Chapter 392-195

Title 392 WAC: Public Instruction, Supt. of

392-195-005 Purpose. The purpose of this chapter is to provide for the allocation of funds for in-service training programs pursuant to the In-Service Training Act of 1977, chapter 28A.71 RCW. [Statutory Authority: RCW 28A.71.210. 78-09-115 (Order 78-7), § 392-195-005, filed 9/6/78.]

WAC 392-195-010 Definitions. As used in this chapter:

(1) "Applicants" shall mean common school districts and educational service districts.

(2) "In-service training" shall mean a cooperatively planned program of training for job-related activities designed to increase the competencies of common school certificate and classified employees in the performance of their assigned responsibilities.

(3) "Needs assessment" shall mean a systematic study of the educational needs of the community, staff and students to be served.

(4) "Funds" shall mean those funds appropriated by the legislature and available for the conduct and evaluation of in-service training programs. [Statutory Authority: RCW 28A.71.210. 78-09-115 (Order 78-7), § 392-195-010, filed 9/6/78.]

WAC 392-195-015 Application for funding. Applicants shall request funds from the superintendent of public instruction in accordance with the provisions set forth below:

(1) Applicants shall conduct a needs assessment.

(2) The board of an applicant shall appoint an advisory in-service training task force of members comprised of representatives from administrators, building principals, teachers, classified and support personnel employed by the applicant, an institution of higher education and the general public in such numbers as shall be established by the applicant board of directors.

(3) The applicant shall establish written goals and objectives, identify training activities relevant thereto and design evaluation procedures and criteria which assess the degree and level of attainment of the goals and objectives.

(4) The task force shall review applications submitted pursuant to this chapter and suggest changes, if any, in direction, focus, or evaluation methods. No application will be accepted which is not approved by a majority vote of the task force.

(5) Nonpublic school personnel may be invited to participate in continuing professional development activities by the applicant.

(6) Funds shall supplement, not supplant, the existing staff development and in-service activities of an applicant. [Statutory Authority: RCW 28A.71.210. 79-12-007 (Order 11-79), § 392-195-015, filed 11/9/79, 78-09-115 (Order 78-7), § 392-195-015, filed 9/6/78.]

WAC 392-195-020 Allocation of funds. The superintendent of public instruction or his or her designee shall evaluate each application approved by the applicant's task force and award funds to those programs which he or she deems to be in the best interest of the public school system. Consideration shall be given to:

(1) The potential of the proposed training activities for accomplishing the stated objectives;

(2) The extent to which the objectives are clearly defined and stated; and

(3) The appropriateness of the evaluation design. [Statutory Authority: RCW 28A.71.210. 78-09-115 (Order 78-7), § 392-195-020, filed 9/6/78.]

WAC 392-195-025 Program reports. Grantees shall report the results of their programs to the superintendent of public instruction. A financial report that sets forth the objects of expenditure, such as released time, contractual services, materials and supplies and travel shall also be submitted to the superintendent of public instruction. [Statutory Authority: RCW 28A.71.210. 78-09-115 (Order 78-7), § 392-195-025, filed 9/6/78.]

Title 402 WAC

RADIATION CONTROL AGENCY

Chapters

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402-20 Licensing of radiation sources.

402-21 General licenses.

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Chapter 402-19 WAC

REQUIREMENTS OF GENERAL APPLICABILITY TO LICENSING OF RADIOACTIVE MATERIAL

WAC

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WAC 402-19-010 Purpose and scope. (1) This chapter prescribes rules governing licensing of radioactive material. No person shall receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to chapters 402-21 or 402-22 WAC or as otherwise provided in this chapter.

[1979 WAC Supp—page 1554]
(2) In addition to the requirements of this chapter, or chapters 402-21 or 402-22 WAC, all licensees are subject to the requirements of chapters 402-12, 402-24, and 402-48 WAC. Licensees engaged in industrial radiographic operations are subject to the requirements of chapter 402-36 WAC, licensees using sealed sources in the healing arts are subject to the requirements of chapter 402-32 WAC, and licensees owning or operating uranium or thorium mills and associated mill tailings are subject to the requirements of chapter 402-52 WAC.

WAC 402-19-190 Exemptions. (1) Source material. (a) Any person is exempt from this chapter and chapters 402-21 and 402-22 WAC to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution or alloy in which the source material is by weight less than 1/20 of one percent (0.05 percent) of the mixture, compound, solution, or alloy.

(b) Any person is exempt from this chapter and chapters 402-21 and 402-22 WAC to the extent that such person receives, possesses, uses or transfers unrefined ore containing source material: Provided, That, except as authorized in a specific license, such person shall not refine or process such ore.

(c) Any person is exempt from this chapter and chapters 402-21 and 402-22 WAC to the extent that such person receives, possesses, uses or transfers:

(i) Any quantities of thorium contained in:

(A) Incandescent gas mantles;
(B) Vacuum tubes;
(C) Welding rods;
(D) Electric lamps for illuminating purposes provided that each lamp does not contain more than fifty milligrams of thorium;
(E) Germicidal lamps, sunlamps and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium;
(F) Rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these; or
(G) Personnel neutron dosimeters, provided each dosimeter does not contain more than 50 milligrams of thorium;

(ii) Source material contained in the following products:

(A) Glazed ceramic tableware: Provided, That the glaze contains not more than twenty percent by weight source material;
(B) Glassware, glass enamel and glass enamel frit containing not more than ten percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass, glass enamel or ceramic used in construction;
(C) Piezoelectric ceramic containing not more than two percent by weight source material; or
(D) Electron tubes;

(iii) Photographic film, negatives and prints containing uranium or thorium;

(iv) Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys: Provided, That the thorium content of the alloy does not exceed four percent by weight and that the exemption contained in this subparagraph shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such product or part;

(v) Depleted uranium contained in counterweights installed in aircraft, rockets, projectiles and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:

(A) The counterweights are manufactured in accordance with a specific license issued by the department, the United States Nuclear Regulatory Commission, or any Agreement State authorizing distribution by the licensee pursuant to this subparagraph or equivalent regulations of the United States Nuclear Regulatory Commission or any Agreement State;

(B) Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM";

(C) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED"; and

(D) "Note: The requirements specified in WAC 402–19–190(1)(c)(v)(B) and (C) need not be met by counterweights manufactured prior to December 31, 1960: Provided, That such counterweights are impressed with the legend, "CAUTION – RADIOACTIVE MATERIAL – URANIUM", as previously required by the regulations.

(vi) Depleted uranium used as shielding constituting part of any shipping container which is conspicuously and legibly impressed with the legend "CAUTION – RADIOACTIVE SHIELDING – URANIUM" and which meets the specification for containers for radioactive material prescribed in Section 173.394 or 173.395 of 49 CFR Part 173, of the regulations published by the United States Department of Transportation;

(vii) Thorium contained in finished optical lenses: Provided, That each lens does not contain more than
thirty percent by weight of thorium, and that the exemption contained in this subparagraph shall not be deemed to authorize either:

(A) The shaping, grinding or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without alteration of the lens; or

(B) The receipt, possession, use or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments;

(viii) Uranium contained in detector heads for use in fire detection units: Provided, That each detector head contains not more than 0.005 microcuries of uranium; or

(ix) Thorium contained in any finished aircraft engine part containing nickel–thoria alloy, provided that:

(A) The thorium is dispersed in the nickel–thoria alloy in the form of finely divided thorium (thorium dioxide); and

(B) The thorium content in the nickel–thoria alloy does not exceed four percent by weight.

(d) The exemptions in WAC 402–19–190(1)(c) do not authorize the manufacture of any of the products described.

(2) Radioactive material other than source material.

(a) Exempt concentrations.

(i) Except as provided in WAC 402–19–190(2)(a)(ii) any person is exempt from this chapter and chapters 402–21 and 402–22 WAC to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing radioactive material in concentrations not in excess of those listed in WAC 402–19–580, Schedule C.

(ii) No person may introduce radioactive material into a product or material, knowing or having reason to believe, that it will be transferred to persons exempt under WAC 402–19–190(2)(a)(i) or equivalent regulations of the United States Nuclear Regulatory Commission or any Agreement State, except in accordance with a specific license issued pursuant to WAC 402–22–110(1) or the general license provided in WAC 402–19–250.

(ii) This paragraph, WAC 402–19–190(2)(b), does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(iii) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in WAC 402–19–550, Schedule B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under WAC 402–19–190(2)(b) or equivalent regulations of the United States Nuclear Regulatory Commission or any Agreement State, except in accordance with a specific license issued by the United States Nuclear Regulatory Commission, pursuant to Section 32.18 of 10 CFR Part 32 or by the department pursuant to WAC 402–22–110(2) which license states that the radioactive material may be transferred by the licensee to persons exempt under WAC 402–19–190(2)(b) or the equivalent regulations of the United States Nuclear Regulatory Commission or any Agreement State.

(c) Exempt items.

(i) Certain items containing radioactive material. Except for persons who apply radioactive material to, or who incorporate radioactive material into the following products, any person is exempt from these regulations to the extent that person receives, possesses, uses, transfers, owns or acquires the following products:* 

*NOTE: Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer and disposal by all other persons who are exempted from regulatory requirements may be obtained only from the United States Nuclear Regulatory Commission, Washington, D.C. 20555.

(A) Timepieces or hands or dials containing not more than the following specified quantities of byproduct material and not exceeding the following specified levels of radiation:

- 25 millicuries of tritium per timepiece;
- 5 millicuries of tritium per hand;
- 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial);
- 100 microcuries of promethium – 147 per watch or 200 microcuries of promethium – 147 per any other timepiece;
- 20 microcuries of promethium – 147 per watch hand or 40 microcuries of promethium – 147 per other timepiece hand;
- 60 microcuries of promethium – 147 per watch dial or 120 microcuries of promethium – 147 per other timepiece dial (bezels when used shall be considered as part of the dial);

The levels of radiation from hands and dials containing promethium – 147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

- For wrist watches, 0.1 millirad per hour at 1 centimeter from any surface;
- For pocket watches, 0.1 millirad per hour at 1 centimeter from any surface;
- For any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface.
One microcurie of radium–226 per timepiece in timepieces manufactured prior to the effective date of these regulations.

(B) Lock illuminators containing not more than 15 millicuries of tritium or not more than 2 millicuries of promethium – 147 installed in automobile locks. The levels of radiation from each lock illuminator containing promethium – 147 will not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.

(C) Precision balances containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part.

(D) Automobile shift quadrants containing not more than 25 millicuries of tritium.

(E) Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas.

(F) Thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat.

(G) Electron tubes: Provided, That each tube does not contain more than one of the following specified quantities of radioactive material:

(aa) 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;

(bb) 1 microcurie of cobalt–60;

(cc) 5 microcuries of nickel–63;

(dd) 30 microcuries of krypton–85;

(ee) 5 microcuries of cesium–137;

(ff) 30 microcuries of promethium–147;

(gg) 1 microcurie of radium–226;

(hh) 1 microcurie of any radioactive material other than source material: And provided further, That the levels of radiation from each electron tube containing radioactive material does not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.*

*NOTE: For purposes of this subdivision, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

(H) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, a source of radioactive material not exceeding the applicable quantity set forth in WAC 402–19–550, Schedule B.

(i) Spark gap irradiators containing not more than 1 microcurie of cobalt–60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least three gallons (11.4 liters) per hour.

(ii) Self-luminous products containing radioactive material(s).

(A) Tritium, krypton–85 or promethium–147. Except for persons who manufacture, process or produce self-luminous products containing tritium, krypton–85 or promethium–147, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires tritium, krypton–85 or promethium–147 in self-luminous products manufactured, processed, produced, imported or transferred in accordance with a specific license issued by the United States Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in WAC 402–19–190(2)(c)(ii) does not apply to tritium, krypton–85 or promethium–147 used in products for frivolous purposes or in toys or adornments.

(B) Radium–226. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers or owns articles containing less than 0.1 microcurie of radium–226 which were manufactured prior to the effective date of these regulations.

(iii) Gas and aerosol detectors containing radioactive material.

(A) Except for persons who manufacture, process or produce gas and aerosol detectors containing radioactive material, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards: Provided, That detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued by the United States Nuclear Regulatory Commission* or an Agreement State, pursuant to Section 32.26 of 10 CFR Part 32, or equivalent, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

*NOTE: Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or by-product material whose subsequent possession, use, transfer and disposal by all other...
persons are exempted from regulatory requirements may be obtained only from the United States Nuclear Regulatory Commission, Washington, D.C. 20555.

(B) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State shall be considered exempt under WAC 402-19-190(2)(c)(iii)(A): Provided, That the device is labeled in accordance with the specific license authorizing distribution of the general licensed device: And provided further, That they meet the requirements of WAC 402-22-110(3).

(C) Gas and aerosol detectors containing naturally occurring and accelerator-produced radioactive material (NARM) previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under WAC 402-19-190(2)(c)(iii)(A): Provided, That the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of WAC 402-22-110(3).

