WSR 24-09-027
PERMANENT RULES
HEALTH CARE AUTHORITY
[Filed April 10, 2024, 10:01 a.m., effective May 11, 2024]

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

Purpose: The health care authority (agency) amended this section to replace outdated terms such as "residential [regional] support network (RSN)" and "mental health designee," to delete references to the department of mental health, and to update language regarding authorization and certification for inpatient psychiatric care consistent with the current managed care and administrative services organization (ASO) structure. The agency also made changes to align with RCW 74.09.520(13), which requires the agency to provide a hospital payment for apple health clients who meet the criteria for discharge from a hospital stay to certain facilities, but who cannot be discharged because placement is unavailable. This revision provides for the payment of medically necessary ancillary services to be billed by and paid to the hospital separately.

Citation of Rules Affected by this Order: Amending WAC 182-550-2600.

Statutory Authority for Adoption: RCW 41.05.021, 41.05.160.

Adopted under notice filed as WSR 24-06-014 on February 26, 2024.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 1, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 1, Repealed 0.

Date Adopted: April 10, 2024.

Wendy Barcus
Rules Coordinator

OTS-5189.1

AMENDATORY SECTION (Amending WSR 19-18-026, filed 8/28/19, effective 9/28/19)

WAC 182-550-2600 Inpatient psychiatric services. (1) The medicaid agency((~~, on behalf of the mental health division (MHD), regional support networks (RSNs) and prepaid inpatient health plans (PIHPs),~~)) or the agency's designee pays for covered inpatient psychiatric services for ((~~a voluntary or involuntary inpatient psychiatric admission of an~~)) eligible Washington apple health ((~~client, subject to the limitation and restrictions in this section and other published rules~~)) clients.

(2) The ((~~following~~)) definitions ((~~and abbreviations and those~~)) found in chapter 182-500 WAC and WAC 182-550-1050 apply to this section ((~~(where there is any discrepancy, this section prevails):~~

~~(a) "Authorization number" refers to a number that is required on a claim in order for a provider to be paid for providing psychiatric inpatient services to a Washington apple health client. An authorization number:~~

~~(i) Is assigned when the certification process and prior authorization process has occurred;~~

~~(ii) Identifies a specific request for the provision of psychiatric inpatient services to a Washington apple health client;~~

~~(iii) Verifies when prior or retrospective authorization has occurred;~~

~~(iv) Will not be rescinded once assigned; and~~

~~(v) Does not guarantee payment.~~

~~(b) "Certification" means a clinical determination by an MHD designee that a client's need for a voluntary or involuntary inpatient psychiatric admission, length of stay extension, or transfer has been reviewed and, based on the information provided, meets the requirements for medical necessity for inpatient psychiatric care. The certification process occurs concurrently with the prior authorization process.~~

~~(c) "IMD" See "institution for mental diseases."~~

~~(d) "Institution for mental diseases (IMD)" means a hospital, nursing facility, or other institution of more than sixteen beds that is primarily engaged in providing diagnosis, treatment, or care of people with mental diseases, including medical attention, nursing care, and related services. The MHD designates whether a facility meets the definition for an IMD.~~

~~(e) "Involuntary admission" refer to chapters 71.05 and 71.34 RCW.~~

~~(f) "Mental health division (MHD)" is the unit within the department of social and health services (DSHS) authorized to contract for and monitor delivery of mental health programs. MHD is also known as the state mental health authority.~~

~~(g) "Mental health division designee" or "MHD designee" means a professional contact person authorized by MHD, who operates under the direction of a regional support network (RSN) or a prepaid inpatient health plan (PIHP).~~

~~(h) "PIHP" see "prepaid inpatient health plan."~~

~~(i) "Prepaid inpatient health plan (PIHP)" see WAC 388-865-0300.~~

~~(j) "Prior authorization" means an administrative process by which hospital providers must obtain an MHD designee's for a client's inpatient psychiatric admission, length of stay extension, or transfer. The prior authorization process occurs concurrently with the certification process.~~

~~(k) "Regional support network (RSN)" see WAC 388-865-0200.~~

~~(l) "Retrospective authorization" means a process by which hospital providers and hospital unit providers must obtain an MHD designee's certification after services have been initiated for a Washington apple health client. Retrospective authorization can be before discharge or after discharge. This process is allowed only when circumstances beyond the control of the hospital or hospital unit provider prevented a prior authorization request, or when the client has been determined to be eligible for Washington apple health after discharge.~~

~~(m) "RSN" see "regional support network."~~

~~(n) "Voluntary admission" refer to chapters 71.05 and 71.34 RCW.~~

~~(3) The following department of health (DOH)-licensed hospitals and hospital units are eligible to be paid for providing inpatient psychiatric services to eligible Washington apple health clients, subject to the limitations listed:~~

~~(a) Medicare-certified distinct part psychiatric units;~~

~~(b) State-designated pediatric psychiatric units;~~

~~(c) Hospitals that provide active psychiatric treatment outside of a medicare-certified or state-designated psychiatric unit, under the supervision of a physician according to WAC 246-322-170; and~~

~~(d) Free-standing psychiatric hospitals approved as an institution for mental diseases (IMD).~~

~~(4) An MHD designee has the authority to approve or deny a request for initial certification for a client's voluntary inpatient psychiatric admission and will respond to the hospital's or hospital unit's request for initial certification within two hours of the request. An MHD designee's certification and authorization, or a denial, will be provided within twelve hours of the request. Authorization must be requested before admission. If the hospital chooses to admit the client without prior authorization due to staff shortages, the request for an initial certification must be submitted the same calendar day (which begins at midnight) as the admission. In this case, the hospital assumes the risk for denial as the MHD designee may or may not authorize the care for that day.~~

~~(5) To be paid for a voluntary inpatient psychiatric admission:~~

~~(a) The hospital provider or hospital unit provider must meet the applicable general conditions of payment criteria in WAC 182-502-0100; and~~

~~(b) The voluntary inpatient psychiatric admission must meet the following:~~

~~(i) For a client eligible for Washington apple health, the admission to voluntary inpatient psychiatric care must:~~

~~(A) Be medically necessary as defined in WAC 182-500-0070;~~

~~(B) Be ordered by an agent of the hospital who has the clinical or administrative authority to approve an admission;~~

~~(C) Be prior authorized and meet certification and prior authorization requirements as defined in subsection (2) of this section. See subsection (8) of this section for a voluntary inpatient psychiatric admission that was not prior authorized and requires retrospective authorization by the client's MHD designee; and~~

~~(D) Be verified by receipt of a certification form dated and signed by an MHD designee (see subsection (2) of this section). The form must document at least the following:~~

~~(I) Ambulatory care resources available in the community do not meet the treatment needs of the client;~~

~~(II) Proper treatment of the client's psychiatric condition requires services on an inpatient basis under the direction of a physician (according to WAC 246-322-170);~~

~~(III) The inpatient services can reasonably be expected to improve the client's level of functioning or prevent further regression of functioning;~~

~~(IV) The client has been diagnosed as having an emotional or behavioral disorder, or both, as defined in the current edition of the Diagnostic and Statistical Manual of the American Psychiatric Association; and~~

~~(V) The client's principle diagnosis must be an MHD covered diagnosis.~~

~~(ii) For a client eligible for both medicare and a Washington apple health program, the agency pays secondary to medicare.~~

~~(iii) For a client eligible for both medicare and a Washington apple health program and who has not exhausted medicare lifetime benefits, the hospital provider or hospital unit provider must notify the MHD designee of the client's admission if the dual eligibility status is known. The admission:~~

~~(A) Does not require prior authorization by an MHD designee; and~~

~~(B) Must be under medicare standards.~~

~~(iv) For a client eligible for both medicare and a Washington apple health program who has exhausted medicare lifetime benefits, the admission must have prior authorization by an MHD designee.~~

~~(v) When a liable third party is identified (other than medicare) for a client eligible for a Washington apple health program, the hospital provider or hospital unit provider must obtain an MHD designee's authorization for the admission.~~

~~(6) To be paid for an involuntary inpatient psychiatric admission:~~

~~(a) The involuntary inpatient psychiatric admission must be under the admission criteria specified in chapters 71.05 and 71.34 RCW; and~~

~~(b) The hospital provider or hospital unit provider:~~

~~(i) Must be certified by the MHD under chapter 388-865 WAC;~~

~~(ii) Must meet the applicable general conditions of payment criteria in WAC 182-502-0100; and~~

~~(iii) When submitting a claim, must include a completed and signed copy of an Initial Certification Authorization form Admission to Inpatient Psychiatric Care form, or an Extension Certification Authorization for Continued Inpatient Psychiatric Care form.~~

~~(7) To be paid for providing continued inpatient psychiatric services to a Washington apple health client who has already been admitted, the hospital provider or hospital unit provider must request from an MHD designee within the time frames specified, certification and authorization as defined in subsection (2) of this section for any of the following circumstances:~~

~~(a) If the client converts from involuntary (legal) status to voluntary status, or from voluntary to involuntary (legal) status as described in chapter 71.05 or 71.34 RCW, the hospital provider or hospital unit provider must notify the MHD designee within twenty-four hours of the change. Changes in legal status may result in issuance of a new certification and authorization. Any previously authorized days under the previous legal status that are past the date of the change in legal status are not billable;~~

~~(b) If an application is made for determination of a patient's Washington apple health eligibility, the request for certification and prior authorization must be submitted within twenty-four hours of the application;~~

~~(c) If there is a change in the client's principal ICD-10-CM diagnosis to an MHD covered diagnosis, the request for certification and prior authorization must be submitted within twenty-four hours of the change;~~

~~(d) If there is a request for a length of stay extension for the client, the request for certification and prior authorization must be submitted before the end of the initial authorized days of services (see subsections (11) and (12) of this section for payment methodology and payment limitations);~~

~~(e) If the client is to be transferred from one community hospital to another community hospital for continued inpatient psychiatric~~

~~care, the request for certification and prior authorization must be submitted before the transfer; or~~

~~(f) If a client who has been authorized for inpatient care by the MHD designee has been discharged or left against medical advice prior to the expiration of previously authorized days, a hospital provider or hospital unit provider must notify the MHD designee within twenty-four hours of discharge. Any previously authorized days past the date the client was discharged or left the hospital are not billable.~~

~~(8) An MHD designee has the authority to approve or deny a request for retrospective certification for a client's voluntary inpatient psychiatric admission, length of stay extension, or transfer when the hospital provider or hospital unit provider did not notify the MHD designee within the notification time frames stated in this section. For a retrospective certification request before discharge, the MHD designee responds to the hospital or hospital unit within two hours of the request, and provides certification and authorization or a denial within twelve hours of the request. For retrospective certification requests after the discharge, the hospital or hospital unit must submit all the required clinical information to the MHD designee within thirty days of discharge. The MHD designee provides a response within thirty days of the receipt of the required clinical documentation. All retrospective certifications must meet the requirements in this section. An authorization or denial is based on the client's condition and the services provided at the time of admission and over the course of the hospital stay, until the date of notification or discharge, as applicable.~~

~~(9) To be paid for a psychiatric inpatient admission of an eligible Washington apple health client, the hospital provider or hospital unit provider must submit on the claim form the authorization (see subsection (2)(a) for definition of prior authorization and retrospective authorization).~~

~~(10) The agency uses the payment methods described in WAC 182-550-2650 through 182-550-5600, as appropriate, to pay a hospital and hospital unit for providing psychiatric services to Washington apple health clients, unless otherwise specified in this section.~~

~~(11) Covered days for a voluntary psychiatric admission are determined by an MHD designee utilizing MHD approved utilization review criteria.~~

~~(12) The number of initial days authorized for an involuntary psychiatric admission is limited to twenty days from date of detention. The hospital provider or hospital unit provider must submit the Extension Certification Authorization for Continued Inpatient Psychiatric Care form twenty-four hours before the expiration of the previously authorized days. Extension requests may not be denied for a person detained under ITA unless a less restrictive alternative is identified by the MHD designee and approved by the court. Extension requests may not be denied for youths detained under ITA who have been referred to the children's long-term inpatient program unless a less restrictive alternative is identified by the MHD designee and approved by the court.~~

~~(13) The~~)).

(3) To be paid for an inpatient psychiatric admission, the hospital provider or hospital unit provider must meet the requirements for payment including the applicable general conditions of payment criteria in WAC 182-502-0100.

(4) When billing the agency directly for Washington apple health clients not enrolled in an agency-contracted managed care organization

(MCO) plan, hospitals may use the expedited prior authorization (EPA) process for inpatient psychiatric services that require authorization when the EPA criteria is met.

(a) To meet the EPA criteria, the inpatient admission must:

(i) Be medically necessary;

(ii) Have psychiatric needs as the focus of treatment and not have an acute medical condition;

(iii) Not have a less-restrictive placement available; and

(iv) Be approved or ordered by the professional in charge of the facility.

(b) If the EPA criteria is not met, a hospital may request prior authorization from the agency or the agency's designee.

(5) Authorization of elective, nonemergency, or emergency-related poststabilization services by an agency-contracted MCO plan are subject to federal rules, including 42 C.F.R. 438.114 and 438.210.

(6) When clients enrolled in an agency-contracted MCO plan are involuntarily detained or committed under chapter 71.05 or 71.34 RCW, the stay must be treated as either an emergency or poststabilization service, and authorization must follow the rules found in 42 C.F.R. 438.114.

(7) When a hospital or hospital unit bills the agency directly, the agency pays the administrative day rate and pays for pharmacy services ((~~and~~)), pharmaceuticals, and medically necessary ancillary services, as determined by the agency, for any authorized days that meet the administrative day definition in WAC 182-550-1050 when ((~~all the following conditions are met:~~

~~(a) The client's legal status is voluntary admission;~~

~~(b) The client's condition is no longer medically necessary;~~

~~(c) The client's condition no longer meets the intensity of service criteria;~~

~~(d)~~)) less restrictive alternative treatments are not available, posing a barrier to the client's safe discharge((~~; and~~

~~(e) The hospital or hospital unit and the MHD designee mutually agree that the administrative day is appropriate.~~

~~(14) The hospital provider or hospital unit provider will use the MHD approved due process for conflict resolution regarding medical necessity determinations provided by the MHD designee.~~

~~(15) In order for an MHD designee to implement and participate in a Washington apple health client's plan of care, the hospital provider or hospital unit provider must provide any clinical and cost of care information to the MHD designee upon request. This requirement applies to all Washington apple health clients admitted for:~~

~~(a) Voluntary inpatient psychiatric services; and~~

~~(b) Involuntary inpatient psychiatric services, regardless of payment source.~~

~~(16) If the number of days billed exceeds the number of days authorized by the MHD designee for any claims paid, the agency will recover any unauthorized days paid~~)).

