS changes as required by OSHA's rule.	Second and third quarter of 2013.
Repeal existing rules and delete, repeal, and change all references to the existing rules.	As applicable, no later than June 1, 2016.

New Sections:

WAC 296-901-140 Hazard communication.

• There are no requirements in this section.

WAC 296-901-14002 Purpose.

- There are no requirements in this section.
- Statement that the purpose of this section is to ensure that the hazards of all chemicals produced or imported is classified, and that information concerning the classified hazards is transmitted to employers and employees.

[89] Permanent

WAC 296-901-14004 Scope and application.

 Requirements relating chemical manufacturers, importers, and employers on providing employees information about the hazardous chemicals to which they are exposed, by means of a hazard communication program, labels, other forms of warning, safety data sheets, and training is located in this section. These requirements are federally driven and consistent with the provisions of the United Nations GHS, Revision 3.

WAC 296-901-14006 Definitions.

• There are no requirements in this section.

WAC 296-901-14008 Hazard classification.

• Requirements relating to hazard classification are located in this section. These requirements are federally driven and consistent with the provisions of the United Nations GHS, Revision 3.

WAC 296-901-14010 Written hazard communication program.

 Requirements relating to written hazard classification are located in this section. These requirements are federally driven and consistent with the provisions of the United Nations GHS, Revision 3.

WAC 296-901-14012 Labels and other forms of warning.

 Requirements relating to labels and other forms of warning are located in this section. These requirements are federally driven and consistent with the provisions of the United Nations GHS, Revision 3.

WAC 296-901-14014 Safety data sheets.

• Requirements relating to safety data sheets are located in this section. These requirements are federally driven and consistent with the provisions of the United Nations GHS, Revision 3.

WAC 296-901-14016 Employee information and training.

• Requirements relating to employee information and training are located in this section. These requirements are federally driven and consistent with the provisions of the United Nations GHS, Revision 3.

WAC 296-901-14018 Trade secrets.

• Requirements relating to trade secrets are located in this section. These requirements are federally driven and consistent with the provisions of the United Nations GHS. Revision 3.

WAC 296-901-14020 Effective dates.

Requirements relating to the effective dates are located in this section. This rule making creates a new rule, WAC 296-901-140, incorporating all the elements of the existing department rules into one rule to be consistent with OSHA's hazard communication standard. OSHA's new standard has lengthy mandatory appendices that make it infeasible to split the rule into separate sections. During the transition period from the effective dates in the new rule, there

- is the option to comply with the applicable requirements in the existing rules or the requirements in the new rule or both (see Table 1). Upon completion of the transition period and the new rule is fully effective, the existing standards will be repealed (see Table 2).
- OSHA's rule also modified other existing OSHA standards that contain hazard classification and communication provisions so that they will be internally consistent and aligned with the GHS modifications to the hazard communication standard. It is anticipated that the department's rule making to modify other existing standards to align with the GHS changes as required by OSHA's rule will be done in subsequent rule makings (see Table 2).

WAC 296-901-14022 Appendix A—Health hazard criteria (mandatory).

Requirements relating to general classification considerations for health hazard criteria are located in this section. These requirements are federally driven and consistent with the provisions of the United Nations GHS, Revision 3.

WAC 296-901-14024 Appendix B—Physical hazard criteria (mandatory).

- Requirements relating to physical hazard criteria are located in this section. These requirements are federally driven and consistent with the provisions of the United Nations GHS, Revision 3.
- This section covers the definitions and general considerations to the following: Explosives; flammable gases; flammable aerosols; oxidizing gases; gases under pressure; flammable liquids; flammable solids; self-reactive chemicals; pyrophoric liquids; pyrophoric solids; self-heating chemicals; chemicals which, in contact with water, emit flammable gases; oxidizing liquids; oxidizing solids; organic peroxides; and corrosive to metals.

WAC 296-901-14026 Appendix C—Allocation of label elements (mandatory).

- Requirements relating to allocation of label elements are located in this section. These requirements are federally driven and consistent with the provisions of the United Nations GHS, Revision 3.
- All the physical illustrations of the required symbols and classes are located in this section.

WAC 296-901-14028 Appendix D—Safety data sheets (mandatory).

 Requirements relating to the minimum information for safety data sheets are located in this section. These requirements are federally driven and consistent with the provisions of the United Nations GHS, Revision 3.

Permanent [90]

WAC 296-901-14030 Appendix E—Definition of "trade secret" (mandatory).

 This section provides a reprint of the "Restatement of Torts" section 757, comment b (1939) giving the definition of trade secret.

WAC 296-901-14032 Appendix F—Guidance for hazard classifications regarding carcinogenicity (nonmandatory).

- There are no requirements in this section.
- This nonmandatory appendix provides additional guidance on hazard classification for carcinogenicity.

Statutory Authority for Adoption: RCW 49.17.010, 49.17.040, 49.17.050, and 49.17.060.

Other Authority: 29 C.F.R. 1910 Subpart Z.

Adopted under notice filed as WSR 13-01-070 on December 18, 2012.

Changes Other than Editing from Proposed to Adopted Version: There was a spelling error in WAC 296-901-14020 Effective dates. The word "preparartion" was corrected to read "preparation."

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 17, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's Own Initiative: New 17, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 17, Amended 0, Repealed 0.

Number of Sections Adopted Using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 17, Amended 0, Repealed 0.

Date Adopted: March 5, 2013.

Joel Sacks Director

NEW SECTION

WAC 296-901-140 Hazard communication.

NEW SECTION

WAC 296-901-14002 Purpose. The purpose of this section is to ensure that the hazards of all chemicals produced or imported are classified, and that information concerning the classified hazards is transmitted to employers and employees. The requirements of this section are intended to be consistent with the provisions of the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Revision 3. The transmittal of information is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, safety data sheets and employee training.

This occupational safety and health standard is intended to address comprehensively the issue of classifying the potential hazards of chemicals, and communicating information concerning hazards and appropriate protective measures to employees, and to preempt any legislative or regulatory enactments of a state, or political subdivision of a state, pertaining to this subject. Classifying the potential hazards of chemicals and communicating information concerning hazards and appropriate protective measures to employees may include, for example, but is not limited to, provisions for: Developing and maintaining a written hazard communication program for the workplace, including lists of hazardous chemicals present; labeling of containers of chemicals in the workplace, as well as of containers of chemicals being shipped to other workplaces; preparation and distribution of safety data sheets to employees and downstream employers; and development and implementation of employee training programs regarding hazards of chemicals and protective measures.

NEW SECTION

WAC 296-901-14004 Scope and application. (1) This section requires chemical manufacturers or importers to classify the hazards of chemicals which they produce or import, and all employers to provide information to their employees about the hazardous chemicals to which they are exposed, by means of a hazard communication program, labels and other forms of warning, safety data sheets, and information and training. In addition, this section requires distributors to transmit the required information to employers. (Employers who do not produce or import chemicals need only focus on those parts of this rule that deal with establishing a workplace program and communicating information to their workers.)

- (2) This section applies to any chemical which is known to be present in the workplace in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency.
 - (3) This section applies to laboratories only as follows:
- (a) Employers must ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;
- (b) Employers must maintain any safety data sheets that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible during each workshift to laboratory employees when they are in their work areas;
- (c) Employers must ensure that laboratory employees are provided information and training in accordance with WAC 296-901-14016, except for the location and availability of the written hazard communication program under WAC 296-901-14016 (2)(c); and
- (d) Laboratory employers that ship hazardous chemicals are considered to be either a chemical manufacturer or a distributor under this rule, and thus must ensure that any containers of hazardous chemicals leaving the laboratory are labeled in accordance with WAC 296-901-14012, and that a safety data sheet is provided to distributors and other employers in accordance with WAC 296-901-14014 (5)(a) and (6).
- (4) In work operations where employees only handle chemicals in sealed containers which are not opened under

[91] Permanent

normal conditions of use (such as are found in marine cargo handling, warehousing, or retail sales), this section applies to these operations only as follows:

- (a) Employers must ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;
- (b) Employers must maintain copies of any safety data sheets that are received with incoming shipments of the sealed containers of hazardous chemicals, must obtain a safety data sheet as soon as possible for sealed containers of hazardous chemicals received without a safety data sheet if an employee requests the safety data sheet, and must ensure that the safety data sheets are readily accessible during each work shift to employees when they are in their work area(s); and
- (c) Employers must ensure that employees are provided with information and training in accordance with WAC 296-901-14016 (except for the location and availability of the written hazard communication program under WAC 296-901-14016 (2)(c), to the extent necessary to protect them in the event of a spill or leak of a hazardous chemical from a sealed container.
- (5) This section does not require labeling of the following chemicals:
- (a) Any pesticide as such term is defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*), when subject to the labeling requirements of that act and labeling regulations issued under that act by the Environmental Protection Agency;
- (b) Any chemical substance or mixture as such terms are defined in the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*), when subject to the labeling requirements of that act and labeling regulations issued under that act by the Environmental Protection Agency;
- (c) Any food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (e.g., flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Virus-Serum-Toxin Act of 1913 (21 U.S.C. 151 et seq.), and regulations issued under those acts, when they are subject to the labeling requirements under those acts by either the Food and Drug Administration or the Department of Agriculture;
- (d) Any distilled spirits (beverage alcohols), wine, or malt beverage intended for nonindustrial use, as such terms are defined in the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) and regulations issued under that act, when subject to the labeling requirements of that act and labeling regulations issued under that act by the Bureau of Alcohol, Tobacco, Firearms and Explosives;
- (e) Any consumer product or hazardous substance as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 *et seq.*) and Federal Hazardous Substances Act (15 U.S.C. 1261 *et seq.*) respectively, when subject to a consumer product safety standard or labeling requirement of those acts, or regulations issued under those acts by the Consumer Product Safety Commission; and
- (f) Agricultural or vegetable seed treated with pesticides and labeled in accordance with the Federal Seed Act (7

- U.S.C. 1551 *et seq.*) and the labeling regulations issued under that act by the Department of Agriculture.
 - (6) This section does not apply to:
- (a) Any hazardous waste as such term is defined by the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6901 *et seq.*), when subject to regulations issued under that act by the Environmental Protection Agency;
- (b) Any hazardous substance as such term is defined by the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) (42 U.S.C. 9601 *et seq.*) when the hazardous substance is the focus of remedial or removal action being conducted under CERCLA in accordance with Environmental Protection Agency regulations;
 - (c) Tobacco or tobacco products;
- (d) Wood or wood products, including lumber which will not be processed, where the chemical manufacturer or importer can establish that the only hazard they pose to employees is the potential for flammability or combustibility (wood or wood products which have been treated with a hazardous chemical covered by this standard, and wood which may be subsequently sawed or cut, generating dust, are not exempted);
- (e) Articles (as that term is defined in WAC 296-901-14006);
- (f) Food or alcoholic beverages which are sold, used, or prepared in a retail establishment (such as a grocery store, restaurant, or drinking place), and foods intended for personal consumption by employees while in the workplace;
- (g) Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (e.g., first-aid supplies);
- (h) Cosmetics which are packaged for sale to consumers in a retail establishment, and cosmetics intended for personal consumption by employees while in the workplace;
- (i) Any consumer product or hazardous substance, as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 *et seq.*) and Federal Hazardous Substances Act (15 U.S.C. 1261 *et seq.*) respectively, where the employer can show that it is used in the workplace for the purpose intended by the chemical manufacturer or importer of the product, and the use results in a duration and frequency of exposure which is not greater than the range of exposures that could reasonably be experienced by consumers when used for the purpose intended;
- (j) Nuisance particulates where the chemical manufacturer or importer can establish that they do not pose any physical or health hazard covered under this section;
 - (k) Ionizing and nonionizing radiation; and
 - (1) Biological hazards.

NEW SECTION

WAC 296-901-14006 Definitions. *Article* means a manufactured item other than a fluid or particle:

Permanent [92]

- (1) Which is formed to a specific shape or design during manufacture;
- (2) Which has end use function(s) dependent in whole or in part upon its shape or design during end use; and
- (3) Which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical (as determined under WAC 296-901-14008), and does not pose a physical hazard or health risk to employees.

Chemical means any substance, or mixture of substances.

Chemical manufacturer means an employer with a workplace where chemical(s) are produced for use or distribution.

Chemical name means the scientific designation of a chemical the nomenclature system developed by the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS) rules of nomenclature, or a name that will clearly identify the chemical for the purpose of conducting a hazard classification.

Classification means to identify the relevant data regarding the hazards of a chemical; review those data to ascertain the hazards associated with the chemical; and decide whether the chemical will be classified as hazardous according to the definition of hazardous chemical in this section. In addition, classification for health and physical hazards includes the determination of the degree of hazard, where appropriate, by comparing the data with the criteria for health and physical hazards.

Commercial account means an arrangement whereby a retail distributor sells hazardous chemicals to an employer, generally in large quantities over time and/or at costs that are below the regular retail price.

Common name means any designation or identification such as code name, code number, trade name, brand name or generic name used to identify a chemical other than by its chemical name.

Container means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

Designated representative means any individual or organization to whom an employee gives written authorization to exercise such employee's rights under this section. A recognized or certified collective bargaining agent must be treated automatically as a designated representative without regard to written employee authorization.

Distributor means a business, other than a chemical manufacturer or importer, which supplies hazardous chemicals to other distributors or to employers.

Employee is a person, as defined under RCW 49.17.020 (5), who may be exposed to hazardous chemicals under normal operating conditions or in foreseeable emergencies. Employees such as office workers or bank tellers who encounter hazardous chemicals only in nonroutine, isolated instances are not covered.

Employer means an employer, as defined under RCW 49.17.020(4), engaged in a business where chemicals are

either used, distributed, or are produced for use or distribution, including a contractor or subcontractor.

Exposure or exposed means that an employee is subjected in the course of employment to a chemical that is a physical or health hazard, and includes potential (e.g., accidental or possible) exposure. "Subjected" in terms of health hazards includes any route of entry (e.g., inhalation, ingestion, skin contact or absorption).

Foreseeable emergency means any potential occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which could result in an uncontrolled release of a hazardous chemical into the workplace.

Hazard category means the division of criteria within each hazard class, e.g., oral acute toxicity and flammable liquids include four hazard categories. These categories compare hazard severity within a hazard class and must not be taken as a comparison of hazard categories more generally.

Hazard class means the nature of the physical or health hazards, e.g., flammable solid, carcinogen, oral acute toxicity.

Hazard not otherwise classified (HNOC) means an adverse physical or health effect identified through evaluation of scientific evidence during the classification process that does not meet the specified criteria for the physical and health hazard classes addressed in this section. This does not extend coverage to adverse physical and health effects for which there is a hazard class addressed in this section, but the effect either falls below the cut-off value/concentration limit of the hazard class or is under a GHS hazard category that has not been adopted by OSHA (e.g., acute toxicity Category 5).

Hazard statement means a statement assigned to a hazard class and category that describes the nature of the hazard(s) of a chemical including, where appropriate, the degree of hazard.

Hazardous chemical means any chemical which is classified as a physical hazard or a health hazard, a simple asphyxiant, combustible dust, pyrophoric gas, or hazard not otherwise classified.

Health hazard means a chemical which is classified as posing one of the following hazardous effects: Acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific target organ toxicity (single or repeated exposure); or aspiration hazard. The criteria for determining whether a chemical is classified as a health hazard are detailed in WAC 296-901-14022, Appendix A—Health hazard criteria.

Immediate use means that the hazardous chemical will be under the control of and used only by the person who transfers it from a labeled container and only within the work shift in which it is transferred.

Importer means the first business with employees within the Customs Territory of the United States which receives hazardous chemicals produced in other countries for the purpose of supplying them to distributors or employers within the United States.

Label means an appropriate group of written, printed or graphic information elements concerning a hazardous chem-

[93] Permanent

ical that is affixed to, printed on, or attached to the immediate container of a hazardous chemical, or to the outside packaging.

Label elements means the specified pictogram, hazard statement, signal word and precautionary statement for each hazard class and category.

Mixture means a combination or a solution composed of two or more substances in which they do not react.

Physical hazard means a chemical that is classified as posing one of the following hazardous effects: Explosive; flammable (gases, aerosols, liquids, or solids); oxidizer (liquid, solid or gas); self-reactive; pyrophoric (liquid or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; or in contact with water emits flammable gas. WAC 296-901-1424, Appendix B—Physical hazard criteria.

Pictogram means a composition that may include a symbol plus other graphic elements, such as a border, background pattern, or color, that is intended to convey specific information about the hazards of a chemical. Eight pictograms are designated under this standard for application to a hazard category.

Precautionary statement means a phrase that describes recommended measures that must be taken to minimize or prevent adverse effects resulting from exposure to a hazardous chemical, or improper storage or handling.

Produce means to manufacture, process, formulate, blend, extract, generate, emit, or repackage.

Product identifier means the name or number used for a hazardous chemical on a label or in the SDS. It provides a unique means by which the user can identify the chemical. The product identifier used must permit cross-references to be made among the list of hazardous chemicals required in the written hazard communication program, the label and the SDS.

Pyrophoric gas means a chemical in a gaseous state that will ignite spontaneously in air at a temperature of 130 degrees F (54.4 degrees C) or below.

Responsible party means someone who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary.

Safety data sheet (SDS) means written or printed material concerning a hazardous chemical that is prepared in accordance with WAC 296-901-14014.

Signal word means a word used to indicate the relative level of severity of hazard and alert the reader to a potential hazard on the label. The signal words used in this section are "danger" and "warning." "Danger" is used for the more severe hazards, while "warning" is used for the less severe.

Simple asphyxiant means a substance or mixture that displaces oxygen in the ambient atmosphere, and can thus cause oxygen deprivation in those who are exposed, leading to unconsciousness and death.

Specific chemical identity means the chemical name, Chemical Abstracts Service (CAS) Registry Number, or any other information that reveals the precise chemical designation of the substance.

Substance means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the pro-

cess used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

Trade secret means any confidential formula, pattern, process, device, information or compilation of information that is used in an employer's business, and that gives the employer an opportunity to obtain an advantage over competitors who do not know or use it. WAC 296-901-14030, Appendix E—Definition of "trade secret," sets out the criteria to be used in evaluating trade secrets.

Use means to package, handle, react, emit, extract, generate as a by-product, or transfer.

Work area means a room or defined space in a workplace where hazardous chemicals are produced or used, and where employees are present.

Workplace means an establishment, job site, or project, at one geographical location containing one or more work areas.

NEW SECTION

WAC 296-901-14008 Hazard classification. (1) Chemical manufacturers and importers must evaluate chemicals produced in their workplaces or imported by them to classify the chemicals in accordance with this section. For each chemical, the chemical manufacturer or importer must determine the hazard classes, and where appropriate, the category of each class that apply to the chemical being classified. Employers are not required to classify chemicals unless they choose not to rely on the classification performed by the chemical manufacturer or importer for the chemical to satisfy this requirement.

- (2) Chemical manufacturers, importers or employers classifying chemicals must identify and consider the full range of available scientific literature and other evidence concerning the potential hazards. There is no requirement to test the chemical to determine how to classify its hazards. WAC 296-901-14022, Appendix A—Health hazard criteria must be consulted for classification of health hazards, and WAC 296-901-14024, Appendix B—Physical hazard criteria must be consulted for the classification of physical hazards.
 - (3) Mixtures.
- (a) Chemical manufacturers, importers, or employers evaluating chemicals must follow the procedures described in WAC 296-901-14022, Appendix A—Health hazard criteria and WAC 296-901-14024, Appendix B—Physical hazard criteria to classify the hazards of the chemicals, including determinations regarding when mixtures of the classified chemicals are covered by this section.
- (b) When classifying mixtures they produce or import, chemical manufacturers and importers of mixtures may rely on the information provided on the current safety data sheets of the individual ingredients, except where the chemical manufacturer or importer knows, or in the exercise of reasonable diligence must know, that the safety data sheet misstates or omits information required by this section.
- (4) Chemical manufacturers, importers and employers evaluating chemicals must treat the following sources as establishing that a chemical is a carcinogen or potential carcinogen for hazard communication purposes:

Permanent [94]

- (a) National Toxicology Program (NTP), Annual Report on Carcinogens (latest edition);
- (b) International Agency for Research on Cancer (IARC) *Monographs* (latest editions); or
 - (c) Chapter 296-841 WAC, Airborne contaminants.

Note:

The Registry of Toxic Effects of Chemical Substances published by the National Institute for Occupational Safety and Health indicates whether a chemical has been found by NTP or IARC to be a potential carcinogen.

- (5) The chemical manufacturer, importer or employer must determine the hazards of mixtures of chemicals as follows:
- (a) If a mixture has been tested as a whole to determine its hazards, the results of such testing must be used to determine whether the mixture is hazardous;
- (b) If a mixture has not been tested as a whole to determine whether the mixture is a health hazard, the mixture must be assumed to present the same health hazards as do the components which comprise one percent (by weight or volume) or greater of the mixture, except that the mixture must be assumed to present a carcinogenic hazard if it contains a component in concentrations of 0.1 percent or greater which is considered to be a carcinogen under subsection (4) of this section:
- (c) If a mixture has not been tested as a whole to determine whether the mixture is a physical hazard, the chemical manufacturer, importer, or employer may use whatever scientifically valid data is available to evaluate the physical hazard potential of the mixture; and
- (d) If the chemical manufacturer, importer, or employer has evidence to indicate that a component present in the mixture in concentrations of less than one percent (or in the case of carcinogens, less than 0.1 percent) could be released in concentrations which would exceed an established OSHA permissible exposure limit or American Conference of Industrial Hygienists (ACGIH) Threshold Limit Value, or could present a health risk to employees in those concentrations, the mixture must be assumed to present the same hazard.
- (6) Chemical manufacturers, importers, or employers evaluating chemicals must describe in writing the procedures they use to determine the hazards of the chemical they evaluate. The written procedures are to be made available, upon request, to employees, their designated representatives, the assistant secretary and the director. The written description may be incorporated into the written hazard communication program required under WAC 296-901-14010.

NEW SECTION

WAC 296-901-14010 Written hazard communication program. (1) Employers must develop, implement, and maintain at each workplace, a written hazard communication program which at least describes how the criteria specified in WAC 296-901-14012, 296-901-14014, and 296-901-14016 for labels and other forms of warning, safety data sheets, and employee information and training will be met, and which also includes the following:

(a) A list of the hazardous chemicals known to be present using a product identifier that is referenced on the appropriate

- safety data sheet (the list may be compiled for the workplace as a whole or for individual work areas); and
- (b) The methods the employer will use to inform employees of the hazards of nonroutine tasks (for example, the cleaning of reactor vessels), and the hazards associated with chemicals contained in unlabeled pipes in their work areas
- (2) Multi-employer workplaces. Employers who produce, use, or store hazardous chemicals at a workplace in such a way that the employees of other employer(s) may be exposed (for example, employees of a construction contractor working on-site) must additionally ensure that the hazard communication programs developed and implemented under this section include the following:
- (a) The methods the employer will use to provide the other employer(s) on-site access to safety data sheets for each hazardous chemical the other employer(s)' employees may be exposed to while working;
- (b) The methods the employer will use to inform the other employer(s) of any precautionary measures that need to be taken to protect employees during the workplace's normal operating conditions and in foreseeable emergencies; and
- (c) The methods the employer will use to inform the other employer(s) of the labeling system used in the workplace.
- (3) The employer may rely on an existing hazard communication program to comply with these requirements, provided that it meets the criteria established in this section.
- (4) The employer must make the written hazard communication program available, upon request, to employees, their designated representatives, the department according to the requirements of this section.
- (5) Where employees must travel between workplaces during a workshift, i.e., their work is carried out at more than one geographical location, the written hazard communication program may be kept at the primary workplace facility.

NEW SECTION

WAC 296-901-14012 Labels and other forms of warning. (1) Labels on shipped containers. The chemical manufacturer, importer, or distributor must ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked. Hazards not otherwise classified do not have to be addressed on the container. Where the chemical manufacturer or importer is required to label, tag or mark the following information must be provided:

- (a) Product identifier;
- (b) Signal word;
- (c) Hazard statement(s);
- (d) Pictogram(s);
- (e) Precautionary statement(s); and
- (f) Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party.
- (2) The chemical manufacturer, importer, or distributor must ensure that the information provided under subsection (1)(a) through (e) of this section is in accordance with WAC 296-901-14026, Appendix C—Allocation of label elements, for each hazard class and associated hazard category for the

[95] Permanent

hazardous chemical, prominently displayed, and in English (other languages may also be included if appropriate).

- (3) The chemical manufacturer, importer, or distributor must ensure that the information provided under subsection (1)(b) through (d) of this section is located together on the label, tag, or mark.
 - (4) Solid materials.
- (a) For solid metal (such as a steel beam or a metal casting), solid wood, or plastic items that are not exempted as articles due to their downstream use, or shipments of whole grain, the required label may be transmitted to the customer at the time of the initial shipment, and need not be included with subsequent shipments to the same employer unless the information on the label changes;
- (b) The label may be transmitted with the initial shipment itself, or with the safety data sheet that is to be provided prior to or at the time of the first shipment; and
- (c) This exception to requiring labels on every container of hazardous chemicals is only for the solid material itself, and does not apply to hazardous chemicals used in conjunction with, or known to be present with, the material and to which employees handling the items in transit may be exposed (for example, cutting fluids or pesticides in grains).
- (5) Chemical manufacturers, importers, or distributors must ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked in accordance with this section in a manner which does not conflict with the requirements of the Hazardous Materials Transportation Act (49 U.S.C. 1801 *et seq.*) and regulations issued under that act by the Department of Transportation.
- (6) Workplace labeling. Except as provided in subsection (7) and (8) of this section, the employer must ensure that each container of hazardous chemicals in the workplace is labeled, tagged or marked with either:
- (a) The information specified under subsection (1)(a) through (d) of this section for labels on shipped containers; or
- (b) Product identifier and words, pictures, symbols, or combination thereof, which provide at least general information regarding the hazards of the chemicals, and which, in conjunction with the other information immediately available to employees under the hazard communication program, will provide employees with the specific information regarding the physical and health hazards of the hazardous chemical.
- (7) The employer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys the information required under subsection (6) of this section to be on a label. The employer must ensure the written materials are readily accessible to the employees in their work area throughout each work shift.
- (8) The employer is not required to label portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer. For purposes of this section, drugs which are dispensed by a pharmacy to a health care provider for direct administration to a patient are exempted from labeling.

- (9) The employer must not remove or deface existing labels on incoming containers of hazardous chemicals, unless the container is immediately marked with the required information.
- (10) The employer must ensure that workplace labels or other forms of warning are legible, in English, and prominently displayed on the container, or readily available in the work area throughout each work shift. Employers having employees who speak other languages may add the information in their language to the material presented, as long as the information is presented in English as well.
- (11) Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical must revise the labels for the chemical within six months of becoming aware of the new information, and must ensure that labels on containers of hazardous chemicals shipped after that time contain the new information. If the chemical is not currently produced or imported, the chemical manufacturer, importer, distributor, or employer must add the information to the label before the chemical is shipped or introduced into the workplace again.

NEW SECTION

- WAC 296-901-14014 Safety data sheets. (1) Chemical manufacturers and importers must obtain or develop a safety data sheet for each hazardous chemical they produce or import. Employers must have a safety data sheet in the workplace for each hazardous chemical which they use.
- (2) The chemical manufacturer or importer preparing the safety data sheet must ensure that it is in English (although the employer may maintain copies in other languages as well), and includes at least the following section numbers and headings, and associated information under each heading, in the order listed (see WAC 296-901-14028, Appendix D—Safety data sheets, for the specific content of each section of the safety data sheet):
 - (a) Section 1, Identification;
 - (b) Section 2, Hazard(s) identification;
 - (c) Section 3, Composition/information on ingredients;
 - (d) Section 4, First-aid measures;
 - (e) Section 5, Firefighting measures;
 - (f) Section 6, Accidental release measures;
 - (g) Section 7, Handling and storage;
 - (h) Section 8, Exposure controls/personal protection;
 - (i) Section 9, Physical and chemical properties;
 - (i) Section 10, Stability and reactivity;
 - (k) Section 11, Toxicological information;
 - (l) Section 12, Ecological information;
 - (m) Section 13, Disposal considerations;
 - (n) Section 14, Transport information;
 - (o) Section 15, Regulatory information; and
- (p) Section 16, Other information, including date of preparation or last revision.

Note 1 to WAC 296-901-14014(2): To be consistent with the GHS, an SDS must also include the headings in WAC 296-901-14014 (2)(m) through (o) in order.

Note 2 to WAC 296-901-14014(2): The department will not be enforcing information requirements in SDS sections

Permanent [96]

- 12 through 15 (WAC 296-901-14014 (2)(l) through (o), as these areas are not under its jurisdiction.
- (3) If no relevant information is found for any subheading within a section on the safety data sheet, the chemical manufacturer, importer or employer preparing the safety data sheet must mark it to indicate that no applicable information was found.
- (4) Where complex mixtures have similar hazards and contents (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture), the chemical manufacturer, importer or employer may prepare one safety data sheet to apply to all of these similar mixtures.
- (5) The chemical manufacturer, importer or employer preparing the safety data sheet must ensure that the information provided accurately reflects the scientific evidence used in making the hazard classification. If the chemical manufacturer, importer or employer preparing the safety data sheet becomes newly aware of any significant information regarding the hazards of a chemical, or ways to protect against the hazards, this new information must be added to the safety data sheet within three months. If the chemical is not currently being produced or imported, the chemical manufacturer or importer must add the information to the safety data sheet before the chemical is introduced into the workplace again.
- (a) Chemical manufacturers or importers must ensure that distributors and employers are provided an appropriate safety data sheet with their initial shipment, and with the first shipment after a safety data sheet is updated;
- (b) The chemical manufacturer or importer must either provide safety data sheets with the shipped containers or send them to the distributor or employer prior to or at the time of the shipment;
- (c) If the safety data sheet is not provided with a shipment that has been labeled as a hazardous chemical, the distributor or employer must obtain one from the chemical manufacturer or importer as soon as possible; and
- (d) The chemical manufacturer or importer must also provide distributors or employers with a safety data sheet upon request.
- (6) Distributors must ensure that safety data sheets, and updated information, are provided to other distributors and employers with their initial shipment and with the first shipment after a safety data sheet is updated.
- (a) The distributor must either provide safety data sheets with the shipped containers, or send them to the other distributor or employer prior to or at the time of the shipment;
- (b) Retail distributors selling hazardous chemicals to employers having a commercial account must provide a safety data sheet to such employers upon request, and must post a sign or otherwise inform them that a safety data sheet is available;
- (c) Wholesale distributors selling hazardous chemicals to employers over-the-counter may also provide safety data sheets upon the request of the employer at the time of the over-the-counter purchase, and must post a sign or otherwise inform such employers that a safety data sheet is available;
- (d) If an employer without a commercial account purchases a hazardous chemical from a retail distributor not

- required to have safety data sheets on file (i.e., the retail distributor does not have commercial accounts and does not use the materials), the retail distributor must provide the employer, upon request, with the name, address, and telephone number of the chemical manufacturer, importer, or distributor from which a safety data sheet can be obtained;
- (e) Wholesale distributors must also provide safety data sheets to employers or other distributors upon request; and
- (f) Chemical manufacturers, importers, and distributors need not provide safety data sheets to retail distributors that have informed them that the retail distributor does not sell the product to commercial accounts or open the sealed container to use it in their own workplaces.
- (7) The employer must maintain in the workplace copies of the required safety data sheets for each hazardous chemical, and must ensure that they are readily accessible during each work shift to employees when they are in their work area(s). (Electronic access and other alternatives to maintaining paper copies of the safety data sheets are permitted as long as no barriers to immediate employee access in each workplace are created by such options.)
- (8) Where employees must travel between workplaces during a workshift, i.e., their work is carried out at more than one geographical location, the material safety data sheets may be kept at the primary workplace facility. In this situation, the employer must ensure that employees can immediately obtain the required information in an emergency.
- (9) Safety data sheets may be kept in any form, including operating procedures, and may be designed to cover groups of hazardous chemicals in a work area where it may be more appropriate to address the hazards of a process rather than individual hazardous chemicals. However, the employer must ensure that in all cases the required information is provided for each hazardous chemical, and is readily accessible during each work shift to employees when they are in their work area(s).
- (10) Safety data sheets must also be made readily available, upon request, to designated representatives, and the department in accordance with the requirements of WAC 296-901-14010.
- (11) The department of labor and industries will translate certain chemical hazard communication documents upon receipt of written or verbal request (within available resources) to employers or the public, a translation into Cambodian, Chinese, Korean, Spanish, or Vietnamese of any of the following:
- An employer's written Chemical Hazard Communication Program;
 - · A material safety data sheet; or
- Written materials prepared by the department to inform employees of their rights described in this rule, regarding chemical hazard communication.

Note: Written request for translations must be directed to:

Department of Labor and Industries Right-To-Know Program P.O. Box 44610 Olympia, WA 98504-4610

[97] Permanent

NEW SECTION

WAC 296-901-14016 Employee information and training. (1) Employers must provide employees with effective information and training on hazardous chemicals in their work area at the time of their initial assignment, and whenever a new chemical hazard the employees have not previously been trained about is introduced into their work area. Information and training may be designed to cover categories of hazards (e.g., flammability, carcinogenicity) or specific chemicals. Chemical-specific information must always be available through labels and safety data sheets.

- (2) *Information*. Employees must be informed of:
- (a) The requirements of this section;
- (b) Any operations in their work area where hazardous chemicals are present; and
- (c) The location and availability of the written hazard communication program, including the required list(s) of hazardous chemicals, and safety data sheets required by this section.
 - (3) Training. Employee training must include at least:
- (a) Methods and observations that may be used to detect the presence or release of a hazardous chemical in the work area (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.);
- (b) The physical, health, simple asphyxiation, combustible dust, and pyrophoric gas hazards, as well as hazards not otherwise classified, of the chemicals in the work area;
- (c) The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used; and
- (d) The details of the hazard communication program developed by the employer, including an explanation of the labels received on shipped containers and the workplace labeling system used by their employer; the safety data sheet, including the order of information and how employees can obtain and use the appropriate hazard information.

Note:

You must make the written Chemical Hazard Communication Program available, upon request, to employees, their designated representatives, the department, and NIOSH, in accordance with the requirements of chapter 296-802 WAC, Employee medical and exposure records.

NEW SECTION

WAC 296-901-14018 Trade secrets. (1) The chemical manufacturer, importer, or employer may withhold the specific chemical identity, including the chemical name, other specific identification of a hazardous chemical, or the exact percentage (concentration) of the substance in a mixture, from the safety data sheet, provided that:

- (a) The claim that the information withheld is a trade secret can be supported;
- (b) Information contained in the safety data sheet concerning the properties and effects of the hazardous chemical is disclosed:

- (c) The safety data sheet indicates that the specific chemical identity and/or percentage of composition is being withheld as a trade secret; and
- (d) The specific chemical identity and percentage is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of this section.
- (2) Where a treating physician or nurse determines that a medical emergency exists and the specific chemical identity and/or specific percentage of composition of a hazardous chemical is necessary for emergency or first-aid treatment, the chemical manufacturer, importer, or employer must immediately disclose the specific chemical identity or percentage composition of a trade secret chemical to that treating physician or nurse, regardless of the existence of a written statement of need or a confidentiality agreement. The chemical manufacturer, importer, or employer may require a written statement of need and confidentiality agreement, in accordance with the provisions of subsections (3) and (4) of this section, as soon as circumstances permit.
- (3) In nonemergency situations, a chemical manufacturer, importer, or employer must, upon request, disclose a specific chemical identity or percentage composition, otherwise permitted to be withheld under subsection (1) of this section, to a health professional (i.e., physician, industrial hygienist, toxicologist, epidemiologist, or occupational health nurse) providing medical or other occupational health services to exposed employee(s), and to employees or designated representatives, if:
 - (a) The request is in writing;
- (b) The request describes with reasonable detail one or more of the following occupational health needs for the information:
- (i) To assess the hazards of the chemicals to which employees will be exposed;
- (ii) To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels;
- (iii) To conduct preassignment or periodic medical surveillance of exposed employees;
- (iv) To provide medical treatment to exposed employees;
- (v) To select or assess appropriate personal protective equipment for exposed employees;
- (vi) To design or assess engineering controls or other protective measures for exposed employees; and
- (vii) To conduct studies to determine the health effects of exposure.
- (c) The request explains in detail why the disclosure of the specific chemical identity or percentage composition is essential and that, in lieu thereof, the disclosure of the following information to the health professional, employee, or designated representative, would not satisfy the purposes described in (b) of this subsection:
 - (i) The properties and effects of the chemical;
- (ii) Measures for controlling workers' exposure to the chemical;
- (iii) Methods of monitoring and analyzing worker exposure to the chemical; and
- (iv) Methods of diagnosing and treating harmful exposures to the chemical.