(iv) Resins containing scandium-46 and designed for sand consolidation in oil wells. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the United States Nuclear Regulatory Commission or shall have been manufactured in accordance with the specifications contained in a specific license issued by the department or any Agreement State to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Sections 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the United States Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing scandium-46. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-19-190, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-200.]

WAC 402-19-220 Types of licenses. Licenses for radioactive materials are of two types: General and specific.

(1) General licenses provided in chapter 402-21 WAC are effective without the filing of applications with the department or the issuance of licensing documents to the particular persons, although the filing of a certificate with the department may be required by the particular general license. The general licensee is subject to all other applicable portions of these regulations and any limitations of the general license.

(2) Specific licenses require the submission of an application to the department and the issuance of a licensing document by the department. The licensee is subject to all applicable portions of these regulations as well as any limitations specified in the licensing document. (See chapter 402-22 WAC). [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-19-220, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-020.]

WAC 402-19-240 Prelicensing inspection. The department may verify information contained in applications and secure additional information deemed necessary to make a reasonable determination as to whether to issue a license and whether any special conditions should be attached thereto by visiting the facility or location where radioactive materials would be possessed or used, and by discussing details of the proposed possession or use of the radioactive materials with the applicant or representatives designated by the applicant. Such visits may be made by the department or its duly authorized representatives. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-19-240, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-200.]

WAC 402-19-250 Reciprocal recognition of licenses. (1) Subject to these regulations, any person who holds a specific license from the United States Nuclear Regulatory Commission or any Agreement State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of one hundred eighty days in any calendar year provided that:

(a) The licensing document does not limit the activity authorized by such document to specified installations or locations;

(b) The out-of-state licensee notifies the department in writing at least three days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the department, obtain permission to proceed sooner. The department may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in this subsection;

(c) The out-of-state licensee complies with all applicable regulations of the department and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the department;

(d) The out-of-state licensee supplies such other information as the department may request; and
(e) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this subsection except by transfer to a person:
   (i) Specifically licensed by the department or by the United States Nuclear Regulatory Commission or an Agreement State to receive such material; or
   (ii) Exempt from the requirements for a license for such material under WAC 402-19-190(2)(a).

(2) Notwithstanding the provisions of subsection (1) of this section, any person who holds a specific license issued by the United States Nuclear Regulatory Commission or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in WAC 402-21-050(4) within the areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service a device in this state provided that:
   (a) Such person shall file a report with the department within thirty days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;
   (b) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the United States Nuclear Regulatory Commission or an Agreement State;
   (c) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and
   (d) The holder of the specific license shall furnish to each general licensee to whom such device is transferred or on whose premises such device is installed a copy of the general license contained in WAC 402-21-050(4).

(3) The department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining undue hazard to public health and safety or property. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-19-250, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-210.]

WAC 402-19-300 Terms and conditions of licenses.
(1) Each license issued pursuant to this part shall be subject to all the provisions of the act, as now or hereafter in effect, and to all rules, regulations, and orders of the department.
(2) No license issued or granted under chapters 402-21 and 402-22 WAC and no right to possess or utilize radioactive material granted by any license issued pursuant to chapters 402-21 and 402-22 WAC shall be transferred, assigned, or in manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the department shall, after securing full information find that the transfer is in accordance with the provisions of the act, and shall give its consent in writing.

(3) Each person licensed by the department pursuant to chapters 402-21 and 402-22 WAC shall confine his use and possession of the material licensed to the locations and purposes authorized in the license.

(4) Each licensee shall notify the department in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license. This notification requirement applies only to all specific licenses issued under chapter 402-22 WAC. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-19-300, filed 11/30/79, effective 1/1/80.]

WAC 402-19-350 Modification, revocation and termination of licenses. (1) The terms and conditions of all licenses shall be subject to amendment, revision, or modification, or the license may be suspended or revoked by reason of amendments to the act, or by reason of rules, regulations, and orders issued by the department.

(2) Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the department to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the act, or of the license, or of any rule, regulation, or order of the department.

(3) Except in cases of wilfulness or those in which the public health, interest, or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefore, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

(4) The department may terminate a specific license upon request submitted by the licensee to the department in writing. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-19-350, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-180.]
(2) Except as otherwise provided in the license and subject to the provisions of this section, any licensee may transfer radioactive material:
   (a) To the department*;
   (b) To the United States Department of Energy, the United States Nuclear Regulatory Commission, the United States Environmental Protection Agency, or any other authorized agency of the federal government;
   (c) To any person exempt from the regulations in this part to the extent permitted under such exemption;
   (d) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the department, the United States Nuclear Regulatory Commission, an Agreement State or Licensing State, or to any person otherwise authorized to receive such material by the federal government or any agency thereof, the department, any Agreement State or any Licensing State; or
   (e) As otherwise authorized by the department in writing.

(3) Before transferring radioactive material to a specific licensee of the department, the United States Nuclear Regulatory Commission, an Agreement State or Licensing State, or to a general licensee who is required to register with the department, the United States Nuclear Regulatory Commission, an Agreement State or Licensing State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(4) The following methods for the verification required by WAC 402-19-400(3) are acceptable:
   (a) The transferor may obtain for possession, and read, a current copy of the transferee's specific license or registration certificate;
   (b) The transferor may obtain for possession a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

*A licensee may transfer material to the department only after receiving prior approval from the department.

(c) For emergency shipments the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date: Provided, That the oral certification is confirmed in writing within ten days;

(d) The transferor may obtain other sources of information compiled by a reporting service from official records of the department, the United States Nuclear Regulatory Commission, the licensing agency of an Agreement State or a Licensing State as to the identity of licensees and the scope and expiration dates of licenses and registration; or

(e) When none of the methods of verification described in subsection (4) of this section are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the department, the United States Nuclear Regulatory Commission, or the licensing agency of an Agreement State or Licensing State that the transferee is licensed to receive the radioactive material.

(5) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of WAC 402-19-500. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-19-400, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-170.]

WAC 402-19-500 Preparation of radioactive material for transport. (1) No licensee shall deliver any radioactive material to a carrier* for transport unless:

*NOTE: For the purpose of this regulation, a licensee who transports the licensee's own material as a private carrier must comply with the same regulations which bind the carrier unless exempted under WAC 402-21-100 and is considered to have delivered such material to a carrier for transport.

   (a) The licensee complies with the applicable requirements of the regulations, appropriate to the mode of transport of the United States Department of Transportation insofar as such regulations relate to the packing of radioactive material, and to the monitoring, marking and labeling of those packages;
   (b) The licensee has established procedures for opening and closing packages in which radioactive material is transported to provide safety and to assure that, prior to the delivery to a carrier for transport, each package is properly closed for transport;
   (c) Prior to delivery of a package to a carrier for transport, the licensee shall assure that any special instructions needed to safely open the package are sent to, or have been available to the consignee;
   (d) A licensee who transports his own material as a private carrier must placard his vehicle according to the United States Department of Transportation regulations; and
   (e) In addition to the requirements of the United States Department of Transportation, each package of Type A or Type B quantity radioactive material prepared for shipment must have the innermost container labeled as to the isotope, chemical form, number of curies or subunits thereof, and date of determination of activity and each innermost container shall be tested to assure that the container is properly sealed and that excessive contamination is not present prior to transportation. This requirement does not apply to properly packaged shipments of radioactive waste consigned to a commercial low level waste burial facility.

(2) Subsection (1) of this section shall not apply to the transportation of licensed material, or to the delivery of licensed material to a carrier for transport, where
such transportation is subject to the regulations of the United States Department of Transportation or the United States Postal Service. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-19-500, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-220.]

### WAC 402-19-550 Schedule B, exempt quantities of radioactive materials. (See also WAC 402-19-190(2)(b).)

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[1979 WAC Supp—page 1561]
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[WAC 402-19-580 Schedule C, exempt concentrations. (See WAC 402-19-190(2)(a).)]

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### Requirements of General Applicability to Licensing of Radioactive Material

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<th>Element (atomic number)</th>
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<th>Column II Liquid and solid concentration µCi/ml</th>
<th>Element (atomic number)</th>
<th>Isotope</th>
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402-19-580

Title 402 WAC: Radiation Control Agency

NOTES:

1 Values are given in Column I only for those materials normally used as gases.

2 µCi/gm for solids

NOTE 1: Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Schedule C the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of WAC 402-19-190(2) where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Schedule C for the specific isotope when not in combination. The sum of such ratios may not exceed '1' (i.e., unity).

EXAMPLE:

Concentration of Isotope A in Product

Exempt concentration of Isotope A

Concentration of Isotope B in Product

Exempt concentration of Isotope B

\[ \leq 1 \]

NOTE 3: For the purpose of determining concentration in a product or device, the total quantity of radioactive material present is divided by only that weight or volume of the discrete part or component throughout which the radioactive material is relatively uniformly distributed. If the weight or volume of this part or component cannot be determined then the product or device should be evaluated on the basis of the total quantity of radioactive material present. [Statutory Authority: RCW 70.98.080, 79-12-073 (Order 1459), § 402-19-580, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-250.]

Chapter 402-20 WAC

LICENSING OF RADIATION SOURCES

Chapters

402-20-010 Repealed.
402-20-020 Repealed.
402-20-030 Repealed.
402-20-040 Repealed.
402-20-050 Repealed.
402-20-060 Repealed.
402-20-070 Repealed.
402-20-073 Repealed.
402-20-076 Repealed.
402-20-080 Repealed.
402-20-090 Repealed.
402-20-100 Repealed.
402-20-110 Repealed.
402-20-120 Repealed.
402-20-130 Repealed.
402-20-170 Repealed.
402-20-180 Repealed.
402-20-190 Repealed.
402-20-200 Repealed.
402-20-210 Repealed.
402-20-220 Repealed.
402-20-240 Repealed.
402-20-250 Repealed.
402-20-260 Repealed.
402-20-270 Repealed.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

402-20-010 Purpose and scope. [Order 1084, § 402-20-010, filed 1/14/76; Order 1, § 402-20-010, filed 1/8/69; Rules (part), filed 10/26/66.] Repealed by 79-12-073 (Order 1459), filed 11/30/79, effective 1/1/80. Statutory Authority: RCW 70.98.080. Later promulgation, see chapters 402-19, 402-21, and 402-22 WAC.


402-20-040 General licenses—Radioactive material other than source material. [Order 1095, § 402-20-040, filed 2/6/76; Order 1, § 402-20-040, filed 1/8/69; Rules (part), filed 10/26/66.] Repealed by 79-12-073 (Order 1459), filed 11/30/79, effective 1/1/80. Statutory Authority: RCW 70.98.080. Later promulgation, see WAC 402-21-050.

402-20-050 Filing application for specific licenses. [Order 1084, § 402-20-050, filed 1/14/76; Order 1, § 402-20-050, filed 1/8/69; Rules (part), filed 10/26/66.] Repealed by 79-12-073 (Order 1459), filed 11/30/79, effective 1/1/80. Statutory Authority: RCW 70.98.080. Later promulgation, see WAC 402-22-020.

402-20-060 General requirements for the issuance of specific licenses. [Order 1084, § 402-20-060, filed 1/14/76; Order 1, § 402-20-060, filed 1/8/69; Rules (part), filed 10/26/66.] Repealed by 79-12-073 (Order 1459), filed 11/30/79, effective 1/1/80. Statutory Authority: RCW 70.98.080. Later promulgation, see WAC 402-22-040.

402-20-070 Special requirements for issuance of certain specific licenses for radioactive material. [Order 1084, § 402-20-070, filed 1/14/76; Order 708, § 402-20-070, filed 8/24/72; Order 1, § 402-20-070, filed 7/2/71; Order 1, § 402-20-070, filed 1/8/69; Rules (part), filed 10/26/66.] Repealed by 79-12-073 (Order 1459), filed 11/30/79, effective 1/1/80. Statutory Authority: RCW 70.98.080. Later promulgation, see WAC 402-22-070.

402-20-073 Special requirements for specific licenses of broad scope. [Order 1084, § 402-20-073, filed 1/14/76.] Repealed by 79-12-073 (Order 1459), filed 11/30/79, effective 1/1/80. Statutory Authority: RCW 70.98.080. Later promulgation, see WAC 402-22-090.

402-20-076 Special requirements for a specific license to manufacture, assemble, repair, or distribute commodities,

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products, or devices which contain radioactive material. [Order 1084, § 402-20-076, filed 1/14/76.] Repealed by 79-12-073 (Order 1459), filed 11/30/79, effective 1/1/80. Statutory Authority: RCW 70.98.080. Later promulgation, see WAC 402-22-045.

402-20-080 Prelicensing inspection. [Order 1084, § 402-20-080, filed 1/14/76; Order 1, § 402-20-080, filed 1/8/69; Rules (part), filed 10/26/66.] Repealed by 79-12-073 (Order 1459), filed 11/30/79, effective 1/1/80. Statutory Authority: RCW 70.98.080. Later promulgation, see WAC 402-22-045.