(8) The agency may review paid claims and recoup any improperly paid claims, including determining whether the client did not meet EPA criteria or other conditions of payment. See WAC 182-502-0230 and chapter 182-502A WAC.

WSR 24-09-028
PERMANENT RULES
HEALTH CARE AUTHORITY
[Filed April 10, 2024, 10:15 a.m., effective May 11, 2024]

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

Purpose: The health care authority removed references to the hospital outpatient ratio of costs-to-charges payment method due to the discontinuation of this payment method.

Citation of Rules Affected by this Order: Amending WAC 182-550-4000 and 182-550-4500.

Statutory Authority for Adoption: RCW 41.05.021, 41.05.160.

Adopted under notice filed as WSR 24-06-034 on February 29, 2024.

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

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

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

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 2, Repealed 0.

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

Date Adopted: April 10, 2024.

Wendy Barcus
Rules Coordinator

OTS-5176.1

AMENDATORY SECTION (Amending WSR 14-12-047, filed 5/29/14, effective 7/1/14)

WAC 182-550-4000 Payment method—Out-of-state hospitals. This section describes the payment methods the agency uses to pay hospitals located out-of-state for providing services to eligible Washington apple health clients. This section does not apply to hospitals located in any of the designated bordering cities listed in WAC 182-501-0175. Payment methods that apply to bordering city hospitals, including critical border hospitals, are described in WAC 182-550-3900. See also WAC 182-501-0180, health care services provided outside the state of Washington - General provisions, and WAC 182-502-0120, payment for health care services provided outside the state of Washington.

(1) Emergency hospital services.

(a) For inpatient hospital claims for emergency services provided in out-of-state hospitals, the agency:

(i) Pays using the same methods used to pay in-state hospitals as specified in this chapter; and

(ii) Calculates the payment using the lowest in-state inpatient hospital rate corresponding to the payment method.

(b) For outpatient hospital claims for emergency services provided in out-of-state hospitals, the agency pays an out-of-state hospital using the following methods:

(i) The agency's outpatient prospective payment system (OPPS) described in WAC 182-550-7000; and

(ii) The maximum allowable fee schedule method described in WAC 182-550-6000. When the maximum allowable fee schedule method is used, the agency limits payment to the lesser of the:

(A) Billed charges; or

(B) Calculated payment amount((~~; and~~

~~(iii) The hospital outpatient RCC payment method described in WAC 182-550-4500. When using the RCC payment method, the agency pays the lowest in-state hospital outpatient RCC, excluding weighted costs-to-charges (WCC) rates that are paid to in-state critical access hospitals~~)).

(2) Nonemergency hospital services.

(a) The agency pays for:

(i) Contracted and prior authorized nonemergency hospital services according to the contract terms whether or not the hospital has signed a core provider agreement; and

(ii) Nonemergency hospital services authorized by the agency after the fact (subsequent to the date of admission, if the client is still at the out-of-state hospital, or after the services have been provided) according to subsections (1) and (3) of this section.

(b) The agency does not pay for:

(i) Nonemergency hospital services provided to a Washington apple health client in a hospital located out-of-state unless the hospital is contracted and prior authorized by the agency or the agency's designee for the specific service provided to a specific client; and

(ii) Unauthorized nonemergency hospital services are not paid by the agency. See WAC 182-501-0182.

(3) The agency makes claim payment adjustments including, but not limited to, client responsibility, third-party liability, and medicare. All applicable adjustments are factored into the final hospital payment amount.

AMENDATORY SECTION (Amending WSR 23-20-048, filed 9/28/23, effective 10/29/23)

WAC 182-550-4500 Payment method—Ratio of costs-to-charges (RCC). (1) The medicaid agency pays hospitals using the ratio of costs-to-charges (RCC) payment method for services exempt from the following payment methods:

(a) Ambulatory payment classification (APC);

(b) Diagnosis-related group (DRG);

(c) Enhanced ambulatory patient group (EAPG);

(d) Per case;

(e) Per diem; and

(f) Maximum allowable fee schedule.

(2) The agency:

(a) Determines the payment for((~~:~~

~~(i)~~)) inpatient claims by multiplying the hospital's inpatient RCC by the allowed covered charges for medically necessary services((~~; and~~

~~(ii) Outpatient claims by multiplying the hospital's outpatient RCC by the allowed covered charges for medically necessary services~~)).

(b) Deducts from the amount derived in (a) of this subsection:

(i) All applicable adjustments for client responsibility;

(ii) Any third-party liability;

(iii) Medicare payments; and

(iv) Any other adjustments as determined by the agency.

(c) Limits the RCC payment to the hospital's usual and customary charges for services allowed by the agency.

(3) The agency uses the RCC payment method to calculate the following:

(a) Payment for the following services:

(i) Organ transplant services (see WAC 182-550-4400 (4)(h));

(ii) Hospital services provided at a long-term acute care (LTAC) facility not covered under the LTAC per diem rate (see WAC 182-550-2596); and

(iii) Any other hospital service identified by the agency as being paid by the RCC payment method; and

(b) Costs for the following:

(i) High outlier qualifying claims (see WAC 182-550-3700); and

(ii) Hospital services provided in hospitals eligible for certified public expenditure (CPE) payments under WAC 182-550-4650(5).

(4) When directed by the legislature to achieve targeted expenditure levels, as described in WAC 182-550-3000(8), the agency may apply an inpatient adjustment factor to the inpatient RCC payments made for the services in subsection (3) of this section.

(5) This section explains how the agency calculates each in-state and critical border hospital's RCC. For noncritical border city hospitals, see WAC 182-550-3900. The agency:

(a) Divides adjusted costs by adjusted patient charges. The agency determines the allowable costs and associated charges.

(b) Excludes agency nonallowed costs and nonallowed charges, such as costs and charges attributable to a change in ownership.

(c) Bases the RCC calculation on data from the hospital's annual medicare cost report (Form 2552) and applicable patient revenue reconciliation data provided by the hospital. The medicare cost report must cover a period of 12 consecutive months in its medicare cost report year.

(d) Updates a hospital's inpatient RCC annually after the hospital sends its hospital fiscal year medicare cost report to the centers for medicare and medicaid services (CMS) and the agency. If medicare grants a delay in submission of the CMS medicare cost report to the medicare fiscal intermediary, the agency may determine an alternate method to adjust the RCC.

(e) Limits a noncritical access hospital's RCC to one point zero (1.0).

(6) For a hospital formed as a result of a merger (see WAC 182-550-4200), the agency combines the previous hospital's medicare cost reports and follows the process in subsection (5) of this section. The agency does not use partial year cost reports for this purpose.

(7) For newly constructed hospitals and hospitals not otherwise addressed in this chapter, the agency annually calculates a weighted average in-state RCC by dividing the sum of agency-determined costs for all in-state hospitals with RCCs by the sum of agency-determined charges for all hospitals with RCCs.

WSR 24-09-030
PERMANENT RULES
BELLEVUE COLLEGE
[Filed April 10, 2024, 12:58 p.m., effective May 11, 2024]

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

Purpose: Housekeeping edits to chapter 132H-169 WAC.

Citation of Rules Affected by this Order: Amending WAC 132H-169-025 and 132H-169-035.

Statutory Authority for Adoption: RCW 28B.50.140(13); chapter 34.05 RCW.

Adopted under notice filed as WSR 24-03-048 on January 10, 2024.

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

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

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

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 2, Repealed 0.

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

Date Adopted: April 10, 2024.

Loreen M. Keller
Associate Director
Policies and Special Projects

OTS-5147.1

Chapter 132H-169 WAC
ACCESS TO PUBLIC RECORDS AT BELLEVUE ((~~COMMUNITY~~)) COLLEGE

AMENDATORY SECTION (Amending WSR 19-05-067, filed 2/19/19, effective 3/22/19)

WAC 132H-169-025 Description of college. (1) **Governance.** Bellevue College is a public institution of higher education established under chapter 28B.50 RCW as a community college, which offers associate and baccalaureate degrees. The college is governed by a board of trustees appointed by the governor. The board appoints a president who serves as the chief executive officer responsible for the administration of the college.

(2) **Main campus.** The main campus of the college is located at 3000 Landerholm Circle S.E., Bellevue, Washington. ((~~The college also offers educational programs online and at another campus located at 14673 N.E. 29th Place, Bellevue, Washington.~~))

(3) **Policies and procedures.** College policies meeting the definition of a "rule" under the Administrative Procedure Act, chapter 34.05 RCW, are adopted by the board of trustees and published in Title 132H of the Washington Administrative Code (WAC). Other college policies approved by the administration are published in policies and procedures available on the college website.

(4) **Documents index.** As an institution of higher education, the college generally does not have occasion to issue nonexempt "final orders," "declaratory orders," "interpretive statements," or "policy statements" as those terms are defined and used in the Public Records Act. The secretary of the college's board of trustees does maintain and publish on the college website a documents index of the board's approved meeting minutes, motions, and resolutions. Inquiries may be directed to the secretary of the board in the office of the president.

(5) **College website.** The college's official website, available at ((~~http://www.bellevuecollege.edu/~~)) https://www.bellevuecollege.edu provides general information about the college and its board of trustees, administration, educational programs, and policies and procedures. Persons seeking public records of the college are encouraged to view the records available on the website prior to submitting a records request.

AMENDATORY SECTION (Amending WSR 19-05-067, filed 2/19/19, effective 3/22/19)

WAC 132H-169-035 Public records officer. (1) Designation. A public records officer designated by the college shall be responsible for responding to public records requests in accordance with the provisions of this chapter and applicable provisions of the Public Records Act, chapter 42.56 RCW. The duties of the public records officer under this chapter may be delegated to one or more public records assistants designated by the college.

(2) Duties. The public records officer shall oversee the college's compliance with the Public Records Act. The records officer (or designee) and the college are responsible for providing the fullest assistance to requestors of public records, for ensuring that public records are protected from damage or disorganization, and for preventing records requests from excessively interfering with essential institutional functions or unreasonably disrupting the operations of the college. The college may take reasonable precautions to prevent a requestor from being unreasonably disruptive or disrespectful to college staff.

(3) Records office. Inquiries regarding public records of the college may be addressed to the public records officer at the following address:

Public Records Officer
Bellevue College
3000 Landerholm Circle S.E.
Bellevue, WA 98007
((~~425-564-2451~~)) 425-564-2477
recordsofficer@bellevuecollege.edu

(4) Office hours. The customary office hours of the public records office are from 8:00 a.m. to 5:00 p.m., Monday through Friday, excluding legal holidays.

WSR 24-09-036
PERMANENT RULES
DEPARTMENT OF HEALTH
(Veterinary Board of Governors)
[Filed April 11, 2024, 12:37 p.m., effective May 12, 2024]

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

Purpose: Apprenticeship programs for veterinary technicians. The veterinary board of governors (board) is adopting an amendment to WAC 246-935-060 Eligibility for examination as a veterinary technician, to clarify that a registered apprenticeship program is an approved post-secondary educational pathway to qualify for licensure exams as a veterinary technician.

Citation of Rules Affected by this Order: Amending WAC 246-935-060.

Statutory Authority for Adoption: RCW 18.92.030 and 18.92.128.

Adopted under notice filed as WSR 23-21-094 on October 18, 2023.

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

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

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Date Adopted: April 11, 2024.

Andrea Sanchez-Chambers, DVM, Chairperson
Veterinary Board of Governors

OTS-4597.1

AMENDATORY SECTION (Amending WSR 15-14-008, filed 6/18/15, effective 7/19/15)

WAC 246-935-060 Eligibility for examination as veterinary technician. Applicants must meet one of the following criteria to be eligible for the examination.

(1) Completion of an approved postsecondary educational program for animal or veterinary technology.

(a) Completion of a program for animal or veterinary technology approved by the Committee on Veterinary Technician Education and Activities (CVTEA) of the American Veterinary Medical Association (AVMA). The board approves all institutions accredited by, and in good standing with, the AVMA.

(b) Completion of a program for animal or veterinary technology approved by the Animal Health Technologist/Veterinary Technician Program Accreditation Committee (AHT/VTPAC) of the Canadian Veterinary

Medical Association (CVMA). The board approves all institutions accredited by, and in good standing with, the CVMA.

(c) Completion of a Washington state apprenticeship program registered in accordance with chapters 296-05 WAC and 49.04 RCW.

(d) Other institutions applying for board approval must meet the accreditation standards of the CVTEA. It is the responsibility of the institution to apply for approval and of a student to ascertain whether or not a school has been approved by the board.

((~~(d)~~)) (e) The examination may be taken no sooner than six months before graduation from the approved course of instruction.

(2) Graduation from a two-year curriculum in animal health or veterinary technology which is not accredited by the CVTEA or AHT/VTPAC plus a minimum of ((~~thirty-six~~)) 36 months of full-time experience under the supervision of a licensed veterinarian(s) who must attest to the completion of that experience.

(3) Award of a D.V.M. or V.M.D. degree or equivalent from an American Veterinary Medical Association accredited or listed college of veterinary medicine.

(4) Registration, certification, or licensure as an animal health or veterinary technician in one or more states and ((~~thirty-six~~)) 36 months of full-time experience under the supervision of a licensed veterinarian(s).

(5) Completion of a course in veterinary technician education as a member of the United States military and completion of a tour of active duty as a veterinary technician or specialist.

WSR 24-09-037
PERMANENT RULES
DEPARTMENT OF
SOCIAL AND HEALTH SERVICES
(Aging and Long-Term Support Administration)
[Filed April 11, 2024, 3:45 p.m., effective May 12, 2024]

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

Purpose: WAC 388-106-0336 What services may I receive under the residential support waiver? Adopting added amendments under the community stability supports, under the residential support waiver amendment WA.1086.R01.10. The amendments also include minor language changes for WAC consistency in service language.

Citation of Rules Affected by this Order: Amending WAC 388-106-0336.

Statutory Authority for Adoption: RCW 74.08.090, 74.09.520, 74.39A.030, 74.39A.400; 42 C.F.R. § 441.300-310, and 42 C.F.R. § 441.500-590.