Permanent [98]

- (d) The request includes a description of the procedures to be used to maintain the confidentiality of the disclosed information; and
- (e) The health professional, and the employer or contractor of the services of the health professional (i.e., downstream employer, labor organization, or individual employee), employee, or designated representative, agree in a written confidentiality agreement that the health professional, employee, or designated representative, will not use the trade secret information for any purpose other than the health need(s) asserted and agree not to release the information under any circumstances other than to the department, as provided in subsection (6) of this section, except as authorized by the terms of the agreement or by the chemical manufacturer, importer, or employer.
- (4) The confidentiality agreement authorized under subsection (3)(d) of this section:
- (a) May restrict the use of the information to the health purposes indicated in the written statement of need;
- (b) May provide for appropriate legal remedies in the event of a breach of the agreement, including stipulation of a reasonable preestimate of likely damages; and
- (c) May not include requirements for the posting of a penalty bond.
- (5) Nothing in this standard is meant to preclude the parties from pursuing noncontractual remedies to the extent permitted by law.
- (6) If the health professional, employee, or designated representative receiving the trade secret information decides that there is a need to disclose it to the department, the chemical manufacturer, importer, or employer who provided the information must be informed by the health professional, employee, or designated representative prior to, or at the same time as, such disclosure.
- (7) If the chemical manufacturer, importer, or employer denies a written request for disclosure of a specific chemical identity or percentage composition, the denial must:
- (a) Be provided to the health professional, employee, or designated representative, within thirty days of the request;
 - (b) Be in writing;
- (c) Include evidence to support the claim that the specific chemical identity or percent of composition is a trade secret;
- (d) State the specific reasons why the request is being denied; and
- (e) Explain in detail how alternative information may satisfy the specific medical or occupational health need without revealing the trade secret.
- (8) The health professional, employee, or designated representative whose request for information is denied under subsection (3) of this section may refer the request and the written denial of the request to the department for consideration.
- (9) When a health professional, employee, or designated representative refers the denial to the department under subsection (8) of this section, the department must consider the evidence to determine if:
- (a) The chemical manufacturer, importer, or employer has supported the claim that the specific chemical identity or percentage composition is a trade secret;

- (b) The health professional, employee, or designated representative has supported the claim that there is a medical or occupational health need for the information; and
- (c) The health professional, employee, or designated representative has demonstrated adequate means to protect the confidentiality.
- (10) If the department determines that the specific chemical identity or percentage composition requested under subsection (3) of this section is not a "bona fide" trade secret, or that it is a trade secret, but the requesting health professional, employee, or designated representative has a legitimate medical or occupational health need for the information, has executed a written confidentiality agreement, and has shown adequate means to protect the confidentiality of the information, the chemical manufacturer, importer, or employer will be subject to citation by DOSH.

If a chemical manufacturer, importer, or employer demonstrates to the department that the execution of a confidentiality agreement would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret, the department may issue such orders or impose such additional limitations or conditions upon the disclosure of the requested chemical information as may be appropriate to assure that the occupational health services are provided without an undue risk of harm to the chemical manufacturer, importer, or employer.

- (11) A chemical manufacturer, importer, or employer may appeal a citation for a failure to release trade secret information according to WAC 296-900-170.
- (12) Notwithstanding the existence of a trade secret claim, a chemical manufacturer, importer, or employer must, upon request, disclose to the department any information which this section requires the chemical manufacturer, importer, or employer to make available. Where there is a trade secret claim, such claim must be made no later than at the time the information is provided to the department so that suitable determinations of trade secret status can be made and the necessary protections can be implemented.
- (13) Nothing in this subsection must be construed as requiring the disclosure under any circumstances of process information which is a trade secret.

NEW SECTION

- WAC 296-901-14020 Effective dates. (1) During the transition period between the adoption date of this rule and the effective dates listed below, employers may comply with the applicable requirements in the employer chemical hazard communication standards under WAC 296-800-170 and chapter 296-307 WAC, Part Y-1, or the requirements of this section, or both.
- (2) During the transition period between the adoption date of this rule and the effective dates listed below, chemical manufacturers, importers, and distributors may comply with the applicable requirements of chapter 296-816 WAC, Protecting trade secrets, chapter 296-62 WAC, Part B-1, Trade secrets, chapter 296-839 WAC, Content and distribution of material safety data sheets (MSDSs) and label information, chapter 296-307 WAC, Part Y-2, Material safety data sheets

[99] Permanent

and label preparation, or the requirements of this section, or both

- (3) Employers must train employees regarding the new label elements and safety data sheets format by June 1, 2014.
- (4) Employers, chemical manufacturers, importers, and distributors must be in compliance with all provisions of this section no later than June 1, 2015, except:
- (a) After December 1, 2015, the distributor must not ship containers labeled by the chemical manufacturer or importer unless the label has been modified to comply with WAC 296-901-14012(1).
- (b) All employers must, as necessary, update any alternative workplace labeling used under WAC 296-901-14012(6), update the hazard communication program required by WAC 296-901-14016(1), and provide any additional employee training in accordance with WAC 296-901-14016(3) for newly identified physical or health hazards no later than June 1, 2016.

NEW SECTION

WAC 296-901-14022 Appendix A—Health hazard criteria.

A.0 GENERAL CLASSIFICATION CONSIDERATIONS

A.0.1 Classification

- A.0.1.1 The term "hazard classification" is used to indicate that only the intrinsic hazardous properties of chemicals are considered. Hazard classification incorporates three steps:
- (a) identification of relevant data regarding the hazards of a chemical;
- (b) subsequent review of those data to ascertain the hazards associated with the chemical;
- (c) determination of whether the chemical will be classified as hazardous and the degree of hazard.
- A.0.1.2 For many hazard classes, the criteria are semi quantitative or qualitative and expert judgment is required to interpret the data for classification purposes.
- A.0.2 Available data, test methods and test data quality
- A.0.2.1 There is no requirement for testing chemicals.
- A.0.2.2 The criteria for determining health hazards are test method neutral, i.e., they do not specify particular test methods, as long as the methods are scientifically validated.
- A.0.2.3 The term "scientifically validated" refers to the process by which the reliability and the relevance of a procedure are established for a particular purpose. Any test that determines hazardous properties, which is conducted according to recognized scientific principles, can be used for purposes of a hazard determination for health hazards. Test conditions need to be standardized so that the results are reproducible with a given substance, and the standardized test yields "valid" data for defining the hazard class of concern.
- A.0.2.4 Existing test data are acceptable for classifying chemicals, although expert judgment also may be needed for classification purposes.

- A.0.2.5 The effect of a chemical on biological systems is influenced, by the physico-chemical properties of the substance and/or ingredients of the mixture and the way in which ingredient substances are biologically available. A chemical need not be classified when it can be shown by conclusive experimental data from scientifically validated test methods that the chemical is not biologically available.
- A.0.2.6 For classification purposes, epidemiological data and experience on the effects of chemicals on humans (e.g., occupational data, data from accident databases) shall be taken into account in the evaluation of human health hazards of a chemical.

A.0.3 Classification based on weight of evidence

- A.0.3.1 For some hazard classes, classification results directly when the data satisfy the criteria. For others, classification of a chemical shall be determined on the basis of the total weight of evidence using expert judgment. This means that all available information bearing on the classification of hazard shall be considered together, including the results of valid in vitro tests, relevant animal data, and human experience such as epidemiological and clinical studies and well-documented case reports and observations.
- A.0.3.2 The quality and consistency of the data shall be considered. Information on chemicals related to the material being classified shall be considered as appropriate, as well as site of action and mechanism or mode of action study results. Both positive and negative results shall be considered together in a single weight-of-evidence determination.
- A.0.3.3 Positive effects which are consistent with the criteria for classification, whether seen in humans or animals, shall normally justify classification. Where evidence is available from both humans and animals and there is a conflict between the findings, the quality and reliability of the evidence from both sources shall be evaluated in order to resolve the question of classification. Reliable, good quality human data shall generally have precedence over other data. However, even well-designed and conducted epidemiological studies may lack a sufficient number of subjects to detect relatively rare but still significant effects, or to assess potentially confounding factors. Therefore, positive results from well-conducted animal studies are not necessarily negated by the lack of positive human experience but require an assessment of the robustness, quality and statistical power of both the human and animal data.
- A.0.3.4 Route of exposure, mechanistic information, and metabolism studies are pertinent to determining the relevance of an effect in humans. When such information raises doubt about relevance in humans, a lower classification may be warranted. When there is scientific evidence demonstrating that the mechanism or mode of action is not relevant to humans, the chemical should not be classified.
- A.0.3.5 Both positive and negative results are considered together in the weight of evidence determination. However, a single positive study performed according to good scientific principles and with statistically and biologically significant positive results may justify classification.

Permanent [100]

A.0.4 Considerations for the classification of mixtures

- A.0.4.1 For most hazard classes, the recommended process of classification of mixtures is based on the following sequence:
- (a) Where test data are available for the complete mixture, the classification of the mixture will always be based on those data:
- (b) Where test data are not available for the mixture itself, the bridging principles designated in each health hazard chapter of this appendix shall be considered for classification of the mixture:
- (c) If test data are not available for the mixture itself, and the available information is not sufficient to allow application of the above-mentioned bridging principles, then the method(s) described in each chapter for estimating the hazards based on the information known will be applied to classify the mixture (e.g., application of cut-off values/concentration limits).
- A.0.4.2 An exception to the above order or precedence is made for Carcinogenicity, Germ Cell Mutagenicity, and Reproductive Toxicity. For these three hazard classes, mixtures shall be classified based upon information on the ingredient substances, unless on a case-by-case basis, justification can be provided for classifying based upon the mixture as a whole. See chapters A.5, A.6, and A.7 for further information on case-by-case bases.

A.0.4.3 Use of cut-off values/concentration limits

A.0.4.3.1 When classifying an untested mixture based on the hazards of its ingredients, cut-off values/concentration limits for the classified ingredients of the mixture are used for several hazard classes. While the adopted cut-off values/concentration limits adequately identify the hazard for most mixtures, there may be some that contain hazardous ingredients at lower concentrations than the specified cut-off values/concentration limits that still pose an identifiable hazard. There may also be cases where the cut-off value/concentration limit is considerably lower than the established non-hazardous level for an ingredient.

A.0.4.3.2 If the classifier has information that the hazard of an ingredient will be evident (i.e., it presents a health risk) below the specified cut-off value/concentration limit, the mixture containing that ingredient shall be classified accordingly.

A.0.4.3.3 In exceptional cases, conclusive data may demonstrate that the hazard of an ingredient will not be evident (i.e., it does not present a health risk) when present at a level above the specified cut-off value/concentration limit(s). In these cases the mixture may be classified according to those data. The data must exclude the possibility that the ingredient will behave in the mixture in a manner that would increase the hazard over that of the pure substance. Furthermore, the mixture must not contain ingredients that would affect that determination.

A.0.4.4 Synergistic or antagonistic effects

When performing an assessment in accordance with these requirements, the evaluator must take into account all available information about the potential occurrence of synergistic effects among the ingredients of the mixture. Lowering classification of a mixture to a less hazardous category on the basis of antagonistic effects may be done only if the determination is supported by sufficient data.

A.0.5 Bridging principles for the classification of mixtures where test data are not available for the complete mixture.

A.0.5.1 Where the mixture itself has not been tested to determine its toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles, subject to any specific provisions for mixtures for each hazard class. These principles ensure that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture.

A.0.5.1.1 Dilution

For mixtures classified in accordance with A.1 through A.10 of this Appendix, if a tested mixture is diluted with a diluent that has an equivalent or lower toxicity classification than the least toxic original ingredient, and which is not expected to affect the toxicity of other ingredients, then:

- (a) the new diluted mixture shall be classified as equivalent to the original tested mixture; or
- (b) for classification of acute toxicity in accordance with A.1 of this Appendix, paragraph A.1.3.6 (the additivity formula) shall be applied.

A.0.5.1.2 Batching

For mixtures classified in accordance with A.1 through A.10 of this Appendix, the toxicity of a tested production batch of a mixture can be assumed to be substantially equivalent to that of another untested production batch of the same mixture, when produced by or under the control of the same chemical manufacturer, unless there is reason to believe there is significant variation such that the toxicity of the untested batch has changed. If the latter occurs, a new classification is necessary.

A.0.5.1.3 Concentration of mixtures

For mixtures classified in accordance with A.1, A.2, A.3, A.8, A.9, or A.10 of this Appendix, if a tested mixture is classified in Category 1, and the concentration of the ingredients of the tested mixture that are in Category 1 is increased, the resulting untested mixture shall be classified in Category 1.

A.0.5.1.4 Interpolation within one toxicity category

For mixtures classified in accordance with A.1, A.2, A.3, A.8, A.9, or A.10 of this Appendix, for three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same toxicity category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same toxicity category as A and B.

A.0.5.1.5 Substantially similar mixtures

For mixtures classified in accordance with A.1 through A.10 of this Appendix, given the following set of conditions:

(a) Where there are two mixtures:

[101] Permanent

- (i) A + B:
- (b) the concentration of ingredient B is essentially the same in both mixtures;
- (c) the concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);
- (d) and data on toxicity for A and C are available and substantially equivalent; i.e., they are in the same hazard category and are not expected to affect the toxicity of B; then

If mixture (i) or (ii) is already classified based on test data, the other mixture can be assigned the same hazard category.

A.0.5.1.6 Aerosols

For mixtures classified in accordance with A.1, A.2, A.3, A.4, A.8, or A.9 of this Appendix, an aerosol form of a mixture shall be classified in the same hazard category as the tested, non-aerosolized form of the mixture, provided the added propellant does not affect the toxicity of the mixture when spraying.

A.1 ACUTE TOXICITY

A.1.1 Definition

Acute toxicity refers to those adverse effects occurring following oral or dermal administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours.

A.1.2 Classification criteria for substances

A.1.2.1 Substances can be allocated to one of four toxicity categories based on acute toxicity by the oral, dermal or inhalation route according to the numeric cut-off criteria as shown in Table A.1.1. Acute toxicity values are expressed as (approximate) LD50 (oral, dermal) or LC50 (inhalation) values or as acute toxicity estimates (ATE). See the footnotes following Table A.1.1 for further explanation on the application of these values.

Table A.1.1: Acute toxicity hazard categories and acute toxicity estimate (ATE) values defining the respective categories

Exposure route	Category 1	Category 2	Category 3	Category 4
Oral (mg/kg bodyweight) see:	≤5	>5 and ≤50	>50 and ≤300	>300 and ≤2000
Note (a)				
Note (b)				
Dermal (mg/kg bodyweight) see:	≤5	>50 and ≤200	>200 and ≤1000	>1000 and ≤2000
Note (a)				
Note (b)				
Inhalation - Gases (ppmV) see:	≤100	>100 and ≤500	>500 and ≤2500	>2500 and ≤20000
Note (a)				
Note (b)				
Note (c)				
Inhalation - Vapors (mg/l) see:	≤0.5	>0.5 and ≤2.0	>2.0 and ≤10.0	>10.0 and ≤20.0
Note (a)				
Note (b)				
Note (c)				
Note (d)				
Inhalation - Dusts and Mists (mg/l) see:	≤0.05	>0.05 and ≤0.5	>0.5 and ≤1.0	>1.0 and ≤5.0
Note (a)				
Note (b)				
Note (c)				

Note: Gas concentrations are expressed in parts per million per volume (ppmV).

Notes to Table A.1.1:

- (a) The acute toxicity estimate (ATE) for the classification of a substance is derived using the LD50/LC50 where available;
- (b) The acute toxicity estimate (ATE) for the classification of a substance or ingredient in a mixture is derived using:
 - (i) the LD50/LC50 where available. Otherwise,
- (ii) the appropriate conversion value from Table 1.2 that relates to the results of a range test, or
- (iii) the appropriate conversion value from Table 1.2 that relates to a classification category;
- (c) Inhalation cut-off values in the table are based on 4 hour testing exposures. Conversion of existing inhalation toxicity data which has been generated according to 1 hour

exposure is achieved by dividing by a factor of 2 for gases and vapors and 4 for dusts and mists;

(d) For some substances the test atmosphere will be a vapor which consists of a combination of liquid and gaseous phases. For other substances the test atmosphere may consist of a vapor which is nearly all the gaseous phase. In these latter cases, classification is based on ppmV as follows: Category 1 (100 ppmV), Category 2 (500 ppmV), Category 3 (2500 ppmV), Category 4 (20000 ppmV).

The terms "dust", "mist" and "vapor" are defined as follows:

- (i) Dust: solid particles of a substance or mixture suspended in a gas (usually air);
- (ii) Mist: liquid droplets of a substance or mixture suspended in a gas (usually air);
- (iii) Vapor: the gaseous form of a substance or mixture released from its liquid or solid state.

Permanent [102]

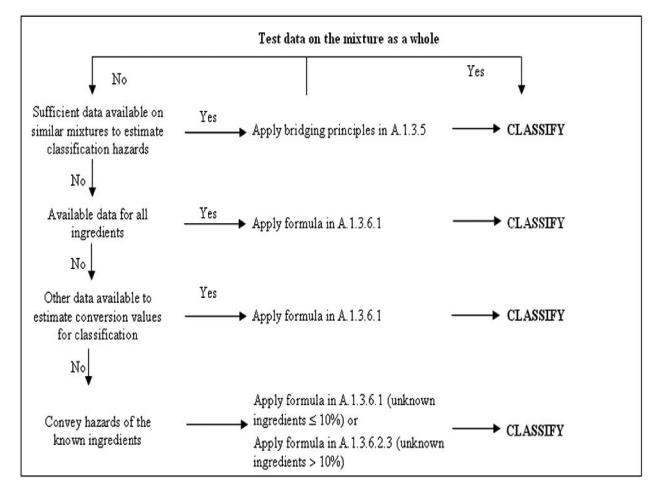
A.1.2.3 The preferred test species for evaluation of acute toxicity by the oral and inhalation routes is the rat, while the rat or rabbit are preferred for evaluation of acute dermal toxicity. Test data already generated for the classification of chemicals under existing systems should be accepted when reclassifying these chemicals under the harmonized system. When experimental data for acute toxicity are available in several animal species, scientific judgment should be used in select-

ing the most appropriate LD50 value from among scientifically validated tests.

A.1.3 Classification criteria for mixtures

A.1.3.1 The approach to classification of mixtures for acute toxicity is tiered, and is dependent upon the amount of information available for the mixture itself and for its ingredients. The flow chart of Figure A.1.1 indicates the process that must be followed:

Figure A.1.1: Tiered approach to classification of mixtures for acute toxicity



- A.1.3.2 Classification of mixtures for acute toxicity may be carried out for each route of exposure, but is only required for one route of exposure as long as this route is followed (estimated or tested) for all ingredients and there is no relevant evidence to suggest acute toxicity by multiple routes. When there is relevant evidence of acute toxicity by multiple routes of exposure, classification is to be conducted for all appropriate routes of exposure. All available information shall be considered. The pictogram and signal word used shall reflect the most severe hazard category; and all relevant hazard statements shall be used.
- A.1.3.3 For purposes of classifying the hazards of mixtures in the tiered approach:
- (a) The "relevant ingredients" of a mixture are those which are present in concentrations $\geq 1\%$ (weight/weight for
- solids, liquids, dusts, mists and vapors and volume/volume for gases). If there is reason to suspect that an ingredient present at a concentration < 1% will affect classification of the mixture for acute toxicity, that ingredient shall also be considered relevant. Consideration of ingredients present at a concentration < 1% is particularly important when classifying untested mixtures which contain ingredients that are classified in Category 1 and Category 2;
- (b) Where a classified mixture is used as an ingredient of another mixture, the actual or derived acute toxicity estimate (ATE) for that mixture is used when calculating the classification of the new mixture using the formulas in A.1.3.6.1 and A.1.3.6.2.4.

Permanent

- (c) If the converted acute toxicity point estimates for all ingredients of a mixture are within the same category, then the mixture should be classified in that category.
- (d) When only range data (or acute toxicity hazard category information) are available for ingredients in a mixture, they may be converted to point estimates in accordance with Table A.1.2 when calculating the classification of the new mixture using the formulas in A.1.3.6.1 and A.1.3.6.2.4.
- A.1.3.4 Classification of mixtures where acute toxicity test data are available for the complete mixture

Where the mixture itself has been tested to determine its acute toxicity, it is classified according to the same criteria as those used for substances, presented in Table A.1.1. If test data for the mixture are not available, the procedures presented below must be followed.

- A.1.3.5 Classification of mixtures where acute toxicity test data are not available for the complete mixture: bridging principles
- A.1.3.5.1 Where the mixture itself has not been tested to determine its acute toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one toxicity category, Substantially similar mixtures, and Aerosols.
- A.1.3.6 Classification of mixtures based on ingredients of the mixture (additivity formula)
- A.1.3.6.1 Data available for all ingredients

The acute toxicity estimate (ATE) of ingredients is considered as follows:

- (a) Include ingredients with a known acute toxicity, which fall into any of the acute toxicity categories, or have an oral or dermal LD50 greater than 2000 but less than or equal to 5000 mg/kg body weight (or the equivalent dose for inhalation);
- (b) Ignore ingredients that are presumed not acutely toxic (e.g., water, sugar);
- (c) Ignore ingredients if the data available are from a limit dose test (at the upper threshold for Category 4 for the appropriate route of exposure as provided in Table A.1.1) and do not show acute toxicity.

Ingredients that fall within the scope of this paragraph are considered to be ingredients with a known acute toxicity estimate (ATE). See note (b) to Table A.1.1 and paragraph A.1.3.3 for appropriate application of available data to the equation below, and paragraph A.1.3.6.2.4.

The ATE of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula below for oral, dermal or inhalation toxicity:

The ATE of the Mixture 2

$$\frac{100}{\text{ATEmix}} = \sum_{n} \frac{\text{Ci}}{\text{ATE}_{i}}$$

where:

Ci = concentration of ingredient i n ingredients and i is running from 1 to n ATEi = acute toxicity estimate of ingredient i.

- A.1.3.6.2 Data are not available for one or more ingredients of the mixture
- A.1.3.6.2.1 Where an ATE is not available for an individual ingredient of the mixture, but available information provides a derived conversion value, the formula in A.1.3.6.1 may be applied. This information may include evaluation of:
- (a) Extrapolation between oral, dermal and inhalation acute toxicity estimates. Such an evaluation requires appropriate pharmacodynamic and pharmacokinetic data;
- (b) Evidence from human exposure that indicates toxic effects but does not provide lethal dose data;
- (c) Evidence from any other toxicity tests/assays available on the substance that indicates toxic acute effects but does not necessarily provide lethal dose data; or
- (d) Data from closely analogous substances using structure/activity relationships.
- A.1.3.6.2.2 This approach requires substantial supplemental technical information, and a highly trained and experienced expert, to reliably estimate acute toxicity. If sufficient information is not available to reliably estimate acute toxicity, proceed to the provisions of A.1.3.6.2.3.
- A.1.3.6.2.3 In the event that an ingredient with unknown acute toxicity is used in a mixture at a concentration $\geq 1\%$, and the mixture has not been classified based on testing of the mixture as a whole, the mixture cannot be attributed a definitive acute toxicity estimate. In this situation the mixture is classified based on the known ingredients only. (Note: A statement that x percent of the mixture consists of ingredient(s) of unknown toxicity is required on the label and safety data sheet in such cases; see Appendix C, Allocation of Label Elements and Appendix D, Safety Data Sheets.)

Where an ingredient with unknown acute toxicity is used in a mixture at a concentration $\geq 1\%$, and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity is required on the label and safety data sheet in such cases; see Appendix C, Allocation of Label Elements and Appendix D, Safety Data Sheets.)

A.1.3.6.2.4 If the total concentration of the relevant ingredient(s) with unknown acute toxicity is $\leq 10\%$ then the formula presented in A.1.3.6.1 must be used. If the total concentration of the relevant ingredient(s) with unknown acute toxicity is < 10%, the formula presented in A.1.3.6.1 is corrected to adjust for the percentage of the unknown ingredient(s) as follows:

Permanent [104]

$$\frac{100 - \left(\sum C_{\text{unknown}} \text{ if } > 10\%\right)}{\text{ATE}_{\text{mix}}} = \sum_{n} \frac{C_{i}}{\text{ATE}_{i}}$$

Table A.1.2: Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for use in the formulas for the classification of mixtures

	Classificatio	Classification category or experimentally		Converted Acute Toxicity point
Exposure routes	obtained a	cute toxicity rang	e estimate	estimate
Oral	0	<category 1="" th="" ≤<=""><th>5</th><th>0.5</th></category>	5	0.5
(mg/kg bodyweight)	5	<category 2="" td="" ≤<=""><td>50</td><td>5</td></category>	50	5
	50	<category 3="" td="" ≤<=""><td>300</td><td>100</td></category>	300	100
	300	<category 4="" td="" ≤<=""><td>2000</td><td>500</td></category>	2000	500
Dermal	0	<category 1="" td="" ≤<=""><td>50</td><td>5</td></category>	50	5
(mg/kg bodyweight)	50	<category 2="" td="" ≤<=""><td>200</td><td>50</td></category>	200	50
	200	<category 3="" td="" ≤<=""><td>1000</td><td>300</td></category>	1000	300
	1000	<category 4="" td="" ≤<=""><td>2000</td><td>1100</td></category>	2000	1100
Gases	0	<category 1="" td="" ≤<=""><td>100</td><td>10</td></category>	100	10
(ppmV)	100	<category 2="" td="" ≤<=""><td>500</td><td>100</td></category>	500	100
	500	<category 3="" td="" ≤<=""><td>2500</td><td>700</td></category>	2500	700
	2500	<category 4="" td="" ≤<=""><td>20000</td><td>4500</td></category>	20000	4500
Vapors	0	<category 1="" td="" ≤<=""><td>0.5</td><td>0.05</td></category>	0.5	0.05
(mg/l)	0.5	<category 2="" td="" ≤<=""><td>2.0</td><td>0.5</td></category>	2.0	0.5
	2.0	<category 3="" td="" ≤<=""><td>10.0</td><td>3</td></category>	10.0	3
	10.0	<category 4="" td="" ≤<=""><td>20.0</td><td>11</td></category>	20.0	11
Dust/mist	0	<category 1="" td="" ≤<=""><td>0.05</td><td>0.005</td></category>	0.05	0.005
(mg/l)	0.05	<category 2="" td="" ≤<=""><td>0.5</td><td>0.05</td></category>	0.5	0.05
	0.5	<category 3="" td="" ≤<=""><td>1.0</td><td>0.5</td></category>	1.0	0.5
	1.0	<category 4="" td="" ≤<=""><td>5.0</td><td>1.5</td></category>	5.0	1.5

Note: Gas concentrations are expressed in parts per million per volume (ppmV).

A.2 SKIN CORROSION/IRRITATION

A.2.1 Definitions and general considerations

A.2.1.1 *Skin corrosion* is the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following the application of a test substance for up to 4 hours. Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discoloration due to blanching of the skin, complete areas of alopecia, and scars. Histopathology should be considered to evaluate questionable lesions.

Skin irritation is the production of reversible damage to the skin following the application of a test substance for up to 4 hours

A.2.1.2 Skin corrosion/irritation shall be classified using a tiered approach as detailed in figure A.2.1. Emphasis shall be placed upon existing human data (See A.0.2.6), followed by

other sources of information. Classification results directly when the data satisfy the criteria in this section. In case the criteria cannot be directly applied, classification of a substance or a mixture is made on the basis of the total weight of evidence (See A.0.3.1). This means that all available information bearing on the determination of skin corrosion/irritation is considered together, including the results of appropriate scientifically validated in-vitro tests, relevant animal data, and human data such as epidemiological and clinical studies and well-documented case reports and observations.

A.2.2 Classification criteria for substances using animal test data

A.2.2.1 Corrosion

A.2.2.1.1 A corrosive substance is a chemical that produces destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least 1 of 3 tested animals after exposure up to a 4-hour duration. Corrosive reactions are typified by ulcers, bleeding, bloody scabs and, by

[105] Permanent

the end of observation at 14 days, by discoloration due to blanching of the skin, complete areas of alopecia and scars. Histopathology should be considered to discern questionable lesions. A.2.2.1.2 Three sub-categories of Category 1 are provided in Table A.2.1, all of which shall be regulated as Category 1.

Table A.2.1: Skin corrosion category and sub-categories

Category 1: Corrosive	Corrosive sub-categories	Corrosive in ≥1 of 3 animals	
		Exposure	Observation
	1A	≤ 3 min	≤ 1 h
	1B	> 3 min ≤ 1 h	≤ 14 days
	1C	> 1 h ≤ 4 h	≤ 14 days

A.2.2.2 Irritation

A.2.2.2.1 A single irritant category (Category 2) is presented in the Table A.2.2. The major criterion for the irritant category is that at least 2 tested animals have a mean score of $\geq 2.3 \geq 4.0$.

Table A.2.2 Skin irritation category

	Criteria
Irritant (Category 2)	(1) Mean value of $\geq 2.3 \geq 4.0$ for erythema/eschar or for edema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours after patch removal or, if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions; or
	(2) Inflammation that persists to the end of the observation period normally 14 days in at least 2 animals, particularly taking into account alopecia (limited area), hyperkeratosis, hyperplasia, and scaling; or (3) In some cases where there is pronounced variability of response among animals, with very definite positive effects related to chemical exposure in a single animal but less than the criteria above.

A.2.2.2.2 Animal irritant responses within a test can be quite variable, as they are with corrosion. A separate irritant criterion accommodates cases when there is a significant irritant response but less than the mean score criterion for a positive test. For example, a substance might be designated as an irritant if at least 1 of 3 tested animals shows a very elevated mean score throughout the study, including lesions persisting at the end of an observation period of normally 14 days. Other responses could also fulfil this criterion. However, it should be ascertained that the responses are the result of chemical exposure. Addition of this criterion increases the sensitivity of the classification system.

A.2.2.2.3. Reversibility of skin lesions is another consideration in evaluating irritant responses. When inflammation persists to the end of the observation period in 2 or more test animals, taking into consideration alopecia (limited area), hyperkeratosis, hyperplasia and scaling, then a chemical should be considered to be an irritant.

A.2.3 Classification Criteria for Substances Using Other Data Elements

A.2.3.1 Existing human and animal data including information from single or repeated exposure should be the first line of analysis, as they give information directly relevant to effects on the skin. If a substance is highly toxic by the dermal route, a skin corrosion/irritation study may not be practicable since the amount of test substance to be applied would considerably exceed the toxic dose and, consequently, would result in the death of the animals. When observations are made of skin corrosion/irritation in acute toxicity studies and

are observed up through the limit dose, these data may be used for classification provided that the dilutions used and species tested are equivalent. In vitro alternatives that have been scientifically validated shall be used to make classification decisions. Solid substances (powders) may become corrosive or irritant when moistened or in contact with moist skin or mucous membranes. Likewise, pH extremes like ≤ 2 and ≥ 11.5 may indicate skin effects, especially when associated with significant buffering capacity. Generally, such substances are expected to produce significant effects on the skin. In the absence of any other information, a substance is considered corrosive (Skin Category 1) if it has a pH \leq 2 or a pH ≥ 11.5. However, if consideration of alkali/acid reserve suggests the substance or mixture may not be corrosive despite the low or high pH value, then further evaluation may be necessary. In some cases enough information may be available from structurally related compounds to make classification decisions.

A.2.3.2 A tiered approach to the evaluation of initial information shall be used (Figure A.2.1) recognizing that all elements may not be relevant in certain cases.

A.2.3.3 The tiered approach explains how to organize information on a substance and to make a weight-of-evidence decision about hazard assessment and hazard classification.

A.2.3.4 All the above information that is available on a substance shall be evaluated. Although information might be gained from the evaluation of single parameters within a tier, there is merit in considering the totality of existing information and making an overall weight of evidence determination.

Permanent [106]

This is especially true when there is information available on some but not all parameters. Emphasis shall be placed upon existing human experience and data, followed by animal experience and testing data, followed by other sources of information, but case-by-case determinations are necessary.

Figure A.2.1: Tiered evaluation of skin corrosion and irritation potential

Step	Parameter		Finding		Conclusion
la	Existing human or animal datal	→	Skin corrosive	→	Category 12
	Not corrosive or no data				
1b	Existing human or animal datal	\longrightarrow	Skin irritant	\longrightarrow	Category 2 ²
	Not an irritant or no data				
lc	Existing human or animal datal	\longrightarrow	Not a skin corrosive or skin irritant	\longrightarrow	Not classified
	No/Insufficient data		Saniman		
2:	Other, existing skin data in animals ³	\rightarrow	Skin corrosive Skin irritant	\rightarrow	Category 1 ² Category 2 ²
	No/Insufficient data				
3:	Existing skin corrosive ex vivo / in vitro data4	\longrightarrow	Positive: Skin corrosive	\longrightarrow	Category 12
	Not corrosive or no data				
	Existing skin irritation ex vivo / in vitro data4	$ egrid{}$	Positive: Skin irritant	\longrightarrow	Category 2 ²
	+	×	Negative: Not a skin irritant ⁵		Not classified
	No/Insufficient data ↓				
4:	pH-Based assessment (with consideration of buffering capacity of the chemical, or no buffering capacity data) ⁵	→	$pH \le 2$ or ≥ 11.5	→	Category 1 ²
	Not a pH extreme, No pH data or extreme pH with low/no buffering capacity				
5:	V alidated Structure/Activity Relationship (SAR) models ↓	$\overline{}$	Skin corrosive	\longrightarrow	Category 12
	No/Insufficient data	×	Skin irritant		Category 2 ²
6:	↓ Consideration of the total Weight of Evidence ⁶	\rightarrow	Skin corrosive	→	Category 12
	No concern based on consideration of the sum of available data	1	Skin irritant		Category 2 ²
7:	Not Classified		→		Not classified

[107] Permanent

Notes to Figure A.2.1:

- 1. Evidence of existing human or animal data may be derived from single or repeated exposure(s) in occupational, consumer, transportation, or emergency response scenarios; from ethically-conducted human clinical studies; or from purposely-generated data from animal studies conducted according to scientifically validated test methods (at present, there is no internationally accepted test method for human skin irritation testing).
- 2. Classify in the appropriate harmonized category, as shown in Tables A.2.1 and A.2.2.
- 3. Pre-existing animal data (e.g. from an acute dermal toxicity test or a sensitisation test) should be carefully reviewed to determine if sufficient skin corrosion/irritation evidence is available through other, similar information. For example, classification/categorization may be done on the basis of whether a chemical has or has not produced any skin irritation in an acute dermal toxicity test in animals at the limit dose, or produces very toxic effects in an acute dermal toxicity test in animals. In the latter case, the chemical would be classified as being very hazardous by the dermal route for acute toxicity, and it would be moot whether the chemical is also irritating or corrosive on the skin. It should be kept in mind in evaluating acute dermal toxicity information that the reporting of dermal lesions may be incomplete, testing and observations may be made on a species other than the rabbit, and species may differ in sensitivity in their responses.
- 4. Evidence from studies using scientifically validated protocols with isolated human/animal tissues or other, nontissue-based, though scientifically validated, protocols should be assessed. Examples of scientifically validated test methods for skin corrosion include OECD TG 430 (Transcutaneous Electrical Resistance Test (TER)), 431 (Human Skin Model Test), and 435 (Membrane Barrier Test Method). OECD TG 439 (Reconstructed Human Epidermis Test Method) is a scientifically validated in vitro test method for skin irritation.
- 5. Measurement of pH alone may be adequate, but assessment of acid or alkali reserve (buffering capacity) would be preferable. Presently, there is no scientifically validated and internationally accepted method for assessing this parameter
- 6. All information that is available on a chemical should be considered and an overall determination made on the total weight of evidence. This is especially true when there is conflict in information available on some parameters. Professional judgment should be exercised in making such a determination.
- A.2.4 Classification criteria for mixtures
- A.2.4.1 Classification of mixtures when data are available for the complete mixture
- A.2.4.1.1 The mixture shall be classified using the criteria for substances (See A.2.3).
- A.2.4.2 Classification of mixtures when data are not available for the complete mixture: bridging principles
- A.2.4.2.1 Where the mixture itself has not been tested to determine its skin corrosion/irritation, but there are sufficient

- data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles, as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one toxicity category, Substantially similar mixtures, and Aerosols.
- A.2.4.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture
- A.2.4.3.1 For purposes of classifying the skin corrosion/irritation hazards of mixtures in the tiered approach:

The "relevant ingredients" of a mixture are those which are present in concentrations > 1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases.) If the classifier has reason to suspect that an ingredient present at a concentration < 1% will affect classification of the mixture for skin corrosion/irritation, that ingredient shall also be considered relevant.