402-20-090 Issuance of specific licenses. [Order 1084, § 402-20-090, filed 1/14/76; Order 1, § 402-20-090, filed 1/8/69; Rules (part), filed 10/26/66.] Repealed by 79-12-073 (Order 1459), filed 11/30/79, effective 1/1/80. Statutory Authority: RCW 70.98.080. Later promulgation, see WAC 402-22-045.

402-20-100 Expiration of licenses. [Order 1084, § 402-20-100, filed 1/14/76; Order 1, § 402-20-100, filed 1/8/69; Rules (part), filed 10/26/66.] Repealed by 79-12-073 (Order 1459), filed 11/30/79, effective 1/1/80. Statutory Authority: RCW 70.98.080. Later promulgation, see WAC 402-22-045.

402-20-110 Transfer of material. [Order 1084, § 402-20-110, filed 1/14/76; Order 1, § 402-20-110, filed 1/8/69; Rules (part), filed 10/26/66.] Repealed by 79-12-073 (Order 1459), filed 11/30/79, effective 1/1/80. Statutory Authority: RCW 70.98.080. Later promulgation, see WAC 402-22-055.

402-20-120 Amendment of licenses at request of licensee. [Order 1084, § 402-20-120, filed 1/14/76; Order 1, § 402-20-120, filed 1/8/69; Rules (part), filed 10/26/66.] Repealed by 79-12-073 (Order 1459), filed 11/30/79, effective 1/1/80. Statutory Authority: RCW 70.98.080. Later promulgation, see WAC 402-22-060.

402-20-130 Agency action on applications to renew or amend. [Order 1084, § 402-20-130, filed 1/14/76; Order 1, § 402-20-130, filed 1/8/69; Rules (part), filed 10/26/66.] Repealed by 79-12-073 (Order 1459), filed 11/30/79, effective 1/1/80. Statutory Authority: RCW 70.98.080. Later promulgation, see WAC 402-22-065.

402-20-140 Transfer of material. [Order 1084, § 402-20-140, filed 1/14/76; Order 1, § 402-20-140, filed 1/8/69; Rules (part), filed 10/26/66.] Repealed by 79-12-073 (Order 1459), filed 11/30/79, effective 1/1/80. Statutory Authority: RCW 70.98.080. Later promulgation, see WAC 402-19-400.

402-20-150 Modification, revocation, and termination of licenses. [Order 1084, § 402-20-150, filed 1/14/76; Order 1, § 402-20-150, filed 1/8/69; Rules (part), filed 10/26/66.] Repealed by 79-12-073 (Order 1459), filed 11/30/79, effective 1/1/80. Statutory Authority: RCW 70.98.080. Later promulgation, see WAC 402-19-400.


402-20-190 Issuance of specific licenses. [Order 1084, § 402-20-190, filed 1/14/76; Order 1, § 402-20-190, filed 1/8/69; Rules (part), filed 10/26/66.] Repealed by 79-12-073 (Order 1459), filed 11/30/79, effective 1/1/80. Statutory Authority: RCW 70.98.080. Later promulgation, see WAC 402-19-200.

WAC 402-20-100 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-020 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-030 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-040 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-050 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-060 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-070 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-073 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-076 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-080 Repealed. See Disposition Table at beginning of this chapter.

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WAC 402-20-090 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-100 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-110 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-120 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-130 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-170 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-180 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-190 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-200 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-210 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-220 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-240 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-250 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-260 Repealed. See Disposition Table at beginning of this chapter.

WAC 402-20-270 Repealed. See Disposition Table at beginning of this chapter.

Chapter 402-21 WAC
GENERAL LICENSES

WAC 402-21-010 Purpose and scope. This chapter establishes general licenses for the possession and use of radioactive material contained in certain items and a general license for ownership of radioactive material. Chapter 402-19 WAC also contains provisions applicable to the subject matter of this part. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-21-010, filed 11/30/79, effective 1/1/80. Formerly chapter 402-20 WAC.]

WAC 402-21-030 General licenses—Source material. (1) A general license is hereby issued authorizing use, possession, and transfer of not more than fifteen pounds of source material at any one time by persons in the following categories:
   (a) Pharmacists using the source material solely for the compounding of medicinals;
   (b) Physicians using the source material for medicinal purposes;
   (c) Persons receiving possession of source material from pharmacists and physicians in the form of medicinals or drugs;
   (d) Commercial and industrial firms, and research, educational, and medical institutions for research, development, educational, or commercial purposes;
   And provided, that no such person shall, pursuant to this general license, receive more than a total of one hundred fifty pounds of source material in any one calendar year.

   (2) Persons who receive, possess, use, or transfer source material pursuant to the general license issued in subsection (1) of this section are exempt from the provisions of chapters 402-24 and 402-48 WAC to the extent that such receipt, possession, use, or transfer is within the terms of such general license: Provided, however, That this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to chapter 402-22 WAC.

   (3) A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.

   (4) Depleted uranium in industrial products and devices.
      (a) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of paragraphs (4)(b), (c), (d), and (e) of this section, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.
      (b) The general license in paragraph (4)(a) of this section applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to WAC 402-22-110(13) or in accordance with a specific license issued to the manufacturer by the United States Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the United States Nuclear Regulatory Commission or an Agreement State.
      (c)(i) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by paragraph (4)(a) of this section shall file Department Form RHF-20 "Registration Certificate – Use of Depleted Uranium Under General License," with the department. The form shall be submitted within thirty
shall be submitted within thirty days after the effective use of the product or device is regulated by United States Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(e) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by paragraph (4)(a) of this section is exempt from the requirements of chapters 402-24 and 402-48 WAC of these regulations with respect to the depleted uranium covered by that general license. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-21-030, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-030.]

WAC 402-21-050 General licenses*—Radioactive material other than source material.

*NOTE: Different general licenses are issued in this section, each of which has its own specific conditions and requirements.

(1) Certain devices and equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the United States Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of WAC 402-12-080 through 402-12-140, chapters 402-19, 402-24** and 402-48 WAC of these regulations.

(a) Static elimination device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium–210 per device.

(b) Ion generating tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium–210 per device or a total of not more than 50 millicuries of hydrogen–3 (tritium) per device.

**Attention is directed particularly to the provisions of chapter 402-24 WAC of these regulations which relate to the labeling of containers.

(2) Reserved.

(3) Reserved.

(4) Certain measuring, gauging or controlling devices.

(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, acquire, receive, possess, use or transfer, in accordance with the provisions of paragraphs (4)(b), (c), and (d) of this section, radioactive material excluding special nuclear and source material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(b) The general license in paragraph (4)(a) of this section applies only to radioactive material contained in

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devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the department pursuant to WAC 402-22-110(4) or in accordance with the Nuclear Regulatory Commission, an Agreement State or a Licensing State, which authorizes distribution of devices to persons generally licensed by the United States Nuclear Regulatory Commission, an Agreement State or Licensing State**.

**NOTE:** Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in Section 179.21 of 21 CFR Part 179.

c) Any person who owns, acquires, receives, possesses, uses or transfers radioactive material excluding special nuclear and source material in a device pursuant to the general license in paragraph (a) of this subsection:

(i) Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(ii) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on/off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label, however:

(A) Devices containing only krypton need not be tested for leakage of radioactive material; and

(B) Devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(iii) Shall assure that the tests required by item (4)(c)(ii) of this section and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(A) In accordance with the instructions provided by the labels; or

(B) By a person holding a specific license from the department or from the United States Nuclear Regulatory Commission or from any Agreement State to perform such activities;

(iv) Shall maintain records showing compliance with the requirements of items (4)(c)(ii) and (iii) of this section. The records shall show the results of tests. The records also shall show the dates of performance and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by item (4)(c)(ii) of this section shall be maintained for one year after the next required leak test is performed or the sealed source is transferred or disposed. Records of tests of the on/off mechanism and indicator required by item (4)(c)(ii) of this section shall be maintained for one year after the next required test of the on/off mechanism and indicator is performed or the sealed source is transferred or disposed. Records of other testing, installation, servicing, and removal from installation required by item (4)(c)(iii) of this section shall be maintained for a period of two years from the date of the recorded event or the device is transferred or disposed;

(v) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on/off mechanism or indicator, or upon the detection of 0.005 microcuries or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license from the department, the United States Nuclear Regulatory Commission, or from an Agreement State to repair such devices, or disposed by transfer to a person authorized by a specific license to receive the radioactive material excluding special nuclear and source material contained in the device and, within thirty days, furnish to the department a report containing a brief description of the event and the remedial action taken;

(vi) Shall not abandon the device containing radioactive material excluding special nuclear and source material;

(vii) Except as provided in item (4)(c)(viii) of this section, shall transfer or dispose the device containing radioactive material excluding special nuclear and source material only by transfer to a person holding a specific license of the department, the United States Nuclear Regulatory Commission, or an Agreement State, or a Licensing State whose specific license authorizes the person to receive the device and within thirty days after transfer of a device to a specific licensee shall furnish to the department a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

(viii) Shall transfer the device to another general licensee only:

(A) Where the device remains in use at a particular location. In such case, the transferor shall give the transferee a copy of this subsection and any safety documents identified in the label of the device and within thirty days of the transfer, report to the department the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the department and the transferee; or

(B) Where the device is held in storage in the original shipping container at its intended location.

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location of use prior to initial use by a general license.

(ix) Shall comply with the provisions of WAC 402-24-180 and 402-24-190 for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of chapters 402-24 and 402-48 WAC.

(d) The general license in paragraph (4)(a) of this section does not authorize the manufacture, import or export of devices containing radioactive material excluding special nuclear and source material.

(e) The general license provided in subsection (4) of this section is subject to the provisions of WAC 402-12-080 through 402-12-100, 402-12-130, 402-12-140, 402-12-170, 402-19-300, 402-19-350, 402-19-400, and 402-19-500.

(5) Luminous safety devices for aircraft.

(a) A general license is hereby issued to own, receive, acquire, possess and use tritium or promethium–147 contained in luminous safety devices for use in aircraft, provided:

(i) Each device contains not more than 10 curies of tritium or 300 millicuries of promethium–147; and

(ii) Each device has been manufactured, assembled or imported in accordance with a specific license issued by the United States Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the department or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32 of the regulations of the United States Nuclear Regulatory Commission.

(b) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in subsection (5) of this section are exempt from the requirements of chapters 402-24 and 402-48 WAC except that they shall comply with the provisions of WAC 402-24-180 and 402-24-190.

(c) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium–147.

(d) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium–147 contained in instrument dials.

(e) This general license is subject to the provisions of WAC 402-12-080 through 402-12-140, 402-12-170, 402-19-300, 402-19-350, 402-19-400, and 402-19-500.

(6) Ownership of radioactive material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this chapter, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

(7) Calibration and reference sources.

(a) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with the provisions of paragraphs (7)(d) and (e) of this section, americium–241 in the form of calibration or reference sources:

(i) Any person who holds a specific license issued by the department which authorizes that person to receive, possess, use and transfer radioactive material; and

(ii) Any person who holds a specific license issued by the United States Nuclear Regulatory Commission which authorizes that person to receive, possess, use and transfer special nuclear material.

(b) A general license is hereby issued to own, receive, possess, use and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of paragraphs (7)(d) and (e) of this section to any person who holds a specific license issued by the department which authorizes that person to receive, possess, use and transfer radioactive material.

(c) A general license is hereby issued to own, receive, possess, use and transfer radium–226 in the form of calibration or reference sources in accordance with the provisions of paragraphs (7)(d) and (e) of this section to any person who holds a specific license issued by the department which authorizes that person to receive, possess, use and transfer radioactive material.

(d) The general licenses in paragraphs (7)(a), (b) and (c) of this section apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the United States Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the department or any Agreement State pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 of the regulations of the United States Nuclear Regulatory Commission.

(e) The general licenses provided in paragraphs (7)(a), (b) and (c) are subject to the provisions of WAC 402-12-080 through 402-12-100, 402-12-130, 402-12-140, 402-12-170, 402-19-300, 402-19-350, 402-19-400, 402-19-500, chapters 402-24 and 402-48 WAC.

In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:

(i) Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of americium–241 and 5 microcuries of plutonium in such sources and 5 microcuries of radium–226;

(ii) Shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements or a substantially similar statement which contains the information called for in the following statement:

(A) The receipt, possession, use and transfer of this source, Model __________, Serial No. __________, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of

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regulatory authority. Do not remove this label.

CAUTION – RADIOACTIVE MATERIAL –
THIS SOURCE CONTAINS (AMERICIUM–241). (PLUTONIUM)*. DO NOT TOUCH RA­
DIOACTIVE PORTION OF THIS SOURCE

Name of manufacturer or importer

*NOTE: Showing only the name of the appropriate material.

(B) The receipt, possession, use and transfer of this source, Model .........., Serial No. .............., are subject to a general license and the regulations of any Licensing State. Do not remove this label.