Adopted under notice filed as WSR 24-03-086 on January 17, 2024.

A final cost-benefit analysis is available by contacting Allison K.F. Garza, Department of Social and Health Services, Home and Community Services, 1200 Alder Street, Union Gap, WA 98902, phone 360-239-6906, email allison.garza@dshs.wa.gov.

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

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

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

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 1, Repealed 0.

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

Date Adopted: April 11, 2024.

Lisa N. H. Yanagida
Chief of Staff

SHS-5006.2

AMENDATORY SECTION (Amending WSR 16-19-055, filed 9/16/16, effective 10/17/16)

WAC 388-106-0336 What services may I receive under the residential support waiver? You may receive the following services under the residential support waiver:

(1) Adult family homes and assisted living facilities with an expanded community services contract that will provide:

(a) Personal care;

(b) ((~~Supportive services;~~

~~(c) Supervision in the home and community;~~

~~(d) Twenty-four~~)) 24-hour on-site support and response staff;

((~~(e)~~)) (c) The development and implementation of an individualized behavior support plan to prevent and respond to crises;

((~~(f)~~)) (d) Medication management; and

((~~(g)~~)) (e) Coordination and collaboration with a contracted behavior support provider;

(2) Adult family homes with a specialized behavior support contract that will provide:

(a) Personal care;

(b) ((~~Supportive services;~~

~~(c) Supervision in the home and community;~~

~~(d) Twenty-four-~~)) 24-hour on-site support and response staff;

((~~(e)~~)) (c) The development and implementation of an individualized behavior support plan to prevent and respond to crises;

((~~(f)~~)) (d) Medication management;

((~~(g)~~)) (e) Coordination and collaboration with a contracted behavior support provider; and

((~~(h)~~)) (f) Specialized behavior support that provides you with six to eight hours a day of individualized staff time;

(3) Assisted living facilities with a community stability support contract that will provide:

(a) Personal care;

(b) 24-hour on-site support and response staff;

(c) The development and implementation of an individualized behavior support plan to prevent and respond to crises;

(d) Medication management; and

(e) On-site staffing ratios and professional staffing as described in the contract;

((~~(3)~~)) (4) Enhanced services facilities that will provide:

(a) Personal care;

(b) ((~~Supportive services;~~

~~(c) Supervision in the home and community;~~

~~(d) Twenty-four~~)) 24-hour on-site support and response staff;

((~~(e)~~)) (c) The development and implementation of an individualized behavior support plan to prevent and respond to crises;

((~~(f)~~)) (d) Medication management; and

((~~(g)~~)) (e) On-site staffing ratios and professional staffing as described in WAC 388-107-0230 through ((~~WAC~~)) 388-107-0270;

((~~(4)~~)) (5) Specialized durable and nondurable medical equipment and supplies under WAC 182-543-1000 when:

(a) Medically necessary under WAC 182-500-0005;

(b) Necessary:

(i) For life support;

(ii) To increase your ability to perform activities of daily living; or

(iii) To perceive, control, or communicate with the environment in which you live;

(c) Directly medically or remedially beneficial to you;

(d) They are additional and do not replace any medical equipment or supplies otherwise provided under medicaid, or medicare, or both; and

(e) In addition to and do not replace the services required by the department's contract with a residential facility;

((~~(5)~~)) (6) Client support training to address your needs identified in your CARE assessment or other professional evaluation that are additional and do not replace the services required by the department's contract with the residential facility and meet a therapeutic goal, such as:

(a) Adjusting to a serious impairment;

(b) Managing personal care needs; or

(c) Developing necessary skills to deal with care providers;

((~~(6)~~)) (7) Nurse delegation under RCW 18.79.260 when:

(a) You receive personal care from a registered or certified nursing assistant who has completed nurse delegation core training;

(b) The delegating nurse considers your medical condition stable and predictable;

(c) The services comply with WAC 246-840-930; and

(d) The services are additional and do not replace the services required by the department's contract with the residential facility;

((~~(7)~~)) (8) Skilled nursing when:

(a) Provided by a registered nurse or licensed practical nurse under a registered nurse's supervision;

(b) Beyond the amount, duration, or scope of medicaid-reimbursed home health services as provided under WAC 182-551-2100; and

(c) Additional and do not replace the services required by the department's contract with the residential facility;

((~~(8)~~)) (9) Nursing services not already received from another resource, based on your individual need as determined by your CARE assessment and any additional collateral contact information obtained by your case manager, including any one or more of the following activities performed by a registered nurse:

(a) Nursing assessment/reassessment;

(b) Instruction to you, your providers, and your caregivers;

(c) Care coordination and referral to other health care providers;

(d) Skilled treatment, only in the event of an emergency as in nonemergency situations, the nurse will refer the need for any skilled medical or nursing treatments to a health care provider or other appropriate resource;

(e) File review; or

(f) Evaluation of health-related care needs affecting service plan and delivery;

((~~(9)~~)) (10) Adult day health services as described in WAC 388-71-0706 when:

(a) Your CARE assessment shows an unmet need for personal care or other core services, whether or not those needs are otherwise met; and

(b) Your CARE assessment shows an unmet need for skilled nursing under WAC 388-71-0712 or skilled rehabilitative therapy under ((~~WAC~~)) 388-71-0714 and:

(i) There is a reasonable expectation that the services will improve, restore, or maintain your health status, or in the case of a progressive disabling condition, will either restore or slow the decline of your health and functional status or ease related pain and suffering;

(ii) You are at risk for deteriorating health, deteriorating functional ability, or institutionalization; or

(iii) You have a chronic acute health condition that you are not able to safely manage due to a cognitive, physical, or other functional impairment.

WSR 24-09-051
PERMANENT RULES
DEPARTMENT OF HEALTH
(Pharmacy Quality Assurance Commission)
[Filed April 15, 2024, 11:04 a.m., effective May 16, 2024]

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

Purpose: Updating reference to United States Pharmacopeia (USP) General Chapters 795 and 797. The pharmacy quality assurance commission (commission) adopted a revision to WAC 246-945-100 Compounding minimum standards, to update the rule to the most recent version of the USP - National Formulary <795> and <797>. This will capture the revisions to the USP <795> and <797>, which have been made official since WAC 246-945-100 became effective on July 1, 2020.

Citation of Rules Affected by this Order: Amending WAC 246-945-100.

Statutory Authority for Adoption: RCW 18.64.005.

Adopted under notice filed as WSR 23-22-035 on October 23, 2023.

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

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

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

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 1, Repealed 0.

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

Date Adopted: April 15, 2024.

Ken Kenyon, PharmD, BCPS, Chair
Pharmacy Quality Assurance Commission

OTS-4925.1

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-100 Compounding minimum standards. (1) All licensees of the commission must comply, at a minimum, with the following chapters of the United States Pharmacopeia (USP) when engaged in compounding nonsterile and sterile products for patient administration or distribution to a licensed practitioner for patient use or administration:

(a) USP General Chapter <795> Pharmaceutical Compounding - Nonsterile Preparations, official as of November 1, 2023;

(b) USP General Chapter <797> Pharmaceutical Compounding - Sterile Preparations, official as of November 1, 2023;

(c) USP General Chapter <800> Hazardous Drugs - Handling in Healthcare Settings; and

(d) USP General Chapter <825> Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging.

(2) Copies of the USP General Chapters listed in subsection (1) of this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501. Requestors may also contact USP directly to obtain copies.

WSR 24-09-057
PERMANENT RULES
STATE BOARD OF EDUCATION
[Filed April 15, 2024, 2:01 p.m., effective May 16, 2024]

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

Purpose: In response to the COVID-19 pandemic, the state board of education (SBE) adopted emergency rules for an emergency waiver program that permitted districts and other local educational agencies to waive graduation requirements for individual students. The purpose of the waiver program was to provide a last resort option to allow students whose education had been disrupted by the pandemic to graduate. SBE later adopted permanent rules and extended the waiver to allow for qualifying students graduating in 2022-23 to waive two credit graduation requirements and the pathway requirement, and for students graduating in 2023-24 to waive one credit graduation requirement. The purpose of current rule making is to modify the emergency waiver for students graduating in the 2023-24 school year to allow a waiver of the graduation pathway requirement with certain limitations. This change responds to public comments received by SBE from parents, students, and educators that student learning and the opportunity to access graduation pathway requirement options continued to be disrupted due to the COVID-19 pandemic for students planning to graduate in 2023-24.

Citation of Rules Affected by this Order: Amending WAC 180-111-050.

Statutory Authority for Adoption: RCW 28A.230.090, 28A.150.220(7).

Adopted under notice filed as WSR 24-03-134 on January 23, 2024.

Changes Other than Editing from Proposed to Adopted Version: Changes were made to clarify the rules consistent with the intent of the proposed rules. Public comment and testimony indicated that some people were confused by wording of the proposed rules. The changes were intended to clarify the applicability of the waiver for students who may need both a credit and a pathway waived.

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

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

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

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

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

Date Adopted: April 11, 2024.

Randy Spaulding
Executive Director

OTS-5135.2

AMENDATORY SECTION (Amending WSR 22-12-025, filed 5/23/22, effective 6/23/22)

WAC 180-111-050 Emergency waiver of certain graduation requirements in response to novel coronavirus. This section is for the novel coronavirus emergency, in response to the gubernatorial declaration of emergency on February 29, 2020. It applies to the classes of 2020 through 2024 beginning in the 2020-21 school year. Beginning from the date of approval of a school district's emergency waiver application, in accordance with WAC 180-111-040:

(1) Waived credit graduation requirements are limited to the student's classes impacted by the novel coronavirus disruption. The school district shall prioritize student completion of core coursework and coursework related to the student's high school and beyond plan under RCW 28A.230.090. School districts may waive credits for eligible students in the classes of 2020 to 2024. In addition to existing waiver authorities as described in WAC 180-111-040 (2)(a):

(a) For the classes of 2020 to 2023, school districts may waive up to two additional credits under this emergency waiver, provided that students graduate with no fewer than a total of 20 credits.

(b) For the class of 2024, school districts may waive up to one additional credit under this emergency waiver, provided that students graduate with no fewer than a total of 21 credits.

(2) For the class of 2020, 2021, 2022, and 2023: The emergency waiver may be applied to core credits or flexible credits, provided that no more than one credit in each core subject area is waived. The terms "core" and "flexible credits" used in this section are defined in WAC 180-51-210.

(3) For the class of 2024: The emergency waiver may be applied to core or flexible credits.

(4) A student's graduation pathway requirement, as outlined in WAC 180-51-230, may be waived for eligible students in the classes of 2020 to ((~~2023~~)) 2024 after a school district has made a good faith effort to help the student meet their pathway requirement, as defined in WAC 180-111-020. For students graduating in 2024, the district may waive the graduation pathway requirement with the following limitations:

(a) If a student receives an emergency waiver of up to one mathematics credit, the student must meet a mathematics pathway option; and

(b) If a student receives an emergency waiver of up to one English credit, the student must meet an English pathway option.

(5) The graduation pathway requirement may also be waived for a student so that the student may earn a diploma before their planned graduation year, provided that:

(a) The student may not be granted an emergency waiver of credit requirements; and

(b) The student must meet all other state graduation requirements including credit requirements under WAC 180-51-210.

(6) This emergency waiver may apply to individual students participating in the international baccalaureate diploma programme as defined in RCW 28A.230.122 to enable these students to earn a Washington high school diploma.

(7) Schools operating under the waiver defined in WAC 180-18-055 may waive graduation requirements in a manner consistent with this section.

WSR 24-09-061
PERMANENT RULES
DEPARTMENT OF
LABOR AND INDUSTRIES

[Filed April 16, 2024, 9:40 a.m., effective May 17, 2024]

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

Purpose: The department of labor and industries (L&I) received a petition requesting L&I engage in rule making to update the language in WAC 296-305-03002 Hazardous materials. There have been many technological advances in the years since this WAC code was written, including in personal protective equipment (PPE) materials, certification, and testing. The adopted rule updates the required standards for hazardous materials protective equipment. The current rule requires compliance with the following National Fire Protection Association (NFPA) standards for hazard material protective equipment: NFPA 1991 (2000 edition), NFPA 1992 (2000 edition), and NFPA 1994 (2001 edition). The adopted rule updates the requirements to the NFPA 1990 (2022 edition), which is a consolidation of the currently referenced NFPA standards and the current edition. As requested in the petition, the adopted rule allows an exemption from the requirement that protective ensembles and liquid splash-protective ensembles completely cover the wearer's respiratory protection when respiratory protection meets the National Institute for Occupational Safety and Health chemical, biological, radiological, and nuclear self-contained breathing apparatus testing.

WAC 296-305-04001 Respiratory equipment protection, which has guidance for breathing air quality for firefighters, was also updated. The reference to ANSI/CGA G6-1, Commodity Specification for Air, needed to be updated to fix a typo in the standard number.

Citation of Rules Affected by this Order: Amending WAC 296-305-03002 and 296-305-04001.

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

Adopted under notice filed as WSR 24-03-149 on January 23, 2024.

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

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

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

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

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

Date Adopted: April 16, 2024.

Joel Sacks
Director

OTS-4787.2

AMENDATORY SECTION (Amending WSR 18-22-116, filed 11/6/18, effective 12/7/18)

WAC 296-305-03002 Hazardous materials. (1) Fire department personnel involved in hazardous materials incidents must be protected against potential chemical hazards. Chemical protective clothing must be selected according to the technical data package provided by the clothing manufacturer and used to protect the skin, eyes, face, hands, feet, head and body.

(2) Fire departments must select, provide, and require the use of additional personal protective equipment as required in chapter 296-842 WAC, Respiratory protection.

(3) ((~~Hazardous chemical protective equipment must be classified by performance and is defined as:~~

~~(a) Vapor-protective suits (level A) meeting the criteria outlined in the 2000 edition of NFPA 1991, Standard on Vapor-Protective Ensembles for Hazardous Materials Emergencies.~~

~~(b) Liquid splash-protective suits (level B) meeting the criteria outlined in the 2000 edition of NFPA 1992, Standard on Liquid Splash-Protective Ensembles and Clothing for Hazardous Materials Emergencies.~~

~~(c) CBRN terrorism incident protective ensembles and ensemble elements meeting the criteria outlined in the 2001 edition of NFPA 1994, Standard on Protective Ensembles for First Responders to CBRN Terrorism Incidents.~~)) Protective ensembles for hazardous materials and CBRN operations must meet the design and performance criteria outlined in the 2022 edition of NFPA 1990.