- A.2.4.3.2 In general, the approach to classification of mixtures as irritant or corrosive to skin when data are available on the ingredients, but not on the mixture as a whole, is based on the theory of additivity, such that each corrosive or irritant ingredient contributes to the overall irritant or corrosive properties of the mixture in proportion to its potency and concentration. A weighting factor of 10 is used for corrosive ingredients when they are present at a concentration below the concentration limit for classification with Category 1, but are at a concentration that will contribute to the classification of the mixture as an irritant. The mixture is classified as corrosive or irritant when the sum of the concentrations of such ingredients exceeds a cut-off value/concentration limit.
- A.2.4.3.3 Table A.2.3 below provides the cut-off value/concentration limits to be used to determine if the mixture is considered to be an irritant or a corrosive to the skin.
- A.2.4.3.4 Particular care shall be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in A.2.4.3.1 and A.2.4.3.2 might not work given that many of such substances are corrosive or irritant at concentrations < 1%. For mixtures containing strong acids or bases the pH should be used as classification criteria since pH will be a better indicator of corrosion than the concentration limits of Table A.2.3. A mixture containing corrosive or irritant ingredients that cannot be classified based on the additivity approach shown in Table A.2.3, due to chemical characteristics that make this approach unworkable, should be classified as Skin Category 1 if it contains \geq 1% of a corrosive ingredient and as Skin Category 2 when it contains ≥ 3% of an irritant ingredient. Classification of mixtures with ingredients for which the approach in Table A.2.3 does not apply is summarized in Table A.2.4 below.
- A.2.4.3.5 On occasion, reliable data may show that the skin corrosion/irritation of an ingredient will not be evident when present at a level above the generic concentration cut-off values mentioned in Tables A.2.3 and A.2.4. In these cases the mixture could be classified according to those data (See Use

Permanent [108]

of cut-off values/concentration limits, paragraph A.0.4.3 of this Appendix).

A.2.4.3.6 If there are data showing that (an) ingredient(s) may be corrosive or irritant at a concentration of < 1% (corrosive) or < 3% (irritant), the mixture shall be classified accordingly (See Use of cut-off values /concentration limits, paragraph A.0.4.3 of this Appendix).

Table A.2.3: Concentration of ingredients of a mixture classified as skin Category 1 or 2 that would trigger classification of the mixture as hazardous to skin (Category 1 or 2)

	Concentration triggering classification of a mixture as:		
Sum of ingredients	Skin corrosive Skin irritant		
classified as:	Category 1	Category 2	
Skin Category 1	≥ 5%	≥ 1% but < 5%	
Skin Category 2		≥ 10%	
(10 x Skin Category 1) + Skin Category 2		≥ 10%	

Table A.2.4: Concentration of ingredients of a mixture for which the additivity approach does not apply, that would trigger classification of the mixture as hazardous to skin

Ingredient:	Concentration:	Mixture classified as: Skin
Acid with pH ≤ 2	≥ 1%	Category 1
Base with pH \geq 11.5	≥ 1%	Category 1
Other corrosive (Category 1) ingredients for which additivity does not apply	≥ 1%	Category 1
Other irritant (Category 2) ingredients for which additivity does not apply, including acids and bases	≥ 3%	Category 2

A.3 SERIOUS EYE DAMAGE/EYE IRRITATION

A.3.1 Definitions and general considerations

A.3.1.1 *Serious eye damage* is the production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application.

Eye irritation is the production of changes in the eye following the application of test substance to the anterior surface of the eye, which are fully reversible within 21 days of application. A.3.1.2 Serious eye damage/eye irritation shall be classified using a tiered approach as detailed in figure A.3.1. Emphasis shall be placed upon existing human data (See A.0.2.6), followed by animal data, followed by other sources of information. Classification results directly when the data satisfy the criteria in this section. In case the criteria cannot be directly applied, classification of a substance or a mixture is made on the basis of the total weight of evidence (See A.0.3.1). This means that all available information bearing on the determination of serious eye damage/eye irritation is considered together, including the results of appropriate scientifically validated in vitro tests, relevant animal data, and human data such as epidemiological and clinical studies and well-documented case reports and observations.

A.3.2 Classification criteria for substances using animal test data

A.3.2.1 Irreversible effects on the eye/serious damage to eyes (Category 1)

A single hazard category is provided in Table A.3.1, for substances that have the potential to seriously damage the eyes. Category 1, irreversible effects on the eye, includes the criteria listed below. These observations include animals with grade 4 cornea lesions and other severe reactions (e.g. destruction of cornea) observed at any time during the test, as well as persistent corneal opacity, discoloration of the cornea by a dye substance, adhesion, pannus, and interference with the function of the iris or other effects that impair sight. In this context, persistent lesions are considered those which are not fully reversible within an observation period of normally 21 days. Category 1 also contains substances fulfilling the criteria of corneal opacity \geq 3 and/or iritis > 1.5 detected in a Draize eye test with rabbits, because severe lesions like these usually do not reverse within a 21-day observation period.

Table A.3.1: Irreversible eye effects

A substance is classified as Serious Eye Damage Category 1 (irreversible effects on the eye) when it produces:

- (a) at least in one tested animal, effects on the cornea, iris or conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 days; and/or
- (b) at least in 2 of 3 tested animals, a positive response of:
 - (i) corneal opacity ≥ 3 ; and/or
 - (ii) iritis > 1.5;

calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the substance.

A.3.2.2 Reversible effects on the eye (Category 2)

A single category is provided in Table A.3.2 for substances that have the potential to induce reversible eye irritation.

Table A.3.2: Reversible eye effects

A substance is classified as **Eye irritant Category 2A** (**irritating to eyes**) when it produces in at least in 2 of 3 tested animals a positive response of:

(i) corneal opacity ≥ 1 ; and/or

[109] Permanent

- (ii) iritis ≥ 1 ; and/or
- (iii) conjunctival redness ≥ 2 ; and/or
- (iv) conjunctival edema (chemosis) ≥ 2

calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the substance, and which fully reverses within an observation period of normally 21 days.

An eye irritant is considered mildly irritating to eyes (Category 2B) when the effects listed above are fully reversible within 7 days of observation.

A.3.2.3 For those chemicals where there is pronounced variability among animal responses, this information may be taken into account in determining the classification.

A.3.3 Classification Criteria for Substances Using Other Data Elements

A.3.3.1 Existing human and animal data should be the first line of analysis, as they give information directly relevant to effects on the eye. Possible skin corrosion shall be evaluated prior to consideration of serious eye damage/eye irritation in order to avoid testing for local effects on eyes with skin corrosive substances. In vitro alternatives that have been scientifically validated and accepted shall be used to make classification decisions. Likewise, pH extremes like ≤ 2 and ≥ 11.5, may indicate serious eye damage, especially when associated with significant buffering capacity. Generally, such substances are expected to produce significant effects on the eyes. In the absence of any other information, a mixture/substance is considered to cause serious eye damage (Eye Category 1) if it has a pH \leq 2 or \geq 11.5. However, if consideration of acid/alkaline reserve suggests the substance may not have the potential to cause serious eye damage despite the low or high pH value, then further evaluation may be necessary. In some cases enough information may be available from structurally related compounds to make classification decisions.

A.3.3.2 A tiered approach to the evaluation of initial information shall be used where applicable, recognizing that all elements may not be relevant in certain cases (Figure A.3.1).

A.3.3.3 The tiered approach explains how to organize existing information on a substance and to make a weight-of-evidence decision, where appropriate, about hazard assessment and hazard classification.

A.3.3.4 All the above information that is available on a substance shall be evaluated. Although information might be gained from the evaluation of single parameters within a tier, consideration should be given to the totality of existing information and making an overall weight of evidence determination. This is especially true when there is conflict in information available on some parameters.

Permanent [110]

Figure A.3.1 Evaluation strategy for serious eye damage and eye irritation (See also Figure A.2.1)

Step	Parameter	Finding		Conclusion
la:	Existing human or animal data, eye1	Serious Eye Damage	→	Category 12
	+	Eye Irritant	\longrightarrow	Category 22
	No/insufficient data or unknown			
1b:	Existing human or animal data, skin corrosion	——►Skin corrosive	→	Category 12
	No/insufficient data or unknown			
1c:	Existing human or animal data, eye ¹	Existing data that show that substance does not cause serious eye damage or eye irritation	→	Not Classified
	No/insufficient data	oyo samago vi oyo minanvii		
2:	Other, existing skin/eye data in animals³ ↓	Yes; existing data that show that substance may cause serious eye damage or eye irritation	-	Category1 or Category 2 ²
	No/insufficient data	,		
3:	Existing <u>ex vivo / in vitro</u> data ⁴	Positive: serious eye damage	\longrightarrow	Category 12
	+	Positive: eye irritant	\longrightarrow	Category 22
	No/insufficient data / negative response			
4:	pH-Based assessment (with consideration of buffering capacity of the chemical, or no buffering capacity data) ⁵	——▶pH ≤ 2 or ≥11.5	-	Category 1 ²
	Not a pH extreme, no pH data, or extreme pH with low/no buffering capacity			
5:	Validated structure/activity relationship	→ Severe damage to eyes	\longrightarrow	Category 12
	(SAR) models	Eye irritant	\longrightarrow	Category 22
	. Y	Skin Corrosive		Category 12
	No/insufficient data			
6:	Consideration of the total weight of	Serious eye damage	\longrightarrow	Category 12
	evidence ⁶	Eye irritant	\longrightarrow	Category 22
	No concern based on consideration of the sum of available data			
7:	Not Classified			

Notes to Figure A.3.1:

I Evidence of existing human or animal data may be derived from single or repeated exposure(s) in occupational, consumer, transportation, or emergency response scenarios; from ethically-conducted human clinical studies; or from purposely-generated data from animal studies conducted according to scientifically validated test methods. At present, there are no internationally accepted test methods for human skin or eve irritation testing.

- 2 Classify in the appropriate harmonized category, as shown in Tables A.3.1 and A.3.2.
- 3 Pre-existing animal data should be carefully reviewed to determine if sufficient skin or eye corrosion/irritation evidence is available through other, similar information.
- 4 Evidence from studies using scientifically validated protocols with isolated human/animal tissues or other, nontissue-based, though scientifically validated, protocols should be assessed. Examples of, scientifically validated test methods for identifying eye corrosives and severe irritants (i.e., Serious Eye Damage) include OECD TG 437 (Bovine Corneal Opacity and Permeability (BCOP)) and TG 438 (Isolated Chicken Eye). Positive test results from a scientifically validated in vitro test for skin corrosion would likely also lead to a conclusion to classify as causing Serious Eye Damage
- 5 Measurement of pH alone may be adequate, but assessment of acid or alkali reserve (buffering capacity) would be preferable.

[111] Permanent

6 All information that is available on a chemical should be considered and an overall determination made on the total weight of evidence. This is especially true when there is conflict in information available on some parameters. The weight of evidence including information on skin irritation could lead to classification of eye irritation. It is recognized that not all skin irritants are eye irritants as well. Professional judgment should be exercised in making such a determination.

A.3.4 Classification criteria for mixtures

A.3.4.1 Classification of mixtures when data are available for the complete mixture

A.3.4.1.1 The mixture will be classified using the criteria for substances

A.3.4.1.2 Unlike other hazard classes, there are alternative tests available for skin corrosivity of certain types of chemicals that can give an accurate result for classification purposes, as well as being simple and relatively inexpensive to perform. When considering testing of the mixture, chemical manufacturers are encouraged to use a tiered weight of evidence strategy as included in the criteria for classification of substances for skin corrosion and serious eye damage and eye irritation to help ensure an accurate classification, as well as avoid unnecessary animal testing. In the absence of any other information, a mixture is considered to cause serious eye damage (Eye Category 1) if it has a pH \leq 2 or \geq 11.5. However, if consideration of acid/alkaline reserve suggests the substance or mixture may not have the potential to cause serious eye damage despite the low or high pH value, then further evaluation may be necessary.

A.3.4.2 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.3.4.2.1 Where the mixture itself has not been tested to determine its skin corrosivity or potential to cause serious eye damage or eye irritation, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles, as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one toxicity category, Substantially similar mixtures, and Aerosols.

A.3.4.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.3.4.3.1 For purposes of classifying the eye corrosion/irritation hazards of mixtures in the tiered approach:

The "relevant ingredients" of a mixture are those which are present in concentrations > 1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases.) If the classifier has reason to suspect that an ingredient present at a concentration < 1% will affect classification of the mixture for eye corrosion/irritation, that ingredient shall also be considered relevant.

A.3.4.3.2 In general, the approach to classification of mixtures as seriously damaging to the eye or eye irritant when

data are available on the ingredients, but not on the mixture as a whole, is based on the theory of additivity, such that each corrosive or irritant ingredient contributes to the overall irritant or corrosive properties of the mixture in proportion to its potency and concentration. A weighting factor of 10 is used for corrosive ingredients when they are present at a concentration below the concentration limit for classification with Category 1, but are at a concentration that will contribute to the classification of the mixture as an irritant. The mixture is classified as seriously damaging to the eye or eye irritant when the sum of the concentrations of such ingredients exceeds a threshold cut-off value/concentration limit.

A.3.4.3.3 Table A.3.3 provides the cut-off value/concentration limits to be used to determine if the mixture should be classified as seriously damaging to the eye or an eye irritant.

A.3.4.3.4 Particular care must be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in A.3.4.3.1 and A.3.4.3.2 might not work given that many of such substances are corrosive or irritant at concentrations < 1%. For mixtures containing strong acids or bases, the pH should be used as classification criteria (See A.3.4.1) since pH will be a better indicator of serious eye damage than the concentration limits of Table A.3.3. A mixture containing corrosive or irritant ingredients that cannot be classified based on the additivity approach applied in Table A.3.3 due to chemical characteristics that make this approach unworkable, should be classified as Eye Category 1 if it contains $\geq 1\%$ of a corrosive ingredient and as Eye Category 2 when it contains $\geq 3\%$ of an irritant ingredient. Classification of mixtures with ingredients for which the approach in Table A.3.3 does not apply is summarized in Table A.3.4.

A.3.4.3.5 On occasion, reliable data may show that the reversible/irreversible eye effects of an ingredient will not be evident when present at a level above the generic cut-off values/concentration limits mentioned in Tables A.3.3 and A.3.4. In these cases the mixture could be classified according to those data (See also A.0.4.3 Use of cut-off values/concentration limits"). On occasion, when it is expected that the skin corrosion/irritation or the reversible/irreversible eye effects of an ingredient will not be evident when present at a level above the generic concentration/cut-off levels mentioned in Tables A.3.3 and A.3.4, testing of the mixture may be considered. In those cases, the tiered weight of evidence strategy should be applied as referred to in section A.3.3, Figure A.3.1 and explained in detail in this chapter.

A.3.4.3.6 If there are data showing that (an) ingredient(s) may be corrosive or irritant at a concentration of < 1% (corrosive) or < 3% (irritant), the mixture should be classified accordingly (See also paragraph A.0.4.3, Use of cut-off values/concentration limits).

Permanent [112]

Table A.3.3: Concentration of ingredients of a mixture classified as Skin Category 1 and/or
Eye Category 1 or 2 that would trigger classification of the mixtures as hazardous to the eye

	Concentration triggering classification of a mixture as:		
Sum of ingredients	Irreversible Reversible ey eye effects effects		
classified as:	Category 1	Category 2	
Eye or Skin Category	≥ 3%	$\geq 1\%$ but $< 3\%$	
Eye Category 2		≥ 10%	
(10 x Eye Category 1) + Eye Category 2		≥ 10%	
Skin Category 1 + Eye Category 1	≥ 3%	≥ 1% but < 3%	
10 x (Skin Category 1 + Eye Category 1) + Eye Category 2		≥ 10%	

Note: A mixture may be classified as Eye Category 2B in cases when all relevant ingredients are classified as Eye Category 2B.

Table A.3.4: Concentration of ingredients of a mixture for which the additivity approach does not apply, that would trigger classification of the mixture as hazardous to the eye

Ingredient	Concentration	Mixture classified as: Eye
Acid with pH ≤ 2	≥ 1%	Category 1
Base with pH \geq 11.5	≥ 1%	Category 1
Other corrosive (Category 1) ingredients for which additivity does not apply	≥ 1%	Category 1
Other irritant (Category 2) ingredients for which additivity does not apply, including acids and bases	≥ 3%	Category 2

A.4 RESPIRATORY OR SKIN SENSITIZATION

A.4.1 Definitions and general considerations

A.4.1.1 *Respiratory sensitizer* means a chemical that will lead to hypersensitivity of the airways following inhalation of the chemical.

Skin sensitizer means a chemical that will lead to an allergic response following skin contact.

A.4.1.2 For the purpose of this chapter, sensitization includes two phases: the first phase is induction of specialized immunological memory in an individual by exposure to an allergen. The second phase is elicitation, i.e., production of a cell-mediated or antibody-mediated allergic response by exposure of a sensitized individual to an allergen.

A.4.1.3 For respiratory sensitization, the pattern of induction followed by elicitation phases is shared in common with skin

sensitization. For skin sensitization, an induction phase is required in which the immune system learns to react; clinical symptoms can then arise when subsequent exposure is sufficient to elicit a visible skin reaction (elicitation phase). As a consequence, predictive tests usually follow this pattern in which there is an induction phase, the response to which is measured by a standardized elicitation phase, typically involving a patch test. The local lymph node assay is the exception, directly measuring the induction response. Evidence of skin sensitization in humans normally is assessed by a diagnostic patch test.

A.4.1.4 Usually, for both skin and respiratory sensitization, lower levels are necessary for elicitation than are required for induction.

A.4.1.5 The hazard class "respiratory or skin sensitization" is differentiated into:

- (a) Respiratory sensitization; and
- (b) Skin sensitization

A.4.2 Classification criteria for substances

A.4.2.1 Respiratory sensitizers

A.4.2.1.1 Hazard categories

A.4.2.1.1.1 Effects seen in either humans or animals will normally justify classification in a weight of evidence approach for respiratory sensitizers. Substances may be allocated to one of the two sub-categories 1A or 1B using a weight of evidence approach in accordance with the criteria given in Table A.4.1 and on the basis of reliable and good quality evidence from human cases or epidemiological studies and/or observations from appropriate studies in experimental animals.

A.4.2.1.1.2 Where data are not sufficient for sub-categorization, respiratory sensitizers shall be classified in Category 1.

Table A.4.1: Hazard category and sub-categories for respiratory sensitizers

Category 1:	Respiratory sensitizer
	A substance is classified as a respira-
	tory sensitizer
	(a) if there is evidence in humans that
	the substance can lead to specific
	respiratory hypersensitivity and/or
	(b) if there are positive results from
	an appropriate animal test.
Sub-category 1A:	Substances showing a high frequency
	of occurrence in humans; or a proba-
	bility of occurrence of a high sensiti-
	zation rate in humans based on animal
	or other tests.1 Severity of reaction
	may also be considered.

[113] Permanent

Category 1:	Respiratory sensitizer
Sub-category 1B:	Substances showing a low to moderate frequency of occurrence in humans; or a probability of occurrence of a low to moderate sensitiza-
	tion rate in humans based on animal or other tests.1 Severity of reaction may also be considered.

A.4.2.1.2 Human evidence

- A.4.2.1.2.1 Evidence that a substance can lead to specific respiratory hypersensitivity will normally be based on human experience. In this context, hypersensitivity is normally seen as asthma, but other hypersensitivity reactions such as rhinitis/conjunctivitis and alveolitis are also considered. The condition will have the clinical character of an allergic reaction. However, immunological mechanisms do not have to be demonstrated.
- A.4.2.1.2.2 When considering the human evidence, it is necessary that in addition to the evidence from the cases, the following be taken into account:
 - (a) the size of the population exposed;
 - (b) the extent of exposure.

A.4.2.1.2.3 The evidence referred to above could be:

- (a) clinical history and data from appropriate lung function tests related to exposure to the substance, confirmed by other supportive evidence which may include:
 - (i) in vivo immunological test (e.g., skin prick test);
- (ii) in vitro immunological test (e.g., serological analysis);
- (iii) studies that may indicate other specific hypersensitivity reactions where immunological mechanisms of action have not been proven, e.g., repeated low-level irritation, pharmacologically mediated effects;
- (iv) a chemical structure related to substances known to cause respiratory hypersensitivity;
- (b) data from positive bronchial challenge tests with the substance conducted according to accepted guidelines for the determination of a specific hypersensitivity reaction.
- A.4.2.1.2.4 Clinical history should include both medical and occupational history to determine a relationship between exposure to a specific substance and development of respiratory hypersensitivity. Relevant information includes aggravating factors both in the home and workplace, the onset and progress of the disease, family history and medical history of the patient in question. The medical history should also include a note of other allergic or airway disorders from childhood and smoking history.
- A.4.2.1.2.5 The results of positive bronchial challenge tests are considered to provide sufficient evidence for classification on their own. It is, however, recognized that in practice many of the examinations listed above will already have been carried out.

A.4.2.1.3 Animal studies

- A.4.2.1.3.1 Data from appropriate animal studies which may be indicative of the potential of a substance to cause sensitization by inhalation in humans may include:
- (a) measurements of Immunoglobulin E (IgE) and other specific immunological parameters, for example in mice
 - (b) specific pulmonary responses in guinea pigs.

A.4.2.2 Skin sensitizers

A.4.2.2.1 Hazard categories

A.4.2.2.1.1 Effects seen in either humans or animals will normally justify classification in a weight of evidence approach for skin sensitizers. Substances may be allocated to one of the two sub-categories 1A or 1B using a weight of evidence approach in accordance with the criteria given in Table A.4.2 and on the basis of reliable and good quality evidence from human cases or epidemiological studies and/or observations from appropriate studies in experimental animals according to the guidance values provided in A.4.2.2.2.1 and A.4.2.2.3.2 for sub-category 1A and in A.4.2.2.2.2 and A.4.2.2.3.3 for sub-category 1B.

A.4.2.2.1.2 Where data are not sufficient for sub-categorization, skin sensitizers shall be classified in Category 1.

Table A.4.2: Hazard category and sub-categories for skin sensitizers

Category 1:	Skin sensitizer	
	A substance is classified as a skin sensitizer	
	(a) if there is evidence in humans that the substance can lead to sensitization by skin contact in a substantial num- ber of persons, or	
	(b) if there are positive results from an appropriate animal test.	
Sub-category 1A:	Substances showing a high frequency of occurrence in humans and/or a high potency in animals can be presumed to have the potential to produce significant sensitization in humans. Severity of reaction may also be considered.	
Sub-category 1B:	Substances showing a low to moderate frequency of occurrence in humans and/or a low to moderate potency in animals can be presumed to have the potential to produce sensitization in humans. Severity of reaction may also be considered.	

A.4.2.2.2 Human evidence

A.4.2.2.2.1 Human evidence for sub-category 1A may include:

Permanent [114]

- (a) positive responses at $\leq 500 \,\mu\text{g/cm}2$ (Human Repeat Insult Patch Test (HRIPT), Human Maximization Test (HMT) induction threshold);
- (b) diagnostic patch test data where there is a relatively high and substantial incidence of reactions in a defined population in relation to relatively low exposure;
- (c) other epidemiological evidence where there is a relatively high and substantial incidence of allergic contact dermatitis in relation to relatively low exposure.
- A.4.2.2.2.2 Human evidence for sub-category 1B may include:
- (a) positive responses at $> 500 \mu g/cm2$ (HRIPT, HMT induction threshold);
- (b) diagnostic patch test data where there is a relatively low but substantial incidence of reactions in a defined population in relation to relatively high exposure;
- (c) other epidemiological evidence where there is a relatively low but substantial incidence of allergic contact dermatitis in relation to relatively high exposure.

A.4.2.2.3 Animal studies

A.4.2.2.3.1 For Category 1, when an adjuvant type test method for skin sensitization is used, a response of at least 30% of the animals is considered as positive. For a non-adjuvant Guinea pig test method a response of at least 15% of the animals is considered positive. For Category 1, a stimulation index of three or more is considered a positive response in the local lymph node assay.

A.4.2.2.3.2 Animal test results for sub-category 1A can include data with values indicated in Table A.4.3 below:

Table A.4.3: Animal test results for sub-category 1A

Assay	Criteria
Local lymph node	EC3 value ≤ 2%
assay	
Guinea pig maxi- mization test	\geq 30% responding at \leq 0.1% intradermal induction dose or
	\geq 60% responding at $> 0.1\%$ to \leq 1% intradermal induction dose
Buehler assay	\geq 15% responding at \leq 0.2% topical induction dose or
	≥ 60% responding at > 0.2% to ≤ 20% topical induction dose

Note: EC3 refers to the estimated concentration of test chemical required to induce a stimulation index of 3 in the local lymph node assay.

A.4.2.2.3.3 Animal test results for sub-category 1B can include data with values indicated in Table A.4.4 below:

Table A.4.4: Animal test results for sub-category 1B

Assay	Criteria
Local lymph node assay	EC3 value > 2%

Guinea pig maximization test	\geq 30% to < 60% responding at > 0.1% to \leq 1% intrader- mal induction dose or
	≥ 30% responding at > 1% intradermal induction dose
Buehler assay	\geq 15% to < 60% responding at > 0.2% to \leq 20% topical induction dose or
	≥ 15% responding at > 20% topical induction dose

Note: EC3 refers to the estimated concentration of test chemical required to induce a stimulation index of 3 in the local lymph node assay.

A.4.2.2.4 Specific considerations

A.4.2.2.4.1 For classification of a substance, evidence shall include one or more of the following using a weight of evidence approach:

- (a) Positive data from patch testing, normally obtained in more than one dermatology clinic;
- (b) Epidemiological studies showing allergic contact dermatitis caused by the substance. Situations in which a high proportion of those exposed exhibit characteristic symptoms are to be looked at with special concern, even if the number of cases is small;
 - (c) Positive data from appropriate animal studies;
- (d) Positive data from experimental studies in man (See paragraph A.0.2.6 of this Appendix);
- (e) Well documented episodes of allergic contact dermatitis, normally obtained in more than one dermatology clinic;
 - (f) Severity of reaction.

A.4.2.2.4.2 Evidence from animal studies is usually much more reliable than evidence from human exposure. However, in cases where evidence is available from both sources, and there is conflict between the results, the quality and reliability of the evidence from both sources must be assessed in order to resolve the question of classification on a case-bycase basis. Normally, human data are not generated in controlled experiments with volunteers for the purpose of hazard classification but rather as part of risk assessment to confirm lack of effects seen in animal tests. Consequently, positive human data on skin sensitization are usually derived from case-control or other, less defined studies. Evaluation of human data must, therefore, be carried out with caution as the frequency of cases reflect, in addition to the inherent properties of the substances, factors such as the exposure situation, bioavailability, individual predisposition and preventive measures taken. Negative human data should not normally be used to negate positive results from animal studies. For both animal and human data, consideration should be given to the impact of vehicle.

A.4.2.2.4.3 If none of the above-mentioned conditions are met, the substance need not be classified as a skin sensitizer. However, a combination of two or more indicators of skin sensitization, as listed below, may alter the decision. This shall be considered on a case-by-case basis.

[115] Permanent

- (a) Isolated episodes of allergic contact dermatitis;
- (b) Epidemiological studies of limited power, e.g., where chance, bias or confounders have not been ruled out fully with reasonable confidence;
- (c) Data from animal tests, performed according to existing guidelines, which do not meet the criteria for a positive result described in A.4.2.2.3, but which are sufficiently close to the limit to be considered significant;
 - (d) Positive data from non-standard methods;
 - (e) Positive results from close structural analogues.

A.4.2.2.4.4 Immunological contact urticaria

A.4.2.2.4.4.1 Substances meeting the criteria for classification as respiratory sensitizers may, in addition, cause immunological contact urticaria. Consideration shall be given to classifying these substances as skin sensitizers.

A.4.2.2.4.4.2 Substances which cause immunological contact urticaria without meeting the criteria for respiratory sensitizers shall be considered for classification as skin sensitizers.

A.4.2.2.4.4.3 There is no recognized animal model available to identify substances which cause immunological contact urticaria. Therefore, classification will normally be based on human evidence, similar to that for skin sensitization.

A.4.3 Classification criteria for mixtures

A.4.3.1 Classification of mixtures when data are available for the complete mixture

When reliable and good quality evidence, as described in the criteria for substances, from human experience or appropriate studies in experimental animals, is available for the mixture, then the mixture shall be classified by weight of evidence evaluation of these data. Care must be exercised in evaluating data on mixtures that the dose used does not render the results inconclusive.

A.4.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.4.3.2.1 Where the mixture itself has not been tested to determine its sensitizing properties, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following agreed bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation, Substantially similar mixtures, and Aerosols.

A.4.3.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

The mixture shall be classified as a respiratory or skin sensitizer when at least one ingredient has been classified as a respiratory or skin sensitizer and is present at or above the appropriate cut-off value/concentration limit for the specific endpoint as shown in Table A.4.5.

Table A.4.5: Cut-off values/concentration limits of ingredients of a mixture classified as either respiratory sensitizers or skin sensitizers that would trigger classification of the mixture

	Cut-off values/concentration limits triggering classification of a mixture as:		
	Respiratory Sensitizer		Skin Sensitizer
	Categor	Category 1	
Ingredient classified as:	Solid/Liquid	Gas	All physical states
Respiratory Sensitizer Category 1	≥ 0.1%	≥ 0.1%	
Respiratory Sensitizer Sub-category 1A	≥ 0.1%	≥ 0.1%	
Respiratory Sensitizer Sub-category 1B	≥ 0.1%	≥ 0.2%	
Skin Sensitizer Category 1			≥ 0.1%
Skin Sensitizer Sub-category 1A			≥ 0.1%
Skin Sensitizer Sub-category 1B			≥ 1.0%

A.5 GERM CELL MUTAGENICITY

A.5.1 Definitions and general considerations

A.5.1.1 *A mutation* is defined as a permanent change in the amount or structure of the genetic material in a cell. The term mutation applies both to heritable genetic changes that may be manifested at the phenotypic level and to the underlying DNA modifications when known (including, for example, specific base pair changes and chromosomal translocations). The term mutagenic and mutagen will be used for agents giving rise to an increased occurrence of mutations in populations of cells and/or organisms.

A.5.1.2 The more general terms *genotoxic* and *genotoxicity* apply to agents or processes which alter the structure, infor-

mation content, or segregation of DNA, including those which cause DNA damage by interfering with normal replication processes, or which in a non-physiological manner (temporarily) alter its replication. Genotoxicity test results are usually taken as indicators for mutagenic effects.

A.5.1.3 This hazard class is primarily concerned with chemicals that may cause mutations in the germ cells of humans that can be transmitted to the progeny. However, mutagenicity/genotoxicity tests *in vitro* and in mammalian somatic cells in vivo are also considered in classifying substances and mixtures within this hazard class.

A.5.2 Classification criteria for substances

Permanent [116]

A.5.2.1 The classification system provides for two different categories of germ cell mutagens to accommodate the weight

of evidence available. The two-category system is described in the Figure A.5.1.

Figure A.5.1: Hazard categories for germ cell mutagens

CATEGORY 1:	Substances known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans	
Category 1A:	Substances known to induce heritable mutations in germ cells of humans	
	Positive evidence from human epidemiological studies.	
Category 1B:	Substances which should be regarded as if they induce heritable mutations in the germ cells of humans	
	(a) Positive result(s) from in vivo heritable germ cell mutagenicity tests in mammals; or	
	(b) Positive result(s) from <i>in vivo</i> somatic cell mutagenicity tests in mammals, in combination with some evidence that the substance has potential to cause mutations to germ cells. This supporting evidence may, for example, be derived from mutagenicity/genotoxicity tests in germ cells <i>in vivo</i> , or by demonstrating the ability of the substance or its metabolite(s) to interact with the genetic material of germ cells; or	
	(c) Positive results from tests showing mutagenic effects in the germ cells of humans, without demonstration of transmission to progeny; for example, an increase in the frequency of aneuploidy in sperm cells of exposed people	
CATEGORY 2: Substances which cause concern for humans owing to the possibility that they may induce in the germ cells of humans		
	Positive evidence obtained from experiments in mammals and/or in some cases from <i>in vitro</i> experiments, obtained from:	
	(a) Somatic cell mutagenicity tests in vivo, in mammals; or	
	(b) Other in vivo somatic cell genotoxicity tests which are supported by positive results from <i>in vitro</i> mutagenicity assays.	
	Note: Substances which are positive in in vitro mammalian mutagenicity assays, and which also show chemical structure activity relationship to known germ cell mutagens, should be considered for classification as Category 2 mutagens.	

- A.5.2.2 Specific considerations for classification of substances as germ cell mutagens:
- A.5.2.2.1 To arrive at a classification, test results are considered from experiments determining mutagenic and/or genotoxic effects in germ and/or somatic cells of exposed animals. Mutagenic and/or genotoxic effects determined in in vitro tests shall also be considered.
- A.5.2.2.2 The system is hazard based, classifying chemicals on the basis of their intrinsic ability to induce mutations in germ cells. The scheme is, therefore, not meant for the (quantitative) risk assessment of chemical substances.
- A.5.2.2.3 Classification for heritable effects in human germ cells is made on the basis of scientifically validated tests. Evaluation of the test results shall be done using expert judgment and all the available evidence shall be weighed for classification.
- A.5.2.2.4 The classification of substances shall be based on the total weight of evidence available, using expert judgment. In those instances where a single well-conducted test is used for classification, it shall provide clear and unambiguously positive results. The relevance of the route of exposure used in the study of the substance compared to the route of human exposure should also be taken into account.
- A.5.3 Classification criteria for mixtures
- A.5.3.1 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture
- A.5.3.1.1 Classification of mixtures shall be based on the available test data for the individual ingredients of the mixture using cut-off values/concentration limits for the ingredients classified as germ cell mutagens.

A.5.3.1.2 The mixture will be classified as a mutagen when at least one ingredient has been classified as a Category 1A, Category 1B or Category 2 mutagen and is present at or above the appropriate cut-off value/concentration limit as shown in Table A.5.1 below for Category 1 and 2 respectively.

Table A.5.1: Cut-off values/concentration limits of ingredients of a mixture classified as germ cell mutagens that would trigger classification of the mixture

	Cut-off/concentration limits triggering classification of a mixture as:		
Ingredient classified as:	Category 1 mutagen	Category 2 mutagen	
Category 1 A/B mutagen	≥ 0.1%	-	
Category 2 mutagen	-	≥ 1.0%	

Note: The cut-off values/concentration limits in the table above apply to solids and liquids (w/w units) as well as gases (v/v units).