CAUTION – RADIOACTIVE MATERIAL –
THIS SOURCE CONTAINS RADIAN–226. DO NOT TOUCH RADIOACTIVE PORTION OF
THIS SOURCE.

Name of manufacturer or importer

(iii) Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a li­cence from the department, the United States Nuclear Regulatory Commission, or an Agreement State to re­ceive the source;

(iv) Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium–241, plutonium, or radium–226 which might otherwise escape during storage; and

(v) Shall not use such source for any purpose other than the calibration of radiation detectors or the stan­dardization of other sources.

(f) These general licenses do not authorize the manu­facture of calibration or reference sources containing americium–241, plutonium, or radium–226.

(8) Medical diagnostic uses.*

*NOTE: WAC 402–22–110(7) requires manufacturers of radiopharmaceuticals which are under the general license in this paragraph to affix a certain identifying label to the container or in the leaflet or brochure which accompanies the radiopharmaceutical. The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in inter­state commerce.

(a) A general license is hereby issued to any physician to receive, possess, transfer or use radioactive material set forth below for the stated diagnostic uses: Provided, however, That the use is in accordance with the provi­sion of paragraphs (8)(b), (c) and (d) of this section, the radioactive material is in the form of capsules, dispos­able syringes, or other prepackaged individual doses; and the radioactive material has been manufactured in ac­cordance with a specific license issued by the department pursuant to WAC 402–22–110(7) or by the United States Nuclear Regulatory Commission, an Agreement State or a Licensing State pursuant to equivalent regu­lations authorizing distribution to persons generally li­censed pursuant to WAC 402–22–110(7) or its equivalent:

(i) Iodine–131 as sodium iodide (NaI) for measure­ment of thyroid uptake;

(ii) Iodine–131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(iii) Iodine–125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(iv) Cobalt–57 for the measurement of intestinal ab­sorption of cyanocobalamin;

(v) Cobalt–58 for the measurement of intestinal ab­sorption of cyanocobalamin;

(vi) Cobalt–60 for the measurement of intestinal ab­sorption of cyanocobalamin; and

(vii) Chromium–51 as sodium radiochromate for de­termination of red blood cell volumes and studies of red blood cell survival time.

(b) No physician shall receive, possess, use or transfer radioactive material pursuant to the general license es­tablished by paragraph (8)(a) of this section until he has filed Department Form RHF–21 "Certificate – Medical Use of Radioactive Material Under General License" with the department and received from the department a validated copy of the Department Form RHF–21 with certification number assigned. The generally licensed physician shall furnish on Department Form RHF–21 the following information and such other information as may be required by the form:

(i) Name and address of the generally licensed physician;

(ii) A statement that the generally licensed physician is a duly licensed physician (authorized to dispense drugs) in the practice of medicine in this state; and

(iii) A statement that the generally licensed physician has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he pro­poses to use radioactive material under the general li­cense of paragraph (8) of this section and is competent in the use of such instruments.

(c) A physician who receives, possesses or uses a pharmaceutical containing radioactive material pursuant to the general license established by paragraph (8)(a) of this section:

(i) Shall not possess at any one time, pursuant to the general license in paragraph (8)(a) more than:

(A) 200 microcuries of iodine–131;

(B) 200 microcuries of iodine–125;

(C) 5 microcuries of cobalt–57;

(D) 5 microcuries of cobalt–58;

(E) 5 microcuries of cobalt–60; and

(F) 200 microcuries of chromium–51.

(ii) Shall store the pharmaceutical until administered in the original shipping container, or a container provid­ing equivalent radiation protection.

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(iii) Shall use the pharmaceutical only for the uses authorized by paragraph (8)(a) of this section.
(iv) Shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the department, the United States Nuclear Regulatory Commission, any Agreement State or Licensing State, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.
(v) Shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under eighteen years of age.

(d) The generally licensed physician possessing or using radioactive material under the general license of paragraph (8)(a) of this section shall report to the department, any changes in the information furnished previously on Department Form RHF-21 "Certificate – Medical Use of Radioactive Material Under General License." The report shall be submitted within thirty days after the effective date of such change.

(e) Any person using radioactive material pursuant to the general license of paragraph (8)(a) of this section is exempt from the requirements of chapters 402-24 and 402-48 WAC of these regulations with respect to the radioactive material covered by the general license.

(9) General license for use of radioactive material for certain in vitro clinical or laboratory testing.*

(a) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of paragraphs (9)(b), (c), (d), (e), and (f) of this section the following radioactive materials in prepackaged units:

(i) Iodine-125, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(ii) Iodine-131, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(iii) Carbon-14, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(iv) Hydrogen–3 (tritium), in units not exceeding 50 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(v) Iron–59, in units not exceeding 20 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(vi) Cobalt–57, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(vii) Selenium–75, in units not to exceed 0.05 microcurie of iodine–129 and 0.005 microcurie of americium–241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(viii) Mock Iodine–125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine–129 and 0.005 microcurie of americium–241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

*NOTE: The New Drug provisions of the Federal Food, Drug and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

(b) No person shall receive, acquire, possess, use or transfer radioactive materials pursuant to the general license established by paragraph (9)(a) of this section until that person has filed Department Form RHF-15, "Certificate – In Vitro Testing with Radioactive Material Under General License", with the department and received from the department a validated copy of Department Form RHF-15 with certificate number assigned, or until that person has been authorized pursuant to WAC 402-22-070(3) to use radioactive material under the general license in subsection (9) of this section. The physician, veterinarian, clinical laboratory or hospital shall furnish on Department Form RHF-15 the following information and such other information as may be required by that form:

(i) Name and address of the physician, veterinarian, clinical laboratory or hospital;
(ii) The location of use; and
(iii) A statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in paragraph (9)(a) of this section and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(c) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by paragraph (9)(a) of this section shall comply with the following:

(i) The general licensee shall not possess at any one time, pursuant to the general license in paragraph (9)(a) of this section at any one location of storage or use, a total amount of iodine–125, iodine–131, selenium–75, iron–59, and/or cobalt–57 in excess of 200 microcuries.

(ii) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(iii) The general licensee shall use the radioactive material only for the uses authorized by paragraph (9)(a) of this section.
(iv) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the department, the United States Nuclear Regulatory Commission, any Agreement State or Licensing State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(v) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in item (9)(a)(viii) of this section as required by WAC 402-24-130 of these regulations.

(d) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to paragraph (9)(a) of this section:

(i) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to WAC 402-22-110(8) or in accordance with the provisions of a specific license issued by the United States Nuclear Regulatory Commission, or any Agreement State or Licensing State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under subsection (9) of this section or its equivalent; and

(ii) Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for ex vivo clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

Name of manufacturer

(c) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of paragraph (9)(a) of this section shall report in writing to the department, any changes in the information previously furnished in the "Certificate — In Vitro Testing with Radioactive Material Under General License", Department Form RHF-15. The report shall be furnished within thirty days after the effective date of such change.

(f) Any person using radioactive material pursuant to the general license of paragraph (9)(a) of this section is exempt from the requirements of chapters 402-24 and 402-48 WAC of these regulations with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in item (9)(a)(viii) of this section shall comply with the provisions of WAC 402-24-130, 402-24-180 and 402-24-190 and of these regulations.

(10) Ice detection devices.

(a) A general license is hereby issued to own, receive, acquire, possess, use and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the United States Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the department or any Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32 of the regulations of the United States Nuclear Regulatory Commission.

(b) Persons who own, receive, acquire, possess, use or transfer strontium-90 contained in ice detection devices pursuant to the general license in paragraph (10)(a) of this section:

(i) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the United States Nuclear Regulatory Commission or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of these regulations;

(ii) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

(iii) Are exempt from the requirements of chapters 402-24 and 402-48 WAC of these regulations except that such persons shall comply with the provisions of WAC 402-24-130, 402-24-180, and 402-24-190.

(c) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

(d) This general license is subject to the provision of WAC 402-12-080 through WAC 402-12-100, 402-12-130, 402-12-140, 402-12-170, 402-19-300, 402-19-350, 402-19-400, and 402-19-500 of these regulations.
Specific Licenses 402-22-040

WAC 402-21-100 Intrastate transportation of radioactive material. (1) A general license is hereby issued to any common or contract carrier to transport and store radioactive material in the regular course of their carriage for another or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements of the regulations, appropriate to the mode of transport, of the United States Department of Transportation insofar as such regulations relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.* Persons who transport and store radioactive material pursuant to the general license in this paragraph are exempt from the requirements of chapters 402-24 and 402-48 WAC of these regulations.

(2) A general license is hereby issued to any private carrier to transport radioactive material: Provided, That the transportation is in accordance with the applicable requirements of the regulations, appropriate to the mode of transport, of the United States Department of Transportation insofar as such regulations relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.* Persons who transport radioactive material pursuant to the general license in subsection (2) of this section are exempt from the requirements of chapters 402-24 and 402-48 WAC of these regulations.

(a) Persons who transport radioactive material pursuant to the general license in subsection (2) of this section are exempt from the requirements of chapters 402-24 and 402-48 WAC of these regulations to the extent that they transport radioactive material.

(b) Physicians as defined in WAC 402-12-050(27) are exempt from the requirements of subsection (2) of this section only to the extent that they transport radioactive material for emergency use in the practice of medicine.

*NOTE: Any notification of incidents referred to in those requirements shall be filed with, or made to the department. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-21-100, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-040.]

Chapter 402-22 WAC
SPECIFIC LICENSES

WAC
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402-22-110 Special requirements for a specific license to manufacture, assemble, repair, or distribute commodities, products, or devices which contain radioactive material.

402-22-200 Schedule A groups of medical uses of radioactive material (Ref. WAC 402-22-070(3) and 402-22-110(10)).
402-22-250 Schedule B, limits for broad licenses.

WAC 402-22-010 Purpose and scope. (1) This chapter prescribes requirements for the issuance of specific licenses.

(2) The provisions and requirements of this chapter are in addition to, and not in substitution for, other requirements of these regulations. In particular the provisions of chapter 402-19 WAC apply to applications and licenses subject to this chapter. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-22-010, filed 11/30/79, effective 1/1/80. Formerly chapter 402-20 WAC.]

WAC 402-22-020 Filing application for specific licenses. (1) Applications for specific licenses shall be filed on Department Form RHF-1.

(2) The department may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the department to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(3) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's behalf.

(4) An application for a license may include a request for a license authorizing one or more activities.

(5) In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the department, providing such references are clear and specific.

(6) Applications and documents submitted to the department may be made available for public inspection except that the department may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-22-020, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-050.]

WAC 402-22-040 General requirements for the issuance of specific licenses. A license application will be approved if the department determines that:

(1) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these regulations in such a manner as to minimize danger to public health and safety or property;

(2) The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

(3) The issuance of the license will not be inimical to the health and safety of the public; and

(4) The applicant satisfies any applicable special requirements in WAC 402-22-070, 402-22-090, and
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WAC 402-22-045 Issuance of specific licenses. (1) Upon a determination that an application meets the requirements of the act and the regulations of the department the department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(2) The department may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this part as it deems appropriate or necessary in order: 
(a) Minimize danger to public health and safety or property;
(b) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and
(c) Prevent loss or theft of material subject to this part. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-22-045, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-060.]

WAC 402-22-050 Expiration of licenses. Except as provided in WAC 402-22-055(2), each specific license shall expire at the end of the day, in the month and year stated therein. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-22-050, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-080.]

WAC 402-22-055 Renewal of license. (1) Applications for renewal of specific licenses shall be filed in accordance with WAC 402-22-020.

(2) In any case in which a licensee, not less than thirty days prior to expiration of the existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the application has been finally determined by the department. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-22-055, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-110.]

WAC 402-22-060 Amendment of licenses at request of licensee. Applications for amendment of a license shall be filed in accordance with WAC 402-22-020 and shall specify the respects in which the licensee desires the license to be amended ad the grounds for such amendment. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-22-060, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-120.]

WAC 402-22-065 Agency action on applications to renew or amend. In considering an application by a licensee to renew or amend the license, the department will apply the criteria set forth in WAC 402-22-040, 402-22-070, 402-22-090, or 402-22-110 as applicable. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-22-065, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-130.]

WAC 402-22-070 Special requirements for issuance of certain specific licenses for radioactive material. (1) Human use of radioactive material in institutions. In addition to the requirements set forth in WAC 402-22-040 a specific license for human use of radioactive material in institutions will be issued if:
(a) The applicant has appointed a radiation safety committee to coordinate the use of radioactive material throughout that institution and to maintain surveillance over the institution's radiation safety program. Membership of the committee should include a specialist (where applicable a physician) from each department where radioactive material is used, a representative of the institution's management, a representative of the nursing staff, and a person trained in radiation safety;
(b) The applicant possesses adequate facilities for the clinical care of patients;
(c) The physician(s) designated on the application as the individual user(s) has (have) substantial experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients; and
(d) If the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of human uses.