(4) Vapor protective ensembles, liquid splash-protective ensembles, and CBRN protective ensembles must completely cover both the wearer and the wearer's respiratory protection unless the respiratory protection has been specifically designed by the manufacturer for that type of chemical exposure, or meet the Statement of Standard for NIOSH CBRN SCBA Testing.

(5) Vapor protective suits and liquid splash-protective suits must not be used alone for any firefighting applications or for protection from radiological, biological, or cryogenic agents or in flammable or explosive atmospheres.

(6) Liquid splash-protective suits must not be used when operations are likely to result in significant exposure to chemicals or specific chemical mixtures with known or suspected carcinogenicity as indicated by any one of the following documents if it can be reasonably expected that the firefighters in vapor-protective suits would be significantly better protected:

(a) Dangerous Properties of Industrial Chemicals, 10th edition-2000, N. Irving Sax.

(b) NIOSH Pocket Guide to Chemical Hazards, 2006 edition.

(c) U.S. Coast Guard Chemical Hazard Response Information System (CHRIS), Volume 13, Hazardous Chemical Data.

(7) Liquid splash-protective suits must not be used when operations are likely to result in significant exposure to chemicals or specific chemical mixtures with skin toxicity notations as indicated by the American Conference of Government Industrial Hygienists (ACGIH) Threshold Limit Values for Chemical Substances and Agents and Biological Exposure Indices for 2004 or 2007 if it can be reasonably expected that firefighters in vapor-protective suits would be significantly better protected.

(8) Firefighters assigned to functional support operations outside the hot zone during hazardous chemical emergencies must be provi-

ded with and must use personal protective garments appropriate for the type of potential chemical hazard exposure.

(9) Fire departments responding to uncontrolled release of hazardous materials must comply with chapter 296-824 WAC, Emergency response.

AMENDATORY SECTION (Amending WSR 18-22-116, filed 11/6/18, effective 12/7/18)

WAC 296-305-04001 Respiratory equipment protection. (1) Firefighter's self-contained breathing apparatus (SCBA) must, at a minimum, meet the requirements of the 1997 edition of NFPA 1981, Standard on Open-Circuit Self-Contained Breathing Apparatus for Fire Fighters. Equipment purchased after the effective date of this rule must meet the 2007 edition of NFPA 1981, Standard on Open-Circuit Self-Contained Breathing Apparatus for Emergency Services.

(2) Closed circuit SCBA must:

(a) Be positive pressure;

(b) Be NIOSH certified; and

(c) Have a minimum ((~~thirty~~)) 30-minute service duration.

(3) Members using SCBAs must operate in teams of two or more.

(4) Except as otherwise provided in this chapter, fire departments must adopt, maintain and implement a written respiratory protection program that addresses the requirements of chapter 296-842 WAC, Respiratory protection. This includes program administration, medical limitations, equipment limitations, equipment selection, inspection, use, maintenance, training, fit testing procedures, air quality, and program evaluation.

Note: Additional information on respirators and respirator usage can be found in ANSI Z88.2 - American National Standard for Respiratory Protection and various NFPA publications (1981, 1404, 1500, etc.).

(5) Reserved.

(6) When the fire department makes its own breathing air or uses vendor supplied breathing air, they must maintain documentation certifying breathing air quality. The breathing air must:

(a) Be tested at least quarterly by using an air sample taken from the same outlet and in the same manner as the respirator breathing air cylinders are filled or air line respirators are connected.

(b) Meet the requirements of either the 2003 edition of NFPA 1989, Standard on Breathing Air Quality for Fire and Emergency Services Respiratory Protection or the 1997 edition of ANSI/CGA ((~~G6-1~~)) G7-1 - Commodity Specification for Air, with a minimum air quality of grade D.

(c) Meet a water vapor level of 24 ppm or less.

(7) Fit testing must be conducted in accordance with this section and chapter 296-842 WAC, Respiratory protection.

(a) Each new member shall be tested by a qualitative or quantitative method before being permitted to use SCBA's in a hazardous atmosphere.

(b) Only firefighters with a properly fitting facepiece must be permitted by the fire department to function in a hazardous atmosphere with SCBA.

(c) Fit testing must be repeated:

(i) At least once every ((~~twelve~~)) 12 months.

(ii) Whenever there are changes in the type of SCBA or facepiece used.

(iii) Whenever there are significant physical changes in the user. Example: Weight change of ((~~ten~~)) 10 percent or more, scarring of face seal area, dental changes, cosmetic surgery, or any other condition that may affect the fit of the facepiece seal.

(d) The fit testing is done only in a negative-pressure mode. If the facepiece is modified for fit testing, the modification must not affect the normal fit of the device. Such modified devices must only be used for fit testing.

(e) The fit test procedures and test exercises described in WAC 296-842-15005 and 296-842-22010 must be followed unless stated otherwise in this chapter.

(f) Respirator fit test records must include:

(i) Written guidelines for the respirator fit testing program including pass/fail criteria;

(ii) Type of respirator tested including manufacturer, model, and size;

(iii) Type of fit test and instrumentation or equipment used;

(iv) Name or identification of test operator;

(v) Name of person tested;

(vi) Date of test; and

(vii) Results of test.

Note: Firefighters should be issued individual facepieces.

(8) Facial hair, contact lenses, and eye and face protective devices.

(a) A negative pressure respirator, any self-contained breathing apparatus, or any respirator which is used in an atmosphere immediately dangerous to life or health (IDLH) equipped with a facepiece must not be worn if facial hair comes between the sealing periphery of the facepiece and the face or if facial hair interferes with the valve function.

(b) The wearer of a respirator must not be allowed to wear contact lenses if the risk of eye damage is increased by their use.

(c) If corrective lenses must be worn with a facepiece, they must be worn so as to not adversely affect the seal of the facepiece to the face. See WAC 296-842-18005(3).

(d) Straps or temple bars must not pass between the seal or surface of the respirator and the user's face.

(9) At the end of suppression activities (to include fire overhaul) and before returning to quarters:

(a) Gross/field decontamination must be performed on firefighters prior to removal of their respirator whenever firefighting activities resulted in exposure to a hazardous substance.

(b) When exchanging air supply bottles during suppression or overhaul activities, reasonable precautions must be taken to maintain uncontaminated atmosphere to the breathing zone and facepiece supply hose.

(10) Self-contained respiratory equipment must be available and used by all firefighters who enter into hazardous atmospheres during structural firefighting activities.

(11) Reserved.

(12) Respirators must be provided for, and shall be used by, all personnel working in areas where:

(a) The atmosphere is hazardous;

(b) The atmosphere is suspected of being hazardous; or

(c) The atmosphere may rapidly become hazardous.

Reference: See WAC 296-305-05002(13) for additional requirements.

(13) Reserved.

(14) Firefighters using a properly functioning SCBA must not compromise the protective integrity of the SCBA by removing the facepiece for any reason in hazardous atmospheres or in atmospheres where the quality of air is unknown.

(15) Firefighters must receive training for each type and manufacturer of respiratory equipment available for their use, the step-by-step procedure for donning the respirator and checking it for proper function. Required training must include:

(a) Recognizing hazards that may be encountered;

(b) Understanding the components of the respirator;

(c) Understanding the safety features and limitations of the respirator; and

(d) Donning and doffing the respirator.

(16) After completing such training, each firefighter must practice at least quarterly, for each type and manufacture of respirator available for use, the step-by-step procedure for donning the respirator and checking it for proper function.

(17) Members must be tested at least annually on the knowledge of respiratory protection equipment operation, safety, organizational policies and procedures, and facepiece seals, to the fire department's standard. Such records must remain part of the member training file.

(18) Members must be allowed to use only the make, model, and size respirator for which they have passed a fit test within the last ((~~twelve~~)) 12 months.

(19) In cases where there is a reported failure of a respirator, it must be removed from service, tagged and recorded as such, and tested before being returned to service.

(20) Firefighters must be thoroughly trained in accordance with the manufacturer's instructions on emergency procedures such as use of regulator bypass valve, corrective action for facepiece and breathing tube damage, and breathing directly from the regulator (where applicable).

(21) Reserved.

(22) SCBA cylinders must be hydrostatically tested within the periods specified by the manufacturer and the applicable governmental agencies.

WSR 24-09-070
PERMANENT RULES
DEPARTMENT OF AGRICULTURE
[Filed April 16, 2024, 1:56 p.m., effective May 17, 2024]

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

Purpose: This rule-making order amends chapter 16-218 WAC, Hops—Certification analyses—Fees. In response to a requirement set by the United States Department of Agriculture's (USDA) Federal Grain Inspection Service (FGIS) under Directive 9100.07 issued on July 19, 2023, the department of agriculture (department) is proposing to amend chapter 16-218 WAC by adding clarifying language which identifies Commodity Cooperative Service Agreement Fees and Agricultural Marketing Act (AMA), as separate line items from the unit fees charged for each service.

The department's hop inspection program facilitates trade in domestic and international markets by providing unbiased, third-party sampling, weighing, quality testing, and grade inspection under an official delegation by USDA, Agricultural Marketing Service, FGIS (USDA-AMS-FGIS). As an official delegate, the department must comply with USDA requirements in order to provide these services.

USDA-AMS-FGIS has notified all delegates that they need to update their rule language to reflect required language pertaining to federal administrative and supervision fees. The department is required to collect these federal oversight fees when providing services and provide them to USDA-AMS-FGIS. Previously, these fees were included in the unit fee rate. With the rule change, these fees will be identified as a separate line item on invoices.

Citation of Rules Affected by this Order: New WAC 16-218-050.

Statutory Authority for Adoption: RCW 22.09.020 and 22.09.790.

Adopted under notice filed as WSR 24-04-084 on February 5, 2024.

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

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

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

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

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

Date Adopted: April 16, 2024.

Derek I. Sandison
Director

OTS-5175.1

NEW SECTION

WAC 16-218-050 Commodity cooperative service agreement fees. In addition to all other applicable fees, commodity cooperative service agreement fees for commodity inspection services (pulses, hops, and miscellaneous processed commodities), excluding rice, will be assessed at the current percentage rate identified in Federal Grain Inspection Service (FGIS) Directive 9180.74 (Service Fees and Billing Codes, Attachment 4). The assessed fees must exclude travel, mailing expenses, and state and local taxes. Invoices will identify assessed commodity cooperative service agreement fees as separate line items.

WSR 24-09-079
PERMANENT RULES
DEPARTMENT OF AGRICULTURE
[Filed April 17, 2024, 9:59 a.m., effective May 18, 2024]

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

Purpose: This rule-making order establishes chapter 16-309 WAC, Cannabis laboratory accreditation standards program, by:

1. Creating education and training requirements for laboratory personnel, which depend on position, or testing responsibilities (WAC 16-309-050 through 16-309-080).

2. Requiring standard operating procedure (SOP) criteria for all laboratory testing (WAC 16-309-090).

3. Requiring sampling and homogenization protocols for sample preparation (WAC 16-309-100).

4. Requiring security and safety protocols for the laboratory and laboratory staff (WAC 16-309-110).

5. Requiring the use of quality control and assurance protocols for laboratory testing (WAC 16-309-120).

6. Establishing facilities and equipment maintenance criteria for the laboratory (chapter 16-130 WAC).

7. Establishing method performance criteria for laboratory testing (WAC 16-309-140).

8. Establishing quality control and method performance criteria specific to each required test: Water activity testing; cannabinoid concentration analysis; foreign matter inspection; microbiological testing; residual solvent testing; mycotoxin testing; pesticide testing; and heavy metals testing (WAC 16-309-140 through 16-309-210).

9. Establishing required standardized testing procedures for cannabinoid concentration analysis, residual solvents testing, and heavy metals testing (WAC 16-309-160, 16-309-190, and 16-309-220).

10. Establishing quality control and method performance criteria for analyte testing outside of product testing requirements as established by the liquor and cannabis board (LCB) (WAC 16-309-230).

11. Creating laboratory computers and information system requirements (WAC 16-309-240).

12. Establishing method validation criteria for laboratory testing (WAC 16-309-2640).

13. Establishing a process by which laboratories can submit their own methods for approval (WAC 16-309-250).

14. Establishing minimum proficiency testing standards for laboratories (WAC 16-309-270).

15. Establishing certificate of analysis report requirements (WAC 16-309-280).

16. Establishing procurement protocols for the selection and purchasing of services and supplies for the laboratory (WAC 16-309-290).

17. Establishing sample subcontracting requirements for third party services (WAC 16-309-300).

Citation of Rules Affected by this Order: New WAC 16-309-010, 16-309-020, 16-309-030, 16-309-040, 16-309-050, 16-309-060, 16-309-070, 16-309-080, 16-309-090, 16-309-100, 16-309-110, 16-309-120, 16-309-130, 16-309-140, 16-309-150, 16-309-160, 16-309-170, 16-309-180, 16-309-190, 16-309-200, 16-309-210, 16-309-220, 16-309-230, 16-309-240, 16-309-250, 16-309-260, 16-309-270, 16-309-280, 16-309-290, and 16-309-300.

Statutory Authority for Adoption: RCW 15.150.030.

Other Authority: Chapter 135, Laws of 2022.

Adopted under notice filed as WSR 24-05-079 on February 21, 2024.

Changes Other than Editing from Proposed to Adopted Version: References to WAC 314-55-102 were replaced with references to chapter 314-55 WAC in response to feedback received from LCB. The term "iCAL" was replaced by the full term, "Initial Calibration."

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 30, Amended 0, Repealed 0.

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

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

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

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

Date Adopted: April 16, 2024.

Derek I. Sandison
Director

OTS-4989.7

Chapter 16-309 WAC
CANNABIS LABORATORY ACCREDITATION STANDARDS PROGRAM

NEW SECTION

WAC 16-309-010 Purpose of chapter. Under the authority of chapter 15.150 RCW, the department adopts rules to establish and maintain quality standards for laboratories conducting analysis of recreational and medicinal cannabis. The standards are the elements used in the evaluation of a product's compliance with established product standards. These rules consist of method approval, method validation protocols, and performance measures and criteria applied to the testing of the product.

NEW SECTION

WAC 16-309-020 Definitions. "Accessioning" means the process of receiving and organizing samples for testing in a laboratory.

"Accreditation" means the formal recognition by the accrediting authority that a cannabis laboratory is capable of producing accurate and defensible analytical data. This recognition is signified by the issuance of a written certificate, accompanied by a scope of accredi-

tation indicating the parameters for which the laboratory is accredited.