A.5.3.2 Classification of mixtures when data are available for the mixture itself

The classification may be modified on a case-by-case basis based on the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g. statistical analysis, test sensitivity) of germ cell mutagenicity test systems.

[117] Permanent

- A.5.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles
- A.5.3.3.1 Where the mixture itself has not been tested to determine its germ cell mutagenicity hazard, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, and Substantially similar mixtures.
- A.5.4 Examples of scientifically validated test methods:
- A.5.4.1 Examples of in vivo heritable germ cell mutagenicity tests are:
 - (a) Rodent dominant lethal mutation test (OECD 478)
 - (b) Mouse heritable translocation assay (OECD 485)
 - (c) Mouse specific locus test
- A.5.4.2 Examples of in vivo somatic cell mutagenicity tests are:
- (a) Mammalian bone marrow chromosome aberration test (OECD 475)
 - (b) Mouse spot test (OECD 484)
- (c) Mammalian erythrocyte micronucleus test (OECD 474)
- A.5.4.3 Examples of mutagenicity/genotoxicity tests in germ cells are:
 - (a) Mutagenicity tests:
- (i) Mammalian spermatogonial chromosome aberration test (OECD 483)
 - (ii) Spermatid micronucleus assay
 - (b) Genotoxicity tests:
 - (i) Sister chromatid exchange analysis in spermatogonia
- (ii) Unscheduled DNA synthesis test (UDS) in testicular cells

- A.5.4.4 Examples of genotoxicity tests in somatic cells are:
- (a) Liver Unscheduled DNA Synthesis (UDS) in vivo (OECD 486)
- (b) Mammalian bone marrow Sister Chromatid Exchanges (SCE)
- A.5.4.5 Examples of in vitro mutagenicity tests are:
- (a) In vitro mammalian chromosome aberration test (OECD 473)
- (b) In vitro mammalian cell gene mutation test (OECD 476)
 - (c) Bacterial reverse mutation tests (OECD 471)
- A.5.4.6 As new, scientifically validated tests arise, these may also be used in the total weight of evidence to be considered.

A.6 CARCINOGENICITY

A.6.1 Definitions

Carcinogen means a substance or a mixture of substances which induce cancer or increase its incidence. Substances and mixtures which have induced benign and malignant tumors in well-performed experimental studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism of tumor formation is not relevant for humans.

Classification of a substance or mixture as posing a carcinogenic hazard is based on its inherent properties and does not provide information on the level of the human cancer risk which the use of the substance or mixture may represent.

A.6.2 Classification criteria for substances

A.6.2.1 For the purpose of classification for carcinogenicity, substances are allocated to one of two categories based on strength of evidence and additional weight of evidence considerations. In certain instances, route-specific classification may be warranted.

Figure A.6.1: Hazard categories for carcinogens

CATEGORY 1:	Known or presumed human carcinogens
	The classification of a substance as a Category 1 carcinogen is done on the basis of epidemiological and/or animal data. This classification is further distinguished on the basis of whether the evidence for classification is largely from human data (Category 1A) or from animal data (Category 1B):
Category 1A:	Known to have carcinogenic potential for humans. Classification in this category is largely based on human evidence.
Category 1B:	Presumed to have carcinogenic potential for humans. Classification in this category is largely based on animal evidence.
	The classification of a substance in Category 1A and 1B is based on strength of evidence together with weight of evidence considerations (See paragraph A.6.2.5). Such evidence may be derived from:
	- human studies that establish a causal relationship between human exposure to a substance and the development of cancer (known human carcinogen); or
	- animal experiments for which there is sufficient evidence to demonstrate animal carcinogenicity (presumed human carcinogen).
	In addition, on a case by case basis, scientific judgment may warrant a decision of pre- sumed human carcinogenicity derived from studies showing limited evidence of carci- nogenicity in humans together with limited evidence of carcinogenicity in experimental animals.

Permanent [118]

WSR 13-06-050

Category 2:	Suspected human carcinogens	
	The classification of a substance in Category 2 is done on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the substance in Category 1A or B. This classification is based on strength of evidence together with weight of evidence considerations (See paragraph A.6.2.5). Such evidence may be from either limited evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies.	
Other considerations:	Where the weight of evidence for the carcinogenicity of a substance does not meet the above criteria, any positive study conducted in accordance with established scientific principles, and which reports statistically significant findings regarding the carcinogenic potential of the substance, must be noted on the safety data sheet.	

- A.6.2.2 Classification as a carcinogen is made on the basis of evidence from reliable and acceptable methods, and is intended to be used for substances which have an intrinsic property to produce such toxic effects. The evaluations are to be based on all existing data, peer-reviewed published studies and additional data accepted by regulatory agencies.
- A.6.2.3 *Carcinogen classification* is a one-step, criterion-based process that involves two interrelated determinations: evaluations of strength of evidence and consideration of all other relevant information to place substances with human cancer potential into hazard categories.
- A.6.2.4 Strength of evidence involves the enumeration of tumors in human and animal studies and determination of their level of statistical significance. Sufficient human evidence demonstrates causality between human exposure and the development of cancer, whereas sufficient evidence in animals shows a causal relationship between the agent and an increased incidence of tumors. Limited evidence in humans is demonstrated by a positive association between exposure and cancer, but a causal relationship cannot be stated. Limited evidence in animals is provided when data suggest a carcinogenic effect, but are less than sufficient. (Guidance on consideration of important factors in the classification of carcinogenicity and a more detailed description of the terms "limited" and "sufficient" have been developed by the International Agency for Research on Cancer (IARC) and are provided in non-mandatory Appendix F.)
- A.6.2.5 Weight of evidence: Beyond the determination of the strength of evidence for carcinogenicity, a number of other factors should be considered that influence the overall likelihood that an agent may pose a carcinogenic hazard in humans. The full list of factors that influence this determination is very lengthy, but some of the important ones are considered here.
- A.6.2.5.1 These factors can be viewed as either increasing or decreasing the level of concern for human carcinogenicity. The rela—tive emphasis accorded to each factor depends upon the amount and coherence of evidence bearing on each. Generally there is a requirement for more complete information to decrease than to increase the level of concern. Additional considerations should be used in evaluating the tumor findings and the other factors in a case-by-case manner.

- A.6.2.5.2 Some important factors which may be taken into consideration, when assessing the overall level of concern are:
 - (a) Tumor type and background incidence;
 - (b) Multisite responses;
 - (c) Progression of lesions to malignancy;
 - (d) Reduced tumor latency;

Additional factors which may increase or decrease the level of concern include:

- (e) Whether responses are in single or both sexes;
- (f) Whether responses are in a single species or several species:
- (g) Structural similarity or not to a substance(s) for which there is good evidence of carcinogenicity;
 - (h) Routes of exposure;
- (i) Comparison of absorption, distribution, metabolism and excretion between test animals and humans;
- (j) The possibility of a confounding effect of excessive toxicity at test doses; and,
- (k) Mode of action and its relevance for humans, such as mutagenicity, cytotoxicity with growth stimulation, mitogenesis, immunosuppression.

Mutagenicity: It is recognized that genetic events are central in the overall process of cancer development. Therefore evidence of mutagenic activity in vivo may indicate that a substance has a potential for carcinogenic effects.

- A.6.2.5.3 A substance that has not been tested for carcinogenicity may in certain instances be classified in Category 1A, Category 1B, or Category 2 based on tumor data from a structural analogue together with substantial support from consi¬deration of other important factors such as formation of common significant metabolites, e.g., for benzidine congener dyes.
- A.6.2.5.4 The classification should also take into consideration whether or not the substance is absorbed by a given route(s); or whether there are only local tumors at the site of administration for the tested route(s), and adequate testing by other major route(s) show lack of carcinogenicity.
- A.6.2.5.5 It is important that whatever is known of the physico-chemical, toxicokinetic and toxicodynamic properties of the substances, as well as any available relevant information on chemical analogues, i.e., structure activity relationship, is taken into consideration when undertaking classification.

[119] Permanent

A.6.3 Classification criteria for mixtures

A.6.3.1 The mixture shall be classified as a carcinogen when at least one ingredient has been classified as a Category 1 or Category 2 carcinogen and is present at or above the appropriate cut-off value/concentration limit as shown in Table A.6.1.

Table A.6.1: Cut-off values/concentration limits of ingredients of a mixture classified as carcinogen that would trigger classification of the mixture

Ingredient classified as:	Category 1 carcinogen	Category 2 carcinogen
Category 1 carcino-	≥ 0.1%	
gen		
Category 2 carcino-		$\geq 0.1\%$ (note 1)
gen		

Note: If a Category 2 carcinogen ingredient is present in the mixture at a concentration between 0.1% and 1%, information is required on the SDS for a product. However, a label warning is optional. If a Category 2 carcinogen ingredient is present in the mixture at a concentration of \geq 1%, both an SDS and a label is required and the information must be included on each.

A.6.3.2 Classification of mixtures when data are available for the complete mixture

A mixture may be classified based on the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g., statistical analysis, test sensitivity) of carcinogenicity test systems.

A.6.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

Where the mixture itself has not been tested to determine its carcinogenic hazard, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution; Batching; and Substantially similar mixtures.

A.6.4 Classification of carcinogenicity

A.6.4.1 Chemical manufacturers, importers and employers evaluating chemicals may treat the following sources as establishing that a substance is a carcinogen or potential carcinogen for hazard communication purposes in lieu of applying the criteria described herein:

A.6.4.1.1 National Toxicology Program (NTP), "Report on Carcinogens" (latest edition);

A.6.4.1.2 International Agency for Research on Cancer (IARC) "Monographs on the Evaluation of Carcinogenic Risks to Humans" (latest editions)

A.6.4.2 Where OSHA has included cancer as a health hazard to be considered by classifiers for a chemical covered by 29 CFR part 1910, Subpart Z, Toxic and Hazardous Substances,

chemical manufacturers, importers, and employers shall classify the chemical as a carcinogen.

A.7 REPRODUCTIVE TOXICITY

A.7.1 Definitions and general considerations

A.7.1.1 Reproductive toxicity includes adverse effects on sexual function and fertility in adult males and females, as well as adverse effects on development of the offspring. Some reproductive toxic effects cannot be clearly assigned to either impairment of sexual function and fertility or to developmental toxicity. Nonetheless, chemicals with these effects shall be classified as reproductive toxicants.

For classification purposes, the known induction of genetically based inheritable effects in the offspring is addressed in Germ cell mutagenicity (See A.5).

A.7.1.2 Adverse effects on sexual function and fertility means any effect of chemicals that interferes with reproductive ability or sexual capacity. This includes, but is not limited to, alterations to the female and male reproductive system, adverse effects on onset of puberty, gamete production and transport, reproductive cycle normality, sexual behaviour, fertility, parturition, pregnancy outcomes, premature reproductive senescence, or modifications in other functions that are dependent on the integrity of the reproductive systems.

A.7.1.3 Adverse effects on development of the offspring means any effect of chemicals which interferes with normal development of the conceptus either before or after birth, which is induced during pregnancy or results from parental exposure. These effects can be manifested at any point in the life span of the organism. The major manifestations of developmental toxicity include death of the developing organism, structural abnormality, altered growth and functional deficiency.

A.7.1.4 Adverse effects on or via lactation are also included in reproductive toxicity, but for classification purposes, such effects are treated separately (See A.7.2.1).

A.7.2 Classification criteria for substances

A.7.2.1 For the purpose of classification for reproductive toxicity, substances shall be classified in one of two categories in accordance with Figure A.7.1(a). Effects on sexual function and fertility, and on development, shall be considered. In addition, effects on or via lactation shall be classified in a separate hazard category in accordance with Figure A.7.1(b).

Permanent [120]

Figure A.7.1(a): Hazard categories for reproductive toxicants

CATEGORY 1:	Known or presumed human reproductive toxicant
	Substance shall be classified in Category 1 for reproductive toxicity when they are known to have produced an adverse effect on sexual function and fertility or on development in humans or when there is evidence from animal studies, possibly supplemented with other information, to provide a strong presumption that the substance has the capacity to interfere with reproduction in humans. The classification of a substance is further distinguished on the basis of whether the evidence for classification is primarily from
	human data (Category 1A) or from animal data (Category 1B).
Category 1A:	Known human reproductive toxicant
	The classification of a substance in this category is largely based on evidence from humans.
Category 1B:	Presumed human reproductive toxicant
	The classification of a substance in this category is largely based on evidence from experimental animals. Data from animal studies shall provide sufficient evidence of an adverse effect on sexual function and fertility or on development in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of other toxic effects. However, when there is mechanistic information that raises doubt about the relevance of the effect for humans, classification in Category 2 may be more appropriate.
Category 2:	Suspected human reproductive toxicant
	Substances shall be classified in Category 2 for reproductive toxicity when there is some evidence from humans or experimental animals, possibly supplemented with other information, of an adverse effect on sexual function and fertility, or on development, in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of the other toxic effects, and where the evidence is not sufficiently convincing to place the substance in Category 1. For instance, deficiencies in the study may make the quality of evidence less convincing, and in view of this, Category 2 would be the more appropriate classification.

Figure A.7.1(b): Hazard category for effects on or via lactation

EFFECTS ON OR VIA LACTATION

Effects on or via lactation shall be classified in a separate single category. Chemicals that are absorbed by women and have been shown to interfere with lactation or that may be present (including metabolites) in breast milk in amounts sufficient to cause concern for the health of a breastfed child, shall be classified to indicate this property hazardous to breastfed babies. This classification shall be assigned on the basis of:

- (a) absorption, metabolism, distribution and excretion studies that indicate the likelihood the substance would be present in potentially toxic levels in breast milk; and/or
- (b) results of one or two generation studies in animals which provide clear evidence of adverse effect in the offspring due to transfer in the milk or adverse effect on the quality of the milk; and/or
- (c) human evidence indicating a hazard to babies during the lactation period.

A.7.2.2 Basis of classification

A.7.2.2.1 Classification is made on the basis of the criteria, outlined above, an assessment of the total weight of evidence, and the use of expert judgment. Classification as a reproductive toxicant is intended to be used for substances which have an intrinsic, specific property to produce an adverse effect on reproduction and substances should not be so classified if such an effect is produced solely as a non-specific secondary consequence of other toxic effects.

A.7.2.2.2 In the evaluation of toxic effects on the developing offspring, it is important to consider the possible influence of maternal toxicity.

A.7.2.2.3 For human evidence to provide the primary basis for a Category 1A classification there must be reliable evidence of an adverse effect on reproduction in humans. Evidence used for classification shall be from well conducted epidemiological studies, if available, which include the use of appropriate controls, balanced assessment, and due consideration of bias or confounding factors. Less rigorous data from studies in humans may be sufficient for a Category 1A classification if supplemented with adequate data from studies in experimental animals, but classification in Category 1B may also be considered.

A.7.2.3 Weight of evidence

[121] Permanent

A.7.2.3.1 Classification as a reproductive toxicant is made on the basis of an assessment of the total weight of evidence using expert judgment. This means that all available information that bears on the determination of reproductive toxicity is considered together. Included is information such as epidemiological studies and case reports in humans and specific reproduction studies along with sub-chronic, chronic and special study results in animals that provide relevant information regarding toxicity to reproductive and related endocrine organs. Evaluation of substances chemically related to the material under study may also be included, particularly when information on the material is scarce. The weight given to the available evidence will be influenced by factors such as the quality of the studies, consistency of results, nature and severity of effects, level of statistical significance for intergroup differences, number of endpoints affected, relevance of route of administration to humans and freedom from bias. Both positive and negative results are considered together in a weight of evidence determination. However, a single, positive study performed according to good scientific principles and with statistically or biologically significant positive results may justify classification (See also A.7.2.2.3).

A.7.2.3.2 Toxicokinetic studies in animals and humans, site of action and mechanism or mode of action study results may provide relevant information, which could reduce or increase concerns about the hazard to human health. If it is conclusively demonstrated that the clearly identified mechanism or mode of action has no relevance for humans or when the toxicokinetic differences are so marked that it is certain that the hazardous property will not be expressed in humans then a chemical which produces an adverse effect on reproduction in experimental animals should not be classified.

A.7.2.3.3 In some reproductive toxicity studies in experimental animals the only effects recorded may be considered of low or minimal toxicological significance and classification may not necessarily be the outcome. These effects include, for example, small changes in semen parameters or in the incidence of spontaneous defects in the fetus, small changes in the proportions of common fetal variants such as are observed in skeletal examinations, or in fetal weights, or small differences in postnatal developmental assessments.

A.7.2.3.4 Data from animal studies shall provide sufficient evidence of specific reproductive toxicity in the absence of other systemic toxic effects. However, if developmental toxicity occurs together with other toxic effects in the dam (mother), the potential influence of the generalized adverse effects should be assessed to the extent possible. The preferred approach is to consider adverse effects in the embryo/fetus first, and then evaluate maternal toxicity, along with any other factors which are likely to have influenced these effects, as part of the weight of evidence. In general, developmental effects that are observed at maternally toxic doses should not be automatically discounted. Discounting developmental effects that are observed at maternally toxic doses can only be done on a case-by-case basis when a causal relationship is established or refuted.

A.7.2.3.5 If appropriate information is available it is important to try to determine whether developmental toxicity is due to a specific maternally mediated mechanism or to a non-specific secondary mechanism, like maternal stress and the disruption of homeostasis. Generally, the presence of maternal toxicity should not be used to negate findings of embryo/fetal effects, unless it can be clearly demonstrated that the effects are secondary non-specific effects. This is especially the case when the effects in the offspring are significant, e.g., irreversible effects such as structural malformations. In some situations it is reasonable to assume that reproductive toxicity is due to a secondary consequence of maternal toxicity and discount the effects, for example if the chemical is so toxic that dams fail to thrive and there is severe inanition; they are incapable of nursing pups; or they are prostrate or dying.

A.7.2.4 Maternal toxicity

A.7.2.4.1 Development of the offspring throughout gestation and during the early postnatal stages can be influenced by toxic effects in the mother either through non-specific mechanisms related to stress and the disruption of maternal homeostasis, or by specific maternally-mediated mechanisms. So, in the interpretation of the developmental outcome to decide classification for developmental effects it is important to consider the possible influence of maternal toxicity. This is a complex issue because of uncertainties surrounding the relationship between maternal toxicity and developmental outcome. Expert judgment and a weight of evidence approach, using all available studies, shall be used to determine the degree of influence to be attributed to maternal toxicity when interpreting the criteria for classification for developmental effects. The adverse effects in the embryo/fetus shall be first considered, and then maternal toxicity, along with any other factors which are likely to have influenced these effects, as weight of evidence, to help reach a conclusion about classification.

A.7.2.4.2 Based on pragmatic observation, it is believed that maternal toxicity may, depending on severity, influence development via non-specific secondary mechanisms, producing effects such as depressed fetal weight, retarded ossification, and possibly resorptions and certain malformations in some strains of certain species. However, the limited numbers of studies which have investigated the relationship between developmental effects and general maternal toxicity have failed to demonstrate a consistent, reproducible relationship across species. Developmental effects which occur even in the presence of maternal toxicity are considered to be evidence of developmental toxicity, unless it can be unequivocally demonstrated on a case by case basis that the developmental effects are secondary to maternal toxicity. Moreover, classification shall be considered where there is a significant toxic effect in the offspring, e.g., irreversible effects such as structural malformations, embryo/fetal lethality, or significant post-natal functional deficiencies.

A.7.2.4.3 Classification shall not automatically be discounted for chemicals that produce developmental toxicity only in association with maternal toxicity, even if a specific maternally-mediated mechanism has been demonstrated. In such a case, classification in Category 2 may be considered more

Permanent [122]

appropriate than Category 1. However, when a chemical is so toxic that maternal death or severe inanition results, or the dams (mothers) are prostrate and incapable of nursing the pups, it is reasonable to assume that developmental toxicity is produced solely as a secondary consequence of maternal toxicity and discount the developmental effects. Classification is not necessarily the outcome in the case of minor developmental changes, e.g., a small reduction in fetal/pup body weight or retardation of ossification when seen in association with maternal toxicity.

- A.7.2.4.4 Some of the endpoints used to assess maternal toxicity are provided below. Data on these endpoints, if available, shall be evaluated in light of their statistical or biological significance and dose-response relationship.
- (a) Maternal mortality: An increased incidence of mortality among the treated dams over the controls shall be considered evidence of maternal toxicity if the increase occurs in a dose-related manner and can be attributed to the systemic toxicity of the test material. Maternal mortality greater than 10% is considered excessive and the data for that dose level shall not normally be considered to need further evaluation.
- (b) Mating index (Number of animals with seminal plugs or sperm/Number of mated x 100)
- (c) Fertility index (Number of animals with implants/ Number of matings x 100)
 - (d) Gestation length (If allowed to deliver
- (e) Body weight and body weight change: Consideration of the maternal body weight change and/or adjusted (corrected) maternal body weight shall be included in the evaluation of maternal toxicity whenever such data are available. The calculation of an adjusted (corrected) mean maternal body weight change, which is the difference between the initial and terminal body weight minus the gravid uterine weight (or alternatively, the sum of the weights of the fetuses), may indicate whether the effect is maternal or intrauterine. In rabbits, the body weight gain may not be a useful indicator of maternal toxicity because of normal fluctuations in body weight during pregnancy.
- (f) Food and water consumption (if relevant): The observation of a significant decrease in the average food or water consumption in treated dams (mothers) compared to the control group may be useful in evaluating maternal toxicity, particularly when the test material is administered in the diet or drinking water. Changes in food or water consumption must be evaluated in conjunction with maternal body weights when determining if the effects noted are reflective of maternal toxicity or more simply, unpalatability of the test material in feed or water.
- (g) Clinical evaluations (including clinical signs, markers, and hematology and clinical chemistry studies): The observation of increased incidence of significant clinical signs of toxicity in treated dams (mothers) relative to the control group is useful in evaluating maternal toxicity. If this is to be used as the basis for the assessment of maternal toxicity, the types, incidence, degree and duration of clinical signs shall be reported in the study. Clinical signs of maternal intoxication include, but are not limited to: coma, prostration, hyperactivity, loss of righting reflex, ataxia, or labored breathing.

(h) Post-mortem data: Increased incidence and/or severity of post-mortem findings may be indicative of maternal toxicity. This can include gross or microscopic pathological findings or organ weight data, including absolute organ weight, organ to body weight ratio, or organ to brain weight ratio. When supported by findings of adverse histopathological effects in the affected organ(s), the observation of a significant change in the average weight of suspected target organ(s) of treated dams (mothers), compared to those in the control group, may be considered evidence of maternal toxicity.

A.7.2.5 Animal and experimental data

- A.7.2.5.1 A number of scientifically validated test methods are available, including methods for developmental toxicity testing (e.g., OECD Test Guideline 414, ICH Guideline S5A, 1993), methods for peri- and post-natal toxicity testing (e.g., ICH S5B, 1995), and methods for one or two-generation toxicity testing (e.g., OECD Test Guidelines 415, 416)
- A.7.2.5.2 Results obtained from screening tests (e.g., OECD Guidelines 421 Reproduction/ Developmental Toxicity Screening Test, and 422 Combined Repeated Dose Toxicity Study with Reproduction/Development Toxicity Screening Test) can also be used to justify classification, although the quality of this evidence is less reliable than that obtained through full studies.
- A.7.2.5.3 Adverse effects or changes, seen in short- or longterm repeated dose toxicity studies, which are judged likely to impair reproductive function and which occur in the absence of significant generalized toxicity, may be used as a basis for classification, e.g., histopathological changes in the gonads.
- A.7.2.5.4 Evidence from *in vitro* assays, or non-mammalian tests, and from analogous substances using structure-activity relationship (SAR), can contribute to the procedure for classification. In all cases of this nature, expert judgment must be used to assess the adequacy of the data. Inadequate data shall not be used as a primary support for classification.
- A.7.2.5.5 It is preferable that animal studies are conducted using appropriate routes of administration which relate to the potential route of human exposure. However, in practice, reproductive toxicity studies are commonly conducted using the oral route, and such studies will normally be suitable for evaluating the hazardous properties of the substance with respect to reproductive toxicity. However, if it can be conclusively demonstrated that the clearly identified mechanism or mode of action has no relevance for humans or when the toxicokinetic differences are so marked that it is certain that the hazardous property will not be expressed in humans then a substance which produces an adverse effect on reproduction in experimental animals should not be classified.
- A.7.2.5.6 Studies involving routes of administration such as intravenous or intraperitoneal injection, which may result in exposure of the reproductive organs to unrealistically high levels of the test substance, or elicit local damage to the reproductive organs, e.g., by irritation, must be interpreted

Permanent

with extreme caution and on their own are not normally the basis for classification.

A.7.2.5.7 There is general agreement about the concept of a limit dose, above which the production of an adverse effect may be considered to be outside the criteria which lead to classification. Some test guidelines specify a limit dose, other test guidelines qualify the limit dose with a statement that higher doses may be necessary if anticipated human exposure is sufficiently high that an adequate margin of exposure would not be achieved. Also, due to species differences in toxicokinetics, establishing a specific limit dose may not be adequate for situations where humans are more sensitive than the animal model.

A.7.2.5.8 In principle, adverse effects on reproduction seen only at very high dose levels in animal studies (for example doses that induce prostration, severe inappetence, excessive mortality) do not normally lead to classification, unless other information is available, for example, toxicokinetics information indicating that humans may be more susceptible than animals, to suggest that classification is appropriate.

A.7.2.5.9 However, specification of the actual "limit dose" will depend upon the test method that has been employed to provide the test results.

A.7.3 Classification criteria for mixtures

A.7.3.1 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.7.3.1.1 The mixture shall be classified as a reproductive toxicant when at least one ingredient has been classified as a Category 1 or Category 2 reproductive toxicant and is present at or above the appropriate cut-off value/concentration limit specified in Table A.7.1 for Category 1 and 2, respectively.

A.7.3.1.2 The mixture shall be classified for effects on or via lactation when at least one ingredient has been classified for effects on or via lactation and is present at or above the appropriate cut-off value/concentration limit specified in Table A.7.1 for the additional category for effects on or via lactation.

Table A.7.1: Cut-off values/concentration limits of ingredients of a mixture classified as reproductive toxicants or for effects on or via lactation that trigger classification of the mixture

	Cut-off values/concentration limits triggering classification of a mixture as:		
Ingredient classified as:	Category 1 reproductive toxicant	Category 2 reproductive toxicant	Additional category for effects on or via lactation
Category 1 reproductive toxicant	≥ 0.1%		
Category 2 reproductive toxicant		≥ 0.1%	
Additional category for effects on or via lactation			≥ 0.1%

A.7.3.2 Classification of mixtures when data are available for the complete mixture

Available test data for the mixture as a whole may be used for classification on a case-by-case basis. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g., statistical analysis, test sensitivity) of reproduction test systems.

A.7.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.7.3.3.1 Where the mixture itself has not been tested to determine its reproductive toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, and Substantially similar mixtures.

A.8 SPECIFIC TARGET ORGAN TOXICITY SINGLE EXPOSURE

A.8.1 Definitions and general considerations

A.8.1.1 Specific target organ toxicity - single exposure, (STOT-SE) means specific, non-lethal target organ toxicity

arising from a single exposure to a chemical. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in A.1 to A.7 and A.10 of this Appendix are included. Specific target organ toxicity following repeated exposure is classified in accordance with SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE (A.9 of this Appendix) and is therefore not included here.

A.8.1.2 Classification identifies the chemical as being a specific target organ toxicant and, as such, it presents a potential for adverse health effects in people who are exposed to it.

A.8.1.3 The adverse health effects produced by a single exposure include consistent and identifiable toxic effects in humans; or, in experimental animals, toxicologically significant changes which have affected the function or morphology of a tissue/organ, or have produced serious changes to the biochemistry or hematology of the organism, and these changes are relevant for human health. Human data is the primary source of evidence for this hazard class.

A.8.1.4 Assessment shall take into consideration not only significant changes in a single organ or biological system but also generalized changes of a less severe nature involving several organs.

Permanent [124]

- A.8.1.5 Specific target organ toxicity can occur by any route that is relevant for humans, i.e., principally oral, dermal or inhalation.
- A.8.1.6 The classification criteria for specific organ systemic toxicity single exposure are organized as criteria for substances Categories 1 and 2 (See A.8.2.1), criteria for substances Category 3 (See A.8.2.2) and criteria for mixtures (See A.8.3). See also Figure A.8.1.

A.8.2 Classification criteria for substances

A.8.2.1 Substances of Category 1 and Category 2

A.8.2.1.1 Substances shall be classified for immediate or delayed effects separately, by the use of expert judgment on the basis of the weight of all evidence available, including the use of recommended guidance values (See A.8.2.1.9). Substances shall then be classified in Category 1 or 2, depending upon the nature and severity of the effect(s) observed, in accordance with Figure A.8.1.

Figure A.8.1: Hazard categories for specific target organ toxicity following single exposure

CATEGORY 1:	Substances that have produced significant toxicity in humans, or that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to produce significant toxicity in humans following single exposure	
	Substances are classified in Category 1 for STOT-SE on the basis of:	
	(a) reliable and good quality evidence from human cases or epidemiological studies; or	
	(b) observations from appropriate studies in experimental animals in which significant and/or severe toxic effects of relevance to human health were produced at generally low exposure concentrations. Guidance dose/concentration values are provided below (See A.8.2.1.9) to be used as part of weight-of-evidence evaluation.	
CATEGORY 2:	Substances that, on the basis of evidence from studies in experimental animals, can be pre-	
	sumed to have the potential to be harmful to human health following single exposure	
	Substances are classified in Category 2 for STOT-SE on the basis of observations from appropriate studies in experimental animals in which significant toxic effects, of relevance to human health, were produced at generally moderate exposure concentrations. Guidance dose/concentration values are provided below (See A.8.2.1.9) in order to help in classification	
	In exceptional cases, human evidence can also be used to place a substance in Category 2 (See A.8.2.1.6).	
CATEGORY 3:	Transient target organ effects	
	There are target organ effects for which a substance does not meet the criteria to be classified in Categories 1 or 2 indicated above. These are effects which adversely alter human function for a short duration after exposure and from which humans may recover in a reasonable period without leaving significant alteration of structure or function. This category only includes narcotic effects and respiratory tract irritation. Substances are classified specifically for these effects as discussed in A.8.2.2.	
Note: The primary tar	get organ/system shall be identified where possible, and where this is not possible, the substance shall	

Note: The primary target organ/system shall be identified where possible, and where this is not possible, the substance shall be identified as a general toxicant. The data shall be evaluated and, where possible, shall not include secondary effects (e.g., a hepatotoxicant can produce secondary effects in the nervous or gastro-intestinal systems).

- A.8.2.1.2 The relevant route(s) of exposure by which the classified substance produces damage shall be identified.
- A.8.2.1.3 Classification is determined by expert judgment, on the basis of the weight of all evidence available including the guidance presented below.
- A.8.2.1.4 Weight of evidence of all available data, including human incidents, epidemiology, and studies conducted in experimental animals is used to substantiate specific target organ toxic effects that merit classification.
- A.8.2.1.5 The information required to evaluate specific target organ toxicity comes either from single exposure in humans (e.g., exposure at home, in the workplace or environmentally), or from studies conducted in experimental animals. The standard animal studies in rats or mice that provide this information are acute toxicity studies which can include clin-

ical observations and detailed macroscopic and microscopic examination to enable the toxic effects on target tissues/organs to be identified. Results of acute toxicity studies conducted in other species may also provide relevant information.

A.8.2.1.6 In exceptional cases, based on expert judgment, it may be appropriate to place certain substances with human evidence of target organ toxicity in Category 2: (a) when the weight of human evidence is not sufficiently convincing to warrant Category 1 classification, and/or (b) based on the nature and severity of effects. Dose/concentration levels in humans shall not be considered in the classification and any available evidence from animal studies shall be consistent with the Category 2 classification. In other words, if there are also animal data available on the substance that warrant Cat-

[125] Permanent

- egory 1 classification, the chemical shall be classified as Category 1.
- A.8.2.1.7 Effects considered to support classification for Category 1 and 2
- A.8.2.1.7.1 Classification is supported by evidence associating single exposure to the substance with a consistent and identifiable toxic effect.
- A.8.2.1.7.2 Evidence from human experience/incidents is usually restricted to reports of adverse health consequences, often with uncertainty about exposure conditions, and may not provide the scientific detail that can be obtained from well-conducted studies in experimental animals.
- A.8.2.1.7.3 Evidence from appropriate studies in experimental animals can furnish much more detail, in the form of clinical observations, and macroscopic and microscopic pathological examination and this can often reveal hazards that may not be life-threatening but could indicate functional impairment. Consequently all available evidence, and evidence relevance to human health, must be taken into consideration in the classification process. Relevant toxic effects in humans and/or animals include, but are not limited to:
 - (a) Morbidity resulting from single exposure;
- (b) Significant functional changes, more than transient in nature, in the respiratory system, central or peripheral nervous systems, other organs or other organ systems, including signs of central nervous system depression and effects on special senses (e.g., sight, hearing and sense of smell);
- (c) Any consistent and significant adverse change in clinical biochemistry, hematology, or urinalysis parameters;
- (d) Significant organ damage that may be noted at necropsy and/or subsequently seen or confirmed at microscopic examination:
- (e) Multi-focal or diffuse necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity;
- (f) Morphological changes that are potentially reversible but provide clear evidence of marked organ dysfunction; and,
- (g) Evidence of appreciable cell death (including cell degeneration and reduced cell number) in vital organs incapable of regeneration.
- A.8.2.1.8 Effects considered not to support classification for Category 1 and 2

- Effects may be seen in humans and/or animals that do not justify classification. Such effects include, but are not limited to:
- (a) Clinical observations or small changes in bodyweight gain, food consumption or water intake that may have some toxicological importance but that do not, by themselves, indicate "significant" toxicity;
- (b) Small changes in clinical biochemistry, hematology or urinalysis parameters and/or transient effects, when such changes or effects are of doubtful or of minimal toxicological importance;
- (c) Changes in organ weights with no evidence of organ dysfunction;
- (d) Adaptive responses that are not considered toxicologically relevant; and,
- (e) Substance-induced species-specific mechanisms of toxicity, i.e., demonstrated with reasonable certainty to be not relevant for human health, shall not justify classification.
- A.8.2.1.9 Guidance values to assist with classification based on the results obtained from studies conducted in experimental animals for Category 1 and 2
- A.8.2.1.9.1 In order to help reach a decision about whether a substance shall be classified or not, and to what degree it shall be classified (Category 1 vs. Category 2), dose/concentration "guidance values" are provided for consideration of the dose/concentration which has been shown to produce significant health effects. The principal argument for proposing such guidance values is that all chemicals are potentially toxic and there has to be a reasonable dose/concentration above which a degree of toxic effect is acknowledged.
- A.8.2.1.9.2 Thus, in animal studies, when significant toxic effects are observed that indicate classification, consideration of the dose/concentration at which these effects were seen, in relation to the suggested guidance values, provides useful information to help assess the need to classify (since the toxic effects are a consequence of the hazardous property(ies) and also the dose/concentration).
- A.8.2.1.9.3 The guidance value (C) ranges for single-dose exposure which has produced a significant non-lethal toxic effect are those applicable to acute toxicity testing, as indicated in Table A.8.1.

		Guidance value ranges for:		
Route of exposure	Units	Category 1	Category 2	Category 3
Oral (rat)	mg/kg body weight	C ≤ 300	$2000 \ge C > 300$	Guidance values do
Dermal (rat or rabbit)	mg/kg body weight	C ≤ 1000	$2000 \ge C > 1000$	not apply
Inhalation (rat) gas	ppmV/4h	C ≤ 2500	$20,000 \ge C > 2500$	
Inhalation (rat) vapor	mg/l/4h	C ≤ 10	20 ≥ C > 10	
Inhalation (rat) dust/mist/fume	mg/l/4h	C ≤ 1.0	$5.0 \ge C > 1.0$	

A.8.2.1.9.4 The guidance values and ranges mentioned in Table A.8.1 are intended only for guidance purposes, i.e., to be used as part of the weight of evidence approach, and to assist with decisions about classification. They are not intended as strict demarcation values. Guidance values are

not provided for Category 3 since this classification is primarily based on human data; animal data may be included in the weight of evidence evaluation.