(2) Licensing of individual physicians for human use of radioactive material. In addition to the requirements set forth in WAC 402-22-040 a specific license for the human use of radioactive material will be issued to an individual physician if:
(a) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and
(b) The applicant has extensive experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients.
(c) The application is for use in the applicant's practice in an office outside a medical institution.
(d) The department will not approve an application by an individual physician or group of physicians for a specific license to receive, possess or use radioactive material on the premises of a medical institution unless:
(i) The use of radioactive material is limited to:
(A) the administration of radiopharmaceuticals for diagnostic or therapeutic purposes,
(B) the performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered,
(C) the performance of in vitro diagnostic studies, or
(D) the calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation and diagnostic instrumentation;

(ii) The physician brings the radioactive material with him and removes the radioactive material when he departs. (The institution cannot receive, possess or store radioactive material other than the amount of material remaining in the patient); and

(iii) The medical institution does not hold a radioactive material license issued pursuant to the provisions of subsection (1) of this section.

(3) Specific licenses for certain groups of medical uses of radioactive material.

(a) Subject to the provisions of paragraphs (3)(b), (c) and (d) of this section an application for a specific license pursuant to subsections (1), (2) or (4) of this section, or for any medical use or uses of radioactive material specified in one or more of Groups I to VI, inclusive, of WAC 402-22-200, Schedule A, will be approved for all of the uses within the group or groups which include the use or uses specified in the application if:

(i) The applicant satisfies the requirements of subsections (1), (2) or (4) of this section;

(ii) The applicant, or the physician designated in the application as the individual user, has adequate clinical experience in the types of uses included in the group or groups;

(iii) The applicant, or the physicians and all other personnel who will be involved in the preparation and use of the radioactive material, have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the group or groups;

(iv) The applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses included in the group or groups;

(v) The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the group or groups.

(b) Any licensee or registrant who is authorized to use radioactive material pursuant to one or more groups in paragraph (3)(a) of this section and WAC 402-22-200, Schedule A, is subject to the following conditions:

(i) For Groups I, II, IV, and V, no licensee or registrant shall receive, possess or use radioactive material except as a radiopharmaceutical manufactured in the form to be administered to the patient, labeled, packaged and distributed in accordance with a specific license issued by the department pursuant to WAC 402-22-110(10), a specific license issued by the United States Nuclear Regulatory Commission pursuant to Section 32.72 of 10 CFR Part 32, or a specific license issued by an Agreement State or a Licensing State pursuant to equivalent regulations.

(ii) For Group III, no licensee or registrant shall receive, possess or use generators or reagent kits containing radioactive material or shall use reagent kits that do not contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except:

(A) Reagent kits not containing radioactive material that are approved by the department, the United States Nuclear Regulatory Commission, an Agreement State or a Licensing State for use by persons licensed pursuant to subsection (3) of this section and WAC 402-22-200, Schedule A, or equivalent regulations; or

(B) Generators or reagent kits containing radioactive material that are manufactured, labeled, packaged and distributed in accordance with a specific license issued by the department pursuant to WAC 402-22-110(11), a specific license issued by the United States Nuclear Regulatory Commission pursuant to Section 32.73 of 10 CFR Part 32, or a specific license issued by an Agreement State or a Licensing State pursuant to equivalent regulations.

(iii) For Group VI, no licensee or registrant shall receive, possess or use radioactive material except as contained in a source or device that has been manufactured, labeled, packaged and distributed in accordance with a specific license issued by the department pursuant to WAC 402-22-110(12), a specific license issued by the United States Nuclear Regulatory Commission pursuant to Section 32.74 of 10 CFR Part 32, or a specific license issued to the manufacturer by an Agreement State or a Licensing State pursuant to equivalent regulations.

(iv) For Group III, any licensee or registrant who uses generators or reagent kits shall elute the generator or reagent kit in accordance with instructions which are approved by the department, the United States Nuclear Regulatory Commission, an Agreement State or a Licensing State and are furnished by the manufacturer on the label attached to or in the leaflet or brochure which accompanies the generator or reagent kit.

(v) For Group VI, any licensee who possesses and uses sources or devices containing radioactive material shall:

(A) Cause each source or device containing more than 100 microcuries of radioactive material with a half-life greater than thirty days, except iridium-192 seeds encased in nylon ribbon, to be tested for contamination and/or leakage at intervals not to exceed six months or at such other intervals as are approved by the department, the United States Nuclear Regulatory Commission, an Agreement State or a Licensing State and described by the manufacturer on the label attached to the source, device, or permanent container thereof, or in the leaflet or brochure which accompanies the source or device. Each source or device shall be so tested prior to its
first use unless the supplier furnishes a certificate that the source or device has been so tested within six months prior to the transfer;

(B) Assure that the test required by item (3)(b)(v)(A) of this section shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample or in the case of radium, the escape of radon at the rate of 0.001 microcurie per twenty-four hours. The test sample shall be taken from the source or from the device in which the source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the department;

(C) If the test required by item (3)(b)(v)(A) of this section reveals the presence of 0.005 microcurie or more of removable contamination or in the case of radium, the escape of radon at the rate of 0.001 microcurie per twenty-four hours, immediately withdraw the source from use and cause it to be decontaminated and repaired or to be disposed of in accordance with department regulations. A report shall be filed within five days of the test with the department, describing the equipment involved, the test results, and the corrective action taken;

(D) Follow the radiation safety and handling instructions approved by the department, the United States Nuclear Regulatory Commission, an Agreement State or a Licensing State and furnished by the manufacturer on the label attached to the source, device or permanent container thereof, or in the leaflet or brochure which accompanies the source or device, and maintain such instruction in a legible and conveniently available form;

(E) Conduct a quarterly physical inventory to account for all sources and devices received and possessed. Records of the inventories shall be maintained for inspection by the department and shall include the quantities and kinds of radioactive material, location of sources and devices, and the date of the inventory;

(F) Assure that needles or standard medical applicator cells containing radium–226 or cobalt–60 as wire are not opened while in the licensee’s possession unless specifically authorized by a license issued by the department;

(G) Assure that patients containing cobalt–60, cesium–137, iridium–192 and/or radium–226 implants shall remain hospitalized until a source count and a radiation survey of the patient confirm that all implants have been removed; and

(H) For Groups I, II and III any licensee using byproduct material for clinical procedures other than those specified in the product labeling (package insert) shall comply with the product labeling regarding:

(aa) Chemical and physical form;

(bb) Route of administration; and

(cc) Dosage range.

(c) Any licensee who is licensed pursuant to paragraph (3)(a) of this section for one or more of the medical use groups in WAC 402–22–200, Schedule A, also is authorized, subject to the provisions of paragraph (3)(c) and (d) of this section to receive, possess and use for calibration and reference standards:

(i) Any radioactive material listed in Group I, Group II, or Group III of WAC 402–22–200, Schedule A, with a half-life not longer than one hundred days, in amounts not to exceed 15 millicuries total;

(ii) Any radioactive material listed in Group I, Group II, or Group III of WAC 402–22–200, Schedule A, with half-life greater than one hundred days in amounts not to exceed 200 microcuries total;

(iii) Technetium–99m in amounts not to exceed 30 millicuries; and

(iv) Any radioactive material, in amounts not to exceed 3 millicuries per source, contained in calibration or reference sources that have been manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the department pursuant to WAC 402–22–110(12), a specific license issued by the United States Nuclear Regulatory Commission pursuant to Section 32.74 of 10 CFR Part 32, or a specific license issued to the manufacturer by an Agreement State or a Licensing State pursuant to equivalent regulations.

(d) Leak tests.

(i) Any licensee or registrant who possesses sealed sources as calibration or reference sources pursuant to paragraph (3)(c) of this section shall cause each sealed source containing radioactive material, other than hydrogen–3, with a half-life greater than thirty days in any form other than gas to be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, the sealed sources should not be used until tested: Provided, however, That no leak tests are required when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material;

(ii) The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which contamination might be expected to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the department.
(iii) If the leak test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee or registrant shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with chapters 402-22 and 402-24 WAC of these regulations. A report shall be filed within five days of the test with the department describing the equipment involved, the test results, and the corrective action taken.

(e) Any licensee or registrant who possesses and uses calibration and reference sources pursuant to item (3)(c)(iv) of this section shall:

(i) Follow the radiation safety and handling instructions approved by the department, the United States Nuclear Regulatory Commission, an Agreement State or a Licensing State and furnished by the manufacturer on the label attached to the source, or permanent container thereof, or in the leaflet or brochure that accompanies the source, and maintain such instruction in a legible and conveniently available form; and

(ii) Conduct a quarterly physical inventory to account for all sources received and possessed. Records of the inventories shall be maintained for inspection by the department and shall include the quantities and kinds of radioactive material, location of sources, and the date of the inventory.

(4) Human use of sealed sources. In addition to the requirements set forth in WAC 402-22-040, a specific license for human use of sealed sources will be issued only if the applicant or, if the application is made by an institution, the individual user:

(a) Has specialized training in the diagnostic or therapeutic use of the sealed source considered, or has experience equivalent to such training; and

(b) Is a physician.

(5) Use of sealed sources in industrial radiography. In addition to the requirements set forth in WAC 402-22-040, a specific license for use of sealed sources in industrial radiography will be issued if:

(a) The applicant will have an adequate program for training radiographers and radiographer's assistants and submits to the department a schedule or description of such program which specifies the:

(i) Initial training;

(ii) Periodic training;

(iii) On-the-job training;

(iv) Means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with department regulations and licensing requirements, and the operating and emergency procedures of the applicant; and

(v) Means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;

(b) The applicant submits to the department and complies with satisfactory written operating and emergency procedures (described in WAC 402-36-110 of these regulations);

(c) The applicant will have an adequate internal inspection system, or other management control, to assure that license provisions, regulations, and the applicant's operating and emergency procedures are followed by radiographers and radiographer's assistants;

(d) The applicant submits to the department a description of the applicant's overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program;

(e) The applicant who desires to conduct leak tests has established adequate procedures to be followed in leak testing sealed sources for possible leakage and contamination and submits to the department a description of such procedures including:

(i) Instrumentation to be used;

(ii) Method of performing tests, e.g., points on equipment to be smeared and method of taking smear; and

(iii) Pertinent experience of the person who will perform the tests;

(f) The licensee shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety.

(6) Environmentally significant licensing actions. In addition to the requirements set forth in WAC 402-22-040, a specific license for any activity within the licensing authority of the department which the department determines will significantly affect the radiological quality of the human environment, including those specified in WAC 197-10-175(7)(a) (i.e., licenses to operate low level waste burial facilities or licenses to operate or expand beyond the design capacity, mineral processing facilities or their tailings areas, whose products, or byproducts, have concentrations of naturally occurring radioactive material in excess of exempt concentrations as specified in WAC 402-19-580, Schedule C), will be issued if the following conditions are met:

(a) The application for a license or license amendment (other than administrative amendments) is accompanied or preceded by a Final Environmental Impact Statement or Final Declaration of Nonsignificance completed in accordance with the State Environmental Policy Act (SEPA) procedures and guidelines specified in chapters 197-10 and 248-06 WAC. For any uranium or thorium mill in operation on or before the effective date of this regulation for which an Environmental Impact Statement has not been prepared previously, an application for license renewal must be accompanied or preceded by a Final Environmental Impact Statement or Final Declaration of Nonsignificance completed in accordance with SEPA guidelines.

NOTE: No construction shall be commenced until the license has been issued or unless an emergency exemption from SEPA requirements is granted in accordance with WAC 197-10-180. For the purposes of subsection (6) of this section, the term "commencement of construction" means any clearing of land, excavation or other substantial action related to a proposed activity for specific licensing that would adversely affect the natural environment of a site; this term does not include changes desirable for

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the temporary use of the land for public recreational use, limited borings to determine site characteristics as necessary for environmental assessment, or other preconstruction monitoring to establish background information related to suitability of a site or to the protection of environmental values. In the case where an exemption is granted, the applicant shall assume all financial risk for construction activity; waive any claim of entitlement to the issuance of a license based solely upon the grant of the exemption or the commencement of construction pursuant thereto; and furnish, if the circumstances warrant and the department so requires, a financial surety arrangement to insure the protection of the public health, safety and the environment in the event of abandonment, default or inability of the licensee to meet the requirements of this regulation and disposal of tailings and for reclamation and disposal of tailings and for decommissioning the site. The bond, or a copy thereof, shall be received by the department prior to issuance of the license, or prior to license renewal for mills of credit or combinations of the foregoing. The amount of the surety arrangement may be revised by the department preceding each license renewal.

(b) For uranium or thorium milling operations, a bond made payable to the department of social and health services or other acceptable government agency, and in an amount specified by the department, shall be posted to ensure the protection of the public health and safety in the event of abandonment, default or other inability of the licensee to meet the requirements for reclamation and disposal of tailings and for decommissioning the site. The bond, or a copy thereof, when the bond is made payable to another government agency, shall be received by the department prior to issuance of the license, or prior to license renewal for mills in operation on or before the effective date of this regulation. Other acceptable surety arrangements in addition to surety bonding include cash deposits, certificates of deposit, deposits of government securities, letters or lines of credit or combinations of the foregoing. The amount and mechanism of the surety arrangement may be reviewed by the department preceding each license renewal and adjustments may be required of the licensee prior to such renewal.