"Accreditation year" means the one-year period as stated on the certificate of accreditation.

"Accrediting authority" means the recognized agency that has the authority to perform audits and inspections to assure laboratories meet the standards established in rule and will issue, suspend, or revoke accreditation to the laboratory.

"Accuracy" means the degree to which an analytical result corresponds to the true or accepted value for the sample being tested. Accuracy is affected by bias and precision.

"Action level" means the level of concern, decision point, cut-off, or target level for an analyte that must be reliably identified or quantified to be considered positive in a sample.

"Aliquot" means a portion of a larger whole, especially a sample taken for chemical analysis or other treatment.

"Analyte" means the constituent or property of a sample measured using an analytical method.

"Analytical batch" means a group of samples, standards, and blanks which are analyzed together with the same method sequence and same lots of reagents and with the manipulations common to each sample within the same time period usually no more than 24 hours. Batch size is usually limited to instrument loading capacity.

"Analytical data" means the recorded qualitative and/or quantitative results of a chemical, physical, biological, microbiological, radiochemical, or other scientific determination.

"Analytical method" means a written procedure for acquiring analytical data.

"Autoclave" means a steam sterilizer device that is intended for use by a laboratory to sterilize biohazardous products by means of pressurized steam.

"Bias" means the difference between the expectation of the test result and the true value or accepted reference value. Bias is the total systematic error, and there may be one or more systematic error components contributing to the bias.

"Biohazardous" means products that are infectious, and sharps materials such as needles and broken glass.

"Biosafety cabinet (BSC)" means biocontainment equipment used in biological laboratories to provide personnel, environmental, and product protection.

"Blank" means a substance that does not contain the analytes of interest and is subjected to the usual measurement process. Blanks can be further classified as method blanks, matrix blanks, reagent blanks, system blanks, and field blanks. Response for target analytes must be less than 50 percent of the limit of quantitation.

"Board" means the Washington state liquor and cannabis board.

"Calibration" means determination of the relationship between the observed analyte signal generated by the measuring/detection system and the quantity of analyte present in the sample measured. Typically, this is accomplished through the use of calibration standards containing known amounts of analyte.

"Calibration curve" means the functional relationship between instrument response and target analyte concentration determined for a series of calibration standards. The calibration curve is obtained by plotting the instrument response versus concentration and performing a regression analysis of the data.

"Calibration standard (CalS)" means a known amount or concentration of analyte used to calibrate the measuring/detection system. May be matrix matched for specific sample matrices.

"Cannabis laboratory analytical standards program (CLASP)" means the interagency coordination team for cannabis laboratory quality standards. The team consists of the department of agriculture (WSDA), the liquor and cannabis board (LCB), and the department of health (DOH). The WSDA is the designated lead agency for the team.

"Cannabis laboratory" or "laboratory" means a facility:

(a) Under the ownership and technical management of a single entity in a single geographical location;

(b) Where scientific determinations are performed on samples taken from cannabis plants and products; and

(c) Where data is submitted to the customer or regulatory agency, or other entity requiring the use of an accredited laboratory under provisions of a regulation, permit, or contractual agreement.

"Carryover" means residual analyte from a previous sample or standard which is retained in the analytical system and measured in subsequent samples. Also called memory.

"Certified reference material (CRM)" means a reference material accompanied by documentation (certificate) issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceability, using valid procedures.

Note: Standard reference material (SRM) is the trademark name of CRMs produced and distributed by the National Institute of Standards and Technology (NIST).

"Certifying scientist" means the person authorized by the scientific director to review the analytical results and issue the certificate of analysis for cannabis samples who has the education, training, and competencies to perform such duties. No certifying duties may be performed by any technical personnel directly involved with the conduct of the analytical findings or testing.

"Clean room" means an isolated environment, strictly controlled with respect to: Airborne particles of viable and nonviable nature, temperature, humidity, air pressure, air flow, air motion, and lighting.

"Continuing calibration verification standard (CCV)" means one of the primary calibration standards used to verify the acceptability of an existing calibration.

"Control" means a sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

"Corrective action" means the process of identifying and eliminating the cause of a problem to prevent it from happening again.

"Cut-off concentration" means, in qualitative analysis, the concentration of the analyte that is either statistically lower than the level of concern (for limit tests) or at which positive identification ceases (for confirmation of identity methods).

"Decision point" means the level of concern, action level, cut-off, or target level for an analyte that must be reliably identified or quantified to be considered positive in a sample.

"Department" means the state of Washington department of agriculture when the term is not followed by another state designation.

"High complexity testing" means laboratory tests that require a level of expertise to perform the test due to the complexity of the test methodology and the risk of erroneous results. These tests require a higher level of scientific knowledge and experience, trouble-shooting skills, and quality control checks.

"Initial calibration blank (ICB)" means an aliquot that consists of the same solvent used for the calibration standards, but without the analytes, analyzed following the initial calibration and prior to quantitating any samples to verify the absence of instrumental interferences.

"Initial calibration verification (ICV)" means a second source standard that is used to verify the correctness of the primary source calibration curve. This standard is initially analyzed prior to sample analysis.

"Incubation" means the act of storing microorganisms at a predetermined temperature, for a predetermined amount of time, to allow for growth of microorganism colonies.

"Inoculation" means the act of introducing microbes into a culture media to induce reproductive growth.

"Interference" means a positive or negative response or effect on response produced by a substance other than the analyte. Includes spectral, physical, and chemical interferences which result in a less certain or accurate measurement of the analyte.

"Intermediate precision" means within-laboratory precision obtained under variable conditions, e.g., different days, different analysts, and/or different instrumentation.

"Internal standard (IS)" means a chemical added to the sample, in known quantity, at a specified stage in the analysis to facilitate quantitation of the analyte. Internal standards are used to correct for matrix effects, incomplete spike recoveries, etc. Analyte concentration is deduced from its response relative to that produced by the internal standard. The internal standard must have similar physiochemical properties to those of the analyte.

"Laboratory control sample (LCS)" means a portion of respective matrix blank that is spiked with known quantities of target analytes and processed as if it were a sample. The LCS is used to evaluate the accuracy of the methodology.

"Laboratory information management system (LIMS)" means a computer software system that is used to collect information about a sample, track results through the testing process, and disseminate the final results to the customer and regulating agency.

"Limit" means a point or level beyond which something does not or may not exceed or pass. Something that bounds, restrains, or confines to the utmost extent. Limits are used to define a specific concept in analysis. Decision points and action levels are examples of limits.

"Limit of detection (LOD)" means the minimum amount or concentration of analyte that can be reliably distinguished from zero. The term is usually restricted to the response of the detection system and is often referred to as the detection limit. When applied to the instrument capability it is known as an instrument detection limit (IDL) or when applied to the complete analytical method it is often referred to as the method detection limit (MDL).

"Limit of quantitation (LOQ)" means the minimum amount or concentration of analyte in the test sample that can be quantified with acceptable precision and accuracy. Limit of quantitation (or quantification) is variously defined but must be a value greater than the MDL and applies to the complete analytical method.

"Linearity" means the ability of a method, within a certain range, to provide an instrumental response or test results proportional to the quantity of analyte to be determined in the test sample.

"Low complexity testing" means laboratory tests that require little to no expertise to perform the test due to the lack of complexity

of the test methodology and the low risk of erroneous results. These tests require a low level of scientific knowledge and experience, troubleshooting skills, and quality control checks.

"Matrix" means the material to be analyzed including, but not limited to, flower, trim, leaves, other plant matter, cannabis concentrate, cannabis infused, and edibles.

"Matrix blank" means a substance that closely matches the samples being analyzed with regard to matrix components. Ideally, the matrix blank does not contain the analyte(s) of interest but is subjected to all sample processing operations including all reagents used to analyze the test samples. The matrix blank is used to determine the absence of significant interference due to matrix, reagents, and equipment used in the analysis.

"Matrix effect" means an influence of one or more components from the sample matrix on the measurement of the analyte concentration or mass. Matrix effects may be observed as increased or decreased detector responses, compared with those produced by simple solvent solutions of the analyte.

"Matrix spike (MS)" means an aliquot of a sample prepared by adding a known amount of analyte(s) to a specified amount of matrix. A matrix spike is subjected to the entire analytical procedure to establish if the method is appropriate for the analysis of a specific analyte(s) in a particular matrix. Also referred to as a laboratory fortified matrix.

"Matrix spike duplicate (MSD)" means a replicate of a sample that has known concentrations of analytes added to it. It is used to evaluate the precision and bias of a method for a specific sample matrix. A matrix spike duplicate is processed along with the same sample batch and follows the same sample preparation and analytical testing.

"Method" means a particular procedure that systematically describes how a cannabis test is performed and analyzed.

"Method validation" means the process of demonstrating or confirming that a method is suitable for its intended purpose. Validation criteria include demonstrating performance characteristics such as accuracy, precision, selectivity, limit of detection, limit of quantitation, linearity, range, ruggedness, and robustness.

"Method validation report" means documentation generated detailing the evidence which established the suitability of the method for its intended use.

"Moderate complexity testing" means laboratory tests that require a level of expertise to perform the test due to the complexity of the test methodology and the risk of erroneous results. These tests require a moderate level of scientific knowledge and experience, troubleshooting skills, and quality control checks.

"Parameter" means the combination of one or more analytes determined by a specific analytical method.

"Performance criteria" means defined, measurable performance characteristics of an analytical method or process-specific requirements for accuracy, precision, recovery, specificity (selectivity), sensitivity (limits of detection), inclusivity, exclusivity, linearity, range, and scope of application. Criteria may also be set by defining process (i.e., method validation protocols).

"Performance-based methods approach" means or conveys "what" needs to be accomplished, but not prescriptively "how" to do it. It is a measurement system based upon established performance criteria for accuracy and precision with use of analytical test methods. Under this measurement system, laboratories must demonstrate that a particular

analytical test method is acceptable for demonstrating compliance. Performance-based method criteria may be published in regulations, technical guidance documents, permits, work plans, or enforcement orders.

"Precision" means the closeness of agreement between independent test results obtained under specified conditions. This is described by statistical methods such as a standard deviation or confidence limit of test results. See also "random error." Precision can be further classified as repeatability, intermediate precision, and reproducibility.

"Preparation batch" means samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A preparation batch consists of one to 20 samples (not including matrix blanks, LCS, matrix spikes and matrix duplicates) of the same matrix.

"Proficiency testing (PT)" means evaluation of the results from the analysis of samples, the true values of which are known to the supplier of the samples but unknown to the laboratory conducting the analyses.

"Proficiency testing provider" means a third-party company, organization, or entity not associated with certified laboratories or a laboratory seeking certification that is approved by the department and provides samples for use in PT testing.

"Qualitative analysis/method" means analysis/method in which substances are identified or classified on the basis of their chemical, biological, or physical properties. The test result is either the presence or absence of the analyte(s) in question.

"Quality assurance (QA)" means activities intended to assure that a quality control program is effective. A QA program is a totally integrated program for assuring reliability of measurement data.

"Quality assurance (QA) manual" means a written record intended to assure the reliability of measurement data. A QA manual documents policies, organization, objectives, and specific QC and QA activities.

"Quality control (QC)" means the routine application of statistically based procedures to evaluate and control the accuracy of analytical results.

"Quantitative analysis/method" means analysis/method in which the amount or concentration of an analyte may be determined (or estimated) and expressed as a numerical value in appropriate units with acceptable accuracy and precision.

"Random error" means component of measurement error that in replicate measurements varies in an unpredictable manner. See also "precision."

"Range" means the interval of concentration over which the method provides suitable accuracy and precision.

"Reagent blank" means reagents used in the procedure taken through the entire method. Reagent blanks are used to determine the absence of significant interference due to reagents or equipment used in the analysis.

"Recovery" means the proportion of analyte (incurred or added) remaining at the point of the final determination from the analytical portion of the sample measured. Commonly expressed as a percentage.

"Reference material" means a material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process or in examination of nominal properties.

"Reference standard" means a standard, generally having the highest metrological quality available at a given location in a given organization, from which measurements are made or derived.

Note: Generally, this refers to recognized national or international traceable standards provided by a standards producing body such as the National Institute of Standards and Technology (NIST).

"Relative percent difference (RPD)" means the comparison of two quantities while taking into account the size of what is being compared as calculated:

$$\text{percent RPD} = |(\text{sample} - \text{duplicate})| / ((\text{sample} + \text{duplicate})/2) * 100$$

"Repeatability (RSDr)" means precision obtained under observable conditions at a specific concentration/spike level where independent test results are obtained with the same method on identical test items in the same test facility by the same operator using the same equipment within short intervals of time.

"Representative matrix" means a cannabis matrix used to assess probable analytical performance with respect to other matrices, or for matrix-matched calibration, in the analysis of broadly similar cannabis products.

"Reproducibility (RSDR)" means precision obtained at a specific concentration/spike level under observation conditions where independent test results are obtained with the same method on identical test items in different test facilities with different operators using different equipment.

"Ruggedness/robustness" means a measure of the capacity of an analytical procedure to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage.

"Sample" means representative portion of material taken from a larger quantity of homogenate for the purpose of examination or analysis, which can be used for judging the quality of a larger quantity for the purpose of compliance.

"Sample package" means the sealed, tamper-resistant container (e.g., plastic bag, box, etc.) which contains the quality control sample and transportation manifest from grower or producer collection.

"Scientific director" means the individual with the proper education and training responsible for the overall laboratory operations, compliance, and training of personnel.

"Selectivity" means the extent to which a method can determine particular analyte(s) in a mixture(s) or matrix(ces) without interferences from other components of similar behavior. Also known as specificity.

"Sensitivity" means the change in instrument response which corresponds to a change in the measured quantity (e.g., analyte concentration). Sensitivity is commonly defined as the gradient of the response curve or slope of the calibration curve at a level near the LOQ.

"Shipping container" means the container (e.g., box, mailer, bag) in which the collector, or laboratory has placed one or more sample packages for transport.

"SI" means the international system of units and more commonly known as the metric system. This is the international standard for measurement. Critical laboratory measurements must be traceable to this system.

"Signal to noise ratio (SNR)" means a measure that compares the level of desired signal of an analyte to the level of background noise

from the instrument thus establishing the instrument's ability to differentiate between the two.