Permanent [126]

A.8.2.1.9.5 Thus, it is feasible that a specific profile of toxicity occurs at a dose/concentration below the guidance value, e.g., < 2000 mg/kg body weight by the oral route, however the nature of the effect may result in the decision not to classify. Conversely, a specific profile of toxicity may be seen in animal studies occurring at above a guidance value, e.g., ≥ 2000 mg/kg body weight by the oral route, and in addition there is supplementary information from other sources, e.g., other single dose studies, or human case experience, which supports a conclusion that, in view of the weight of evidence, classification is the prudent action to take.

A.8.2.1.10 Other considerations

A.8.2.1.10.1 When a substance is characterized only by use of animal data the classification process includes reference to dose/concentration guidance values as one of the elements that contribute to the weight of evidence approach.

A.8.2.1.10.2 When well-substantiated human data are available showing a specific target organ toxic effect that can be reliably attributed to single exposure to a substance, the substance shall be classified. Positive human data, regardless of probable dose, predominates over animal data. Thus, if a substance is unclassified because specific target organ toxicity observed was considered not relevant or significant to humans, if subsequent human incident data become available showing a specific target organ toxic effect, the substance shall be classified.

A.8.2.1.10.3 A substance that has not been tested for specific target organ toxicity shall, where appropriate, be classified on the basis of data from a scientifically validated structure activity relationship and expert judgment-based extrapolation from a structural analogue that has previously been classified together with substantial support from consideration of other important factors such as formation of common significant metabolites.

A.8.2.2 Substances of Category 3

A.8.2.2.1 Criteria for respiratory tract irritation

The criteria for classifying substances as Category 3 for respiratory tract irritation are:

- (a) Respiratory irritant effects (characterized by localized redness, edema, pruritis and/or pain) that impair function with symptoms such as cough, pain, choking, and breathing difficulties are included. It is recognized that this evaluation is based primarily on human data;
- (b) Subjective human observations supported by objective measurements of clear respiratory tract irritation (RTI) (e.g., electrophysiological responses, biomarkers of inflammation in nasal or bronchoalveolar lavage fluids);
- (c) The symptoms observed in humans shall also be typical of those that would be produced in the exposed population rather than being an isolated idiosyncratic reaction or response triggered only in individuals with hypersensitive airways. Ambiguous reports simply of "irritation" should be excluded as this term is commonly used to describe a wide range of sensations including those such as smell, unpleasant taste, a tickling sensation, and dryness, which are outside the scope of classification for respiratory tract irritation;

- (d) There are currently no scientifically validated animal tests that deal specifically with RTI; however, useful information may be obtained from the single and repeated inhalation toxicity tests. For example, animal studies may provide useful information in terms of clinical signs of toxicity (dyspnoea, rhinitis etc) and histopathology (e.g., hyperemia, edema, minimal inflammation, thickened mucous layer) which are reversible and may be reflective of the characteristic clinical symptoms described above. Such animal studies can be used as part of weight of evidence evaluation; and,
- (e) This special classification will occur only when more severe organ effects including the respiratory system are not observed as those effects would require a higher classification

A.8.2.2.2 Criteria for narcotic effects

The criteria for classifying substances in Category 3 for narcotic effects are:

- (a) Central nervous system depression including narcotic effects in humans such as drowsiness, narcosis, reduced alertness, loss of reflexes, lack of coordination, and vertigo are included. These effects can also be manifested as severe headache or nausea, and can lead to reduced judgment, dizziness, irritability, fatigue, impaired memory function, deficits in perception and coordination, reaction time, or sleepiness; and,
- (b) Narcotic effects observed in animal studies may include lethargy, lack of coordination righting reflex, narcosis, and ataxia. If these effects are not transient in nature, then they shall be considered for classification as Category 1 or 2.

A.8.3 Classification criteria for mixtures

A.8.3.1 Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures may be classified for specific target organ toxicity following single exposure, repeated exposure, or both

A.8.3.2 Classification of mixtures when data are available for the complete mixture

When reliable and good quality evidence from human experience or appropriate studies in experimental animals, as described in the criteria for substances, is available for the mixture, then the mixture shall be classified by weight of evidence evaluation of this data. Care shall be exercised in evaluating data on mixtures, that the dose, duration, observation or analysis, do not render the results inconclusive.

A.8.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.8.3.3.1 Where the mixture itself has not been tested to determine its specific target organ toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one toxicity category, Substantially similar mixtures, or Aerosols.

[127] Permanent

A.8.3.4 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.8.3.4.1 Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, repeated exposure, or both when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant and is present at or above the appropriate cut-off value/concentration limit specified in Table A.8.2 for Categories 1 and 2, respectively.

Table A.8.2: Cut-off values/concentration limits of ingredients of a mixture classified as a specific target organ toxicant that would trigger classification of the mixture as Category 1 or 2

	Cut-off values/concentration limits triggering classification of a mixture as:		
Ingredient classified as:	Category 1	Category 2	
Category 1	≤ 1.0%		
Target organ toxicant			
Category 2		≤ 1.0%	
Target organ toxicant			

A.8.3.4.2 These cut-off values and consequent classifications shall be applied equally and appropriately to both single- and repeated-dose target organ toxicants.

A.8.3.4.3 Mixtures shall be classified for either or both single and repeated dose toxicity independently.

A.8.3.4.4 Care shall be exercised when toxicants affecting more than one organ system are combined that the potentiation or synergistic interactions are considered, because certain substances can cause target organ toxicity at < 1% concentration when other ingredients in the mixture are known to potentiate its toxic effect.

A.8.3.4.5 Care shall be exercised when extrapolating the toxicity of a mixture that contains Category 3 ingredient(s). A cut-off value/concentration limit of 20%, considered as an additive of all Category 3 ingredients for each hazard endpoint, is appropriate; however, this cut-off value/concentration limit may be higher or lower depending on the Category 3 ingredient(s) involved and the fact that some effects such as respiratory tract irritation may not occur below a certain concentration while other effects such as narcotic effects may occur below this 20% value. Expert judgment shall be exercised. Respiratory tract irritation and narcotic effects are to

be evaluated separately in accordance with the criteria given in A.8.2.2. When conducting classifications for these hazards, the contribution of each ingredient should be considered additive, unless there is evidence that the effects are not additive.

A.9 SPECIFIC TARGET ORGAN TOXICITY REPEATED OR PROLONGED EXPOSURE

A.9.1 Definitions and general considerations

A.9.1.1 Specific target organ toxicity - repeated exposure (STOT-RE) means specific target organ toxicity arising from repeated exposure to a substance or mixture. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in A.1 to A.7 and A.10 of this Appendix are included. Specific target organ toxicity following a single-event exposure is classified in accordance with SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE (A.8 of this Appendix) and is therefore not included here.

A.9.1.2 Classification identifies the substance or mixture as being a specific target organ toxicant and, as such, it may present a potential for adverse health effects in people who are exposed to it.

A.9.1.3 These adverse health effects produced by repeated exposure include consistent and identifiable toxic effects in humans, or, in experimental animals, toxicologically significant changes which have affected the function or morphology of a tissue/organ, or have produced serious changes to the biochemistry or hematology of the organism and these changes are relevant for human health. Human data will be the primary source of evidence for this hazard class.

A.9.1.4 Assessment shall take into consideration not only significant changes in a single organ or biological system but also generalized changes of a less severe nature involving several organs.

A.9.1.5 Specific target organ toxicity can occur by any route that is relevant for humans, e.g., principally oral, dermal or inhalation.

A.9.2 Classification criteria for substances

A.9.2.1 Substances shall be classified as STOT-RE by expert judgment on the basis of the weight of all evidence available, including the use of recommended guidance values which take into account the duration of exposure and the dose/concentration which produced the effect(s), (See A.9.2.9). Substances shall be placed in one of two categories, depending upon the nature and severity of the effect(s) observed, in accordance with Figure A.9.1.

Figure A.9.1: Hazard categories for specific target organ toxicity following repeated exposure

CATEGORY 1:	Substances that have produced significant toxicity in humans, or that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to produce significant toxicity in humans following repeated or prolonged exposure
	Substances are classified in Category 1 for specific target organ toxicity (repeated exposure) on the basis of:

Permanent [128]

CATEGORY 2:

(a) reliable and good quality evidence from human cases or epidemiological studies; or,

(b) observations from appropriate studies in experimental animals in which significant and/or severe toxic effects, of relevance to human health, were produced at generally low exposure concentrations. Guidance dose/concentration values are provided below (See A.9.2.9) to be used as part of weight-of-evidence evaluation.

Substances that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to be harmful to human health following repeated or prolonged exposure

Substances are classified in Category 2 for specific target organ toxicity (repeated exposure) on the basis of observations from appropriate studies in experimental animals in which significant toxic effects, of relevance to human health, were produced at generally moderate exposure concentrations. Guidance dose/concentration values are provided below (See A.9.2.9) in order to help in classification.

In exceptional cases human evidence can also be used to place a substance in Category 2 (See A.9.2.6).

Note: The primary target organ/system shall be identified where possible, or the substance shall be identified as a general toxicant. The data shall be carefully evaluated and, where possible, shall not include secondary effects (e.g., a hepatotoxicant can produce secondary effects in the nervous or gastro-intestinal systems).

- A.9.2.2 The relevant route of exposure by which the classified substance produces damage shall be identified.
- A.9.2.3 Classification is determined by expert judgment, on the basis of the weight of all evidence available including the guidance presented below.
- A.9.2.4 Weight of evidence of all data, including human incidents, epidemiology, and studies conducted in experimental animals, is used to substantiate specific target organ toxic effects that merit classification.
- A.9.2.5 The information required to evaluate specific target organ toxicity comes either from repeated exposure in humans, e.g., exposure at home, in the workplace or environmentally, or from studies conducted in experimental animals. The standard animal studies in rats or mice that provide this information are 28 day, 90 day or lifetime studies (up to 2 years) that include hematological, clinico-chemical and detailed macroscopic and microscopic examination to enable the toxic effects on target tissues/organs to be identified. Data from repeat dose studies performed in other species may also be used. Other long-term exposure studies, e.g., for carcinogenicity, neurotoxicity or reproductive toxicity, may also provide evidence of specific target organ toxicity that could be used in the assessment of classification.
- A.9.2.6 In exceptional cases, based on expert judgment, it may be appropriate to place certain substances with human evidence of specific target organ toxicity in Category 2: (a) when the weight of human evidence is not sufficiently convincing to warrant Category 1 classification, and/or (b) based on the nature and severity of effects. Dose/concentration levels in humans shall not be considered in the classification and any available evidence from animal studies shall be consistent with the Category 2 classification. In other words, if there are also animal data available on the substance that warrant Category 1 classification, the substance shall be classified as Category 1.
- A.9.2.7 Effects considered to support classification

- A.9.2.7.1 Classification is supported by reliable evidence associating repeated exposure to the substance with a consistent and identifiable toxic effect.
- A.9.2.7.2 Evidence from human experience/incidents is usually restricted to reports of adverse health consequences, often with uncertainty about exposure conditions, and may not provide the scientific detail that can be obtained from well-conducted studies in experimental animals.
- A.9.2.7.3 Evidence from appropriate studies in experimental animals can furnish much more detail, in the form of clinical observations, hematology, clinical chemistry, macroscopic and microscopic pathological examination and this can often reveal hazards that may not be life-threatening but could indicate functional impairment. Consequently all available evidence, and relevance to human health, must be taken into consideration in the classification process. Relevant toxic effects in humans and/or animals include, but are not limited to:
- (a) Morbidity or death resulting from repeated or longterm exposure. Morbidity or death may result from repeated exposure, even to relatively low doses/concentrations, due to bioaccumulation of the substance or its metabolites, or due to the overwhelming of the de-toxification process by repeated exposure;
- (b) Significant functional changes in the central or peripheral nervous systems or other organ systems, including signs of central nervous system depression and effects on special senses (e.g., sight, hearing and sense of smell);
- (c) Any consistent and significant adverse change in clinical biochemistry, hematology, or urinalysis parameters;
- (d) Significant organ damage that may be noted at necropsy and/or subsequently seen or confirmed at microscopic examination:
- (e) Multi-focal or diffuse necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity;
- (f) Morphological changes that are potentially reversible but provide clear evidence of marked organ dysfunction (e.g., severe fatty change in the liver); and,

[129] Permanent

- (g) Evidence of appreciable cell death (including cell degeneration and reduced cell number) in vital organs incapable of regeneration.
- A.9.2.8 Effects considered not to support classification

Effects may be seen in humans and/or animals that do not justify classification. Such effects include, but are not limited to:

- (a) Clinical observations or small changes in bodyweight gain, food consumption or water intake that may have some toxicological importance but that do not, by themselves, indicate "significant" toxicity;
- (b) Small changes in clinical biochemistry, hematology or urinalysis parameters and /or transient effects, when such changes or effects are of doubtful or of minimal toxicological importance;
- (c) Changes in organ weights with no evidence of organ dysfunction;
- (d) Adaptive responses that are not considered toxicologically relevant;
- (e) Substance-induced species-specific mechanisms of toxicity, i.e., demonstrated with reasonable certainty to be not relevant for human health, shall not justify classification.
- A.9.2.9 Guidance values to assist with classification based on the results obtained from studies conducted in experimental animals
- A.9.2.9.1 In studies conducted in experimental animals, reliance on observation of effects alone, without reference to the duration of experimental exposure and dose/concentration, omits a fundamental concept of toxicology, i.e., all substances are potentially toxic, and what determines the toxicity is a function of the dose/concentration and the duration of exposure. In most studies conducted in experimental animals the test guidelines use an upper limit dose value.
- A.9.2.9.2 In order to help reach a decision about whether a substance shall be classified or not, and to what degree it shall be classified (Category 1 vs. Category 2), dose/concentration "guidance values" are provided in Table A.9.1 for consideration of the dose/concentration which has been shown to pro-

duce significant health effects. The principal argument for proposing such guidance values is that all chemicals are potentially toxic and there has to be a reasonable dose/concentration above which a degree of toxic effect is acknowledged. Also, repeated-dose studies conducted in experimental animals are designed to produce toxicity at the highest dose used in order to optimize the test objective and so most studies will reveal some toxic effect at least at this highest dose. What is therefore to be decided is not only what effects have been produced, but also at what dose/concentration they were produced and how relevant is that for humans.

- A.9.2.9.3 Thus, in animal studies, when significant toxic effects are observed that indicate classification, consideration of the duration of experimental exposure and the dose/concentration at which these effects were seen, in relation to the suggested guidance values, provides useful information to help assess the need to classify (since the toxic effects are a consequence of the hazardous property(ies) and also the duration of exposure and the dose/concentration).
- A.9.2.9.4 The decision to classify at all can be influenced by reference to the dose/concentration guidance values at or below which a significant toxic effect has been observed.
- A.9.2.9.5 The guidance values refer to effects seen in a standard 90-day toxicity study conducted in rats. They can be used as a basis to extrapolate equivalent guidance values for toxicity studies of greater or lesser duration, using dose/exposure time extrapolation similar to Haber's rule for inhalation, which states essentially that the effective dose is directly proportional to the exposure concentration and the duration of exposure. The assessment should be done on a case-by-case basis; for example, for a 28-day study the guidance values below would be increased by a factor of three.
- A.9.2.9.6 Thus for Category 1 classification, significant toxic effects observed in a 90-day repeated-dose study conducted in experimental animals and seen to occur at or below the (suggested) guidance values (C) as indicated in Table A.9.1 would justify classification:

Table A.9.1: Guidance values to assist in Category 1 classification (applicable to a 90-day study)

Route of exposure	Units	Guidance values (dose/concentration)
Oral (rat)	mg/kg body weight/day	C ≤ 10
Dermal (rat or rabbit)	mg/kg body weight/day	C ≤ 20
Inhalation (rat) gas	ppmV/6h/day	C ≤ 50
Inhalation (rat) vapor	mg/liter/6h/day	C ≤ 0.2
Inhalation (rat) dust/mist/fume	mg/liter/6h/day	C ≤ 0.02

A.9.2.9.7 For Category 2 classification, significant toxic effects observed in a 90-day repeated-dose study conducted in experimental animals and seen to occur within the (suggested) guidance value ranges as indicated in Table A.9.2 would justify classification:

Table A.9.2: Guidance values to assist in Category 2 classification (applicable to a 90-day study)

Route of exposure	Units	Guidance values range (dose/concentration)
Oral (rat)	mg/kg body weight/day	10 < C ≤ 100

Permanent [130]

Route of exposure	Units	Guidance values range (dose/concentration)
Dermal (rat or rabbit)	mg/kg body weight/day	20 < C ≤ 200
Inhalation (rat) gas	ppmV/6h/day	50 < C ≤ 250
Inhalation (rat) vapor	mg/liter/6h/day	$0.2 < C \le 1.0$
Inhalation (rat) dust/mist/fume	mg/liter/6h/day	$0.02 < C \le 0.2$

A.9.2.9.8 The guidance values and ranges mentioned in A.2.9.9.6 and A.2.9.9.7 are intended only for guidance purposes, i.e., to be used as part of the weight of evidence approach, and to assist with decisions about classification. They are not intended as strict demarcation values.

A.9.2.9.9 Thus, it is possible that a specific profile of toxicity occurs in repeat-dose animal studies at a dose/concentration below the guidance value, e.g., < 100 mg/kg body weight/day by the oral route, however the nature of the effect, e.g., nephrotoxicity seen only in male rats of a particular strain known to be susceptible to this effect, may result in the decision not to classify. Conversely, a specific profile of toxicity may be seen in animal studies occurring at above a guidance value, e.g., ≥ 100 mg/kg body weight/day by the oral route, and in addition there is supplementary information from other sources, e.g., other long-term administration studies, or human case experience, which supports a conclusion that, in view of the weight of evidence, classification is prudent.

A.9.2.10 Other considerations

A.9.2.10.1 When a substance is characterized only by use of animal data the classification process includes reference to dose/concentration guidance values as one of the elements that contribute to the weight of evidence approach.

A.9.2.10.2 When well-substantiated human data are available showing a specific target organ toxic effect that can be reliably attributed to repeated or prolonged exposure to a substance, the substance shall be classified. Positive human data, regardless of probable dose, predominates over animal data. Thus, if a substance is unclassified because no specific target organ toxicity was seen at or below the dose/concentration guidance value for animal testing, if subsequent human incident data become available showing a specific target organ toxic effect, the substance shall be classified.

A.9.2.10.3 A substance that has not been tested for specific target organ toxicity may in certain instances, where appropriate, be classified on the basis of data from a scientifically validated structure activity relationship and expert judgment-based extrapolation from a structural analogue that has previously been classified together with substantial support from consideration of other important factors such as formation of common significant metabolites.

A.9.3 Classification criteria for mixtures

A.9.3.1 Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures may be classified for specific target organ toxicity following single exposure, repeated exposure, or both.

A.9.3.2 Classification of mixtures when data are available for the complete mixture

When reliable and good quality evidence from human experience or appropriate studies in experimental animals, as described in the criteria for substances, is available for the mixture, then the mixture shall be classified by weight of evidence evaluation of these data. Care shall be exercised in evaluating data on mixtures, that the dose, duration, observation or analysis, do not render the results inconclusive.

A.9.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.9.3.3.1 Where the mixture itself has not been tested to determine its specific target organ toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution; Batching; Concentration of mixtures; Interpolation within one toxicity category; Substantially similar mixtures; and Aerosols.

A.9.3.4 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.9.3.4.1 Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, repeated exposure, or both when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant and is present at or above the appropriate cut-off value/concentration limit specified in Table A.9.3 for Category 1 and 2 respectively.

Table A.9.3: Cut-off value/concentration limits of ingredients of a mixture classified as a specific target organ toxicant that would trigger classification of the mixture as Category 1 or 2

	Cut-off values/concentration limits triggering classification of a mixture as:	
Ingredient classified as:	Category 1	Category 2
Category 1	≥ 1.0%	
Target organ toxicant		
Category 2		≥ 1.0%
Target organ toxicant		

Permanent

A.9.3.4.2 These cut-off values and consequent classifications shall be applied equally and appropriately to both single- and repeated-dose target organ toxicants.

A.9.3.4.3 Mixtures shall be classified for either or both single- and repeated-dose toxicity independently.

A.9.3.4.4 Care shall be exercised when toxicants affecting more than one organ system are combined that the potentiation or synergistic interactions are considered, because certain substances can cause specific target organ toxicity at < 1% concentration when other ingredients in the mixture are known to potentiate its toxic effect.

A.10 ASPIRATION HAZARD

A.10.1 Definitions and general and specific considerations

A.10.1.1 *Aspiration* means the entry of a liquid or solid chemical directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system.

A.10.1.2 Aspiration toxicity includes severe acute effects such as chemical pneumonia, varying degrees of pulmonary injury or death following aspiration.

A.10.1.3 Aspiration is initiated at the moment of inspiration, in the time required to take one breath, as the causative material lodges at the crossroad of the upper respiratory and digestive tracts in the laryngopharyngeal region.

A.10.1.4 Aspiration of a substance or mixture can occur as it is vomited following ingestion. This may have consequences for labeling, particularly where, due to acute toxicity, a recommendation may be considered to induce vomiting after ingestion. However, if the substance/mixture also presents an aspiration toxicity hazard, the recommendation to induce vomiting may need to be modified.

A.10.1.5 Specific considerations

A.10.1.5.1 The classification criteria refer to kinematic viscosity. The following provides the conversion between dynamic and kinematic viscosity:

$$\frac{\text{Dynamic viscosity (mPa·s)}}{\text{Density (g/cm}^3)} = \text{Kinematic viscosity (mm}^2/\text{s)}$$

A.10.1.5 Specific Considerations

A.10.1.5.2 Although the definition of aspiration in A.10.1.1 includes the entry of solids into the respiratory system, classification according to (b) in table A.10.1 for Category 1 is intended to apply to liquid substances and mixtures only.

A.10.1.5.3 Classification of aerosol/mist products

Aerosol and mist products are usually dispensed in containers such as self-pressurized containers, trigger and pump sprayers. Classification for these products shall be considered if their use may form a pool of product in the mouth,

which then may be aspirated. If the mist or aerosol from a pressurized container is fine, a pool may not be formed. On the other hand, if a pressurized container dispenses product in a stream, a pool may be formed that may then be aspirated. Usually, the mist produced by trigger and pump sprayers is coarse and therefore, a pool may be formed that then may be aspirated. When the pump mechanism may be removed and contents are available to be swallowed then the classification of the products should be considered.

A.10.2 Classification criteria for substances

Table A.10.1: Criteria for aspiration toxicity

Category	Criteria
Category 1: Chemicals known to cause human aspiration toxicity hazards or to be regarded as if they cause human aspiration toxicity hazard	A substance shall be classified in Category 1: (a) If reliable and good quality human evidence indicates that it causes aspiration toxicity (See note); or (b) If it is a hydrocarbon and has a kinematic viscosity ≤20.5 mm²/s, measured at
	40°C.

Note: Examples of substances included in Category 1 are certain hydrocarbons, turpentine and pine oil.

A.10.3 Classification criteria for mixtures

A.10.3.1 Classification when data are available for the complete mixture

A mixture shall be classified in Category 1 based on reliable and good quality human evidence.

A.10.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.10.3.2.1 Where the mixture itself has not been tested to determine its aspiration toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazard of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution; Batching; Concentration of mixtures; Interpolation within one toxicity category; and Substantially similar mixtures. For application of the dilution bridging principle, the concentration of aspiration toxicants shall not be less than 10%.

A.10.3.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.10.3.3.1 A mixture which contains \geq 10% of an ingredient or ingredients classified in Category 1, and has a kinematic viscosity \leq 20.5 mm²/s, measured at 40°C, shall be classified in Category 1.

A.10.3.3.2 In the case of a mixture which separates into two or more distinct layers, one of which contains $\geq 10\%$ of an ingredient or ingredients classified in Category 1 and has a

Permanent [132]

kinematic viscosity ≤ 20.5 mm²/s, measured at 40°C, then the entire mixture shall be classified in Category 1.

Reviser's note: The typographical errors in the above section occurred in the copy filed by the agency and appear in the Register pursuant to the requirements of RCW 34.08.040.

NEW SECTION

WAC 296-901-14024 Appendix B—Physical hazard criteria.

B.1 EXPLOSIVES

- B.1.1 Definitions and general considerations.
- B.1.1.1 An *explosive chemical* is a solid or liquid chemical which is in itself capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings. Pyrotechnic chemicals are included even when they do not evolve gases.

A *pyrotechnic chemical* is a chemical designed to produce an effect by heat, light, sound, gas or smoke or a combination of these as the result of non-detonative self-sustaining exothermic chemical reactions.

An *explosive item* is an item containing one or more explosive chemicals.

A *pyrotechnic item* is an item containing one or more pyrotechnic chemicals.

An *unstable explosive* is an explosive which is thermally unstable and/or too sensitive for normal handling, transport, or use

An *intentional explosive* is a chemical or item which is manufactured with a view to produce a practical explosive or pyrotechnic effect.

- B.1.1.2 The class of explosives comprises:
 - (a) Explosive chemicals;
- (b) Explosive items, except devices containing explosive chemicals in such quantity or of such a character that their inadvertent or accidental ignition or initiation must not cause any effect external to the device either by projection, fire, smoke, heat or loud noise; and
- (c) Chemicals and items not included under (a) and (b) above which are manufactured with the view to producing a practical explosive or pyrotechnic effect.

B.1.2 Classification criteria

Chemicals and items of this class must be classified as unstable explosives or must be assigned to one of the following six divisions depending on the type of hazard they present:

- (a) Division 1.1 Chemicals and items which have a mass explosion hazard (a mass explosion is one which affects almost the entire quantity present virtually instantaneously);
- (b) Division 1.2 Chemicals and items which have a projection hazard but not a mass explosion hazard;
- (c) Division 1.3 Chemicals and items which have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but not a mass explosion hazard:
- (i) Combustion of which gives rise to considerable radiant heat; or
- (ii) Which burn one after another, producing minor blast or projection effects or both;

- (d) Division 1.4 Chemicals and items which present no significant hazard: chemicals and items which present only a small hazard in the event of ignition or initiation. The effects are largely confined to the package and no projection of fragments of appreciable size or range is to be expected. An external fire must not cause virtually instantaneous explosion of almost the entire contents of the package;
- (e) Division 1.5 Very insensitive chemicals which have a mass explosion hazard: chemicals which have a mass explosion hazard but are so insensitive that there is very little probability of initiation or of transition from burning to detonation under normal conditions;
- (f) Division 1.6 Extremely insensitive items which do not have a mass explosion hazard: Items which contain only extremely insensitive detonating chemicals and which demonstrate a negligible probability of accidental initiation or propagation.

B.1.3 Additional classification considerations

B.1.3.1 Explosives must be classified as unstable explosives or must be assigned to one of the six divisions identified in B.1.2 in accordance with the three step procedure in Part I of the UN ST/SG/AC.10/Rev. 4, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003. The first step is to ascertain whether the substance or mixture has explosive effects (Test Series 1). The second step is the acceptance procedure (Test Series 2 to 4) and the third step is the assignment to a hazard division (Test Series 5 to 7). The assessment whether a candidate for "ammonium nitrate emulsion or suspension or gel, intermediate for blasting explosives (ANE)" is insensitive enough for inclusion as an oxidizing liquid (See B.13) or an oxidizing solid (See B.14) is determined by Test Series 8 tests.

NOTE: Classification of solid chemicals must be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form

B.1.3.2 Explosive properties are associated with the presence of certain chemical groups in a molecule which can react to produce very rapid increases in temperature or pressure. The screening procedure in B.1.3.1 is aimed at identifying the presence of such reactive groups and the potential for rapid energy release. If the screening procedure identifies the chemical as a potential explosive, the acceptance procedure (See section 10.3 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6)) is necessary for classification.

NOTE: Neither a Series 1 type (a) propagation of detonation test nor a Series 2 type (a) test of sensitivity to detonative shock is necessary if the exothermic decomposition energy of organic materials is less than 800 J/g.

B.1.3.3 If a mixture contains any known explosives, the acceptance procedure is necessary for classification.

Permanent

B.1.3.4 A chemical is not classified as explosive if:

- (a) There are no chemical groups associated with explosive properties present in the molecule. Examples of groups which may indicate explosive properties are given in Table A6.1 in Appendix 6 of the UN ST/SG/AC.10/Rev. 4, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003; or
- (b) The substance contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than -200.

The oxygen balance is calculated for the chemical reaction:

$$C_x H_y O_z + [x + (y/4) - (z/2)] O_2 \Rightarrow x.CO_2 + (y/2) H_2 O_2$$

using the formula: oxygen balance = -1600[2x + (y/2)-z]/molecular weight; or

- (c) The organic substance or a homogenous mixture of organic substances contains chemical groups associated with explosive properties but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500°C (932°F). The exothermic decomposition energy may be determined using a suitable calorimetric technique; or
- (d) For mixtures of inorganic oxidizing substances with organic material(s), the concentration of the inorganic oxidizing substance is:
- (i) less than 15%, by mass, if the oxidizing substance is assigned to Category 1 or 2;
- (ii) less than 30%, by mass, if the oxidizing substance is assigned to Category 3.

B.2 FLAMMABLE GASES

B.2.1 Definition

Flammable gas means a gas having a flammable range with air at 20°C (68°F) and a standard pressure of 101.3 kPa (14.7 psi).

B.2.2 Classification criteria

A flammable gas must be classified in one of the two categories for this class in accordance with Table B.2.1:

TABLE B.2.1—CRITERIA FOR FLAMMABLE GASES

Category	Criteria
1	Gases, which at 20°C (68°F) and a standard pressure of 101.3 kPa (14.7 psi): (a) are ignitable when in a mixture of 13% or less by volume in air; or (b) have a flammable range with air of at least 12 percentage points regardless of the lower flammable limit.
2	Gases, other than those of Category 1, which, at 20°C (68°F) and a standard pressure of 101.3 kPa (14.7 psi), have a flammable range while mixed in air.

NOTE: Aerosols must not be classified as flammable gases. See B.3.

B.2.3 Additional classification considerations

Flammability must be determined by tests or by calculation in accordance with ISO 10156:1996 (E), Gases and Gas Mixtures—Determination of Fire Potential and Oxidizing Ability for the Selection of Cylinder Valve Outlets, Second Edition, Feb. 15, 1996, ISO 10156-2:2005 (E), Gas Cylinders—Gases and Gas Mixtures—Part 2: Determination of Oxidizing Ability of Toxic and Corrosive Gases and Gas Mixtures, First Edition Aug. 1, 2005. Where insufficient data are available to use this method, equivalent validated methods may be used.

B.3 FLAMMABLE AEROSOLS

B.3.1 Definition

Aerosol means any non-refillable receptacle containing a gas compressed, liquefied or dissolved under pressure, and fitted with a release device allowing the contents to be ejected as particles in suspension in a gas, or as a foam, paste, powder, liquid or gas.

B.3.2 Classification criteria

B.3.2.1 Aerosols must be considered for classification as flammable if they contain any component which is classified as flammable in accordance with this Appendix, i.e.:

Flammable liquids (See B.6);

Flammable gases (See B.2);

Flammable solids (See B.7).

NOTE 1: Flammable components do not include pyrophoric, self-heating or water-reactive chemicals.

NOTE 2: Flammable aerosols do not fall additionally within the scope of flammable gases, flammable liquids, or flammable solids.

B.3.2.2 A flammable aerosol must be classified in one of the two categories for this class in accordance with Table B.3.1.

TABLE B.3.1—CRITERIA FOR FLAMMABLE AEROSOLS

Category	Criteria
1	Contains ≥85% flammable components and
	the chemical heat of combustion is ≥30 kJ/g;
	or
	(a) For spray aerosols, in the ignition distance
	test, ignition occurs at a distance ≥75 cm
	(29.5 in), or
	(b) For foam aerosols, in the aerosol foam
	flammability test
	(i) the flame height is ≥20 cm (7.87 in) and
	the flame duration ≥2 s; or
	(ii) the flame height is ≥ 4 cm (1.57 in) and the
	flame duration ≥ 7 s.

Permanent [134]

Category	Criteria
2	Contains > 1% flammable components, or the
	heat of combustion is ≥20 kJ/g; and
	(a) For spray aerosols, in the ignition distance
	test, ignition occurs at a distance ≥15 cm (5.9
	in), or in the enclosed space ignition test, the
	(i) time equivalent is ≥300 s/m³; or
	(ii) Deflagration density is ≥300 g/m ³
	(b) For foam aerosols, in the aerosol foam
	flammability test, the flame height is ≥4 cm
	and the flame duration is ≥ 2 s and it does not
	meet the criteria for Category 1

NOTE: Aerosols not submitted to the flammability classification procedures in this Appendix must be classified as extremely flammable (Category 1).

B.3.3 Additional classification considerations

B.3.3.1 To classify a flammable aerosol, data on its flammable components, on its chemical heat of combustion and, if applicable, the results of the aerosol foam flammability test (for foam aerosols) and of the ignition distance test and enclosed space test (for spray aerosols) are necessary.

B.3.3.2 The chemical heat of combustion (Δ Hc), in kilojoules per gram (kJ/g), is the product of the theoretical heat of combustion (Δ Hcomb), and a combustion efficiency, usually less than 1.0 (a typical combustion efficiency is 0.95 or 95%).

For a composite aerosol formulation, the chemical heat of combustion is the summation of the weighted heats of combustion for the individual components, as follows:

$$\Delta \text{Hc (product)} = \sum_{i=1}^{n} [\text{wi\%} \times \Delta \text{Hc(i)}]$$

where:

 $\Delta Hc = chemical heat of combustion (kJ/g);$

wi% = mass fraction of component i in the product;

ΔHc(i) = specific heat of combustion (kJ/a) of component i in the product;

The chemical heats of combustion must be found in literature, calculated or determined by tests (See ASTM D240-02 (Reapproved 2007), Standard Test Method for Heat of Combustion of Liquid Hydrocarbon Fuels by Bomb Calorimeter, ISO 13943:2000 (E/F), Fire Safety—Vocabulary, First Edition, April 15, 2000, Sections 86.1 to 86.3, and NFPA 30B, Code for the Manufacture and Storage of Aerosol Products, 2007 Edition).

B.3.3.3 The Ignition Distance Test, Enclosed Space Ignition Test and Aerosol Foam Flammability Test must be performed in accordance with sub-sections 31.4, 31.5 and 31.6 of the of the UN ST/SG/AC.10/Rev. 4, The UN Recommendations of the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003.

B.4 OXIDIZING GASES

B.4.1 Definition

Oxidizing gas means any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.

NOTE: "Gases which cause or contribute to the combustion of other material more than air does" means pure gases or gas mixtures with an oxidizing power greater than 23.5% (as determined by a method specified in ISO 10156:1996 (E), Gases and Gas Mixtures—Determination of Fire Potential and Oxidizing Ability for the Selection of Cylinder Valve Outlets, Second Edition, Feb. 15, 1996, 10156-2:2005 (E), Gas Cylinders—Gases and Gas Mixtures—Part 2:Determination of Oxidizing Ability of Toxic and Corrosive Gases and Gas Mixtures, First Edition Aug. 1, 2005 or an equivalent testing method.

B.4.2 Classification criteria

An oxidizing gas must classified in a single category for this class in accordance with Table B.4.1:

TABLE B.4.1—CRITERIA FOR OXIDIZING GASES

Category	Criteria
1	Any gas which may, generally by providing
	oxygen, cause or contribute to the combus-
	tion of other material more than air does.