(c) The owner of the proposed uranium or thorium mill and tailings site(s) agrees to transfer or revert to the appropriate state or federal agency upon termination of the license, all lands, buildings and grounds, and any interest therein, necessary to fulfill the purposes of this subsection, except where the lands are held in trust for, or are owned by any Indian tribe. For any uranium or thorium mill in operation on or before the effective date of this regulation, such an agreement will be required prior to license renewal.

(d) For all uranium and thorium milling operations, the owner or operator shall arrange to pay to the department or its designee on a quarterly basis a charge on each pound of uranium or thorium compound which is milled out of the raw ore on or after January 1, 1980. For uranium or thorium mills in operation on or before the effective date of this regulation, the mill owner or operator shall determine the appropriate manner in which to make said payments prior to April 1, 1980.

(i) The specific charge shall be five cents per pound on each pound of uranium or thorium compound milled out of the raw ore.

(ii) The specific charge may be increased or decreased as is considered necessary to provide a special security fund for the further maintenance, surveillance or care which may be required after a licensee has ceased to operate.

(iii) The total charge shall not exceed one million dollars.

(e) The application for a license includes a description of an appropriate program for effluent monitoring, environmental monitoring and data reporting. Such description shall encompass locations, frequency, and types of sampling, analytical plans and procedures, minimum detection levels, sampling equipment and quality assurance programs. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-22-070, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-070.]

WAC 402-22-090 Special requirements for specific licenses of broad scope. This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material ("broad licenses") and certain regulations governing holders of such licenses.*

*NOTE: Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity or other product containing source material or by-product material whose subsequent possession, use, transfer and disposal by all other persons who are exempted from regulatory requirements may be obtained only from the United States Nuclear Regulatory Commission, Washington, D.C. 20555.

(1) The different types of broad licenses are set forth below:

(a) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

(b) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in WAC 402-22-250 Schedule B, for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in WAC 402-22-250 Schedule B, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in WAC 402-22-250 Schedule B, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.
(c) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in WAC 402-22-250 Schedule B, for any authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in WAC 402-22-250 Schedule B, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in WAC 402-22-250 Schedule B, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(2) An application for a Type A specific license of broad scope will be approved if:
(a) The applicant satisfies the general requirements specified in WAC 402-22-040.
(b) The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and
(c) The applicant has established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including:
(i) The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;
(ii) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and
(iii) The establishment of appropriate administrative procedures to assure:
(A) Control of procurement and use of radioactive material;
(B) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and
(C) Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with item (3)(b)(ii)(B) of this section prior to use of the radioactive material.

(4) An application for a Type C specific license of broad scope will be approved if:
(a) The applicant satisfies the general requirements specified in WAC 402-22-040.
(b) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of individuals, who have received:
(i) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and
(ii) At least forty hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and
(c) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, recordkeeping, material control and accounting, and management review necessary to assure safe operations.

(5) Specific licenses of broad scope are subject to the following conditions:
(a) Unless specifically authorized by the department, persons licensed pursuant to this section shall not:
(i) Conduct tracer studies in the environment involving direct release of radioactive material;
(ii) Receive, acquire, own, possess, use or transfer devices containing 100,000 curies or more of radioactive material in sealed sources used for irradiation of materials;
(iii) Conduct activities for which a specific license issued by the department under WAC 402-22-070 or 402-22-110 is required; or
(iv) Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug or other product designed for ingestion or inhalation by, or application to, a human being.
(b) Each Type A specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only
be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(c) Each Type B specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(d) Each Type C specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of subsection (4) of this section. [Statutory Authority: RCW 70.98.080. 073 (Order 1459), § 402-22-090, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-073.]

WAC 402-22-110 Special requirements for a specific license to manufacture, assemble, repair, or distribute commodities, products, or devices which contain radioactive material. (1) Licensing the introduction of radioactive material into products in exempt concentrations. In addition to the requirements set forth in WAC 402-22-040, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under WAC 402-19-190(2)(a) will be issued if:

(a) The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and

(b) The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in WAC 402-19-580, Schedule C, that reconstruction of the radioactive material in concentrations exceeding those in WAC 402-19-580, Schedule C, is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(c) Each person licensed under subsection (1) of this section shall file an annual report with the department which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product and material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to subsection (1) of this section during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within thirty days thereafter.

(2) Licensing the distribution of radioactive material in exempt quantities.*

*NOTE: Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing source material or by-product material whose subsequent possession, use, transfer and disposal by all other persons who are exempted from regulatory requirements may be obtained only from the United States Nuclear Regulatory Commission, Washington, D.C. 20555.

(a) An application for a specific license to distribute naturally occurring and accelerator-produced radioactive material (NARM) to persons exempted from these regulations pursuant to WAC 402-19-190(2)(b) will be approved if:

(i) The radioactive material is not contained in any food, beverage, cosmetic, drug or other commodity designed for ingestion or inhalation by, or application to, a human being;

(ii) The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(iii) The applicant submits copies of prototype labels and brochures and the department approves such labels and brochures.

(b) The license issued under paragraph (2)(a) of this section subject to the following conditions:

(i) No more than ten exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

(ii) Each exempt quantity shall be separately and individually packaged. No more than ten such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to WAC 402-19-190(2)(b). The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

(iii) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

(A) Identifies the radionuclide and the quantity of radioactivity; and

(B) Bears the words "Radioactive Material."
(iv) In addition to the labeling information required by item (2)(b)(iii) of this section, the label affixed to the immediate container, or an accompanying brochure, shall:

(A) State that the contents are exempt from Licensing State requirements;
(B) Bear the words "Radioactive Material—Not for Human Use—Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited—Exempt Quantities Should Not Be Combined"; and
(C) Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage and disposal of the radioactive material.

(c) Each person licensed under paragraph (2)(a) of this section shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under WAC 402-19-190(2)(b) or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the department. Each report shall cover the year ending June 30, and shall be filed within thirty days thereafter. If no transfers of radioactive material have been made pursuant to subsection (2) of this section during the reporting period, the report shall so indicate.

(3) Licensing the incorporation of naturally occurring and accelerator-produced radioactive material into gas and aerosol detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under WAC 402-19-190(2)(b) or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the department. Each report shall cover the year ending June 30, and shall be filed within thirty days thereafter. If no transfers of radioactive material have been made pursuant to subsection (2) of this section during the reporting period, the report shall so indicate.

(4) Licensing the manufacture and distribution of devices to person generally licensed under WAC 402-21-050(4).

(a) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under WAC 402-21-050(4) or equivalent regulations of the United States Nuclear Regulatory Commission, an Agreement State or a Licensing State will be approved if:

(i) The applicant satisfies the general requirements of WAC 402-22-040;
(ii) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:
(A) The device can be safely operated by persons not having training in radiological protection;
(B) Under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar quarter a dose in excess of ten percent of the limits specified in the table in WAC 402-24-020(1); and
(C) Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye 15 rems
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter 200 rems
Other organs 50 rems

(iii) Each device bears a durable, legible, clearly visible label or labels approved by the department, which contain in a clearly identified and separate statement:
(A) Instructions and precautions necessary to assure safe installation, operation and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);
(B) The requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and
(C) The information called for in one of the following statements, as appropriate, in the same or substantially similar form:
(aa) The receipt, possession, use and transfer of this device, Model __________, Serial No. __________. Note*, are subject to a general license or the equivalent, and the regulations of the United States Nuclear Regulatory Commission or a state with which the United States Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

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CAUTION – RADIOACTIVE MATERIAL

(Name of manufacturer or distributor)*

(bb) The receipt, possession, use and transfer of this device, Model __________, Serial No. __________. Note*, are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION – RADIOACTIVE MATERIAL

(Name of manufacturer or distributor)*

*NOTE: The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

(b) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the department will consider information which includes, but is not limited to:

(i) Primary containment (source capsule);
(ii) Method of sealing containment;
(iii) Containment construction materials;
(iv) Form of contained radioactive material;
(v) Maximum temperature withstood during prototype tests;
(vi) Maximum pressure withstood during prototype tests;
(vii) Maximum quantity of contained radioactive material;
(viii) Radiotoxicity of contained radioactive material;

and

(x) Operating experience with identical devices or similarly designed and constructed devices.

(c) In the event the applicant desires that the general licensee under WAC 402–21–050(4), or under equivalent regulations of the United States Nuclear Regulatory Commission, an Agreement State or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, he shall include in his application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of ten percent of the limits specified in the table in WAC 402–24–020(1).

(d) Each person licensed under paragraph (4)(a) of this section to distribute to generally licensed persons shall:

(i) Furnish a copy of the general license contained in WAC 402–21–050(4) to each person to whom the person directs or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in WAC 402–21–050(4);

(ii) Furnish a copy of the general license contained in the United States Nuclear Regulatory Commission's Agreement State's, or Licensing State's regulation equivalent to WAC 402–21–050(4), or alternatively, furnish a copy of the general license contained in WAC 402–21–050(4) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the United States Nuclear Regulatory Commission, the Agreement State or the Licensing State. If a copy of the general license in WAC 402–21–050(4) is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the United States Nuclear Regulatory Commission, Agreement State or Licensing State under requirements substantially the same as those in WAC 402–21–050(4);

(iii) Report to the department all transfers of such devices to persons for use under the general license in WAC 402–21–050(4). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the department and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under WAC 402–21–050(4) during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within thirty days thereafter.

(iv) Reports to other departments.

(A) Report to the United States Nuclear Regulatory Commission all transfers of such devices to persons for use under the United States Nuclear Regulatory Commission general license in Section 31.5 of 10 CFR Part 31.
Specific Licenses

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(B) Report to the responsible department all transfers of devices manufactured and distributed pursuant to subsection (4) of this section for use under a general license in that state's regulations equivalent to WAC 402-21-050(4).

(C) Such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the department and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within thirty days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.

(D) If no transfers have been made to United States Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the United States Nuclear Regulatory Commission.

(E) If no transfers have been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible department upon request of the department.

(v) Keep records showing the name, address and the point of contact for each general licensee to whom the person directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in WAC 402-21-050(4), or equivalent regulations of the United States Nuclear Regulatory Commission, an Agreement State or a Licensing State. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of paragraph (4)(d) of this section.

5 Special requirements for the manufacture, assembly or repair of luminous safety devices for use in aircraft. An application for a specific license to manufacture, assemble or repair luminous safety devices containing tritium or promethium-147 for use in aircraft for distribution to persons generally licensed under WAC 402-21-050(5) will be approved subject to the following conditions:

(a) The applicant satisfies the general requirements specified in WAC 402-22-040; and

(b) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56, 32.101 of 10 CFR Part 32 or their equivalent.

6 Special requirements for license to manufacture calibration sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under WAC 402-21-050(7). An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under WAC 402-21-050(7) will be approved subject to the following conditions:

(a) The applicant satisfies the general requirement of WAC 402-22-040; and

(b) The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.

7 Manufacture and distribution of radioactive material for medical use under general license. In addition to requirements set forth in WAC 402-22-040, a specific license authorizing the distribution of radioactive material for use by physicians under the general license in WAC 402-21-050(8) will be issued if:

(a) The applicant submits evidence that the radioactive material is to be manufactured, labeled, and packaged in accordance with a new drug application which the Commissioner of Food and Drugs, United States Food and Drug Administration, has approved, or in accordance with a license for a biologic product issued by the Secretary, Department of Health, Education, and Welfare; and

(b) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on the label affixed to the container or appears in the leaflet or brochure which accompanies the package:

(i) This radioactive drug may be received, possessed and used only by physicians licensed (to dispense drugs) in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license or its equivalent of the United States Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

(ii) This radioactive drug may be received, possessed and used only by physicians licensed (to dispense drugs) in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license or its equivalent of a Licensing State.

Name of manufacturer

8 Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of WAC 402-21-050(9) will be approved if:

(a) The applicant satisfies the general requirements specified in WAC 402-22-040;

(b) The radioactive material is to be prepared for distribution in prepackaged units of:

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(i) Iodine-125 in units not exceeding 10 microcuries each;
(ii) Iodine-131 in units not exceeding 10 microcuries each;
(iii) Carbon-14 in units not exceeding 10 microcuries each;
(iv) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each;
(v) Iron-59 in units not exceeding 20 microcuries each;
(vi) Cobalt-57 in units not exceeding 10 microcuries each;
(vii) Selenium-75 in units not exceeding 10 microcuries each;
(viii) Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.

(c) Each prepackaged unit bears a durable, clearly visible label:

(i) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries of hydrogen-3 (tritium); 20 microcuries of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each; and
(ii) Displaying the radiation caution symbol described in WAC 402-24-090(1)(a) and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".

(d) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(i) This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

(ii) This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

Name of manufacturer

(e) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in WAC 402-24-130 of these regulations.