"Specificity" means the ability of a method to measure analyte(s) in the presence of components which may be expected to be present.

"Spike recovery" means the fraction of analyte remaining at the point of final determination after it is added to a specified amount of matrix and subjected to the entire analytical procedure. Spike recovery is typically expressed as a percentage. Spike recovery must be calculated for the method as written. For example, if the method prescribes using deuterated internal standards or matrix-matched calibration standards, then the reported analyte recoveries must be calculated according to those procedures.

"Spore bioindicators" means a biological indicator that is made up of a carrier material, on which bacterial spores with a defined resistance to the sterilization process have been applied.

"Standard operating procedures (SOP)" means a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.

"Standard reference material (SRM)" means a certified reference material issued by the National Institutes of Standards and Technology (NIST) in the United States.

"Standard (solution)" means a solution containing a precisely known concentration of an element, analyte, or a substance.

"Sterilization" means a validated process used to render a product free of all forms of viable microorganisms.

"Stock standard" means a concentrated solution of method analyte(s) prepared in the laboratory from referenced and certified analyte standards, where available, or a concentrated solution of method analyte(s) purchased directly from a referenced and certified source, where available.

"Surrogate (SUR)" means a pure compound that shall not be found in any sample but is similar in nature to the compounds of interest. This compound is added to a sample in a known amount before processing to monitor method performance for each sample. It is quantified in a manner analogous to that used for the analytes. The SUR is useful in ensuring that there were no problems in sample preparation.

"Systematic error" means component of measurement error that in replicate measurements remains constant or varies in a predictable manner. This may also be referred to as bias.

"Target analytes" means those analytes required to be tested on samples by the laboratory as defined in chapter 314-55 WAC.

"Testing personnel" means those qualified on the basis of education, training, experience and demonstrated skills to perform analytical testing on cannabis, cannabis concentrates, and cannabis infused products.

"Uncertainty" means nonnegative parameter characterizing the dispersion of the values being attributed to the measured value.

"Unidirectional flow" means performing a standard operating procedure in a single direction to reduce the risk of microbiological contamination.

"Upper level of linearity (ULOL)" means the highest level at which an instrument can measure the concentration of a substance accurately within an acceptable measure of deviation.

"Validated methods" means the methods that have undergone validation.

"Validation (method)" means the process of demonstrating or confirming the performance characteristics through assessments of data quality indicators for a method of analysis.

NEW SECTION

WAC 16-309-030 Laboratory instructions. (1) A cannabis testing laboratory must be accredited by the accrediting authority prior to conducting quality assurance tests on any cannabis flower or products derived under chapter 69.50 RCW.

(a) Accredited labs must conspicuously display the accreditation letter received by the accrediting authority at the lab's premises in a location where a customer may observe it unobstructed in plain sight.

(b) The laboratory must maintain a list of all tests they are currently accredited to test.

(2) The laboratory must identify potential conflicts of interest among key personnel in the organization that have involvement or influence on the testing activities of the laboratory.

(a) The laboratory conducting third-party testing must be independent of other cannabis businesses and have no financial interest in another cannabis license, excluding multiple lab accreditations.

(b) If a potential conflict of interest is identified, the laboratory must notify the accrediting authority for review, determination, and resolution of the conflict.

(3) The customer's confidential information and proprietary rights must be protected by the laboratory. The laboratory must maintain policies and procedures to protect confidential information.

(4) Cannabis labs must report certificate of analysis test results both to the customer and directly to the board in the required format(s).

(5) The department, board, and or accrediting authority may require the laboratory to submit raw data and information related to testing. The laboratory must keep and maintain all raw data and testing information for a period of five years.

(6) Laboratories must conduct an internal audit of laboratory operations to verify compliance with the accreditation checklist within 60 days of their scheduled audit. This self-audit will be reviewed by the accrediting authority at their yearly laboratory audit.

NEW SECTION

WAC 16-309-040 Laboratory personnel. (1) The laboratory must have a training and retraining program for all personnel that is kept current and is documented and maintained with personnel records.

(2) The laboratory must maintain personnel files on all employees detailing their qualifications and duties for all positions that include:

(a) Resume of training and experience.

(b) Job description of current position.

(c) Copies of certificates.

(d) Copies of diploma(s).

(e) Training checklists which include what training was performed, who did the training, and when it was performed.

(f) Documentation of continuing education, if any.

(g) Documentation of demonstrated abilities and competencies.

(3) The laboratory must document the technical staff's competency for each method performed on a yearly basis demonstrating their abilities to perform their specific job functions. Completion must be signed and dated by the scientific director.

(a) Demonstration of competencies include performing instrument setup or maintenance, sample handling, extractions, testing on each instrument used, quality control acceptance, and reporting of results.

(b) Testing personnel must demonstrate acceptable performance on precision, accuracy, selectivity, reportable ranges, blanks, and unknown challenges through the use of proficiency samples or internally generated quality controls. Completion must be signed and dated by the scientific director.

(4) The laboratory must have a personnel organization chart showing the chain of command and responsibilities approved, initialed, and dated by the scientific director.

(5) The scientific director may delegate some responsibilities in their absence or for other management staff. The delegation must be in writing, indicating what functions are being delegated (i.e., quality control data review, assessment of competency, or review of proficiency testing performance), and the delegate must be qualified and approved by the scientific director.

(6) If the laboratory performs microbiological testing, at least one member of the laboratory staff must have a bachelor's degree in a biological or clinical laboratory science or medical technology from an accredited institution, or associate degree in a biological or clinical laboratory science or medical laboratory technology from an accredited institution. The scientific director may satisfy this requirement if they hold a biological or clinical laboratory science degree or medical technology from an accredited institution, as described in WAC 16-309-050.

(7) All staff must be properly trained and evaluated for proper test performance prior to starting sample testing and reporting results.

(8) The accrediting authority may waive the academic requirements listed in WAC 16-309-050 through 16-309-070, on a case-by-case basis, for highly experienced analysts. The accrediting authority may also waive the need for the specified training, on a case-by-case basis, for supervisors of laboratories associated with testing of cannabis and cannabis products.

(9) Laboratory testing personnel must be supervised by persons familiar with test methods and procedures.

(10) Supervisors of testing personnel must meet one of the qualifications for a scientific director or have at least a bachelor's degree in one of the natural sciences and three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing. A combination of education and experience may substitute for the three years of full-time laboratory experience.

(11) The laboratory must designate a quality assurance manager or officer with defined responsibilities for ensuring the quality system is implemented and followed. The QA manager must be a separate person from the scientific director.

(12) The laboratory must report to the accrediting authority any change in the status of the scientific director. A laboratory cannot be without a scientific director for more than 30 days.

NEW SECTION

WAC 16-309-050 Scientific director. (1) Each laboratory must employ a scientific director to ensure the achievement and maintenance of quality standards of practice who meets the following minimum qualifications:

(a) Must possess a doctorate in the chemical or microbiological sciences from a college or university accredited by a national or regional certifying authority with a minimum of two years post-degree laboratory experience; or

(b) A master's degree in the chemical or microbiological sciences from a college or university accredited by a national or regional certifying authority with a minimum of four years of post-degree laboratory experience; or

(c) A bachelor's degree in the chemical or microbiological sciences from a college or university accredited by a national or regional certifying authority with a minimum of six years of post-education laboratory experience.

(2) The scientific director must have supervisory authority over all personnel involved with the accessioning, testing and storage of samples, and the reporting of results.

(3) The scientific director is not required to have direct supervisory authority over client service or IT personnel. However, they are responsible for ensuring laboratory compliance with chapters 314-55 and 246-70 WAC and this chapter, even if functions are performed by staff outside the cannabis laboratory (e.g., another department, off-site staff, corporate staff) ensuring that the confidentiality of reported results is maintained.

(4) The scientific director's responsibilities include, but are not limited to:

(a) Engaging in and responsible for the daily management of the laboratory;

(b) Establishing a training program for personnel;

(c) Ensuring that personnel are sufficiently trained;

(d) Ensuring that all personnel have demonstrated proficiency in assigned duties prior to working independently on customer cannabis samples;

(e) Ensuring that the standard operating procedures (SOP) manual is complete, current, available, signed, and followed by all personnel;

(f) Reviewing and approving any requests to modify analytical methods and documentation;

(g) Ensuring that all personnel are properly informed, and training documented when changes occur in the SOP;

(h) Ensuring that analytical methods are properly validated;

(i) Establishing a quality assurance program sufficient to legally and scientifically support results;

(j) Establishing acceptable performance limits for calibrators and controls;

(k) Ensuring that corrective action is taken in response to unacceptable QC performance or when other errors occur;

(l) Ensuring that results are not reported until after corrective actions have been taken and that the results provided are accurate and reliable;

(m) Fully understanding the function of the laboratory information management systems (LIMS) and other laboratory computer systems in sample receiving, accessioning, chain of custody, testing, and the review and reporting of results;

(n) Ensuring that the LIMS software and other software in the laboratory have been properly validated;

(o) Fully understanding the role of any external service providers and the functions of external information systems and computer systems in the laboratory's activities associated with cannabis testing;

(p) Ensuring that external information systems and software used by the laboratory have been properly validated;

(q) Ensuring that corrective actions are taken in response to issues identified in the inspection and proficiency testing (PT) phases of the program;

(r) Demonstrating knowledge of the cannabis regulatory documents and the cannabis laboratory analysis standards program.

NEW SECTION

WAC 16-309-060 Laboratory personnel performing high complexity testing. Personnel performing high complexity testing must be qualified on the basis of education, training, experience and demonstrated skills, and must meet the following minimum requirements:

(1) Have a bachelor's degree in a chemical, physical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(2) Must have an associate degree in a laboratory science (chemical or biological science) or medical laboratory technology from an accredited institution; or

(3) Have education and training equivalents that includes at least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either:

(a) Twenty-four semester hours of medical, clinical, or chemical laboratory technology courses; or

(b) Twenty-four semester hours of science courses that include:

(i) Six semester hours of chemistry;

(ii) Six semester hours of biology; and

(iii) An additional 12 semester hours of chemistry, biology, or medical laboratory technology in any combination;

(c) Be evaluated for competencies to perform the test by someone who is already qualified to perform the test;

(d) Be approved by the scientific director to perform the test.

NEW SECTION

WAC 16-309-070 Laboratory personnel performing moderate complexity testing. Personnel performing moderate complexity testing must be qualified on the basis of education, training, experience and demonstrated skills, and must meet the following minimum requirements:

(1) Have at least a high school diploma or equivalent;
(2) Have documented training to perform the test;
(3) Have the skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;
(4) Have the skills required to implement the quality control policies and procedures of the laboratory;
(5) Have the awareness of factors that influence test results;
(6) Be evaluated for competencies to perform the test by someone who is already qualified to perform the test;
(7) Be approved by the scientific director to perform the test.

NEW SECTION

WAC 16-309-080 Laboratory personnel performing low complexity testing. Personnel performing low complexity testing must be qualified on the basis of education, training, experience and demonstrated skills, and must meet the following minimum requirements:
(1) Have at least a high school diploma or equivalent;
(2) Have training to perform the test;
(3) Be evaluated for competencies to perform the test by someone who is already qualified to perform the test;
(4) Be approved by the scientific director to perform the test.

NEW SECTION

WAC 16-309-090 Standard operating procedures. (1) The laboratory must have a complete and current standard operating procedures (SOP) manual that describes in detail all laboratory operations and ensures all samples are tested in a consistent manner using the same procedures.
(2) Copies of relevant sections of the SOP must be available to all staff in their work areas.
(3) The scientific director must review and show written approval of all sections of the SOP dating when they were implemented. An itemized list of changes and versions made within the last five years must be documented on a summary of changes sheet for each section.
(4) The SOP must include a safety manual, procedure, or policy that describes specific precautionary issues throughout the lab that makes employees aware of, and know how to safely maneuver through, the issue as described in the OSHA laboratory safety guidance document.
(5) The SOP must include a procedure for decontamination and cleaning of instruments, bench space, and ventilation and microbial hoods.
(6) The SOP must include testing procedures that include pertinent information for the scope and complexity of the procedure, including:
(a) Title that identifies the activity or procedure;
(b) Scope and principle;
(c) Sample requirements;
(d) Calibration and control preparation and usage protocol;
(e) Instrumentation, equipment, materials and supplies used;

(f) Instrument settings, data acquisition, system operation, parameters and conditions for testing;

(g) Procedure for sample preparation and testing;

(h) Results review and acceptability;

(i) Additional information, notes, safety requirements, and precautions to include calculations, interferences, limitations, background corrections, and proper disposal of lab waste including biohazardous waste and cannabis waste compliant with WAC 314-55-097; and

(j) References.

(7) The SOP must include a policy for the use of personal protective equipment (PPE) when working with samples, reagents, chemicals, or potential hazards in the workplace along with a written and documented system on the competency of personnel on how to handle chemical spills and the use of chemical spill kits.

(8) The SOP must include a policy for limiting access to controlled areas of testing, storage of samples, disposal of samples, and records. Personnel must be assigned limited access according to their job responsibilities.

(9) The SOP must include a policy or procedure informing employees how to interact with law enforcement should they request information or come on-site for regulatory issues.

(10) The SOP must include a policy or procedure that informs employees and staff what tasks need to be performed and what information or documents need to be gathered prior to an audit or inspection.

(11) The SOP must include information on the proper handling and disposal of used and unused samples once testing is completed.

(12) The SOP must include information on how employees can access medical attention for chemical or other exposures, including follow-up examinations, without cost or loss of pay.

(13) The SOP must include a record or log of any deviations from the SOP detailing the reason for the deviation, the date, and approval from the scientific director.

(14) The laboratory must maintain retired procedures for at least five years beyond the retirement date and must be able to reconstruct the procedures that were in effect when a given sample was tested.

NEW SECTION

WAC 16-309-100 Sampling and homogenization protocols. (1) Upon receipt, the laboratory must inspect each sample package and transportation manifest, assuring they meet the following minimum requirements:

(a) Each sample package must have a transportation manifest accompanying it to the laboratory.

(b) Each manifest must have the identifying information on it documented at the time of collection prior to sending it to the laboratory.

(c) Each manifest must have a unique sample identification number matching the label on the sample.

(d) The laboratory must reject samples when the sample ID number or label on sample container does not match the sample ID number or label on the manifest or when the container shows evidence of tampering.

(2) The laboratory must transfer samples to a secure, limited access area of the laboratory upon receipt for processing and analysis.