B.4.3 Additional classification considerations

Classification must be in accordance with tests or calculation methods as described in ISO 10156:1996 (E), Gases and Gas Mixtures—Determination of Fire Potential and Oxidizing Ability for the Selection of Cylinder Valve Outlets, Second Edition, Feb. 15, 1996 and ISO 10156-2:2005 (E), Gas Cylinders—Gases and Gas Mixtures—Part 2: Determination of Oxidizing Ability of Toxic and Corrosive Gases and Gas Mixtures, First Edition Aug. 1, 2005.

B.5 GASES UNDER PRESSURE

B.5.1 Definition

Gases under pressure are gases which are contained in a receptacle at a pressure of 200 kPa (29 psi) (gauge) or more, or which are liquefied or liquefied and refrigerated.

They comprise compressed gases, liquefied gases, dissolved gases and refrigerated liquefied gases.

B.5.2 Classification criteria

Gases under pressure must be classified in one of four groups in accordance with Table B.5.1:

[135] Permanent

TABLE B.5.1—CRITERIA FOR GASES UNDER PRESSURE

Group	Criteria
Compressed gas	A gas which when under pressure is entirely gaseous at -50°C (-58°F), including all gases with a crit-
	ical temperature ¹ ≤ 50 °C (-58°F).
Liquefied gas	A gas which when under pressure is partially liquid at temperatures above -50°C (-58°F). A distinction is made between: (a) High pressure liquefied gas: a gas with a critical temperature between -50°C (-58°F) and +65°C (149°F); and (b) Low pressure liquefied gas: a gas with a critical temperature above +65°C (149°F).
Refrigerated liquefied	A gas which is made partially liquid because of its low temperature.
gas	
Dissolved gas	A gas which when under pressure is dissolved in a liquid phase solvent.

¹ The critical temperature is the temperature above which a pure gas cannot be liquefied, regardless of the degree of compression.

B.6 FLAMMABLE LIQUIDS

B.6.1 Definition

Flammable liquid means a liquid having a flash point of not more than 93°C (199.4°F).

Flash point means the minimum temperature at which a liquid gives off vapor in sufficient concentration to form an ignitable mixture with air near the surface of the liquid, as determined by a method identified in Section B.6.3.

B.6.2 Classification criteria

A flammable liquid must be classified in one of four categories in accordance with Table B.6.1:

TABLE B.6.1—CRITERIA FOR FLAMMABLE LIQUIDS

Category	Criteria
1	Flash point < 23°C (73.4°F) and initial boil-
	ing point $\leq 35^{\circ}$ C (95°F)
2	Flash point < 23°C (73.4°F) and initial boiling point > 35°C (95°F)
3	Flash point $\ge 23^{\circ}$ C (73.4°F) and $\le 60^{\circ}$ C (140°F)
4	Flash point > 60°C (140°F) and ≤ 93°C (199.4°F)

B.6.3 Additional classification considerations

The flash point must be determined in accordance with ASTM D56-05, Standard Test Method for Flash Point by Tag Closed Cup Tester, ASTM D3278-96 (Reapproved 2004) E1, Standard Test Methods for Flash Point of Liquids by Small Scale Closed-Cup Apparatus, ASTM D3828-07a, Standard Test Methods for Flash Point by Small Scale Closed Cup Tester, Approved, ASTM D93-08, Standard Test Methods for Flash Point by Pensky-Martens Closed Cup Tester, or any other method specified in GHS Revision 3, Chapter 2.6.

The initial boiling point must be determined in accordance with ASTM D86-07a, Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure or ASTM D1078-05, Standard Test Method for Distillation Range of Volatile Organic Liquids.

B.7 FLAMMABLE SOLIDS

B.7.1 Definitions

Flammable solid means a solid which is a readily combustible solid, or which may cause or contribute to fire through friction.

Readily combustible solids are powdered, granular, or pasty chemicals which are dangerous if they can be easily ignited by brief contact with an ignition source, such as a burning match, and if the flame spreads rapidly.

B.7.2 Classification criteria

B.7.2.1 Powdered, granular or pasty chemicals must be classified as flammable solids when the time of burning of one or more of the test runs, performed in accordance with the test method described in the UN ST/SG/AC.10/Rev. 4, The UN Recommendations of the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003, Part III, sub-section 33.2.1, is less than 45 s or the rate of burning is more than 2.2 mm/s (0.0866 in/s).

B.7.2.2 Powders of metals or metal alloys must be classified as flammable solids when they can be ignited and the reaction spreads over the whole length of the sample in 10 min or less.

B.7.2.3 Solids which may cause fire through friction must be classified in this class by analogy with existing entries (e.g., matches) until definitive criteria are established.

B.7.2.4 A flammable solid must be classified in one of the two categories for this class using Method N.1 as described in Part III, sub-section 33.2.1 of the UN ST/SG/AC.10/Rev. 4, The UN Recommendations of the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003, in accordance with Table B.7.1:

TABLE B.7.1—CRITERIA FOR FLAMMABLE SOLIDS

Category	Criteria
1	Burning rate test:
	Chemicals other than metal powders:
	(a) wetted zone does not stop fire; and >
	(b) burning time <45 s or burning rate >2.2
	mm/s
	Metal powders: burning time ≤5 min

Permanent [136]

Category	Criteria
2	Burning rate test:
	Chemicals other than metal powders:
	(a) wetted zone stops the fire for at least 4
	min; and >
	(b) burning time <45 s or burning rate >2.2
	mm/s
	Metal powders: burning time >5 min
	and ≤10 min

NOTE: Classification of solid chemicals must be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.8 SELF-REACTIVE CHEMICALS

B.8.1 Definitions

Self-reactive chemicals are thermally unstable liquid or solid chemicals liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). This definition excludes chemicals classified under this section as explosives, organic peroxides, oxidizing liquids or oxidizing solids.

A self-reactive chemical is regarded as possessing explosive properties when in laboratory testing the formulation is liable to detonate, to deflagrate rapidly or to show a violent effect when heated under confinement.

B.8.2 Classification criteria

- B.8.2.1 A self-reactive chemical must be considered for classification in this class unless:
- (a) It is classified as an explosive according to B.1 of this appendix;
- (b) It is classified as an oxidizing liquid or an oxidizing solid according to B.13 or B.14 of this appendix, except that a mixture of oxidizing substances which contains 5% or more of combustible organic substances must be classified as a self-reactive chemical according to the procedure defined in B.8.2.2;
- (c) It is classified as an organic peroxide according to B.15 of this appendix;
 - (d) Its heat of decomposition is less than 300 J/g; or
- (e) Its self-accelerating decomposition temperature (SADT) is greater than 75°C (167°F) for a 50 kg (110 lb) package.
- B.8.2.2 Mixtures of oxidizing substances, meeting the criteria for classification as oxidizing liquids or oxidizing solids, which contain 5% or more of combustible organic substances and which do not meet the criteria mentioned in B.8.2.1 (a), (c), (d) or (e), must be subjected to the self-reactive chemicals classification procedure in B.8.2.3. Such a mixture showing the properties of a self-reactive chemical type B to F must be classified as a self-reactive chemical.

- B.8.2.3 Self-reactive chemicals must be classified in one of the seven categories of "types A to G" for this class, according to the following principles:
- (a) Any self-reactive chemical which can detonate or deflagrate rapidly, as packaged, will be defined as self-reactive chemical TYPE A;
- (b) Any self-reactive chemical possessing explosive properties and which, as packaged, neither detonates nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package will be defined as self-reactive chemical TYPE B:
- (c) Any self-reactive chemical possessing explosive properties when the chemical as packaged cannot detonate or deflagrate rapidly or undergo a thermal explosion will be defined as self-reactive chemical TYPE C;
- (d) Any self-reactive chemical which in laboratory testing meets the criteria in (d)(i), (ii), or (iii) will be defined as self-reactive chemical TYPE D:
- (i) Detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement; or
- (ii) Does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement; or
- (iii) Does not detonate or deflagrate at all and shows a medium effect when heated under confinement;
- (e) Any self-reactive chemical which, in laboratory testing, neither detonates nor deflagrates at all and shows low or no effect when heated under confinement will be defined as self-reactive chemical TYPE E;
- (f) Any self-reactive chemical which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows only a low or no effect when heated under confinement as well as low or no explosive power will be defined as self-reactive chemical TYPE F;
- (g) Any self-reactive chemical which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows no effect when heated under confinement nor any explosive power, provided that it is thermally stable (self-accelerating decomposition temperature is 60°C (140°F) to 75°C (167°F) for a 50 kg (110 lb) package), and, for liquid mixtures, a diluent having a boiling point greater than or equal to 150°C (302°F) is used for desensitization will be defined as self-reactive chemical TYPE G. If the mixture is not thermally stable or a diluent having a boiling point less than 150°C (302°F) is used for desensitization, the mixture must be defined as self-reactive chemical TYPE F.

B.8.3 Additional classification considerations

- B.8.3.1 For purposes of classification, the properties of self-reactive chemicals must be determined in accordance with test series A to H as described in Part II of the UN ST/SG/AC.10/Rev. 4, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003.
- B.8.3.2 Self-accelerating decomposition temperature (SADT) must be determined in accordance with the UN ST/SG/AC.10/Rev. 4, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003.

Permanent

- B.8.3.3 The classification procedures for self-reactive substances and mixtures need not be applied if:
- (a) There are no chemical groups present in the molecule associated with explosive or self-reactive properties; examples of such groups are given in Tables A6.1 and A6.2 in the Appendix 6 of the UN ST/SG/AC.10/Rev. 4, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003; or
- (b) For a single organic substance or a homogeneous mixture of organic substances, the estimated SADT is greater than 75°C (167°F) or the exothermic decomposition energy is less than 300 J/g. The onset temperature and decomposition energy may be estimated using a suitable calorimetric technique (See 20.3.3.3 in Part II of the UN ST/SG/AC.10/Rev. 4, the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003).

B.9 PYROPHORIC LIQUIDS

B.9.1 Definition

Pyrophoric liquid means a liquid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air.

B.9.2 Classification criteria

A pyrophoric liquid must be classified in a single category for this class using test N.3 in Part III, sub-section 33.3.1.5 of the UN ST/SG/AC.10/Rev. 4, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003, in accordance with Table B.9.1:

TABLE B.9.1—CRITERIA FOR PYROPHORIC LIQUIDS

Category	Criteria
1	The liquid ignites within 5 min when added to
	an inert carrier and exposed to air, or it ignites
	or chars a filter paper on contact with air
	within 5 min.

B.9.3 Additional classification considerations

The classification procedure for pyrophoric liquids need not be applied when experience in production or handling shows that the chemical does not ignite spontaneously on coming into contact with air at normal temperatures (i.e., the substance is known to be stable at room temperature for prolonged periods of time (days)).

B.10 PYROPHORIC SOLIDS

B.10.1 Definition

Pyrophoric solid means a solid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air.

B.10.2 Classification criteria

A pyrophoric solid must be classified in a single category for this class using test N.2 in Part III, sub-section 33.3.1.4 of the UN ST/SG/AC.10/Rev. 4, The UN Recommendations of the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003, in accordance with Table B.10.1:

TABLE B.10.1—CRITERIA FOR PYROPHORIC SOLIDS

Category	Criteria
1	The solid ignites within 5 min of coming into
	contact with air.

NOTE: Classification of solid chemicals must be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.10.3 Additional classification considerations

The classification procedure for pyrophoric solids need not be applied when experience in production or handling shows that the chemical does not ignite spontaneously on coming into contact with air at normal temperatures (i.e., the chemical is known to be stable at room temperature for prolonged periods of time (days)).

B.11 SELF-HEATING CHEMICALS

B.11.1 Definition

A *self-heating chemical* is a solid or liquid chemical, other than a pyrophoric liquid or solid, which, by reaction with air and without energy supply, is liable to self-heat; this chemical differs from a pyrophoric liquid or solid in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days).

NOTE: Self-heating of a substance or mixture is a process where the gradual reaction of that substance or mixture with oxygen (in air) generates heat. If the rate of heat production exceeds the rate of heat loss, then the temperature of the substance or mixture will rise which, after an induction time, may lead to self-ignition and combustion.

B.11.2 Classification criteria

B.11.2.1 A self-heating chemical must be classified in one of the two categories for this class if, in tests performed in accordance with test method N.4 in Part III, sub-section 33.3.1.6 of the UN ST/SG/AC.10/Rev. 4, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003, the result meets the criteria shown in Table B.11.1.

TABLE B.11.1—CRITERIA FOR SELF-HEATING CHEMICALS

Category	Criteria
1	A positive result is obtained in a test using a
	25 mm sample cube at 140°C (284°F)
2	A negative result is obtained in a test using a
	25 mm cube sample at 140°C (284°F), a pos-
	itive result is obtained in a test using a 100
	mm sample cube at 140°C (284°F), and:
	(a) The unit volume of the chemical is
	more than 3 m ³ ; or
	(b) A positive result is obtained in a test
	using a 100 mm cube sample at 120°C
	(248°F) and the unit volume of the chemical
	is more than 450 liters; or

Permanent [138]

Category	Criteria
	(c) A positive result is obtained in a test
	using a 100 mm cube sample at 100°C
	(212°F).

- B.11.2.2 Chemicals with a temperature of spontaneous combustion higher than 50°C (122°F) for a volume of 27 m³ must not be classified as self-heating chemicals.
- B.11.2.3 Chemicals with a spontaneous ignition temperature higher than 50°C (122°F) for a volume of 450 liters must not be classified in Category 1 of this class.

B.11.3 Additional classification considerations

B.11.3.1 The classification procedure for self-heating chemicals need not be applied if the results of a screening test can be adequately correlated with the classification test and an appropriate safety margin is applied.

B.11.3.2 Examples of screening tests are:

- (a) The Grewer Oven test (VDI guideline 2263, part 1, 1990, Test methods for the Determination of the Safety Characteristics of Dusts) with an onset temperature 80°K above the reference temperature for a volume of 1 *l*;
- (b) The Bulk Powder Screening Test (Gibson, N. Harper, D. J. Rogers, R. Evaluation of the fire and explosion risks in drying powders, Plant Operations Progress, 4 (3), 181-189, 1985) with an onset temperature 60°K above the reference temperature for a volume of 1 *l*.

B.12 CHEMICALS WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES

B.12.1 Definition

Chemicals which, in contact with water, emit flammable gases are solid or liquid chemicals which, by interaction with water, are liable to become spontaneously flammable or to give off flammable gases in dangerous quantities.

B.12.2 Classification criteria

B.12.2.1 A chemical which, in contact with water, emits flammable gases must be classified in one of the three categories for this class, using test N.5 in Part III, sub-section 33.4.1.4 of the UN ST/SG/AC.10/Rev. 4, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003, in accordance with Table B.12.1:

TABLE B.12.1—CRITERIA FOR CHEMICALS WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES

Category	Criteria
1	Any chemical which reacts vigorously with
	water at ambient temperatures and demon-
	strates generally a tendency for the gas pro-
	duced to ignite spontaneously, or which
	reacts readily with water at ambient tempera-
	tures such that the rate of evolution of flam-
	mable gas is equal to or greater than 10 liters
	per kilogram of chemical over any one min-
	ute.

Category	Criteria
2	Any chemical which reacts readily with water at ambient temperatures such that the maximum rate of evolution of flammable gas is equal to or greater than 20 liters per kilogram of chemical per hour, and which does not meet the criteria for Category 1.
3	Any chemical which reacts slowly with water at ambient temperatures such that the maximum rate of evolution of flammable gas is equal to or greater than 1 liter per kilogram of chemical per hour, and which does not meet the criteria for Categories 1 and 2.

NOTE: Classification of solid chemicals must be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.12.2.2 A chemical is classified as a chemical which, in contact with water, emits flammable gases if spontaneous ignition takes place in any step of the test procedure.

B.12.3 Additional classification considerations

The classification procedure for this class need not be applied if:

- (a) The chemical structure of the chemical does not contain metals or metalloids;
- (b) Experience in production or handling shows that the chemical does not react with water, (e.g., the chemical is manufactured with water or washed with water); or
- (c) The chemical is known to be soluble in water to form a stable mixture.

B.13 OXIDIZING LIQUIDS

B.13.1 Definition

Oxidizing liquid means a liquid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.

B.13.2 Classification criteria

An oxidizing liquid must be classified in one of the three categories for this class using test O.2 in Part III, sub-section 34.4.2 of the UN ST/SG/AC.10/Rev. 4, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003, in accordance with Table B.13.1:

TABLE B.13.1—CRITERIA FOR OXIDIZING LIQUIDS

Category	Criteria
1	Any chemical which, in the 1:1 mixture, by
	mass, of chemical and cellulose tested, spon-
	taneously ignites; or the mean pressure rise
	time of a 1:1 mixture, by mass, of chemical
	and cellulose is less than that of a 1:1 mixture,
	by mass, of 50% perchloric acid and cellu-
	lose;

[139] Permanent

Category	Criteria
2	Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 40% aqueous sodium chlorate solution and cellulose; and the criteria for Category 1 are not met;
3	Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 65% aqueous nitric acid and cellulose; and the criteria for Categories 1 and 2 are not met.

B.13.3 Additional classification considerations

- B.13.3.1 For organic chemicals, the classification procedure for this class must not be applied if:
- (a) The chemical does not contain oxygen, fluorine or chlorine; or
- (b) The chemical contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.
- B.13.3.2 For inorganic chemicals, the classification procedure for this class must not be applied if the chemical does not contain oxygen or halogen atoms.
- B.13.3.3 In the event of divergence between test results and known experience in the handling and use of chemicals which shows them to be oxidizing, judgments based on known experience must take precedence over test results.
- B.13.3.4 In cases where chemicals generate a pressure rise (too high or too low), caused by chemical reactions not characterizing the oxidizing properties of the chemical, the test described in Part III, sub-section 34.4.2 of the UN ST/SG/AC.10/Rev. 4, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003, must be repeated with an inert substance (e.g., diatomite (kieselguhr in place of the cellulose) in order to clarify the nature of the reaction).

B.14 OXIDIZING SOLIDS

B.14.1 Definition

Oxidizing solid means a solid which, while in itself is not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.

B.14.2 Classification criteria

An oxidizing solid must be classified in one of the three categories for this class using test O.1 in Part III, sub-section 34.4.1 of the UN ST/SG/AC.10/Rev. 4, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003, in accordance with Table B.14.1:

TABLE B.14.1—CRITERIA FOR OXIDIZING SOLIDS

Category	Criteria
1	Any chemical which, in the 4:1 or 1:1 sam-
	ple-to-cellulose ratio (by mass) tested, exhib-
	its a mean burning time less than the mean
	burning time of a 3:2 mixture, by mass, of
	potassium bromate and cellulose.
2	Any chemical which, in the 4:1 or 1:1 sam-
	ple-to-cellulose ratio (by mass) tested, exhib-
	its a mean burning time equal to or less than
	the mean burning time of a 2:3 mixture (by
	mass) of potassium bromate and cellulose
	and the criteria for Category 1 are not met.
3	Any chemical which, in the 4:1 or 1:1 sam-
	ple-to-cellulose ratio (by mass) tested, exhib-
	its a mean burning time equal to or less than
	the mean burning time of a 3:7 mixture (by
	mass) of potassium bromate and cellulose
	and the criteria for Categories 1 and 2 are not
	met.

NOTE 1: Some oxidizing solids may present explosion hazards under certain conditions (e.g., when stored in large quantities). For example, some types of ammonium nitrate may give rise to an explosion hazard under extreme conditions and the "Resistance to detonation test" (IMO: Code of Safe Practice for Solid Bulk Cargoes, 2005, Annex 3, Test 5) may be used to assess this hazard. When information indicates that an oxidizing solid may present an explosion hazard, it must be indicated on the Safety Data Sheet.

NOTE 2: Classification of solid chemicals must be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.14.3 Additional classification considerations

- B.14.3.1 For organic chemicals, the classification procedure for this class must not be applied if:
- (a) The chemical does not contain oxygen, fluorine or chlorine; or
- (b) The chemical contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.
- B.14.3.2 For inorganic chemicals, the classification procedure for this class must not be applied if the chemical does not contain oxygen or halogen atoms.
- B.14.3.3 In the event of divergence between test results and known experience in the handling and use of chemicals which shows them to be oxidizing, judgements based on known experience must take precedence over test results.

B.15 ORGANIC PEROXIDES

B.15.1 Definition

Permanent [140]

- B.15.1.1 Organic peroxide means a liquid or solid organic chemical which contains the bivalent -0-0- structure and as such is considered a derivative of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term organic peroxide includes organic peroxide mixtures containing at least one organic peroxide. Organic peroxides are thermally unstable chemicals, which may undergo exothermic self-accelerating decomposition. In addition, they may have one or more of the following properties:
 - (a) Be liable to explosive decomposition;
 - (b) Burn rapidly;
 - (c) Be sensitive to impact or friction;
 - (d) React dangerously with other substances.
- B.15.1.2 An organic peroxide is regarded as possessing explosive properties when in laboratory testing the formulation is liable to detonate, to deflagrate rapidly or to show a violent effect when heated under confinement.
- B.15.2 Classification criteria
- B.15.2.1 Any organic peroxide must be considered for classification in this class, unless it contains:
- (a) Not more than 1.0% available oxygen from the organic peroxides when containing not more than 1.0% hydrogen peroxide; or
- (b) Not more than 0.5% available oxygen from the organic peroxides when containing more than 1.0% but not more than 7.0% hydrogen peroxide.

NOTE: The available oxygen content (%) of an organic peroxide mixture is given by the formula:

$$16 \times \sum_{i}^{n} \left(\frac{n_{i} \times c_{i}}{m_{i}} \right)$$

Where:

 n_i = number of peroxygen groups per molecule of organic peroxide i;

 c_i = concentration (mass %) of organic peroxide i;

 m_i = molecular mass of organic peroxide i.

- B.15.2.2 Organic peroxides must be classified in one of the seven categories of "Types A to G" for this class, according to the following principles:
- (a) Any organic peroxide which, as packaged, can detonate or deflagrate rapidly must be defined as organic peroxide TYPE A:
- (b) Any organic peroxide possessing explosive properties and which, as packaged, neither detonates nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package must be defined as organic peroxide TYPE B;
- (c) Any organic peroxide possessing explosive properties when the chemical as packaged cannot detonate or deflagrate rapidly or undergo a thermal explosion must be defined as organic peroxide TYPE C;

- (d) Any organic peroxide which in laboratory testing meets the criteria in (d)(i), (ii), or (iii) must be defined as organic peroxide TYPE D:
- (i) detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement; or
- (ii) does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement; or
- (iii) does not detonate or deflagrate at all and shows a medium effect when heated under confinement;
- (e) Any organic peroxide which, in laboratory testing, neither detonates nor deflagrates at all and shows low or no effect when heated under confinement must be defined as organic peroxide TYPE E;
- (f) Any organic peroxide which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows only a low or no effect when heated under confinement as well as low or no explosive power must be defined as organic peroxide TYPE F;
- (g) Any organic peroxide which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows no effect when heated under confinement nor any explosive power, provided that it is thermally stable (self-accelerating decomposition temperature is 60°C (140°F) or higher for a 50 kg (110 lb) package), and, for liquid mixtures, a diluent having a boiling point of not less than 150°C (302°F) is used for desensitization, must be defined as organic peroxide TYPE G. If the organic peroxide is not thermally stable or a diluent having a boiling point less than 150°C (302°F) is used for desensitization, it must be defined as organic peroxide TYPE F.

B.15.3 Additional classification considerations

- B.15.3.1 For purposes of classification, the properties of organic peroxides must be determined in accordance with test series A to H as described in Part II of the UN ST/SG/AC.10/Rev. 4, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003.
- B.15.3.2 Self-accelerating decomposition temperature (SADT) must be determined in accordance with the UN ST/SG/AC.10/Rev. 4, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003, Part II, section 28.
- B.15.3.3 Mixtures of organic peroxides may be classified as the same type of organic peroxide as that of the most dangerous ingredient. However, as two stable ingredients can form a thermally less stable mixture, the SADT of the mixture must be determined.

B.16 CORROSIVE TO METALS

B.16.1 Definition

A *chemical which is corrosive to metals* means a chemical which by chemical action will materially damage, or even destroy, metals.

B.16.2 Classification criteria

A chemical which is corrosive to metals must be classified in a single category for this class, using the test in Part III, sub-section 37.4 of the UN ST/SG/AC.10/Rev. 4, The UN Recommendations on the Transport of Dangerous

[141] Permanent

Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003, in accordance with Table B.16.1:

TABLE B.16.1—CRITERIA FOR CHEMICALS CORROSIVE TO METAL

Category	Criteria
1	Corrosion rate on either steel or aluminium
	surfaces exceeding 6.25 mm per year at a test
	temperature of 55°C (131°F) when tested on
	both materials.

NOTE: Where an initial test on either steel or aluminium indicates the chemical being tested is corrosive the follow-up test on the other metal is not necessary.

B.16.3 Additional classification considerations

The specimen to be used for the test must be made of the following materials:

- (a) For the purposes of testing steel, steel types S235JR+CR (1.0037 resp.St 37-2), S275J2G3+CR (1.0144 resp.St 44-3), ISO 3574, Unified Numbering System (UNS) G 10200, or SAE 1020;
- (b) For the purposes of testing aluminium: non-clad types 7075-T6 or AZ5GU-T6.

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency and appear in the Register pursuant to the requirements of RCW 34.08.040.

NEW SECTION

WAC 296-901-14026 Appendix C—Allocation of label elements.

- C.1 The label for each hazardous chemical must include the product identifier used on the safety data sheet.
- C.1.1 The labels on shipped containers must also include the name, address, and telephone number of the chemical manufacturer, importer, or responsible party.
- C.2 The label for each hazardous chemical that is classified must include the signal word, hazard statement(s), pictogram(s), and precautionary statement(s) specified in C.4 for each hazard class and associated hazard category, except as provided for in C.2.1 through C.2.4.
- C.2.1 Precedence of hazard information
- C.2.1.1 If the signal word "Danger" is included, the signal word "Warning" must not appear.
- C.2.1.2 If the skull and crossbones pictogram is included, the exclamation mark pictogram must not appear where it is used for acute toxicity.
- C.2.1.3 If the corrosive pictogram is included, the exclamation mark pictogram must not appear where it is used for skin or eye irritation.
- C.2.1.4 If the health hazard pictogram is included for respiratory sensitization, the exclamation mark pictogram must not appear where it is used for skin sensitization or for skin or eye irritation.

C.2.2 Hazard statement text

C.2.2.1 The text of all applicable hazard statements must appear on the label, except as otherwise specified. The information in italics must be included as part of the hazard statement as provided. For example: "causes damage to organs (state all organs affected) through prolonged or repeated exposure (state route of exposure if no other routes of exposure cause the hazard)". Hazard statements may be combined where appropriate to reduce the information on the label and improve readability, as long as all of the hazards are conveyed as required.

C.2.2.2 If the chemical manufacturer, importer, or responsible party can demonstrate that all or part of the hazard statement is inappropriate to a specific substance or mixture, the corresponding statement may be omitted from the label.

C.2.3 Pictograms

- C.2.3.1 Pictograms must be in the shape of a square set at a point and must include a black hazard symbol on a white background with a red frame sufficiently wide to be clearly visible. A square red frame set at a point without a hazard symbol is not a pictogram and is not permitted on the label.
- C.2.3.2 One of eight standard hazard symbols must be used in each pictogram. The eight hazard symbols are depicted in Figure C.1. A pictogram using the exclamation mark symbol is presented in Figure C.2, for the purpose of illustration.

Permanent [142]

Figure C.1 - Hazard Symbols and Classes Flame Flame Over Circle Exclamation Mark Exploding Bomb Flammables Oxidizers Irritant Explosives Self Reactives Dermal Sensitizer Self Reactives Pyrophorics Acute Toxicity (harmful) Organic Peroxides Self-heating Narcotic Effects Emits Flammable Gas Respiratory Tract Irritation Organic Peroxides Corrosion Gas Cylinder Health Hazard Skull and Crossbones Corrosives Gases Under Pressure Carcinogen Acute Toxicity (severe) Respiratory Sensitizer Reproductive Toxicity Target Organ Toxicity Mutagenicity Aspiration Toxicity

Figure C.2 – Exclamation Mark Pictogram



C.2.3.3 Where a pictogram required by the Department of Transportation under Title 49 of the Code of Federal Regulations appears on a shipped container, the pictogram specified in C.4 for the same hazard must not appear.

C.2.4 Precautionary statement text

C.2.4.1 There are four types of precautionary statements presented, "prevention," "response," "storage," and "disposal." The core part of the precautionary statement is presented in bold print. This is the text, except as otherwise specified, that must appear on the label. Where additional information is required, it is indicated in plain text.

C.2.4.2 When a backslash or diagonal mark (/) appears in the precautionary statement text, it indicates that a choice has to be made between the separated phrases. In such cases, the chemical manufacturer, importer, or responsible party can choose the most appropriate phrase(s). For example, "Wear

protective gloves/protective clothing/eye protection/face protection" could read "wear eye protection".

C.2.4.3 When three full stops (...) appear in the precautionary statement text, they indicate that all applicable conditions are not listed. For example, in "Use explosion-proof electrical/ventilating/lighting/.../equipment", the use of "..." indicates that other equipment may need to be specified. In such cases, the chemical manufacturer, importer, or responsible party can choose the other conditions to be specified.

C.2.4.4 When text in italics is used in a precautionary statement, this indicates specific conditions applying to the use or allocation of the precautionary statement. For example, "Use explosion-proof electrical/ventilating/lighting/.../equipment" is only required for flammable solids "if dust clouds can occur". Text in italics is intended to be an explanatory, conditional note and is not intended to appear on the label.

C.2.4.5 Where square brackets ([]) appear around text in a precautionary statement, this indicates that the text in square brackets is not appropriate in every case and must be used only in certain circumstances. In these cases, conditions for use explaining when the text must be used are provided. For example, one precautionary statement states: "[In case of inadequate ventilation] wear respiratory protection." This statement is given with the condition for use "- text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use". This means that, if additional information is provided with the chemical explaining what type of ventilation would be adequate for

Permanent

safe use, the text in square brackets must be used and the statement would read: "In case of inadequate ventilation wear respiratory protection." However, if the chemical is supplied without such ventilation information, the text in square brackets must not be used, and the precautionary statement must read: "Wear respiratory protection."

- C.2.4.6 Precautionary statements may be combined or consolidated to save label space and improve readability. For example, "Keep away from heat, sparks and open flame," "Store in a well-ventilated place" and "Keep cool" can be combined to read "Keep away from heat, sparks and open flame and store in a cool, well-ventilated place."
- C.2.4.7 In most cases, the precautionary statements are independent (e.g., the phrases for explosive hazards do not modify those related to certain health hazards, and products that are classified for both hazard classes must bear appropriate precautionary statements for both). Where a chemical is classified for a number of hazards, and the precautionary statements are similar, the most stringent must be included on the label (this will be applicable mainly to preventive measures). An order of precedence may be imposed by the chemical manufacturer, importer or responsible party in situations where phrases concern "Response." Rapid action may be crucial. For example, if a chemical is carcinogenic and acutely toxic, rapid action may be crucial, and first aid measures for acute toxicity will take precedence over those for long-term effects. In addition, medical attention to delayed health effects may be required in cases of incidental exposure, even if not associated with immediate symptoms of intoxication.
- C.2.4.8 If the chemical manufacturer, importer, or responsible party can demonstrate that a precautionary statement is inappropriate to a specific substance or mixture, the precautionary statement may be omitted from the label.

C.3 Supplementary hazard information

- C.3.1 To ensure that non-standardized information does not lead to unnecessarily wide variation or undermine the required information, supplementary information on the label is limited to when it provides further detail and does not contradict or cast doubt on the validity of the standardized hazard information.
- C.3.2 Where the chemical manufacturer, importer, or distributor chooses to add supplementary information on the label, the placement of supplemental information must not impede identification of information required by this section.
- C.3.3 Where an ingredient with unknown acute toxicity is used in a mixture at a concentration $\geq 1\%$, and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity is required on the label.

Permanent [144]

C.4 REQUIREMENTS FOR SIGNAL WORDS, HAZARD STATEMENTS, PICTOGRAMS, AND PRECAUTIONARY STATEMENTS

C.4.1 ACUTE TOXICITY – ORAL

(Classified in Accordance with WAC 296-901-14022(A.1))

up.

Pictogram

Skull and crossbones

Hazard category	Signal word	Hazard statement
1	Danger	Fatal if swallowed
2	Danger	Fatal if swallowed



Precautionary statements

Prevention

Wash ...thoroughly after handling.

... Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling.

Do not eat, drink or smoke when using this product.

Response

If swallowed: Immediately call a poison center/doctor/...

... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.

Specific treatment (see ... on this label)

... Reference to supplemental first aid instruction. - if immediate administration of antidote is required.

Rinse mouth.

Storage **Disposal**

Store locked Dispose of contents/container to...

... in accordance with local/regional/national/international regulations (to be specified).

[145] Permanent

C.4.1 ACUTE TOXICITY - ORAL (CONTINUED) (Classified in Accordance with Appendix A.1)

Pictogram Skull and crossbones

Hazard category Signal word Hazard statement

Toxic if swallowed 3 Danger

Precautionary statements

using this product.

Prevention Response Storage

Store locked up.

Wash ... thoroughly after handling.

... Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling.

Do not eat, drink or smoke when

If swallowed: Immediately call a poison center/doctor/...

... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.

Specific treatment (see ... on this

... Reference to supplemental first aid instruction.

- if immediate administration of antidote is required.

Rinse mouth.

Disposal

Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).

C.4.1 ACUTE TOXICITY – ORAL (CONTINUED) (Classified in Accordance with WAC 296-901-14022(A.1))

Pictogram Exclamation mark

Hazard category Signal word **Hazard statement** 4 Warning Harmful if swallowed



Precautionary statements

Prevention Response Disposal Storage

Wash ... thoroughly after handling.

... Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling.

Do not eat, drink or smoke when using this product.

If swallowed: Call a poison center/doctor/.../ if you feel unwell.

... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.

Rinse mouth.

Dispose of contents/container to...

... in accordance with local/regional/national/international regulations (to be specified).

Permanent [146]

C.4.2 ACUTE TOXICITY - DERMAL (Classified in Accordance with WAC 296-901-14022(A.1))

Storage

Store locked

up.

Pictogram

Skull and crossbones

Hazard category	Signal word	Hazard statement
1	Danger	Fatal in contact with skin
2	Danger	Fatal in contact with skin



Precautionary statements

Prevention

Do not get in eyes, on skin, or on clothing.

Wash ... thoroughly after handling.

... Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling.

Do not eat, drink or smoke when using this product.

Wear protective gloves/protective clothing.

Chemical manufacturer, importer, or distributor to specify type of equipment.

If on skin:

Response

Wash with plenty of water/... ... Chemical manufacturer,

importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate.

Immediately call a poison center/doctor/...

... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.

Specific treatment (see ... on this label)

... Reference to supplemental first aid instruction. - if immediate measures such as specific cleansing agent is advised.

Take off immediately all contaminated clothing and wash it before reuse.

Disposal

Dispose of contents/container to...

... in accordance with local/regional/national/international regulations (to be specified).

Permanent

C.4.2 ACUTE TOXICITY - DERMAL (CONTINUED) (Classified in Accordance with WAC 296-901-14022(A.1))

Pictogram

Skull and crossbones

Hazard category

Signal word

Hazard statement

Storage

3

Danger Toxic in contact with skin



Precautionary statements

Prevention

Wear protective gloves/protective clothing.

Chemical manufacturer, importer, or distributor to specify type of equipment.

Response

If on skin: Wash with plenty of water/...

... Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water

Call a poison center/doctor/.../if you feel unwell.

is clearly inappropriate.

... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.

Specific treatment (see ... on this label)

... Reference to supplemental first aid instruction. - if measures such as specific cleansing agent is advised.

Take off immediately all contaminated clothing and wash it before reuse.

Disposal

Store locked Dispose of contents/container up. to...

... in accordance with local/regional/national/international regulations (to be specified).