(9) Licensing the manufacture and distribution of ice detection devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under WAC 402-21-050(10) will be approved subject to the following conditions:

(a) The applicant satisfies the general requirements of WAC 402-22-040; and
(b) The criteria of Sections 32.61, 32.62, 32.103 of 10 CFR Part 32 are met.

(10) Manufacture and distribution of radiopharmaceuticals containing radioactive material for medical use under group licenses. An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to WAC 402-22-070(3) for the uses listed in Group I, Group II, Group IV, or Group V of WAC 402-22-200, Schedule A, will be approved if:

(a) The applicant satisfies the general requirements specified in WAC 402-22-040 of this part;
(b) The applicant submits evidence that:

(i) The radiopharmaceutical containing radioactive material will be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the United States Food and Drug Administration (FDA), a biologic product license issued by FDA or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA; or
(ii) The manufacture, compounding and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act except for Sections 501, 502, and 704 of the Food, Drug and Cosmetic Act which deal with adulteration, misbranded drugs and records inspection, respectively. Nuclear pharmacies licensed by the state board of pharmacy, or nuclear physicians licensed by the state board of medical examiners are, for the purpose of this regulation, not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(c) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and
(d) The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity and date of assay, and the label affixed to...
each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the department for distribution to persons licensed pursuant to WAC 402-22-070(3) and 402-22-200 Schedule A, Group I, Group II, Group IV, and Group V, as appropriate, or under equivalent regulations of the United States Nuclear Regulatory Commission, an Agreement State or a Licensing State. The labels, leaflets or brochures required by subsection (10) of this section are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(11) Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing radioactive material. An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to WAC 402-22-070(3) for the uses listed in Group III of WAC 402-22-200, Schedule A will be approved if:

(a) The applicant satisfies the general requirements specified in WAC 402-22-040;

(b) The applicant submits evidence that:

(i) The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), a biologic product license issued by FDA, or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA; or

(ii) The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act except for Sections 501, 502 and 704 of the Food, Drug and Cosmetic Act which deal with adulteration, misbranded drugs and records inspection, respectively. Nuclear pharmacies licensed by the state board of pharmacy, or nuclear physicians licensed by the state board of medical examiners are, for the purpose of this regulation, not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(c) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(d) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

(e) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit; contains:

(i) Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit; and

(ii) A statement that this generator or reagent kit (as appropriate) is approved for use by persons licensed by the department pursuant to WAC 402-22-070(3) and Group III of WAC 402-22-200, Schedule A, or under equivalent regulations of the United States Nuclear Regulatory Commission, an Agreement State or a Licensing State. The labels, leaflets or brochures required by subsection (11) of this section are in addition to the labeling required by FDA and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

NOTE: Although the department does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the department for use by persons licensed pursuant to WAC 402-22-070(3) and Group III of WAC 402-22-200 Schedule A may submit the pertinent information specified in subsection (11) of this section.

(12) Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to WAC 402-22-070(3) for use as a calibration or reference source or for the uses listed in Group VI of WAC 402-22-200 Schedule A of this part will be approved if:

(a) The applicant satisfies the general requirements in WAC 402-22-040 of this part;

(b) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) The radioactive material contained, its chemical and physical form and amount;

(ii) Details of design and construction of the source or device;

(iii) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

(iv) For devices containing radioactive material, the radiation profile of a prototype device;

(v) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

(vi) Procedures and standards for calibrating sources and devices;

(vii) Legend and methods for labeling sources and devices as to their radioactive content; and
(viii) Instructions for handling and storing the source or device from the radiation safety standpoint, these instructions are to be included on a durable label attached to the source or device, or to a permanent storage container for the source or device: Provided, That instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label.

(c) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the named source or device is licensed by the department for distribution to persons licensed pursuant to WAC 402-22-070(3) and Group VI of WAC 402-22-200 Schedule A or under equivalent regulations of the United States Nuclear Regulatory Commission, an Agreement State or a Licensing State: Provided, That such labeling for sources which do not require long term storage (e.g., gold-198 seeds) may be on a leaflet or brochure which accompanies the source.

(d) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance and characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(e) In determining the acceptable interval for test of leakage of radioactive material, the department will consider information that includes, but is not limited to:

(i) Primary containment (source capsule);
(ii) Protection of primary containment;
(iii) Method of sealing containment;
(iv) Containment construction materials;
(v) Form of contained radioactive material;
(vi) Maximum temperature withstood during prototype tests;
(vii) Maximum pressure withstood during prototype tests;
(viii) Maximum quantity of contained radioactive material;
(ix) Radiotoxicity of contained radioactive material;
(x) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(13) Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications.

(a) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to WAC 402-21-030(4) or equivalent regulations of the United States Nuclear Regulatory Commission or an Agreement State will be approved if:

(i) The applicant satisfies the general requirements specified in WAC 402-22-040;

(ii) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses and potential hazards of the industrial product or device to provide reasonable assurance that possession, use or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of ten percent of the limits specified in WAC 402-24-020(1); and

(iii) The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(b) In the case of an industrial product or device whose unique benefits are questionable, the department will approve an application for a specific license under subsection (13) of this section only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(c) The department may deny any application for a specific license under subsection (13) of this section if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(d) Each person licensed pursuant to paragraph (13)(a) of this section shall:

(i) Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

(ii) Label or mark each unit to:

(A) Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(B) State that the receipt, possession, use and transfer of the product or device are subject to a general license or the equivalent and the regulations of the United States Nuclear Regulatory Commission or of an Agreement State;

(iii) Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

(iv) Furnish to each person to whom depleted uranium in a product or device is transferred for use pursuant to the general license contained in WAC 402-21-030(4) or its equivalent:

(A) A copy of the general license contained in WAC 402-21-030(4) and a copy of Department Form RHF-21; or
(B) A copy of the general license contained in the United States Nuclear Regulatory Commission’s or Agreement State’s regulation equivalent to WAC 402–21–030(4) and a copy of the United States Nuclear Regulatory Commission’s or Agreement State’s certificate, or alternatively, furnish a copy of the general license contained in WAC 402–21–030(4) and a copy of Department Form RHF–21 with a note explaining that use of the product or device is regulated by the United States Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in WAC 402–21–030(4).

(v) Report to the department all transfers of industrial products or devices to persons for use under the general license in WAC 402–21–030(4). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the department and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under chapter 402–21 WAC during the reporting period, the report shall so indicate;

(vi) Provide certain other reports as follows:
(A) Report to the United States Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the United States Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40;
(B) Report to the responsible department all transfers of devices manufactured and distributed pursuant to subsection (13) of this section for use under a general license in that state’s regulations equivalent to WAC 402–21–030(4);
(C) Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the department and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person;
(D) If no transfers have been made to United States Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the United States Nuclear Regulatory Commission;
(E) If no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible department; and

(vii) Keep records showing the name, address and point of contact for each general licensee to whom the person transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in WAC 402–21–030(4) or equivalent regulations of the United States Nuclear Regulatory Commission or of an Agreement State. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

(14) Repackaging and distribution of radioactive material and reagent kits for medical use.*

An application for a specific license to repackage and distribute radioactive material for medical use and reagent kits for the preparation of radiopharmaceuticals will be approved if:
(a) Applicant satisfies general requirements in WAC 402–22–040;
(b) The applicant submits evidence that:
(i) Radioactive material to be repackaged is obtained only from elution of an NDA approved radionuclide generator;
(ii) The packaging of other radioactive material will not be violated prior to distribution;
(iii) Reagent kits for the preparation of radiopharmaceuticals will be obtained only as NDA approved products or from a licensed nuclear pharmacy;
(iv) The packaging of reagent kits will not be violated prior to distribution;
(v) Only sterile, pyrogen-free containers, syringes, needles, filters, etc., will be used in the repackaging operation.
(c) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging which is appropriate for safe handling and storage of the radioactive material or prepared radiopharmaceutical.

*NOTE: The "good neighbor" transfer of radioactive material or reagent kits is excluded from this licensing requirement provided such transfers are for the emergency replacement of radioactive material which is otherwise not available due to transportation or supplier difficulties and is not provided as a cost-sharing procedure.

[Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459). § 402–22–110, filed 11/30/79, effective 1/1/80. Formerly WAC 402–20–076.]

WAC 402–22–200 Schedule A groups of medical uses of radioactive material (Ref. WAC 402–22–070(3)
and 402-22-110(10). (1) Group I. Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution and excretion. This group does not include imaging or localization studies.

(a) Any radioactive material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution or excretion for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA) or for which a "New Drug Application" (NDA) is in effect.

(b) Any radioactive material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution or excretion which has been compounded, prepared and distributed by a nuclear pharmacy licensed by the state board of pharmacy and this department.

(c) The provisions of paragraphs (1)(a) and (b) of this section notwithstanding, no radioactive material in gaseous form or for use as an aerosol is permitted by this subsection except as specifically authorized in a license.

(2) Group II. Use of prepared radiopharmaceuticals for diagnostic imaging and localization studies.

(a) Any radioactive material in a radiopharmaceutical prepared from a reagent kit authorized in subsection (3) of this section which has been prepared and distributed by a nuclear pharmacy licensed by the state board of pharmacy and this department;

(b) Any radioactive material in a radiopharmaceutical and for a diagnostic use involving imaging or localizing for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA) or for which a "New Drug Application" (NDA) is in effect;

(c) The provisions of paragraphs (2)(a) and (b) of this section notwithstanding, no radioactive material in gaseous form or for use as an aerosol is permitted by this subsection except as specifically authorized in a license.

(3) Group III. Use of generators and reagent kits for the preparation and use of radiopharmaceuticals containing radioactive material for diagnostic imaging and localization studies.

(a) Any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for which generator or reagent kit a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA) or for which a "New Drug Application" (NDA) is in effect.

(b) Any reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material which has been compounded, prepared and distributed by a nuclear pharmacy licensed by the state board of pharmacy and this department.

(c) The provisions of paragraphs (3)(a) and (b) of this section notwithstanding, no generator or reagent kit is authorized for preparation of any gaseous form or aerosol of a radioactive material, except as specifically authorized in a license.

(4) Group IV. Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety.

(a) Iodine-131 as iodide for treatment of hyperthyroidism and cardiac dysfunction;

(b) Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases;

(c) Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions;

(d) Any radioactive material in a radiopharmaceutical and for a therapeutic use not normally requiring hospitalization for purposes of radiation safety for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA) or for which a "New Drug Application" (NDA) is in effect.

(5) Group V. Use of prepared radiopharmaceuticals for certain therapeutic uses that normally require hospitalization for purposes of radiation safety.

(a) Gold-198 as colloid for intracavitary treatment of malignant effusions;

(b) Iodine-131 as iodide for treatment of thyroid carcinoma;

(c) Any radioactive material in a radiopharmaceutical and for a therapeutic use normally requiring hospitalization for radiation safety reasons for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA) or for which a "New Drug Application" (NDA) is in effect.

(6) Group VI. Use of sources and devices containing radioactive material for certain medical uses.

(a) Americium-241 as a sealed source in a device for bone mineral analysis;

(b) Cesium-137 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(c) Cobalt-60 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(d) Gold-198 as seeds for interstitial treatment of cancer;

(e) Iodine-125 as a sealed source in a device for bone mineral analysis;

(f) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

(g) Strontium-90 sealed in an applicator for treatment of superficial eye conditions; and

(h) Iodine-125 as seeds for interstitial treatment of cancer. [Statutory Authority: RCW 70.98.080, 79-12-073 (Order 1459), § 402-22-200, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-260.]

WAC 402-22-250 Schedule B, limits for broad licenses. (See also WAC 402-22-090)

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WAC 402-52-005 Reclamation and decommissioning. A specific plan for reclamation and disposal of tailings and for decommissioning the site of uranium or thorium milling operations shall be included as part of the proposed action assessed under SEPA regulations and guidelines as required by WAC 402-22-070(6)(a) for licensing of environmentally significant operations. For any uranium or thorium mill in operation on or before the effective date of this regulation for which a plan for reclamation and disposal of tailings and decommissioning of the site has not been submitted and assessed, such a plan must be submitted to the department and a final environmental impact statement or final declaration of nonsignificance must accompany or precede the license renewal. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-22-250, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-270.]

Chapter 402-52 WAC

URANIUM AND/OR THORIUM MILL OPERATION AND STABILIZATION OF MILL TAILING PILES

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| Uranium and thorium mill tailing piles and ponds—Control. All uranium and thorium mill tailing piles and ponds shall be controlled in the following manner:

1. Access to the pile area shall be controlled by the operator or owner and properly posted.
2. The pile shall be maintained in such a manner that hazardous erosion of, or environmental hazard from, radioactive materials does not occur.
3. Tailing piles shall be surrounded by a fence of sufficient size and strength to prevent range animals from gaining entry.
4. Tailings should be stabilized as much as practicably achievable during operation to preclude off-site hazards and to minimize the extent of final stabilization.
5. All plans for stabilization of mill tailings shall be submitted to the department for review prior to construction. The department may, however, require further controls at a future date after approval of such plans.
6. The operator or owner shall cause regular monitoring of the milling site, the mill tailings, and adjacent

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courses to avoid contamination in event of flooding or waste from small operations such as in situ extraction or seepage or contamination; so as to keep releases of airborne radioactive effluents as low as is reasonably achievable below the limits specified in chapter 402-24 WAC.