(3) Receipt of samples must be documented as to condition of the package, who took possession, and whether there were any unacceptable conditions.

(4) The laboratory must document all persons handling the original sample, aliquots, and extracts.

(5) The laboratory must establish the minimum volume or weight required to conduct all testing requested and any additional tests (i.e., repeat tests, differential tests, or reflex tests) that may be required.

(6) The laboratory must establish storage requirements for all sample types upon receipt at the lab.

All samples received for residual solvent testing must have an aliquot placed in an enclosed container that minimizes the evaporation of any solvents that may be present as soon as possible upon receipt.

(7) Samples that do not undergo initial testing within seven days of arrival at the laboratory must be placed in a secure temperature-controlled storage until testing.

(8) Samples must be handled in a way that avoids cross-contamination during aliquoting and handling by keeping other samples closed and out of the immediate vicinity. Analyte standards must be handled in areas separate from sample preparation areas.

(9) It is not acceptable to reuse any labware that comes into contact with samples or aliquots until after proper cleaning. Labware, equipment, and surfaces must be properly cleaned between each sample preparation or handling.

(10) All disposable pipettes/sample measuring devices can be used only once and must be discarded after use to prevent the possibility of cross-contamination.

(11) Aliquots must be labeled with a unique identifier assigned to the sample both with a barcode and in human-readable form, or just in human-readable form.

(12) When multi-well plates are used for testing, the laboratory must ensure the correct sample is aliquoted into the correct plate well and map the location of each sample on the plate.

(13) The laboratory must have a system to easily retrieve and track samples that are maintained in storage.

(14) Laboratories must ensure sample homogenization is appropriate for each test method performed.

NEW SECTION

WAC 16-309-110 Security. (1) Laboratories must control and document access into operation areas (e.g., accessioning, data entry, sample handling, analytical, certification), along with sample storage areas, and records storage areas during both operating and nonworking hours.

(2) Individuals who do not have routine duties in secured areas (with the exception of auditors and emergency personnel) must be escorted, and their entries and exits must be properly documented (i.e., date, time of entry and exit, purpose of visit, and authorized escort).

(3) If a laboratory uses external service provider(s) to perform services on the laboratory's behalf (i.e., records storage, software service provider, or cloud service providers), the laboratory must show due diligence in verifying that the service provider has proce-

dures in place to protect the confidentiality, integrity, and availability of data for the services that they will perform. The laboratory is responsible for ensuring the external service provider is in compliance with applicable requirements.

(4) Samples must be stored in a limited access, secured area.

(5) Only personnel who are assigned to the limited access, secured area can have unescorted access.

(6) Samples may be transported outside a secured area if they are in the custody of an authorized individual who is moving them to another secured location.

(7) Laboratories must maintain physical custody of samples and are not allowed to delegate sample storage to external service providers.

(8) Original hard copy records for reported samples must be maintained in a secure room, area, or file cabinet at all times suitable to prevent damage or deterioration and to prevent loss.

(9) Laboratories may use off-site record storage locations or services if they meet the limited access and security requirements listed above.

(10) The laboratory must establish a system to ensure records are protected from loss or accidental destruction. This could include backup copies of electronic records, cloud storage, or off-site secured storage of back up tapes or disks.

(11) The laboratory must establish a procedure for documenting record retrieval, removal, and disposal assuring destruction is only allowed on records held past the five-year storage requirement.

(12) The laboratory must establish a procedure for securing documents past the five-year storage requirement when specifically requested by the accrediting authority or for legal purposes.

NEW SECTION

WAC 16-309-120 Quality control and assurance. (1) The laboratory must develop and maintain an extensive quality control (QC) program which involves the concurrent analysis of calibrators and controls with samples to demonstrate if the analytical system is operating within defined tolerance limits and that random and systematic errors can be identified in a timely manner.

(2) Laboratories must use controls that evaluate the performance of the sample prep and analytical instrument(s) in each preparation batch and must monitor the results of those samples within each batch and across batches for methods that include:

(a) A negative or blank control to demonstrate the assay(s) ability to perform without interference or contamination.

(b) A CCV above the cutoff or decision point but below the upper limit of linearity. Using a calibrator from the initial calibration is an acceptable CCV.

(c) A matrix spike (MS) and matrix spiked duplicate (MSD) at least every 20 samples per matrix for high complexity tests.

(d) If a matrix is not available, a representative matrix may be used and must be spiked at a concentration above the action limit with the target analytes. This is also known as a laboratory control sample (LCS).

(e) A laboratory control sample (LCS) may be used in place of a continuing calibration verification (CCV)(but not as a replacement for

a failing CCV) for methods where the calibration goes through the same process as the LCS.

(f) A sample duplicate and a singular matrix spike is acceptable, when a matrix spike duplicate is not used, for each preparation batch.

(3) Positive control materials must be processed in the same manner and included with the test sample batches through the entire testing process. This does not include the ICV or CCV.

(4) Calibration curves must be verified from a second source including, but not limited to, an ICV. Laboratories must use a standard obtained from a second manufacturer if available for purchase. Laboratories may use a separate lot prepared independently by the same manufacturer if a standard obtained from a second manufacturer is unavailable for purchase. The ICV must include all required analytes for each analysis performed.

(5) Laboratories must use reference standards that are traceable to a primary standard through a certificate of analysis, when possible.

(6) Laboratories must use surrogate analytes or internal standards for all high complexity testing. Internal standard response must be within 50-200 percent of the response of a midpoint initial calibration standard.

(7) The use of quality control material must determine the accuracy and precision of all required analytes in each analyses performed.

(8) For any method in which quality control acceptance criteria is not defined, the criteria must not exceed 30 percent.

(9) New lots of reagents, calibrators, and control material must be validated against a currently validated calibration or method before it is put into service.

(10) All control results must be documented in a manner to allow the laboratory to detect instrument or process failure and to identify trends or bias.

(11) Quality control results must be reviewed by a qualified analyst and must meet the acceptance limits prior to reporting out sample results.

(12) Cumulative quality control records must be reviewed by the individual responsible for oversight of the laboratory's QC program on a regular basis so that they can detect assay problems, trends, shifts, and bias.

(13) The laboratory must have procedures describing corrective action to be taken and take action when cumulative control results show evidence of problems. Control records must include documentation of the specific problem noted and documented evidence of the corrective actions to resolve the problem.

(14) The laboratory must use notebooks, logbooks, or other electronic means of communicating with staff regarding issues, problems, or communications between shifts.

(15) The laboratory must have a quality assurance manual, policy, or procedure to identify operational procedures, organization objectives, functional activities, and quality control activities designed to achieve quality goals desired for operation of the lab.

(16) The laboratory must designate a quality manager who, irrespective of other duties and responsibilities, must have defined responsibility and authority for ensuring that the quality system is implemented and followed. The quality manager must have direct access to the highest level of management at which decisions are made on laboratory policy or resources.

(17) The laboratory's quality assurance plan must measure meaningful data throughout laboratory processes that establish thresholds or limits for the indicators to trigger evaluation of the services if not met. Meaningful indicators established within the laboratory can be qualitative or quantitative and may be related to structure, processes, or outcome of the service involved.

(18) The quality assurance data must be reviewed by the scientific director on an ongoing basis that allows timely identification of problems to catch trends or issues early enough to make changes.

(19) The laboratory must maintain documentation and tracking of failed samples and batches like all other data and must make them available when requested.

(20) Instruments that use a multipoint curve must be calibrated using a minimum of a four-point curve with the first calibrator at the LOQ. No blanks can be used as a point unless required by the manufacturer. The linear correlation determination (r^2) must be ≥ 0.9950 or the correlation coefficient (r) must be ≥ 0.9975, unless otherwise specified in a CLASP-approved method. Linear regression with 1/x or no weighting must be used. Forcing the curve through zero is not allowed.

(21) To ensure the quality of data for mass spectrometry methods, the laboratory must:

(a) Perform mass spectrometric tuning at relevant frequencies or at the frequency specified by the manufacturer.

(b) Ensure method performance by comparing transitions and retention times between duplicated controls, calibrators, and samples.

(c) Use an internal or external standard to minimize errors caused by evaporation of solvents and injection errors or discrepancies.

(d) Have a detailed procedure for the manual integration of any peaks, including the review of automated integration and adjustments.

(e) Maintain all information necessary for reconstruction of the data.

(22) To ensure the quality of data for an immunoassay method, the laboratory must:

(a) Ensure functionality of new test kits and reagent lots by utilizing positive and negative controls.

(b) Ensure absorbance intensity is within the acceptable range as defined by the manufacturer.

(c) Challenge the linearity of the calibration curve by using:

(i) Different levels of positive controls to challenge the low and high end of the corresponding curve assuring results are reliable throughout the whole range of the curve;

(ii) A negative or blank control to demonstrate the assay's ability to distinguish a positive from a negative and to perform without interference or contamination.

(d) Perform second source verification by utilizing a control separate from calibration material:

(i) For multianalyte assays, calibration curves and controls must be specific for each analyte;

(ii) Control analytes with similar chemical properties as the target analyte may be used.

(23) The laboratory may verify expired neat analytical standards if the standard is recertified by the vendor and new documentation is obtained or the standard is verified by comparison to unexpired neat standard. The response factors must be within 10 percent to be considered fit for purpose. Verified expired standards must be recorded in the verification logs.

(24) The laboratory may only report quantitative results that are above the limit of quantification and below the upper limit of linearity.

(25) The laboratory must use at minimum reagent grade acids and bases, ultra-high purity grade gases, Type II water, and analytical quality materials in the preparation of standards and sample processing.

(26) Laboratory records must be legible and in ink or computerized system. Documents must be signed and dated. Changes must be initialed and dated, and there must be evidence of periodic review.

(27) When corrective action is needed, the laboratory must identify and document the issue, determine a plan for corrective actions, evaluate the results from the plan, and ensure that sample results are not reported until after the corrective actions have provide accurate and reliable results.

NEW SECTION

WAC 16-309-130 Facilities, equipment, and maintenance. (1) Facilities where laboratory testing is performed must be designed for dealing with preanalytical, analytical, and postanalytical functions.

(2) The laboratory must monitor, control, and record environmental conditions as required by the relevant specifications, methods, and procedures where they influence the quality of the results. Due attention must be paid to biological sterility, dust, electromagnetic disturbances, humidity, electrical supply, temperature, and sound and vibration levels, as necessary to the technical activities concerned.

(3) Laboratories recycling solvents by roto-evaporator or similar equipment must have a procedure for evaluating recycled solvent performance prior to use in testing. This must be applied any time the laboratory recycles solvents.

(4) The laboratory must have space for the number of personnel and separation of work areas.

(5) The arrangement of space must allow for workflow, sampling, lab space, office space, and break areas.

(6) The laboratory must have eyewash stations, safety showers, and sinks within the laboratory in areas where exposure to corrosive chemicals or substances may occur. Eyewash facilities must be no greater than 10 seconds unobstructed travel distance from the area in the laboratory where hazardous chemicals are present.

(7) The laboratory must have chemical spill kits on-site and placed in locations that are well-labeled and easily available to personnel.

(8) The laboratory must have adequate electrical outlets, unobstructed, single-use, multiplug adaptors with surge control; single-use extension cords; ground fault circuit interrupters near wet areas.

(9) The laboratory must have sufficient numbers and types of safety equipment to minimize personnel exposure to biological hazards and toxic materials. There must be vacuum traps, ventilation for fume hoods and around solvent use or storage of solvents or waste. There must be storage cabinets for flammable solvent, acids, and bases. There must be vented hoods for any microbiological analysis (i.e., Class II Type A biosafety cabinets as applicable).

(10) The laboratory must assign a unique identifier to distinguish the individual test instrument and software version used. Each

test result must be traceable back to the instrument used at the time of testing.

(11) The laboratory must comply with the scheduled maintenance and function checks recommended by the manufacturer at minimum and perform preventive maintenance and check critical operating characteristics of each instrument used in the testing process. Records must be retained for all instruments and equipment.

(12) For automated liquid handling equipment performing quantitative aliquoting, the laboratory must check the accuracy and precision of each system, perform a contamination check, and monitor and detect system issues or failures (e.g., drips or leaks, short sampling, bubbles, or air gaps in reagent dispensing lines) on a regular basis.

(13) The laboratory must verify the accuracy and precision of each pipette or pipetting device prior to placing it into service. Each device must be rechecked at least every six months. If the pipette or pipetting device is used to make measurements at different volumes, accuracy and precision must be checked at each volume used. Devices that do not meet stated precision and accuracy criteria must be removed from service.

(14) The laboratory must check and record temperatures on temperature sensitive devices (e.g., water baths, heating blocks, incubators, ovens, refrigerators, freezers, and refrigerated centrifuges) on a daily or when used basis. The laboratory must establish acceptance ranges to ensure proper storage conditions for samples, calibrator and control materials, test materials, and to ensure correct analytical conditions according to manufacturer and procedure requirements. Temperature records must be complete and clearly document the date and individual performing the check, and the laboratory must document corrective actions taken to address unacceptable temperature readings.

(15) Analytical balances must be mounted in accordance with manufacturer's instructions. They must be serviced and checked periodically over the relevant weight range using ANSI/ASTM Classes 1-3 or equivalent weights.

(16) The laboratory must verify instrument and equipment performance prior to initial use, after major maintenance or service, and after relocation to ensure that they run within defined tolerance limits and according to expectations.

(17) Instrument maintenance records and function check documents must be reviewed by technical supervisory staff or the scientific director at least monthly.

(18) Instruments that do not meet performance specifications must be placed out of service and labeled as "Not in Use" until it has been repaired and shown by verification that it will perform correctly.

(19) Laboratories must demonstrate, when possible, that calibrations of critical equipment and hence the measurement results generated by that equipment, relevant to their scope of accreditation, are traceable to the SI through an unbroken chain of calibrations.

(20) Laboratories must have breakrooms separate from the laboratory and ensure that food is not kept in refrigerators that have specimens, chemicals, or other laboratory related materials.

NEW SECTION

WAC 16-309-140 Method performance criteria. (1) Accredited labs may reference samples for testing by subcontracting fields of testing to another accredited laboratory.

(2) Laboratories must maintain the integrity of the sample by testing samples on an "as is" or "as received" basis before sample prep unless otherwise specified in rules.

(3) Laboratories may use historical calibrations for high complexity testing as long as it is supported by analytical data through quality control results. Historical calibrations cannot extend past 30 days.