Permanent [148]

C.4.2 ACUTE TOXICITY – DERMAL (CONTINUED) (Classified in Accordance with WAC 296-901-14022(A.1))

Pictogram Exclamation mark

Hazard category

Signal word

Hazard statement

4

Warning

Harmful in contact with skin



Precautionary statements

Prevention

Wear protective gloves/protective clothing

Chemical manufacturer, importer, or distributor to specify type of equipment.

Response

If on skin: Wash with plenty of water/...

... Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate.

Call a poison center/doctor/.../if you feel unwell.

... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.

Specific treatment (see ... on this label)

... Reference to supplemental first aid instruction.
- if measures such as specific cleansing agent is advised.

Take off contaminated clothing and wash it before reuse.

Storage Disposal

Dispose of contents/container to...

... in accordance with local/regional/national/international regulations (to be specified).

[149] Permanent

C.4.3 ACUTE TOXICITY - INHALATION (Classified in Accordance with WAC 296-901-14022(A.1))

PictogramSkull and crossbones

Do not breathe	If inhaled: Remove	Store in a well-	Dispose of contents/contain
Prevention	Response	Storage	Disposal
Precautionary statements			
2	Danger	Fatal if inhaled	
			395
1	Danger	Fatal if inhaled	
Hazard category	Signal word	Hazard statement	
			Skull and crossbories

dust/fume/gas/mist/ vapors/spray. Chemical manufacturer,

importer, or distributor to specify applicable conditions.

Use only outdoors or in a well-ventilated area.

[In case of inadequate ventilation] wear respiratory protection.

Chemical manufacturer, importer, or distributor to specify equipment.

- Text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use.

If inhaled: Remove person to fresh air and keep comfortable for breathing.

Immediately call a poison center/doctor/...

... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.

Specific treatment is urgent (see ... on this label)

... Reference to

supplemental first aid instruction. - if immediate administration of antidote is required. Store in a wellventilated place. Keep container tightly closed.

- if product is volatile as to generate hazardous atmosphere.

Store locked up.

Dispose of contents/container to...

... in accordance with local/regional/national/international regulations (to be specified).

Permanent [150]

C.4.3 ACUTE TOXICITY – INHALATION (CONTINUED) (Classified in Accordance with WAC 296-901-14022(A.1))

Pictogram

Skull and crossbones

Hazard category	Signal word	Hazard statement
3	Danger	Toxic if inhaled



Precautionary statements

Prevention Avoid breathing

vapors/spray.
Chemical manufacturer, importer, or distributor to specify applicable conditions.

dust/fume/gas/mist/

Use only outdoors or in a well-ventilated area.

Response

If inhaled: Remove person to fresh air and keep comfortable for breathing.

Call a poison center/doctor/...

... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.

Specific treatment (see ... on this label) ... Reference to

supplemental first aid instruction. - *if immediate specific measures are required.*

Storage

Store in a wellventilated place. Keep container tightly closed.

- if product is volatile so as to generate hazardous atmosphere.

Store locked up.

Disposal

Dispose of content/container to...

... in accordance with local/regional/national/international regulations (to be specified).

[151] Permanent

C.4.3 ACUTE TOXICITY – INHALATION (CONTINUED) (Classified in Accordance with WAC 296-901-14022(A.1))

Pictogram Exclamation mark

Hazard category Signal word Hazard statement

4 Warning Harmful if inhaled



Precautionary statements

Prevention Response Storage Disposal

Avoid breathing dust/fume/gas/mist/vapors/spray.

Chemical manufacturer, importer, or distributor to specify applicable conditions.

Use only outdoors or in a well-ventilated area.

If inhaled: Remove person to fresh air and keep comfortable for breathing.

Call a poison center/doctor/.../if you feel unwell.

... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.

Permanent [152]

C.4.4 SKIN CORROSION/IRRITATION (Classified in Accordance with WAC 296-901-14022(A.2))

Pictogram Corrosion

Hazard category

Signal word

Hazard statement

1A to 1C

Danger

Causes severe skin burns and eye damage

Storage



Precautionary statements

Prevention

Do not breathe dusts or mists.

- if inhalable particles of dusts or mists may occur during use.

Wash ...thoroughly after handling.

...Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling.

Wear protective gloves/protective clothing/eye protection/face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment.

Response

If swallowed: Rinse mouth. Do NOT induce vomiting.

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

Wash contaminated clothing before reuse.

If inhaled: Remove person to fresh air and keep comfortable for breathing.

Immediately call a poison center/doctor/...

... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.

Specific treatment (see ... on this label)

... Reference to supplemental first aid instruction. - Manufacturer, importer, or distributor may specify a

cleansing agent if appropriate.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Disposal

Store locked Dispose of contents/container up. to...

 ... in accordance with local/regional/national/international regulations (to be specified).

[153] Permanent

C.4.4 SKIN CORROSION/IRRITATION (CONTINUED) (Classified in Accordance with WAC 296-901-14022(A.2))

Pictogram Exclamation mark

Hazard category 2

Signal word Warning

Hazard statement

Causes skin irritation



Precautionary statements

Prevention

Response

Storage

Disposal

Wash ... thoroughly after handling.

... Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling.

Wear protective gloves.

Chemical manufacturer, importer, or distributor to specify type of equipment.

If on skin: Wash with plenty of water/...

... Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate.

Specific treatment (see ... on this label)

... Reference to supplemental first aid instruction. - Manufacturer, importer, or distributor may specify a cleansing agent if appropriate.

If skin irritation occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

Permanent [154]

C.4.5 EYE DAMAGE/IRRITATION (Classified in Accordance with WAC 296-901-14022(A.3))

Pictogram Corrosion

Hazard category Signal word Hazard statement

Danger

Causes serious eye damage



Precautionary statements

1

Prevention

Wear eye

protection/face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment. Response

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a poison center/doctor/...

... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. Storage Disposal

Permanent

C.4.5 EYE DAMAGE/IRRITATION (CONTINUED) (Classified in Accordance with WAC 296-901-14022(A.3))

Pictogram Exclamation mark

Hazard category

Signal word

Hazard statement

2A

Warning

Causes serious eye irritation



Precautionary statements

Prevention

Response

Storage

Disposal

Wash ... thoroughly after handling.

... Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Wear eye protection/face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment.

If eye irritation persists:

Get medical
advice/attention.

Pictogram *No Pictogram*

Hazard category

Signal word

Hazard statement

2B

Warning

Causes eye irritation

Precautionary statements

Prevention

Response

Storage

Disposal

Wash ... thoroughly after handling.

... Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue

rinsing.

If eye irritation persists:

Get medical

advice/attention.

Permanent [156]

C.4.6 SENSITIZATION - RESPIRATORY (Classified in Accordance with WAC 296-901-14022(A.4))

Pictogram Health hazard

Hazard category	Signal word	Hazard statement	
1 (including both sub- categories 1A and 1B)	Danger	May cause allergy or asthma symptoms or breathing difficulties if inhaled	

Precautionary statements

Prevention

Avoid breathing dust/fume/gas/mist/vapors/spray.

Chemical manufacturer, importer, or distributor to specify applicable conditions.

[In case of inadequate ventilation] wear respiratory protection.

Chemical manufacturer, importer, or distributor to specify equipment

- Text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use.

Response

If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.

If experiencing respiratory symptoms: Call a poison center/doctor/...

... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.

Storage Disposal

Dispose of contents/container to...

... in accordance with local/regional/national/international regulations (to be specified).

[157] Permanent

C.4.7 SENSITIZATION - SKIN (Classified in Accordance with WAC 296-901-14022(A.4))

Pictogram Exclamation mark

Hazard category

Signal word

Hazard statement

1 (including both sub-categories 1A and Warning 1B)

May cause an allergic skin reaction



Precautionary statements

Prevention

Avoid breathing dust/fume/gas/mist/vapors/spray.

Chemical manufacturer, importer, or distributor to specify applicable conditions.

Contaminated work clothing must not be allowed out of the workplace.

Wear protective gloves.

Chemical manufacturer, importer, or distributor to specify type of equipment.

Response

If on skin: Wash with plenty of water/...

... Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate.

If skin irritation or rash occurs: Get medical advice/attention.

Specific treatment (see ... on this label)

... Reference to supplemental first aid instruction. - Manufacturer, importer, or distributor may specify a cleansing agent if appropriate.

Wash contaminated clothing before reuse.

Storage Disposal

Dispose of contents/container to...

... in accordance with local/regional/national/international regulations (to be specified).

Permanent [158]

C.4.8 GERM CELL MUTAGENICITY (Classified in Accordance with Appendix A.5)

Pictogram Health hazard

Hazard category	Signal word	Hazard statement
1A and 1B	Danger	May cause genetic defects <>
2	Warning	Suspected of causing genetic defects <>
		(state route of exposure if no other routes of exposure cause the hazard)



Precautionary statements

understood.

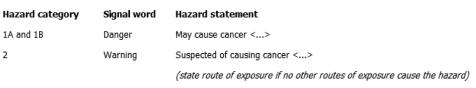
Prevention Response Storage Disposal Obtain special instructions before If exposed or concerned: Get Store locked up. Dispose of contents/container to... medical advice/attention. ... in accordance with local/regional/national/international regulations (to be specified). Do not handle until all safety precautions have been read and

Wear protective gloves/protective clothing/eye protection/face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment, as required.

C.4.9 CARCINOGENICITY (Classified in Accordance with Appendix A.6)

Pictogram Health hazard



medical advice/attention.



Precautionary statements

Prevention Response Storage Disposal Obtain special instructions before If exposed or concerned: Get Store locked up.

Do not handle until all safety

precautions have been read and understood.

Wear protective gloves/protective clothing/eye protection/face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment, as required.

Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).

Note: If a Category 2 carcinogen ingredient is present in the mixture at a concentration between 0.1% and 1%, information is required on the SDS for a product; however, a label warning is optional. If a Category 2 carcinogen ingredient is present in the mixture at a concentration of 3 1%, both an SDS and a label is required and the information must be included on each.

> [159] Permanent

C.4.10 TOXIC TO REPRODUCTION (Classified in Accordance with Appendix A.7)

Pictogram Health hazard

Hazard category	Signal word	Hazard statement
1A and 1B	Danger	May damage fertility or the unborn child $<> <<>>$
2	Warning	Suspected of damaging fertility or the unborn child $<> <<>>$
		(state specific effect if known)
		(state route of exposure if no other routes of exposure cause the hazard)



Precautionary statements

understood.

Prevention Response Storage Disposal

Obtain special instructions before use.

If exposed or concerned: Get medical advice/attention.

If exposed or concerned: Get medical advice/attention.

Do not handle until all safety

Precautions have been read and

Response Storage Disposal

Dispose of contents/container to...

... in accordance with local/regional/inational/international regulations (to be specified).

Wear protective gloves/protective clothing/eye protection/face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment, as required.

C.4.10 TOXIC TO REPRODUCTION (CONTINUED)
(Classified in Accordance with Appendix A.7)
(EFFECTS ON OR VIA LACTATION)

Pictogram No Pictogram

Hazard category Signal word Hazard statement

No designated number No signal word May cause harm to breast-fed children

(See Table A.7.1 in Appendix A.7)

Precautionary statements

Prevention Response Storage Disposal

Obtain special instructions before use.

If exposed or concerned: Get medical advice/attention.

Do not breathe dusts or mists.

- if inhalable particles of dusts or mists may occur during use.

Avoid contact during pregnancy/while nursing.

Wash ... thoroughly after handling....Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling.

Do not eat, drink or smoke when using this product.

Permanent [160]

C.4.11 SPECIFIC TARGET ORGAN TOXICITY (Single Exposure) (Classified in Accordance with WAC 296-901-14022(A.8))

Pictogram Health hazard

Hazard category	Signal word	Hazard statement	
1	Danger	Causes damage to organs <> <<>>	(35)
		<> (or state all organs affected if known)	
		<<>> (state route of exposure if no other routes of exposure cause the hazard)	

Precautionary statements			
Prevention	Response	Storage	Disposal
Do not breathe dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. If exposed: Call a poison center/doctor/ Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.		Store locked up.	Dispose of contents/container to in accordance with local/regional/national/international regulations (to be specified).
Washthoroughly			
after handling Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling.	Specific treatment (see on this label) Reference to supplemental first aid instruction if immediate measures are required.		
Do not eat, drink or smoke when using this product.			

[161] Permanent

C.4.11 SPECIFIC TARGET ORGAN TOXICITY (Single Exposure) (CONTINUED) (Classified in Accordance with WAC 296-901-14022(A.8))

Pictogram Health hazard

Hazard category	Signal word	Hazard statement	
2	Warning	May cause damage to organs <> <<>>	(35)
		<> (or state all organs affected, if known)	
		<<>> (state route of exposure if no other routes of exposure	

	cause	the hazard)	,
Precautionary statements			
Prevention	Response	Storage	Disposal
Do not breathe dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. Wash thoroughly after handling Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling.	If exposed or concerned: Call a poison center/doctor/ Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.	Store locked up.	Dispose of contents/container to in accordance with local/regional/national/international regulations (to be specified).
Do not eat, drink or smoke when using this product.			

Permanent [162]

C.4.11 SPECIFIC TARGET ORGAN TOXICITY (Single Exposure) (CONTINUED) (Classified in Accordance with WAC 296-901-14022(A.8))

Pictogram Exclamation mark

Hazard category	Signal word	Hazard statement	
3	Warning	May cause respiratory irritation; or	
		May cause drowsiness or dizziness	•

Precautionary statements

Precautionary statements			
Prevention	Response	Storage	Disposal
Avoid breathing dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions.	If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor//if you feel unwell.	Store in a well- ventilated place. Keep container tightly closed. - if product is volatile so as to generate	Dispose of contents/container to in accordance with local/regional/national/international regulations (to be specified).
Use only outdoors or in a well-ventilated area.	Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.	hazardous atmosphere. Store locked up.	

[163] Permanent

C.4.12 SPECIFIC TARGET ORGAN TOXICITY (Repeated Exposure) (Classified in Accordance with WAC 296-901-14022(A.9))

Pictogram Health hazard

			пеаш падаги
Hazard category	Signal word	Hazard statement	
1	Danger	Causes damage to organs <> through prolonged or repeated exposure <<>>	
		<> (state all organs affected, if known)	V
		<<>> (state route of exposure if no other routes of exposure	

cause the hazard)

Precautionary statements

product.

Precautionary statements			
Prevention	Response	Storage	Disposal
Do not breathe dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions.	Get medical advice/attention if you feel unwell.		Dispose of contents/container to in accordance with local/regional/national/international regulations (to be specified).
Wash thoroughly after handlingChemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling.			
Do not eat, drink or smoke when using this			

Permanent [164]

C.4.12 SPECIFIC TARGET ORGAN TOXICITY (Repeated Exposure) (CONTINUED) (Classified in Accordance with WAC 296-901-14022(A.9))

Pictogram Health hazard

Pictogram

Hazard category	Signal word	Hazard statement	
2	Warning	May cause damage to organs <> through prolonged or repeated exposure <<>>	
		<> (state all organs affected, if known)	

<<...>> (state route of exposure if no other routes of exposure cause the hazard)

Precautionary statements

Prevention	Response	Storage	Disposal
Do not breathe dust/fume/gas/mist/ vapors/spray.	Get medical advice/attention if you feel unwell.		Dispose of contents/container to in accordance with
Chemical manufacturer, importer, or distributor to specify applicable conditions.			local/regional/national/international regulations (to be specified).

C.4.13 ASPIRATION HAZARD (Classified in Accordance with WAC 296-901-14022(A.10))

			Health hazard
Hazard category	Signal word	Hazard statement	
1	Danger	May be fatal if swallowed and enters airways	

Precautionary statements

Prevention	Response	Storage	Disposal
	If swallowed: Immediately call a poison center/doctor/ Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.	Store locked up.	Dispose of contents/container to in accordance with local/regional/national/international regulations (to be specified).
	Do NOT induce vomiting.		

[165] Permanent

C.4.14 EXPLOSIVES (Classified in Accordance with WAC 296-901-14024(B.1))

Pictogram Exploding bomb

Hazard category

Signal word

Hazard statement

Unstable explosive

Danger

Unstable explosive



Precautionary statements

Prevention

Response **Explosion risk in case of** fire.

Storage Store ...

Disposal Dispose of

Obtain special instructions before use.

Do NOT fight fire when

fire reaches explosives.

Evacuate area.

...in accordance with **contents/container to ...** local/regional/ national/international regulations (to be

specified).

...in accordance with local/regional/ national/international regulations (to be

specified).

Do not handle until all safety precautions have been read and understood.

> Wear personal protective equipment/face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment, as required.

[166] Permanent

C.4.14 EXPLOSIVES (CONTINUED) (Classified in Accordance with WAC 296-901-14024(B.1))

Pictogram Exploding bomb

Hazard category	Signal word	Hazard statement
Division 1.1	Danger	Explosive; mass explosion hazard
Division 1.2	Danger	Explosive; severe projection hazard
Division 1.3	Danger	Explosive; fire, blast or projection



Precautionary statements

Prevention	
------------	--

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).

Keep wetted with...

... Chemical manufacturer, importer, or distributor to specify appropriate material. - if drying out increases explosion hazard, except as needed for manufacturing or operating processes (e.g., nitrocellulose).

Ground/bond container and receiving equipment.

- if the explosive is electrostatically sensitive.

Do not subject to grinding/shock/.../friction.

...Chemical manufacturer, importer, or distributor to specify applicable rough handling.

Wear face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment.

Response

In case of fire: ...in accordance with evacuate area. local/regional/national/ international **Explosion risk in case**

Do NOT fight fire when fire reaches explosives.

of fire.

Storage Disposal

Store ...

regulations (to be

specified).

Dispose of contents/container to

... in accordance with local/ regional/national/ international regulations (to be specified).

Note: Unpackaged explosives or explosives repacked in packagings other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in Appendix B.1, in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.

> [167] Permanent

C.4.14 EXPLOSIVES (CONTINUED) (Classified in Accordance with WAC 296-901-14024(B.1))

Pictogram Exploding bomb¹

Hazard category

Division 1.4

Signal word
Warning

Hazard statement

Fire or projection hazard



Precautionary statements¹

Prevention

Response
In case of fire:
Evacuate area.

Storage Store ... Disposal

Dispose of contents/container
to...

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).

Explosion risk in case of fire.

- except if explosives are 1.4S ammunition and components thereof. ...in accordance with local/regional/ ... in accordance with national/international regulations (to be specified).

to...

... in accordance with local/regional/national/international regulations (to be specified).

Ground/bond container and receiving equipment.

- if the explosive is electrostatically sensitive.

Do not subject to grinding/shock/.../friction.

Chemical manufacturer, importer, or distributor to specify applicable rough handling.

Wear face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment.

fire when fire reaches explosives. Fight fire with

Do NOT fight

normal
precautions
from a
reasonable
distance

- if explosives are 1.4S ammunition and components thereof.

Note: Unpackaged explosives or explosives repacked in packagings other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in Appendix B.1, in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned. 1

Permanent [168]

C.4.14 EXPLOSIVES (CONTINUED) (Classified in Accordance with WAC 296-901-14024(B.1))

Pictogram No Pictogram

Hazard category	Signal word	Hazard statement	
Division 1.5	Danger	May mass explode in fire	
Precautionary statements			
Prevention	Response	Storage	Disposal
Keep away from heat/sparks/open flames/hot surfaces No	In case of fire: Evacuate area.	Store in accordance with local/regional/	Dispose of contents/container to
smoking. Chemical manufacturer, importer, or distributor to	Explosion risk in case of fire.	national/international regulations (to be specified).	in accordance with local/regional/national/international
specify applicable ignition source(s).	Do NOT fight fire whe		regulations (to be specified).

fire reaches explosives.

Keep wetted with...

... Chemical manufacturer, importer, or distributor to specify appropriate material. - if drying out increases explosion hazard, except as needed for manufacturing or operating processes (e.g., nitrocellulose).

Ground/bond container and receiving equipment

- if the explosive is electrostatically sensitive.

Do not subject to grinding/shock/.../friction.

...Chemical manufacturer, importer, or distributor to specify applicable rough handling.

Wear face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment.

Note: Unpackaged explosives or explosives repacked in packagings other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in Appendix B.1, in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.

> [169] Permanent

C.4.14 EXPLOSIVES (CONTINUED) (Classified in Accordance with WAC 296-901-14024(B.1))

Pictogram *No Pictogram*

Hazard category	Signal word	Hazard statement
Division 1.6	No signal word	No hazard statement

Precautionary statements

Prevention	Response	Storage	Disposal	
None assigned	None assigned	None assigned	None assigned	

Note: Unpackaged explosives or explosives repacked in packagings other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in Appendix B.1, in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.

Permanent [170]

C.4.15 FLAMMABLE GASES (Classified in Accordance with WAC 296-901-14024(B.2))

Pictogram Flame

Hazard category

Signal word

Hazard statement

1

Danger

Extremely flammable gas



Precautionary statements

Prevention

Response

Storage Store in well**Disposal**

Keep away from heat/sparks/open flames/hot surfaces. -No smoking.

Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).

Leaking gas fire: Store in well-Do not extinguish, unless ventilated place. leak can be stopped safely.

Eliminate all ignition sources if safe to do so.

Pictogram *No Pictogram*

Hazard category
2

Signal word

Hazard statement

Warning

Flammable gas

Precautionary statements

Prevention

Storage

Disposal

Keep away from heat/sparks/open flames/hot surfaces. -No smoking.

Chemical manufacturer, importer, or distributor to specify applicable ignition sources(s).

Response

Leaking gas fire: Do not extinguish, unless leak can be stopped safely.

Eliminate all ignition sources if safe to do so.

Store in wellventilated place.

[171] Permanent

C.4.16 FLAMMABLE AEROSOLS (Classified in Accordance with WAC 296-901-14024(B.3))

Pictogram Flame

Hazard category	Signal word	Hazard statement
1	Danger	Extremely flammable aerosol
2	Warning	Flammable aerosol



Precautionary statements

Prevention Disposal Response Storage **Keep away from Protect from** heat/sparks/open sunlight. Do not flames/hot surfaces. -No expose to smokina. temperatures Chemical manufacturer, exceeding 50 importer, or distributor to °C/122 °F. specify applicable ignition sources(s).

Do not spray on an open flame or other ignition source.

Pressurized container: Do not pierce or burn, even after use.

C.4.17 OXIDIZING GASES (Classified in Accordance with WAC 296-901-14024(B.4))

Pictogram Flame over circle

Hazard category Signal word **Hazard statement** 1 Danger May cause or intensify fire; oxidizer

Precautionary statements

Prevention Response Storage **Disposal Keep/Store away from**

materials. ...Chemical manufacturer, importer, or distributor to

specify other incompatible materials.

clothing/.../combustible

Keep reduction valves/valves and fittings free from oil and grease.

In case of fire: Stop leak Store in wellif safe to do so. ventilated place.

[172] Permanent

C.4.18 GASES UNDER PRESSURE (Classified in Accordance with WAC 296-901-14024(B.5))

				Pictogram Gas cylinder
Hazard category	Signal word	Haz	ard statement	^
Compressed gas	Warning	Contains gas under	oressure; may explode if heated	
Liquefied gas	Warning	Contains gas under	oressure; may explode if heated	
Dissolved gas	Warning	Contains gas under	pressure; may explode if heated	
Precautionary stater	ments			
Prevention	ı	Response	Storage	Disposal
			Protect from sunlight. Store in a well-ventilated place.	
				Pictogram Gas cylinder

Hazard category Signal word

Refrigerated liquefied gas Contains refrigerated gas; may cause cryogenic burns or injury



Precautionary statements

Prevention	Response	Storage	Disposal
Wear cold insulating gloves/face shield/eye protection.	Thaw frosted parts with lukewarm water. Do not rub affected area.	Store in well- ventilated place.	

Get immediate medical advice/attention.

[173] Permanent

C.4.19 FLAMMABLE LIQUIDS (Classified in Accordance with WAC 296-901-14024(B.6))

Pictogram Flame

Hazard category	Signal word	Hazard statement	
1	Danger	Extremely flammable liquid and vapor	
2	Danger	Highly flammable liquid and vapor	
3	Warning	Flammable liquid and vapor	



Precautionary statements

Prevention

Keep away from heat/sparks/open flames/hot surfaces.— No smoking.

Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).

Keep container tightly closed.

Ground/Bond container and receiving equipment

 if electrostatically sensitive material is for reloading.
 if product is volatile so as to generate hazardous atmosphere.

Use explosion-proof electrical/ventilating/lighting/.../equipment.

... Chemical manufacturer, importer, or distributor to specify other equipment.

Use only non-sparking tools.

Take precautionary measures against static discharge.

Wear protective gloves/eye protection/face protection

Chemical manufacturer, importer, or distributor to specify type of equipment.

Response

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

In case of fire: Use ... to extinguish.

... Chemical manufacturer, importer, or distributor to specify appropriate media. - if water increases risk.

Storage

Store in a wellventilated place. Keep cool.

Disposal

Dispose of contents/container to...

... in accordance with local/regional/national/international regulations (to be specified).

Permanent [174]

C.4.19 FLAMMABLE LIQUIDS (CONTINUED) (Classified in Accordance with WAC 296-901-14024(B.6))

Pictogram *No Pictogram*

Hazard category	Signal word	Hazard statement	_
4	Warning	Combustible liquid	
Precautionary statements			
Prevention	Response	Storage	Disposal
Keep away from flames and hot surfaces. – No smoking. Wear protective gloves/eye protection/face protection Chemical manufacturer, importer, or distributor to specify type of equipment.	In case of fire: Use to extinguish Chemical manufacturer, importer, or distributor to specify appropriate media if water increases risk.	Store in a well- ventilated place. Keep cool.	Dispose of contents/container to in accordance with local/regional/national/international regulations (to be specified).

[175] Permanent

C.4.20 FLAMMABLE SOLIDS (Classified in Accordance with WAC 296-901-14024(B.7))

Pictogram Flame

Hazard category	Signal word	Hazard statement
1	Danger	Flammable solid
2	Warning	Flammable solid



Precautionary statements

Prevention Response **Storage Disposal**

Keep away from heat/sparks/open flames/hot surfaces. -No smoking.

Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).

Ground/Bond container and receiving equipment.

- if electrostatically sensitive material is for reloading.

Use explosion-proof electrical/ventilating/ lighting/.../equipment.

... Chemical manufacturer, importer, or distributor to specify other equipment.

- if dust clouds can occur.

Wear protective gloves/eye protection/face protection

Chemical manufacturer, importer, or distributor to specify type of equipment. In case of fire: Use ... to extinguish

- ... Chemical manufacturer, importer, or distributor to specify appropriate media.
- if water increases risk.

[176] Permanent

C.4.21 SELF-REACTIVE SUBSTANCES AND MIXTURES (Classified in Accordance with WAC 296-901-14024(B.8))

Pictogram Flame

Hazard category

Signal word

Hazard statement

Exploding bomb

Type A

Danger

Heating may cause an explosion



Precautionary statements

Prevention

Keep away from heat/sparks/open flames/hot surfaces. -No smoking.

Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).

Keep/Store away from clothing/.../combustible materials.

... Chemical manufacturer, importer, or distributor to specify other incompatible materials.

Keep only in original container.

Wear protective gloves/eye protection/face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment.

Response

In case of fire: Use ... to extinguish

... Chemical manufacturer, importer, or distributor to specify appropriate media. - if water increases risk.

In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.

Storage

Store in a wellventilated place. Keep cool.

Store at temperatures not exceeding ...°C/...°F.

... Chemical manufacturer, importer, or distributor to specify temperature.

Store away from other materials.

Disposal

Dispose of contents/container to...

... in accordance with local/regional/national/international regulations (to be specified).

[177] Permanent

C.4.21 SELF-REACTIVE SUBSTANCES AND MIXTURES (CONTINUED) (Classified in Accordance with WAC 296-901-14024(B.8))

Pictogram

Exploding bomb and flame

Hazard Signal category word		Hazard statement		
Type B	Danger	Heating may cause a fire or explosion	<u> </u>	





Precautionary statements			
Prevention	Response	Storage	Disposal
Keep away from heat/sparks/open flames/hot surfaces No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).	In case of fire: Use to extinguish Chemical manufacturer, importer, or distributor to specify appropriate media if water increases risk.	ventilated place. Keep cool. Store at temperatures	Dispose of contents/container toin accordance with local/regional/national/international regulations (to be specified).
Keep/Store away from clothing//combustible materials Chemical manufacturer, importer, or distributor to specify other incompatible materials.	In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.	not exceeding°C/°F Chemical manufacturer, importer, or distributor to specify temperature.	
Keep only in original container.		Store away from other materials.	

Wear protective gloves/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.

Permanent [178]

C.4.21 SELF-REACTIVE SUBSTANCES AND MIXTURES (CONTINUED) (Classified in Accordance with WAC 296-901-14024(B.8))

Pictogram

Hazard category	Signal word	Hazard stateme	nt
Type C	Danger	Heating may cause a	a fire
Type D	Danger	Heating may cause a	a fire
Type E	Warning	Heating may cause a	a fire
Type F	Warning	Heating may cause a	ı fire
Precautionary statements			
Prevention	Response	Storage	Disposal
Keep away from heat/sparks/open flames/hot surfaces No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). Keep/Store away from clothing//combustible materialsChemical manufacturer, importer, or distributor to specify other incompatible materials.	In case of fire: Use to extinguish Chemical manufacturer, importer or distributor to specify appropriate media if water increases risk	ventilated place. Keep cool. Store at temperatures not exceeding°C/°FChemical manufacturer, importer, or distributor to specify temperature.	Dispose of contents/container toin accordance with local/regional/national/international regulations (to be specified).
Keep only in original container.		Store away from other materials.	
Wear protective gloves/eye protection/face protection. Chemical manufacturer,			

importer, or distributor to specify type of equipment.

[179] Permanent

C.4.22 PYROPHORIC LIQUIDS (Classified in Accordance with WAC 296-901-14024(B.9))

Hazard category Signal word

Pictogram Flame

Danger

Catches fire spontaneously if exposed to air

Hazard statement

1



Precautionary statements

Prevention

Keep away from heat/sparks/open flames/hot surfaces. -No smoking.

Chemical manufacturer, importer, or distributor to specify applicable ignition sources(s).

Do not allow contact with air.

Wear protective gloves/eye protection/face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment.

Response

If on skin: Immerse in cool water/wrap with wet bandages

In case of fire: Use ... to extinguish

... Chemical manufacturer, importer, or distributor to specify appropriate media.

- if water increases risk.

Storage

Store contents under ...

... Chemical manufacturer, importer, or distributor to specify appropriate liquid or inert gas. Disposal

Permanent [180]

C.4.23 PYROPHORIC SOLIDS (Classified in Accordance with WAC 296-901-14024(B.10))

Hazard category Signal word

Hazard statement

Danger

Catches fire spontaneously if exposed to air

1



Disposal

Pictogram Flame

Precautionary statements

Prevention

Keep away from heat/sparks/open flames/hot surfaces. -No smoking.

Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).

Do not allow contact with air.

Wear protective gloves/eye protection/face protection

Chemical manufacturer, importer, or distributor to specify type of equipment.

Response

Brush off loose particles from skin. Immerse in cool water/wrap in wet bandages.

In case of fire: Use ... to extinguish

... Chemical manufacturer, importer, or distributor to specify appropriate media. - if water increases risk.

[181]

Storage

Store contents under ...

...Chemical manufacturer, importer, or distributor to specify appropriate liquid or inert gas.

C.4.24 SELF-HEATING SUBSTANCES AND MIXTURES (Classified in Accordance with WAC 296-901-14024(B.11))

Pictogram Flame

Hazard categorySignal wordHazard statement1DangerSelf-heating; may catch fire2WarningSelf-heating in large quantities; may catch fire

Precautionary statements

Prevention	Response	Storage	Disposal
Keep cool. Protect from sunlight.		Maintain air gap between stacks/pallets.	
Wear protective gloves/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.		Store bulk masses greater than kg/lbs at temperatures not exceeding°C/°F Chemical manufacturer, importer, or distributor to specify mass and temperature.	
		Store away from	

other materials.

Permanent [182]

C.4.25 SUBSTANCES AND MIXTURES WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES

(Classified in Accordance with WAC 296-901-14024(B.12))

Hazard statement

Signal

Hazard

Pictogram	
Flame	

category	word				
1	Danger	In contact with water relea ignite s	ses flammable gas pontaneously	es, which may	
2	Danger	In contact with water	er releases flamma	ble gas	
Precautionary sta	atements				
Preventi	on	Response	Storage	Dis	sposal
Do not allow with wat Handle unde gas. Protect moistur	er. er inert t from	Brush off loose particles from skin and immerse in cool water/wrap in wet bandages.	Store in a dry place. Store in a closed container.	in acco	ntents/container to ordance with ational/international (to be specified).
Wear prote gloves/e protection, protection Chemical manu importer, or dist specify type of e	eye /face on. facturer, ributor to	In case of fire: Use to extinguish Chemical manufacturer, importer, or distributor to specify appropriate media if water increases risk.			

[183] Permanent

C.4.25 SUBSTANCES AND MIXTURES WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES (CONTINUED)

(Classified in Accordance with WAC 296-901-14024(B.12))

Pictogram Flame

Hazard category S

3

Signal word
Warning

Hazard statement

In contact with water releases flammable gas



Precautionary statements

Prevention

Handle under inert gas.

Protect from moisture.

Wear protective

In case of fire: Use ... to extinguish.

Response

... Chemical manufacturer, importer, or distributor to specify appropriate media. - if water increases risk.

Storage

Store in a dry place. Store in a closed container.

Disposal

Dispose of contents/container to...
...in accordance with

...in accordance with local/regional/national/international regulations (to be specified).

gloves/eye protection/face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment.

Permanent [184]

C.4.26 OXIDIZING LIQUIDS (Classified in Accordance with WAC 296-901-14024(B.13))

Pictogram Flame over circle

Hazard category Signal word

Danger

Hazard statement

1

May cause fire or explosion; strong oxidizer



Precautionary statements

Prevention

Keep away from heat.

Keep/Store away from clothing and other combustible materials.

Take any precaution to avoid mixing with combustibles/...

... Chemical manufacturer, importer, or distributor to specify other incompatible materials.

Wear protective gloves /eye protection/face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment.

Wear fire/flame resistant/retardant clothing.

Response

If on clothing: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.

In case of major fire and large quantities:
Evacuate area. Fight fire remotely due to the risk of explosion.

In case of fire: Use ... to extinguish.

... Chemical manufacturer, importer, or distributor to specify appropriate media. - if water increases risk.

Storage

Disposal

Dispose of contents/container to...

...in accordance with local/regional/ national/international regulations (to be specified).

[185] Permanent

C.4.26 OXIDIZING LIQUIDS (CONTINUED) (Classified in Accordance with WAC 296-901-14024(B.13))

Pictogram Flame over circle

Hazard category	Signal word	Hazard statement
2	Danger	May intensify fire; oxidizer
3	Warning	May intensify fire; oxidizer



Precautionary statements

Prevention Response **Storage Disposal** In case of fire: Use ... to **Keep away from heat.** Dispose of extinguish. contents/container to... ... Chemical manufacturer, ...in accordance with **Keep/Store away from** clothing/.../combustible importer, or distributor to local/regional/ specify appropriate media. national/international materials. - if water increases risk. regulations (to be specified). ...Chemical manufacturer, importer, or distributor to

Take any precaution to avoid mixing with combustibles/...

specify other incompatible materials.

... Chemical manufacturer, importer, or distributor to specify other incompatible materials.

Wear protective gloves/eye protection/face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment.

Permanent [186]

C.4.27 OXIDIZING SOLIDS (Classified in Accordance with WAC 296-901-14024(B.14))

Pictogram Flame over circle

Hazard category Signal word

Hazard statement

1

Danger

May cause fire or explosion; strong oxidizer



Precautionary statements

Prevention

Keep away from heat.

Keep away from clothing and other combustible materials.

Take any precaution to avoid mixing with combustibles/...