(7) Steps should be taken to control dusting from dry surfaces of the tailings impoundment area or storage areas so as to keep releases of airborne radioactive effluents as low as is reasonably achievable below the limits specified in chapter 402-24 WAC.

(8) With the exception of use at a mill or for reprocessing at the site or another location, prior written approval of the department must be obtained before any tailings material is removed from any active or inactive mill.

(9) The department may waive individual requirements in regard to stabilization or utilization of tailings material if it can be shown that they are unnecessary or impracticable in specific areas. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-52-015, filed 11/30/79, effective 1/1/80; Order 1095, § 402-52-010, filed 2/6/76.]

WAC 402-52-015 Proposed tailing disposal facilities. (1) New tailing piles shall be located in areas of low population. Consideration should be given to the utilization of existing large tailings piles for the disposal of waste from small operations such as in situ extraction or heap leaching.

(2) The site shall be located such that disruption and dispersion by natural forces are eliminated or reduced to the maximum extent reasonably achievable. In particular, the site should be:

(a) Removed from set or dry water courses and located in an area with minimal upstream drainage with adequate provisions made for preventing surface run-off water from entering or eroding embankments;
(b) Sufficiently removed from permanent water courses to avoid contamination in event of flooding or failure of embankments;
(c) Sufficiently removed from water supplies to avoid seepage or contamination;
(d) Provided with upstream rainfall catchment areas or diversion channels to minimize or divert the maximum possible flooding; and
(e) Located where the topography provides good wind protection.

(3) The tailing shall be disposed below grade except where it can be demonstrated that an above-grade disposal program will provide reasonably equivalent isolation of the tailings from natural erosional forces.

(4) A tailings impoundment shall not be located near a potentially active fault that could cause a maximum credible earthquake larger than that which the impoundment could reasonably be expected to withstand.

(5) The tailings impoundment should be designed to incorporate features which will promote deposition enhancing the thickness of the impoundment structure.

(6) Steps shall be taken to reduce seepage of toxic material into groundwater by:

(a) Lining the tailings impoundment area;
(b) Reducing the inventory of liquid in the impoundment by such means as dewatering and/or recycling water from the tailings impoundment to the mill;
(c) Neutralization of the tailings to promote immobilization of toxic materials; and/or
(d) Lining and/or compaction of ore storage areas.

(7) Preoperational monitoring shall be conducted for at least one full year prior to any major site construction.

(8) The requirements of WAC 402-52-010 and 402-52-020 shall also be met. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-52-015, filed 11/30/79, effective 1/1/80.]

WAC 402-52-020 Inactive mills—Stabilization procedures. All uranium mill tailing piles and ponds from inactive mills shall be stabilized prior to termination of the license such that ongoing active maintenance is not necessary to preserve isolation in the following manner:

(1) Ponds shall be drained and covered with materials that prevent wind erosion. Liquid drained from the ponds shall be disposed of in compliance with WAC 402-24-220, Appendix A, Table II, Col. 2.

(2) Taking into consideration the types of materials at each site, piles shall be leveled and graded so that there is, insofar as possible, a gradual slope to ensure that there shall be no low places on the pile where water might collect. Side slopes shall be stabilized by riprap, dikes, reduction of grades, vegetation, or any other method or combination of methods that will ensure stabilization. Sufficient natural cover shall be placed over tailings or wastes at the end of milling operations to result in a calculated reduction in surface exhalation of radon from the tailings or waste to less than two picocuries per square meter per second above natural background levels. Direct gamma exposure from the tailings or waste should be reduced to background levels. Plastic or other synthetic caps should not be used to reduce radon exhalation from the tailings or waste. Material used for cover must be essentially the same as far as radioactivity is concerned, as that of surrounding soils.

(3) If pile edges are adjacent to a river, creek gulch or other watercourse that might reasonably be expected to erode the edges during periods of high water, the exposed slopes shall be stabilized and the edges shall be diked and riprapped sufficiently to prevent erosion of the pile.

(4) Drainage ditches shall be provided around the pile edges sufficient to prevent surface runoff water from neighboring land from reaching and eroding the pile.

(5) The pile shall be stabilized against wind and water erosion. The method of stabilization may consist of vegetation or a cover of soil, soil containing rock or stone,
rock or stone, cement or concrete products, petroleum products, or any other soil stabilization material presently recognized or which may be recognized in the future, or any combination of the foregoing as may be required for proper protection from wind, or water erosion.

(6) Where vegetation is used for pile stabilization, sufficient topsoil shall be placed to prevent plant uptake of the radioactive materials contained in the pile.

(7) The requirements of WAC 402-52-010 shall also be met. [Statutory Authority: RCW 70.98.080, 79-12-073 (Order 1459), § 402-52-020, filed 11/30/79, effective 1/1/80; Order 1095, § 402-52-020, filed 2/6/76.]

WAC 402-52-025 Milling operations. (1) Milling operations shall be conducted so as to avoid site contamination and so that all airborne effluent releases are reduced to as low as is reasonably achievable below the limits specified in chapter 402-24 WAC.

(2) Yellowcake drying and packaging operations should cease when effluent control devices are inoperative or not working at their reasonably expected best performance levels.

(3) The licensee shall have written operating procedures documenting steps to be taken to control dusting from the tailings pile and ore storage areas, and steps to be taken when effluent control devices are inoperative or not working at their reasonably expected best performance levels.

(4) The licensee shall have written operating procedures documenting steps to be taken to control dusting from the tailings pile and ore storage areas, and steps to be taken when effluent control devices are inoperative or not working at their reasonably expected best performance levels.

(5) The requirements of WAC 402-52-010 shall also be met. [Statutory Authority: RCW 70.98.080, 79-12-073 (Order 1459), § 402-52-020, filed 11/30/79, effective 1/1/80; Order 1095, § 402-52-020, filed 2/6/76.]

Chapter 402-70 WAC

SCHEDULE OF FEES

WAC

402-70-010 Purpose and scope.
402-70-020 Definitions.
402-70-030 Payment of fees.
402-70-050 Method of payment.
402-70-070 Fees for licensing and compliance actions.
402-70-090 Failure by applicant or licensee to pay prescribed fees.

WAC 402-70-020 Purpose and scope. This chapter establishes fees charged for licensing and inspection services rendered by the Radiation Control Program as authorized under section 3, chapter 110, Laws of 1979 1st ex. sess. These fees apply to owners and operators of uranium or thorium milling operations and their associated tailings or waste. [Statutory Authority: RCW 70.98.080, 79-12-073 (Order 1459), § 402-70-010, filed 11/30/79, effective 1/1/80.]

WAC 402-70-025 Milling operations. (1) Milling operations shall be conducted so as to avoid site contamination and so that all airborne effluent releases are reduced to as low as is reasonably achievable below the limits specified in chapter 402-24 WAC.

(2) Yellowcake drying and packaging operations should cease when effluent control devices are inoperative or not working at their reasonably expected best performance levels.

(3) The licensee shall have written operating procedures documenting steps to be taken to control dusting from the tailings pile and ore storage areas, and steps to be taken when effluent control devices are inoperative or not working at their reasonably expected best performance levels.

(4) The licensee shall have written operating procedures documenting steps to be taken to control dusting from the tailings pile and ore storage areas, and steps to be taken when effluent control devices are inoperative or not working at their reasonably expected best performance levels.

(5) The requirements of WAC 402-52-010 shall also be met. [Statutory Authority: RCW 70.98.080, 79-12-073 (Order 1459), § 402-52-020, filed 11/30/79, effective 1/1/80; Order 1095, § 402-52-020, filed 2/6/76.]

WAC 402-70-030 Payment of fees. (1) Application fees: Each application for which a fee is prescribed shall be accompanied by a remittance in the full amount of the fee. No application will be processed prior to payment of the full amount specified. Applications for which no remittance is received may be returned to the applicant. All application fees will be charged irrespective of the department's disposition of the application or of a withdrawal of the application.

(2) License fees: A fee to cover the cost of the independent environmental assessment plus any cost of an extensive program review not covered by the application fee will be payable upon notification by the department when the review of the project is complete. The license fee will not exceed that specified in WAC 402-70-070. The fee must be received prior to issuance of the license.

(3) Amendment fees: The appropriate amendment fees shall accompany the application for amendment. The department will examine the expenditures for professional manpower and appropriate support services and will, where applicable, refund any overcharges or bill the applicant for the additional amendment fee. In no event will the fee exceed that specified in WAC 402-70-070(1). The fee for administrative amendments is a fixed charged. Unilateral amendments or amendments which result from written department requests may be exempted from these fees at the discretion of the department when the amendment is issued for the convenience of the department.

(4) Renewal fees: The renewal fee shall accompany the renewal application. Upon completion of the program review, the department will examine the expenditures for professional manpower and appropriate support services and will, where applicable, refund any overcharges.

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(5) Inspection fees: An annual fee shall be charged to cover the cost of inspections for determining compliance with the provisions of the license including the manpower, laboratory and support services costs associated with the routine environmental monitoring undertaken. The department will examine the expenditures for professional manpower and appropriate support services and will, when applicable, refund any overcharges. In no event will the annual fee exceed that specified in WAC 402-70-070(2). [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-70-030, filed 11/30/79, effective 1/1/80.]

WAC 402-70-050 Method of payment. (1) Fee payments shall be by check, draft or money order made payable to the department of social and health services.
(2) Fees are due and payable upon submission of the application for license, license renewal or amendment, or upon notification by the department.
(3) The provisions of subsection (2) of this section notwithstanding, the department may enter into an agreement with any applicant or licensee to prorate any or all fees which may be required on whatever frequency or payment schedule which may be mutually satisfactory. Such agreement may provide for adjustments in the amount of the periodic payments to compensate for actual costs to the department for program review. The agreement shall be renewed in conjunction with each license renewal. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-70-050, filed 11/30/79, effective 1/1/80.]

WAC 402-70-070 Fees for licensing and compliance actions. (1) Licenses specifically authorizing the receipt, possession or use of natural uranium and its decay daughters for the extraction of uranium or thorium compound and for the reclamation and disposal of the associated tailings or waste shall be subject to the following fees for the listed licensing actions.
(a) Application fee .................. $ 27,000
(b) License fee ........................ $ 165,000
(c) Amendment fee
   Major ................................ $ 10,000
   Minor ................................ $ 800
   Administrative ..................... $ 85
(d) Renewal fee ...................... $ 10,000
(2) Licenses specifically authorizing the receipt, possession, or use of natural uranium and its decay daughters for the extraction of uranium or thorium compound and for the reclamation and disposal of the associated tailings or waste shall be subject to an annual inspection fee of ninety thousand dollars to cover the cost of monitoring for compliance with the terms and conditions of the license. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-70-070, filed 11/30/79, effective 1/1/80.]

WAC 402-70-090 Failure by applicant or licensee to pay prescribed fees. In any case where the department finds that an applicant or a licensee has failed to pay a prescribed fee required by this chapter, the department will not process any application and may suspend or revoke any license or approval involved or may issue an order with respect to licensed activities as the department determines to be appropriate or necessary in order to carry out the provisions of this chapter. [Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-70-090, filed 11/30/79, effective 1/1/80.]

Title 415 WAC
DEPARTMENT OF RETIREMENT SYSTEMS

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Chapter 415-02 WAC
GENERAL PROVISIONS

WAC
415-02-040 Definition of Plan II.
415-02-050 State Environmental Policy Act—Interface.
415-02-060 Refund of contributions—Application.
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WAC 415-02-040 Definition of Plan II. Wherever used in this title, the term "Plan II" has reference to the retirement plans established by chapters 293, 294 and 295, Laws of 1977 ex. sess. The term "Plan II" shall have reference to those plans in existence prior to the enactment of the above-referenced laws. [Statutory Authority: RCW 41.50.050(6) and 41.50.090. 78-03-023 (Order IV), § 415-02-040, filed 2/15/78.]

WAC 415-02-050 State Environmental Policy Act—Interface. The actions and activities of the department of retirement systems are not major actions significantly affecting the quality of the environment as described in chapter 43.21C RCW. All of the activities of the department are exempted from the threshold determination and environmental impact statement requirements of the State Environmental Policy Act (SEPA) by WAC 197-10-175. The responsible official of the agency for the purposes of SEPA is the director. [Statutory Authority: RCW 41.50.050(6) and 41.50.090. 78-03-023 (Order IV), § 415-02-050, filed 2/15/78.]

WAC 415-02-060 Refund of contributions—Application. A request for a refund of contributions will not be honored if it was executed more than thirty days prior to its receipt by the department. A member may

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