...Chemical manufacturer, importer, or distributor to specify other incompatible materials.

Wear protective gloves/eye protection/face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment.

Wear fire/flame resistant/retardant clothing.

Response

If on clothing: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.

In case of major fire and large quantities:
Evacuate area. Fight fire remotely due to the risk of explosion.

In case of fire: Use ... to extinguish.

... Chemical manufacturer, importer, or distributor to specify appropriate media.

- if water increases risk.

Storage Disposal

Dispose of contents/container to...

...in accordance with local/regional/ national/international regulations (to be specified).

[187] Permanent

C.4.27 OXIDIZING SOLIDS (CONTINUED) (Classified in Accordance with WAC 296-901-14024(B.14))

Pictogram Flame over circle

Hazard category	Signal word	Hazard statement
2	Danger	May intensify fire; oxidizer
3	Warning	May intensify fire; oxidizer



Precautionary statements

Prevention Response **Storage Disposal** Keep away from heat. In case of fire: Use ... **Dispose of contents/container** to extinguish. to... ... Chemical manufacturer, ... in accordance with **Keep/Store away from** importer, or distributor to local/regional/national/international clothing/.../ specify appropriate media. regulations (to be specified). combustible materials. - if water increases risk. ... Chemical manufacturer, importer, or distributor to specify incompatible

Take any precaution to avoid mixing with combustibles/...

materials.

...Chemical manufacturer, importer, or distributor to specify other incompatible materials.

> Wear protective gloves/eye protection/face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment.

Permanent [188]

C.4.28 ORGANIC PEROXIDES (Classified in Accordance with WAC 296-901-14024(B.15))

Pictogram Exploding bomb

Hazard category

Signal word

Hazard statement

Type A

Danger

Heating may cause an explosion



Precautionary statements

Prevention

Response

Storage

Disposal

Keep away from heat/sparks/open flames/hot surfaces.-No smoking.

Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).

Keep/Store away from clothing/.../combustible materials.

... Chemical manufacturer, importer, or distributor to specify incompatible materials.

Keep only in original container.

Wear protective gloves/eye protection/face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment.

Store at temperatures not exceeding ...°C/...°F. Keep cool.

... Chemical manufacturer, importer, or distributor to specify temperature.

Protect from sunlight.

Store away from other materials.

Dispose of contents/container to...

... in accordance with local/regional/national/international regulations (to be specified).

C.4.28 ORGANIC PEROXIDES (CONTINUED) (Classified in Accordance with WAC 296-901-14024(B.15))

Pictogram

Exploding bomb and flame

Hazard category	Signal word	Hazard statement
-----------------	-------------	------------------

Type B Danger Heating may cause an explosion





Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat/sparks/open flames/hot surfaces No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).		Store at temperatures not exceeding°C/°F. Keep cool. Chemical manufacturer, importer, or distributor to	Dispose of contents/container to in accordance with local/regional/national/international regulations (to be specified).
Keep /Store away from clothing//combustible materials.		specify temperature.	
Chemical manufacturer, importer, or distributor to specify incompatible		Protect from sunlight.	
materials. Keep only in original container.		Store away from other materials.	

Wear protective gloves/eye protection/face protection.

Chemical manufacturer, importer, or distributor to specify type of equipment.

Permanent [190]

C.4.29 CORROSIVE TO METALS (Classified in Accordance with WAC 296-901-14024(B.16))

Pictogram Corrosion

Hazard category Signal word **Hazard statement** 1 May be corrosive to metals

Warning



Precautionary statements

Prevention Response **Storage Disposal**

Keep only in original container.

Absorb spillage to Store in prevent material corrosive damage. resistant/... container with a resistant inner

> liner. ... Chemical manufacturer, importer, or distributor to specify other compatible materials.

[191] Permanent

C.4.30 Label elements for OSHA defined hazards

Hazard category Signal word Hazard statement

Pyrophoric Gas Danger Catches fire spontaneously if exposed to air

Pictogram
No Pictogram

Pictogram

Hazard category Signal word Hazard statement

Simple Asphyxiant Warning May displace oxygen and cause rapid suffocation

Pictogram *No Pictogram*

Hazard category Signal word Hazard statement

Combustible Dust² Warning May form combustible dust concentrations in air

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency and appear in the Register pursuant to the requirements of RCW 34.08.040.

NEW SECTION

WAC 296-901-14028 Appendix D—Safety data sheets. A safety data sheet (SDS) must include the information specified in Table D.1 under the section number and heading indicated for sections 1-11 and 16. If no relevant information is found for any given subheading within a section, the SDS must clearly indicate that no applicable information is available. Sections 12-15 may be included in the SDS, but are not mandatory.

Table D.1. Minimum Information for an SDS

	Heading	Subheading	
1.	Identification	(a) Product identifier used on the label;	
		(b) Other means of identification;	
		(c) Recommended use of the chemical and restrictions on use;	
		(d) Name, address, and telephone number of the chemical manufacturer, importer,	
		or other responsible party;	
		(e) Emergency phone number.	

Permanent [192]

¹ Except no pictogram is required for explosives that are 1.4S small arms ammunition and components thereof. Labels for 1.4S small arms ammunition and components shall include appropriate precautionary statements.

² The chemical manufacturer or importer shall label chemicals that are shipped in dust form, and present a combustible dust hazard in that form when used downstream, under paragraph (f)(1); 2) the chemical manufacturer or importer shipping chemicals that are in a form that is not yet a dust must provide a label to customers under paragraph (f)(4) if, under normal conditions of use, the chemicals are processed in a downstream workplace in such a way that they present a combustible dust hazard/ and 3) the employer shall follow the workplace labeling requirements under paragraph (f)(6) where combustible dust hazards are present.

	Heading	Subheading	
2.	Hazard(s) identification	(a) Classification of the chemical in accordance with WAC 296-901-14008; (b) Signal word, hazard statement(s), symbol(s) and precautionary statement(s) in accordance with WAC 296-901-14012. (Hazard symbols may be provided as graphical reproductions in black and white or the name of the symbol, e.g., flame, skull and crossbones); (c) Describe any hazards not otherwise classified that have been identified during the classification process; (d) Where an ingredient with unknown acute toxicity is used in a mixture at a concentration = 1% and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity is required.	
3.	Composition/information on	Except as provided for in WAC 296-901-14018 on trade secrets:	
	ingredients	For Substances (a) Chemical name; (b) Common name and synonyms; (c) CAS number and other unique identifiers; (d) Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance. For Mixtures In addition to the information required for substances: (a) The chemical name and concentration (exact percentage) or concentration ranges of all ingredients which are classified as health hazards in accordance with WAC 296-901-14008 and (1) are present above their cut-off/concentration limits; or (2) present a health risk below the cut-off/concentration limits. (b) The concentration (exact percentage) must be specified unless a trade secret claim is made in accordance with WAC 296-901-14018, when there is batch-to-batch variability in the production of a mixture, or for a group of substantially similar mixtures (See WAC 296-901-14022 (A.0.5.1.2)) with similar chemical composition. In these cases, concentration ranges may be used. For All Chemicals Where a Trade Secret is Claimed Where a trade secret is claimed in accordance with WAC 296-901-14018, a statement that the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret is required.	
4.	First-aid measures	 (a) Description of necessary measures, subdivided according to the different routes of exposure, i.e., inhalation, skin and eye contact, and ingestion; (b) Most important symptoms/effects, acute and delayed. (c) Indication of immediate medical attention and special treatment needed, if necessary. 	
5.	Fire-fighting measures	 (a) Suitable (and unsuitable) extinguishing media. (b) Specific hazards arising from the chemical (e.g., nature of any hazardous combustion products). (c) Special protective equipment and precautions for fire-fighters. 	
6.	Accidental release measures	(a) Personal precautions, protective equipment, and emergency procedures.(b) Methods and materials for containment and cleaning up.	
7.	Handling and storage	(a) Precautions for safe handling. (b) Conditions for safe storage, including any incompatibilities.	
8.	Exposure controls/personal protection	(a) DOSH permissible exposure limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available. (b) Appropriate engineering controls. (c) Individual protection measures, such as personal protective equipment.	

[193] Permanent

	Heading	Subheading	
9.	Physical and chemical proper-	(a) Appearance (physical state, color, etc.);	
	ties	(b) Odor;	
		(c) Odor threshold;	
		(d) pH;	
		(e) Melting point/freezing point;	
		(f) Initial boiling point and boiling range;	
		(g) Flash point;	
		(h) Evaporation rate;	
		(i) Flammability (solid, gas);	
		(j) Upper/lower flammability or explosive limits;	
		(k) Vapor pressure;	
		(l) Vapor density;	
		(m) Relative density;	
		(n) Solubility(ies);	
		(o) Partition coefficient: n-octanol/water;	
		(p) Auto-ignition temperature;	
		(q) Decomposition temperature;	
		(r) Viscosity.	
10.	Stability and reactivity	(a) Reactivity;	
		(b) Chemical stability;	
		(c) Possibility of hazardous reactions;	
		(d) Conditions to avoid (e.g., static discharge, shock, or vibration);	
		(e) Incompatible materials;	
		(f) Hazardous decomposition products.	
11.	Toxicological information	Description of the various toxicological (health) effects and the available data	
		used to identify those effects, including:	
		(a) Information on the likely routes of exposure (inhalation, ingestion, skin and	
		eye contact);	
		(b) Symptoms related to the physical, chemical and toxicological characteristics;	
		(c) Delayed and immediate effects and also chronic effects from short-and long-	
		term exposure;	
		(d) Numerical measures of toxicity (such as acute toxicity estimates).	
		(e) Whether the hazardous chemical is listed in the National Toxicology Program	
		(NTP) Report on Carcinogens (latest edition) or has been found to be a potential	
		carcinogen in the International Agency for Research on Cancer (IARC) Mono-	
		graphs (latest edition), or by DOSH.	
12.	Ecological information (Non-	(a) Ecotoxicity (aquatic and terrestrial, where available);	
	mandatory)	(b) Persistence and degradability;	
		(c) Bioaccumulative potential;	
		(d) Mobility in soil;	
		(e) Other adverse effects (such as hazardous to the ozone layer).	
13.	Disposal considerations (Non-	Description of waste residues and information on their safe handling and methods	
	mandatory)	of disposal, including the disposal of any contaminated packaging.	
14.	Transport information (Non-	(a) UN number;	
	mandatory)	(b) UN proper shipping name;	
		(c) Transport hazard class(es);	
		(d) Packing group, if applicable;	
		(e) Environmental hazards (e.g., Marine pollutant (Yes/No));	
		(f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC	
		Code);	
		(g) Special precautions which a user needs to be aware of, or needs to comply	
		with, in connection with transport or conveyance either within or outside their	
		premises.	

Permanent [194]

	Heading	Subheading
15.	Regulatory information (Non-	Safety, health and environmental regulations specific for the product in question.
	mandatory)	
16.	Other information, including	The date of preparation of the SDS or the last change to it.
	date of preparation or last revi-	
	sion	

NEW SECTION

WAC 296-901-14030 Appendix E—Definition of "trade secret." The following is a reprint of the "Restatement of Torts" section 757, comment b (1939):

b. "Definition of trade secret." A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers. It differs from other secret information in a business (see s759 of the Restatement of Torts which is not included in this Appendix) in that it is not simply information as to single or ephemeral events in the conduct of the business, as, for example, the amount or other terms of a secret bid for a contract or the salary of certain employees, or the security investments made or contemplated, or the date fixed for the announcement of a new policy or for bringing out a new model or the like. A trade secret is a process or device for continuous use in the operations of the business. Generally it relates to the production of goods, as, for example, a machine or formula for the production of an article. It may, however, relate to the sale of goods or to other operations in the business, such as a code for determining discounts, rebates or other concessions in a price list or catalogue, or a list of specialized customers, or a method of bookkeeping or other office management.

"Secrecy." The subject matter of a trade secret must be secret. Matters of public knowledge or of general knowledge in an industry cannot be appropriated by one as his secret. Matters which are completely disclosed by the goods which one markets cannot be his secret. Substantially, a trade secret is known only in the particular business in which it is used. It is not requisite that only the proprietor of the business know it. He may, without losing his protection, communicate it to employees involved in its use. He may likewise communicate it to others pledged to secrecy. Others may also know of it independently, as, for example, when they have discovered the process or formula by independent invention and are keeping it secret. Nevertheless, a substantial element of secrecy must exist, so that, except by the use of improper means, there would be difficulty in acquiring the information. An exact definition of a trade secret is not possible. Some factors to be considered in determining whether given information is one's trade secret are: (1) The extent to which the information is known outside of his business; (2) the extent to which it is known by employees and others involved in his business; (3) the extent of measures taken by him to guard the secrecy of the information; (4) the value of the information to him and his competitors; (5) the amount of effort or money

expended by him in developing the information; (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

"Novelty and prior art." A trade secret may be a device or process which is patentable; but it need not be that. It may be a device or process which is clearly anticipated in the prior art or one which is merely a mechanical improvement that a good mechanic can make. Novelty and invention are not requisite for a trade secret as they are for patentability. These requirements are essential to patentability because a patent protects against unlicensed use of the patented device or process even by one who discovers it properly through independent research. The patent monopoly is a reward to the inventor. But such is not the case with a trade secret. Its protection is not based on a policy of rewarding or otherwise encouraging the development of secret processes or devices. The protection is merely against breach of faith and reprehensible means of learning another's secret. For this limited protection it is not appropriate to require also the kind of novelty and invention which is a requisite of patentability. The nature of the secret is, however, an important factor in determining the kind of relief that is appropriate against one who is subject to liability under the rule stated in this Section. Thus, if the secret consists of a device or process which is a novel invention, one who acquires the secret wrongfully is ordinarily enjoined from further use of it and is required to account for the profits derived from his past use. If, on the other hand, the secret consists of mechanical improvements that a good mechanic can make without resort to the secret, the wrongdoer's liability may be limited to damages, and an injunction against future use of the improvements made with the aid of the secret may be inappropriate.

NEW SECTION

WAC 296-901-14032 Appendix F—Guidance for hazard classifications regarding carcinogenicity. The mandatory criteria for classification of a chemical for carcinogenicity under HCS are found in WAC 296-901-14022 (A.6). This non-mandatory Appendix provides additional guidance on hazard classification for carcinogenicity. Part A of Appendix F includes background guidance provided by GHS based on the Preamble of the International Agency for Research on Cancer (IARC) "Monographs on the Evaluation of Carcinogenic Risks to Humans" (2006). Part B provides IARC classification information. Part C provides background guidance from the National Toxicology Program (NTP) "Report on Carcinogens" (RoC), and Part D is a table that compares GHS carcinogen hazard categories to carcinogen classifications under IARC and NTP, allowing classifiers to be able to use information from IARC and NTP RoC car-

cinogen classifications to complete their classifications under the GHS, and thus the HCS.

Part A: Background Guidance¹

As noted in Footnote 6 of WAC 296-901-14022 (A.6)., the GHS includes as guidance for classifiers information taken from the Preamble of the International Agency for Research on Cancer (IARC) "Monographs on the Evaluation of Carcinogenic Risks to Humans" (2006), providing guidance on the evaluation of the strength and evidence of carcinogenic risks to humans. This guidance also discusses some additional considerations in classification and an approach to analysis, rather than hard-and-fast rules. Part A is consistent with WAC 296-901-14022 (A.6), and must help in evaluating information to determine carcinogenicity.

Carcinogenicity in humans:

The evidence relevant to carcinogenicity from studies in humans is classified into one of the following categories:

- (a) *Sufficient evidence of carcinogenicity*: A causal relationship has been established between exposure to the agent and human cancer. That is, a positive relationship has been observed between the exposure and cancer in studies in which chance, bias and confounding could be ruled out with reasonable confidence.
- (b) *Limited evidence of carcinogenicity*: A positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence.

In some instances, the above categories may be used to classify the degree of evidence related to carcinogenicity in specific organs or tissues.

Carcinogenicity in experimental animals:

The evidence relevant to carcinogenicity in experimental animals is classified into one of the following categories:

(a) Sufficient evidence of carcinogenicity: A causal relationship has been established between the agent and an increased incidence of malignant neoplasms or of an appropriate combination of benign and malignant neoplasms in (i) two or more species of animals or (ii) two or more independent studies in one species carried out at different times or in different laboratories or under different protocols. An increased incidence of tumors in both sexes of a single species in a well-conducted study, ideally conducted under Good Laboratory Practices, can also provide sufficient evidence.

Exceptionally, a single study in one species and sex might be considered to provide sufficient evidence of carcinogenicity when malignant neoplasms occur to an unusual degree with regard to incidence, site, type of tumor or age at onset, or when there are strong findings of tumors at multiple sites.

(a) Limited evidence of carcinogenicity: The data suggest a carcinogenic effect but are limited for making a definitive evaluation because, e.g. (i) the evidence of carcinogenicity is restricted to a single experiment; (ii) there are unresolved questions regarding the adequacy of the design, conduct or

interpretation of the studies; (iii) the agent increases the incidence only of benign neoplasms or lesions of uncertain neoplastic potential; or (iv) the evidence of carcinogenicity is restricted to studies that demonstrate only promoting activity in a narrow range of tissues or organs.

Guidance on how to consider important factors in classification of carcinogenicity (See Reference Section)

The weight of evidence analysis called for in GHS and the HCS is an integrative approach that considers important factors in determining carcinogenic potential along with the strength of evidence analysis. The IPCS "Conceptual Framework for Evaluating a Mode of Action for Chemical Carcinogenesis" (2001), International Life Sciences Institute (ILSI) "Framework for Human Relevance Analysis of Information on Carcinogenic Modes of Action" (Meek, et al., 2003; Cohen et al., 2003, 2004), and Preamble to the IARC Monographs (2006; Section B.6. (Scientific Review and Evaluation; Evaluation and Rationale)) provide a basis for systematic assessments that may be performed in a consistent fashion. The IPCS also convened a panel in 2004 to further develop and clarify the human relevance framework. However, the above documents are not intended to dictate answers, nor provide lists of criteria to be checked off.

Mode of action

Various documents on carcinogen assessment all note that mode of action in and of itself, or consideration of comparative metabolism, must be evaluated on a case-by-case basis and are part of an analytic evaluative approach. One must look closely at any mode of action in animal experiments, taking into consideration comparative toxicokinetics/toxicodynamics between the animal test species and humans to determine the relevance of the results to humans. This may lead to the possibility of discounting very specific effects of certain types of substances. Life stage-dependent effects on cellular differentiation may also lead to qualitative differences between animals and humans. Only if a mode of action of tumor development is conclusively determined not to be operative in humans may the carcinogenic evidence for that tumor be discounted. However, a weight of evidence evaluation for a substance calls for any other tumorigenic activity to be evaluated, as well.

Responses in multiple animal experiments

Positive responses in several species add to the weight of evidence that a substance is a carcinogen. Taking into account all of the factors listed in WAC 296-901-14022 (A.6.2.5.2) and more, such chemicals with positive outcomes in two or more species would be provisionally considered to be classified in GHS Category 1B until human relevance of animal results are assessed in their entirety. It must be noted, however, that positive results for one species in at least two independent studies, or a single positive study showing unusually strong evidence of malignancy may also lead to Category 1B.

Responses are in one sex or both sexes

Any case of gender-specific tumors must be evaluated in light of the total tumorigenic response to the substance observed at other sites (multi-site responses or incidence

Permanent [196]

above background) in determining the carcinogenic potential of the substance.

If tumors are seen only in one sex of an animal species, the mode of action must be carefully evaluated to see if the response is consistent with the postulated mode of action. Effects seen only in one sex in a test species may be less convincing than effects seen in both sexes, unless there is a clear patho-physiological difference consistent with the mode of action to explain the single sex response.

Confounding effects of excessive toxicity or localized effects

Tumors occurring only at excessive doses associated with severe toxicity generally have doubtful potential for carcinogenicity in humans. In addition, tumors occurring only at sites of contact and/or only at excessive doses need to be carefully evaluated for human relevance for carcinogenic hazard. For example, forestomach tumors, following administration by gavage of an irritating or corrosive, non-mutagenic chemical, may be of questionable relevance. However, such determinations must be evaluated carefully in justifying the carcinogenic potential for humans; any occurrence of other tumors at distant sites must also be considered.

Tumor type, reduced tumor latency

Unusual tumor types or tumors occurring with reduced latency may add to the weight of evidence for the carcinogenic potential of a substance, even if the tumors are not statistically significant.

Toxicokinetic behavior is normally assumed to be similar in animals and humans, at least from a qualitative perspective. On the other hand, certain tumor types in animals may be associated with toxicokinetics or toxicodynamics that are unique to the animal species tested and may not be predictive of carcinogenicity in humans. Very few such examples have been agreed internationally. However, one example is the lack of human relevance of kidney tumors in male rats associated with compounds causing a2u-globulin nephropathy (IARC, Scientific Publication N° 1472). Even when a particular tumor type may be discounted, expert judgment must be used in assessing the total tumor profile in any animal experiment.

Part B: International Agency for Research on Cancer (IARC)³

IARC Carcinogen Classification Categories:

Group 1: The agent is carcinogenic to humans.

This category is used when there is *sufficient evidence of carcinogenicity* in humans. Exceptionally, an agent may be placed in this category when evidence of carcinogenicity in humans is less than *sufficient* but there is *sufficient evidence of carcinogenicity* in experimental animals and strong evidence in exposed humans that the agent acts through a relevant mechanism of carcinogenicity.

Group 2:

This category includes agents for which, at one extreme, the degree of evidence of carcinogenicity in humans is almost *sufficient*, as well as those for which, at the other extreme,

there are no human data but for which there is evidence of carcinogenicity in experimental animals. Agents are assigned to either Group 2A (probably carcinogenic to humans) or Group 2B (possibly carcinogenic to humans) on the basis of epidemiological and experimental evidence of carcinogenicity and mechanistic and other relevant data. The terms probably carcinogenic and possibly carcinogenic have no quantitative significance and are used simply as descriptors of different levels of evidence of human carcinogenicity, with probably carcinogenic signifying a higher level of evidence than possibly carcinogenic.

Group 2A: The agent is probably carcinogenic to humans.

This category is used when there is *limited evidence of carcinogenicity* in humans and *sufficient evidence of carcinogenicity* in experimental animals. In some cases, an agent may be classified in this category when there is *inadequate evidence of carcinogenicity* in humans and *sufficient evidence of carcinogenicity* in experimental animals and strong evidence that the carcinogenesis is mediated by a mechanism that also operates in humans. Exceptionally, an agent may be classified in this category solely on the basis of *limited evidence of carcinogenicity* in humans. An agent may be assigned to this category if it clearly belongs, based on mechanistic considerations, to a class of agents for which one or more members have been classified in Group 1 or Group 2A.

Group 2B: The agent is possibly carcinogenic to humans.

This category is used for agents for which there is *limited evidence of carcinogenicity* in humans and less than **sufficient evidence of carcinogenicity** in experimental animals. It may also be used when there is *inadequate evidence of carcinogenicity* in humans but there is *sufficient evidence of carcinogenicity* in experimental animals. In some instances, an agent for which there is *inadequate evidence of carcinogenicity* in humans and less than *sufficient evidence of carcinogenicity* in experimental animals together with supporting evidence from mechanistic and other relevant data may be placed in this group. An agent may be classified in this category solely on the basis of strong evidence from mechanistic and other relevant data.

Part C: National Toxicology Program (NTP), "Report on Carcinogens", Background Guidance

NTP Listing Criteria⁴:

The criteria for listing an agent, substance, mixture, or exposure circumstance in the Report on Carcinogens (RoC) are as follows:

Known To Be A Human Carcinogen: There is sufficient evidence of carcinogenicity from studies in humans that indicates a causal relationship between exposure to the agent, substance, or mixture, and human cancer.

Reasonably Anticipated To Be A Human Carcinogen: There is limited evidence of carcinogenicity from studies in humans that indicates that a causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding factors, could not adequately be excluded,

or

there is sufficient evidence of carcinogenicity from studies in experimental animals that indicates there is an increased incidence of malignant and/or a combination of malignant and benign tumors (1) in multiple species or at multiple tissue sites, or (2) by multiple routes of exposure, or (3) to an unusual degree with regard to incidence, site, or type of tumor, or age at onset,

OF

there is less than sufficient evidence of carcinogenicity in humans or laboratory animals; however, the agent, substance, or mixture belongs to a well-defined, structurally-related class of substances whose members are listed in a previous Report on Carcinogens as either known to be a human carcinogen or reasonably anticipated to be a human carcinogen, or there is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.

Conclusions regarding carcinogenicity in humans or experimental animals are based on scientific judgment, with consideration given to all relevant information. Relevant information includes, but is not limited to, dose response, route of exposure, chemical structure, metabolism, pharmacokinetics, sensitive sub-populations, genetic effects, or other data relating to mechanism of action or factors that may be unique to a given substance. For example, there may be substances for which there is evidence of carcinogenicity in laboratory animals, but there are compelling data indicating that the agent acts through mechanisms that do not operate in humans and would therefore not reasonably be anticipated to cause cancer in humans.

Part D. Table Relating Approximate Equivalences among IARC, NTP RoC, and GHS Carcinogenicity Classifications

The following table may be used to perform hazard classifications for carcinogenicity under the HCS. It relates the approximated GHS hazard categories for carcinogenicity to the classifications provided by IARC and NTP, as described in Parts B and C of this Appendix.

Approximate Equivalences Among Carcinogen Classification Schemes

IARC	GHS	NTP RoC
Group 1	Category 1A	Known.
Group 2A	Category 1B	Reasonably anticipated.
Group 2B	Category 2	(See Note 1).

Note 1: 1. Limited evidence of carcinogenicity from studies in humans (corresponding to IARC 2A/GHS 1B);

- 2. Sufficient evidence of carcinogenicity from studies in experimental animals (again, essentially corresponding to IARC 2A/GHS 1B);
- 3. Less than sufficient evidence of carcinogenicity in humans or laboratory animals; however:
- a. The agent, substance, or mixture belongs to a well-defined, structurally-related class of substances whose members are listed in a previous RoC as either "Known" or "Reasonably Anticipated" to be a human carcinogen, or
- b. There is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.

*References:

Cohen, S.M., J. Klaunig, M.E. Meek, R.N. Hill, T. Pastoor, L. Lehman-McKeeman, J. Bucher, D.G. Longfellow, J. Seed, V. Dellarco, P. Fenner-Crisp, and D. Patton. 2004. Evaluating the human relevance of chemically induced animal tumors. **Toxicol. Sci.** 78(2):181-186.

Cohen, S.M., M.E. Meek, J.E. Klaunig, D.E. Patton, P.A. Fenner-Crisp. 2003. The human relevance of information on carcinogenic modes of action: Overview. **Crit. Rev. Toxicol.** 33(6):581-9.

Meek, M.E., J.R. Bucher, S.M. Cohen, V. Dellarco, R.N. Hill, L. Lehman-McKeeman, D.G. Longfellow, T. Pastoor, J. Seed, D.E. Patton. 2003. A framework for human relevance analysis of information on carcinogenic modes of action. **Crit. Rev. Toxicol.** 33(6):591-653.

Sonich-Mullin, C., R. Fielder, J. Wiltse, K. Baetcke, J. Dempsey, P. Fenner-Crisp, D. Grant, M. Hartley, A. Knapp, D. Kroese, I. Mangelsdorf, E. Meek, J.M. Rice, and M. Younes. 2001. The conceptual framework for evaluating a mode of action for chemical carcinogenesis. **Reg. Toxicol. Pharm.** 34:146-152.

International Programme on Chemical Safety Harmonization Group. 2004. Report of the First Meeting of the Cancer Working Group. World Health Organization. Report IPCS/HSC-CWG-1/04. Geneva.

International Agency for Research on Cancer. IARC Monographs on the Evaluation of Carcinogenic Risks to Human. Preambles to Volumes. World Health Organization. Lyon, France.

Cohen, S.M., P.A. Fenner-Crisp, and D.E. Patton. 2003. Special Issue: Cancer Modes of Action and Human Relevance. Critical Reviews in Toxicology, R.O. McClellan, ed., Volume 33/Issue 6. CRC Press.

Capen, C.C., E. Dybing, and J.D. Wilbourn. 1999. Species differences in thyroid, kidney and urinary bladder carcinogenesis. International Agency for Research on Cancer, Scientific Publication N° 147.

Doi, A.M., G. Hill, J. Seely, J.R. Hailey, G. Kissling, and J.R. Buchera. 2007. a2u-Globulin nephropathy and renal tumors in National Toxicology Program studies. Toxicol. Pathol. 35:533-540

Footnote 1 The text of Appendix F, Part A, on the IARC Monographs, is paraphrased from the 2006 Preamble to the "Monographs on the Evaluation of Carcinogenic Risks to Humans" the Classifier is referred to the full IARC Preamble for the complete text. The text is not part of the agreed GHS text on the harmonized system developed by the OECD Task Force-HCL.

Footnote 2 While most international agencies do not consider kidney tumors coincident with a2u-globulin nephropathy to be a predictor of risk in humans, this view is not universally held. (See: Doi et al., 2007)

Footnote 3 Preamble of the International Agency for Research on Cancer (IARC) "Monographs on the Evaluation of Carcinogenic Risks to Humans" (2006)

Footnote 4 See: http://ntp.niehs.nih.gov/go/15209

Footnote 5 This evidence can include traditional cancer epidemiology studies, data from clinical studies, and/or data derived from the study of tissues

Permanent [198]

or cells from humans exposed to the substance in question that can be useful for evaluating whether a relevant cancer mechanism is operating in people.

WSR 13-06-070 PERMANENT RULES DEPARTMENT OF FISH AND WILDLIFE

[Order 13-27—Filed March 6, 2013, 9:53 a.m., effective April 6, 2013]

Effective Date of Rule: Thirty-one days after filing.

Purpose: Allows recreational anglers fishing for tuna species in Pacific Ocean waters outside three miles from shore to use multiple rods or lines per angler as long as the anglers do not possess any other species onboard the vessel. This proposal also prohibits fishing for salmon for personal use with hand lines in Puget Sound east of the Sekiu River, and in the waters of Grays Harbor, Willapa Bay and the Columbia River. These rules conform to federal regulations adopted by the National Marine Fisheries Service. Finally, the proposal makes some minor technical changes, including moving a subsection and renumbering other subsections, to improve the rule's clarity. This reduces reader confusion.

These changes conform state regulations to federal regulations. Allowing multiple lines per angler while fishing for albacore maximizes access to the resource in the waters adjacent to Washington state but does not compromise that status of the resource.

Citation of Existing Rules Affected by this Order: Amending WAC 220-56-115.

Statutory Authority for Adoption: RCW 77.04.020, 77.12.045, and 77.12.047.

Other Authority: 50 C.F.R. Part 660, Subpart K.

Adopted under notice filed as WSR 13-01-083 on December 18, 2012.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 1, Repealed 0; Federal Rules or Standards: New 0, Amended 1, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's Own Initiative: New 0, Amended 1, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted Using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 0, Repealed 0.

Date Adopted: March 6, 2013.

Philip Anderson Director AMENDATORY SECTION (Amending Order 12-190, filed 8/23/12, effective 9/23/12)

- WAC 220-56-115 Angling gear—Lawful and unlawful acts. (1) It is unlawful for any person to use more than one line while angling for personal use, except:
- (a) Anglers in possession of a valid two-pole endorsement may use up to two lines while fishing in lakes, ponds, and reservoirs open to fishing unless listed as an exception in WAC 220-55-220. Anglers in possession of a valid two-pole endorsement may use up to two lines while fishing in rivers and marine areas as noted in WAC 220-55-220 and 232-28-619
- (b) A second line using forage fish jigger gear is permissible while fishing in Catch Record Card Areas 5, 6, 7, 8-1, 8-2, 9, 10, 11, 12, and 13.
- (c) When fishing outside 3 miles from shore in Pacific Ocean waters for tuna species, anglers are not restricted on the number of rods or lines fished per angler, provided that no other species are possessed onboard the vessel. A violation of this subsection is an infraction, punishable under RCW 77.15.160, Infractions.
- (2) It is unlawful for any person to take, fish for, or possess fish taken for personal use by any means other than angling with a line attached to a pole held in hand while landing the fish((5)) or with a hand-operated line without rod or reel, except ((as follows)):
- (a) It is unlawful to fish for or possess salmon taken for personal use with hand lines in marine waters of Puget Sound east of the mouth of the Sekiu River and in Washington waters at the mouth of the Columbia River east of a line projected true north and south through Buoy 10, Grays Harbor, and Willapa Bay.
- (b) It is permissible to leave ((the)) <u>a</u> pole in a pole holder while playing or landing the fish if the pole is capable of being readily removed from the pole holder.
- $((\frac{b}{b}))$ (c) It is permissible to use an electric power-operated reel designed for sport fishing attached to a pole.
- (((e) It is permissible to fish for or possess salmon taken for personal use with hand lines (lines not attached to a handheld pole), except that use of hand lines is unlawful in those waters west of the mouth of the Sekiu River, the Pacific Ocean, Washington waters at the mouth of the Columbia River west of a line projected true north and south through Buoy 10, Grays Harbor, and Willapa Bay.))
- (3) It is unlawful for any person while angling to fail to keep his angling gear under his or her direct and immediate physical control.
- (4) In areas where a saltwater license is valid, each fisher aboard a vessel may continue to deploy angling gear or shell-fish gear until the daily limit of food fish or shellfish for all licensed anglers and juvenile anglers aboard has been retained.
- (5) Violation of this section is an infraction, punishable under RCW 77.15.160, unless the person has harvested fish or shellfish. If the person has harvested fish or shellfish, the violation is punishable under RCW 77.15.380, Unlawful recreational fishing in the second degree—Penalty, unless the fish or shellfish are taken in the amounts or manner to constitute a violation of RCW 77.15.370, Unlawful recreational fishing in the first degree—Penalty.

[199] Permanent

(6) It is unlawful to possess fish or shellfish taken with gear in violation of the provisions of this section. Possession of fish or shellfish while using gear in violation of the provisions of this section is a rebuttable presumption that the fish or shellfish were taken with such gear. Possession of such fish or shellfish is punishable under RCW 77.15.380, Unlawful recreational fishing in the second degree—Penalty, unless the fish or shellfish are taken in the amounts or manner to constitute a violation of RCW 77.15.370, Unlawful recreational fishing in the first degree—Penalty.

WSR 13-06-074 PERMANENT RULES DEPARTMENT OF COMMERCE

[Filed March 6, 2013, 11:38 a.m., effective April 6, 2013]

Effective Date of Rule: Thirty-one days after filing.

Purpose: Purpose of the proposal and its anticipated effects, including any changes in existing rules: Establish the state greenhouse gas emission performance standard for utility baseload electric generation as nine hundred and seventy pounds per megawatt-hour, the average greenhouse gas emission rate as directed by RCW 80.80.050.

Statutory Authority for Adoption: RCW 80.80.050.

Adopted under notice filed as WSR 13-02-098 on January 2, 2013.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 2, Amended 0, Repealed 0.

Number of Sections Adopted at Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's Own Initiative: New 0, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted Using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 0, Repealed 0.

Date Adopted: March 6, 2013.

Nick Demerice Director of Government Affairs

Chapter 194-26 WAC

GREENHOUSE GAS EMISSIONS PERFORMANCE STANDARD

NEW SECTION

WAC 194-26-010 Authority. This chapter is promulgated pursuant to the authority granted in RCW 80.80.040, requiring the department of commerce to adopt the average available greenhouse gases emissions output as determined

under RCW 80.80.050 as the greenhouse gas emissions performance standard for all baseload electric generation for which electric utilities enter into long-term financial commitments

NEW SECTION

WAC 194-26-020 Average available greenhouse gas emissions output. The energy policy division of the department of commerce has surveyed new combined-cycle natural gas thermal electric generation turbines commercially available and offered for sale by manufacturers and purchased in the United States, and finds the average rate of emissions of greenhouse gases for these turbines to be nine hundred and seventy pounds per megawatt-hour.

Permanent [200]