(4) The samples fail quality control testing if the results exceed the limits indicated in chapter 314-55 WAC.

(5) Sample results are positive for the analyte being tested if their results are greater than or equal to the decision point or cut-off limits as indicated in chapter 314-55 WAC.

(6) Sample results are to be reported out in the number of digits and units of measure described in chapter 314-55 WAC.

(7) Laboratories may be accredited to conduct the following fields of testing:

Field of Testing	Level of Complexity
water activity	low
cannabinoid concentration analysis	high
foreign matter inspection	low
microbiological testing	
culture method	moderate
immunoassay method	moderate
polymerase chain reaction (PCR) method	high
residual solvent testing	high
mycotoxin testing	
enzyme-linked immunosorbent assay (ELISA) method	moderate
liquid chromatography with tandem mass spectrometry (LC-MS/MS) method	high
pesticide testing	high
heavy metals testing	high

NEW SECTION

WAC 16-309-150 Water activity testing. (1) Water activity (a_w) analysis is intended to quantitatively report out the presence of water in the sample.

The laboratory must run two continuing calibration verifications at levels bracketing the action limit concentration at the beginning of each day of testing.

(2) One sample must be run in duplicate with difference in values of 80 percent - 120 percent as a quality control specimen.

(3) The laboratory must monitor and record temperature and humidity daily or when testing is performed.

(4) The laboratory must calibrate the a_w instrument when:

(a) The instrument has been physically moved from one location to another.

(b) The instrument has been cleaned.
(c) The manufacturer's instruction manual recommends.

NEW SECTION

WAC 16-309-160 Cannabinoid concentration analysis. (1) Cannabinoid concentration analysis, previously known as potency, is intended to quantitate and accurately report cannabinoids above the lower limit of quantitation as described in chapter 314-55 WAC.

(2) Laboratories must use a method approved by the department to analyze cannabinoids.

(3) Laboratories must limit batch size to 20 samples in a preparation batch not including quality controls.

(4) ICV, CCV, and surrogate must meet a minimum of 80-120 percent recovery for each analyte.

(5) LCS and matrix spike samples must meet a minimum of 70-130 percent recovery for each analyte.

(6) Sample and matrix spike duplicates must have a relative percent difference (RPD) value of less than 20 percent.

(7) Chromatographic performance must be described in method and must include, but is not limited to, the following criteria:
(a) Tailing factor less than 2.0;
(b) Column performance resolution greater than 1.0;
(c) Retention time shift less than two percent.

NEW SECTION

WAC 16-309-170 Foreign matter inspection. (1) The laboratory must analyze not less than 30 percent of the total representative sample of cannabis and cannabis products prior to sample homogenization to determine whether foreign material is present.

(2) The laboratory must report the result of the foreign material test by indicating "pass" or "fail."

(3) The laboratory must use a microscope with photographic capabilities or a camera with magnification or resolution to document the presence of foreign matter. Magnification will only be required when something is identified and the picture without magnification does not allow identification of the foreign matter.

(4) The laboratory must document the observation with a detailed description of any foreign matter and photograph the sample supporting the report.

(5) The foreign matter inspection must be performed in a clean and sanitary location that prevents contamination or degradation prior to other testing.

NEW SECTION

WAC 16-309-180 Microbiological testing. (1) Microbiological testing is intended to accurately measure qualitative, semi-quantitative, or quantitate results, and report microorganisms incurred

through the production and processing of cannabis and cannabis products.

(2) The laboratory must have a microbiological testing SOP that contains a detailed description of the preparation of any material that does not come as a working stock (i.e., culture media, master mix, spiked controls).

(3) The laboratory may use either culture-based testing methods, immunoassay methods, molecular assay methods, or a combination of culture-based, immunoassay, and molecular assay methods for microbiological testing.

(4) Quality control must be performed on each new media lot, PCR reagent lot, or kit lot used. For molecular assays, DNA controls must be included with each analytical run and internal amplification controls (IACs) must be included with each individual reaction.

(a) Acceptability criteria for all calibration and QC materials such as controls, spikes, and blanks, must be defined, as well as the action to be taken when results are outside control limits. The laboratory must set controls at relevant limits around the decision points for the microbial assay(s) as defined above.

(b) Positive and negative controls must be included in all microbial assay tests. Quality controls must be analyzed in the same manner as samples.

(i) The laboratory must use control organisms that represent the target organism. Controls for the confirmation of a target, such as salmonella or Shiga toxin-producing *E. coli* (STEC), must be as similar as possible to the presumptive organism.

(ii) The laboratory must maintain documentation of quality control organisms and ensure purity of the control organism is maintained by limiting the number of cell divisions from the original culture.

(5) The laboratory must have a record of all microbial quality control and sample results. If the laboratory does not use equipment capable of recording and printing results (i.e., a PCR instrument or plate reader), then the laboratory must photograph all microbial quality control and sample results for recordkeeping.

(6) The laboratory must have a procedure in place which must specify any safety requirements or precautions unique to the microbial assay(s) used, including:

(a) Biohazard labels on equipment used to store biohazardous materials and waste such as restricted areas, refrigerators, and waste receptacles;

(b) Performing microbial assay(s) in either a Class II biosafety cabinet (BSC) or a designated clean room;

(c) Sterilization of biohazardous waste, including any materials that have come into contact with control organisms, either by autoclave or by chemical disinfectants;

(d) For safety reasons, biosafety level (BSL) 1 organisms for salmonella and STEC may be used as control organisms.

(e) Lab-prepared media must be sterilized by autoclave and undergo a quality control check for sterility before use.

Sterilization by autoclave must be documented using materials such as autoclave tape, and autoclave functionality must be tested using materials such as spore bioindicators.

(7) The laboratory must have a procedure and training for shipping and receiving bacterial enrichments, organisms, or presumptive positive samples. Biohazardous shipping and receiving training must be documented.

(8) The laboratory must perform microbial analysis in a unidirectional (i.e., one way) manner to reduce possible contamination of microbial test materials.

(a) For molecular microbial assays, the laboratory must use materials to reduce contamination such as reaction tubes that are RNAase-free and DNAase-free and use aerosol barrier pipette tips.

(b) For culture-based testing methods, all samples and controls must initiate incubation within 10 minutes of inoculation.

(9) For qualitative methods, all results must be reported as qualitative designations such as "detected," "not detected," "positive," or "negative." For quantitative methods, the laboratory may only report results that are above the limit of quantification and below the upper limit of linearity.

(10) The laboratory may not report colony-forming units (CFU) counts with greater than two significant figures.

NEW SECTION

WAC 16-309-190 Residual solvent testing. (1) Residual solvent analysis is intended to accurately quantitate and report solvent residue left behind from product processing.

(2) Laboratories must use a method approved by the department to analyze residual solvents.

(3) Methanol and any other solvent listed in chapter 314-55 WAC must not be used in any preparation or analysis procedure for residual solvent testing.

(4) Upon receipt of a sample at a laboratory, the sample treatment must follow the method requirements for preservation and storage.

(5) When an extraction solvent is used in method it must be an organic solvent that is capable of accomplishing the dilution of the sample while still able to meet the quality control requirements of this method and regulatory requirements, and is NOT a required analyte per regulations. The selected solvent must be specifically cited in a lab's standard operating procedure(s).

(6) Subsampling and homogenization protocols must be specified in the approved method(s) to include:

(a) The lab must analyze at least 0.2 grams of sample per residual solvents analysis.

(b) Upon receipt of sample, the portion of the sample that is to be used for residual solvents analysis must be stored to minimize solvent evaporation.

(c) Homogenization of residual solvent samples by the lab is prohibited unless necessary due to sample composition. If homogenization is necessary, steps must be taken to minimize evaporative loss.

(7) Laboratories must limit batch size to 20 samples in a preparation batch not including quality controls.

(8) The ICV must meet a minimum of 80-120 percent recovery for each analyte.

(9) CCV, surrogate, LCS and matrix spike samples must meet a minimum of 70-130 percent recovery for each analyte.

(10) Sample duplicates and matrix spike duplicates must have a relative percent difference (RPD) value of less than 20 percent.

NEW SECTION

WAC 16-309-200 Mycotoxin testing. (1) Mycotoxin testing is intended to accurately measure semi-quantitative or quantitate results, and report mycotoxins incurred through the production and processing of cannabis and cannabis products.

(2) For semi-quantitative or qualitative methods, the laboratory may report negative results. The limit of detection must be equal to or less than the analyte limit. Positive detections must be confirmed and reported using a quantitative method.

(3) For quantitative methods, the laboratory may only report numerical results that are above the limit of quantification and below the upper limit of linearity.

(4) The analytical processes for mycotoxin testing must include the following:

(a) A matrix negative and a matrix positive for each sample matrix tested per batch;

(b) Matrix positive controls at relevant levels above the decision point;

(c) The laboratory must perform a second-source calibration verification (ICV) above the decision point concentration.

(5) For high complexity testing, additional quality control is required.

(a) ICV, CCV, and surrogate must meet a minimum of 70-130 percent recovery for each analyte.

(b) Matrix spike samples must meet a minimum of 70-130 percent recovery for each analyte.

(c) Sample and matrix duplicates must have a relative percent difference (RPD) value of less than 20 percent.

(6) Analyze matrix spike duplicates or sample duplicates at a frequency of one in 20 samples per matrix, per sample extraction or preparation method, to measure repeatability and precision of the mycotoxin assay(s).

(7) Mass spectrometry testing criteria.

(a) A minimum of three structurally significant ions (meeting the three to one signal to noise ratio) are required for confirmation. If instrument conditions or ionization techniques limit the number of ions available, the laboratory may request a deviation from the department in order to report results under these conditions.

(b) The confidence limits of the relative abundance of structurally significant ions and precursor-to-product ion transitions used for single ion monitoring and multiple reaction monitoring must be ± 30 percent (relative) when compared to the same relative abundances observed from a standard solution injection made during the same analytical run.

(8) The laboratory must have procedures that include the following:

(a) Special safety precautions required for handling mycotoxin standards;

(b) Mycotoxin standards may only be opened and used within a certified fume hood;

(c) A mycotoxin spill cleanup procedure must be included;

(d) The laboratory must ensure stability of mycotoxin standards;

(e) A detailed description of how potentially hazardous waste is disposed of.

NEW SECTION

WAC 16-309-210 Pesticide testing. (1) Pesticide testing is intended to accurately quantitate and report pesticides incurred through the production and processing of cannabis and cannabis products.

(2) Pesticide standards and stock solutions must be prepared in an area separate from samples.

(3) Laboratories must use a method approved by the department to analyze pesticides.

(4) Laboratories must limit batch size to 20 samples in a preparation batch not including quality controls.

(5) ICV, CCV, and surrogate must meet a minimum of 70-130 percent recovery for each analyte.

(6) LCS and matrix spike samples must meet a minimum of 70-130 percent recovery for each analyte.

(7) Sample and matrix duplicates must have a relative percent difference (RPD) value of less than 20 percent.

(8) Mass spectrometry confirmation criteria.

(a) A minimum of three structurally significant ions (meeting the three to one signal to noise ratio) are required for confirmation. If instrument conditions or ionization techniques limit the number of ions available, the laboratory may request a deviation from the department in order to report results under these conditions.

(b) The confidence limits of the relative abundance of structurally significant ions and precursor-to-product ion transitions used for single ion monitoring and multiple reaction monitoring must be ± 30 percent (relative) when compared to the same relative abundances observed from a standard solution injection made during the same analytical run.

NEW SECTION

WAC 16-309-220 Heavy metals testing. (1) Heavy metals testing is intended to accurately quantitate and report metals incurred through the production and processing of cannabis and cannabis products.

(2) Analytical standards and solutions must be National Institutes of Standards (NIST) traceable or equivalent.

(3) The ICP-MS must be tuned each day of analysis using a tuning solution containing elements representing all of the mass regions of interest.

(4) Instruments must be calibrated every day of testing using a minimum of a four-point curve (no blanks can be used as a point).

(5) Laboratories must use a method approved by the department to analyze heavy metals.

(6) A stabilizer must be added during sample preparation to stabilize mercury through the acid digestion and analysis. The stabilizer must be at the same level in the calibration standards as the samples.

(7) An internal standard (IS) must be added and analyzed in all calibration standards and samples.

(8) Spectral interference checks (SIC) must be used to verify that the interference levels are corrected by the instrument's data system. The SIC must contain known amounts of interfering elements that will demonstrate the magnitude of interference and test for any corrections.

(9) An initial calibration verification (ICV) and initial calibration blank (ICB) must be analyzed each day of testing.

(a) The ICB is analyzed after the ICV and must not contain target analytes.

(b) The ICV must meet a minimum of 70-130 percent recovery for each analyte.

(10) Laboratories must limit batch size to 20 samples in a preparation batch not including quality controls.

(11) CCV, surrogate, LCS, and matrix spike samples must meet a minimum of 70-130 percent recovery for each analyte.

(12) Sample duplicates and matrix spike duplicates must have a relative percent difference (RPD) value of less than 20 percent.

(13) Sample concentrations that exceed the highest calibration standard must be diluted and reanalyzed to fall within the linear calibration range.

NEW SECTION

WAC 16-309-230 Other analytes. Should a laboratory test for analytes beyond the analytes required in chapter 314-55 or 246-70 WAC, they must adhere to the following guidelines:

(1) Additional test results must be identified as analytes outside the scope of accreditation on the certificate of analysis.

(2) Additional analytes that are tested using methods that also include required analytes for compliance must meet similar requirements for testing and reporting.

(3) Additional analytes that are tested using methods that do not include required analytes for compliance must be validated and tested using standards established in this chapter.

NEW SECTION

WAC 16-309-240 Laboratory computers and information systems. (1) The laboratory must have computer systems and software for sample tracking throughout the laboratory's possession from receipt of the samples through testing, reporting, and disposal.

(2) The laboratory must maintain a system security plan (SSP) for each information system used, including corporate systems and external service provider systems.

(3) The laboratory must have security controls (i.e., management, operations, and technical controls) in place to protect the confidentiality, integrity, and availability of the system and its information.

(4) If the laboratory contracts with an external service provider such as a cloud service provider, the laboratory must show due diligence in verifying that the service provider has procedures in place to protect the confidentiality, integrity, and availability of data for the services that they will perform on behalf of the laboratory.

(5) The laboratory must protect any internal computer systems (e.g., desktops, servers, instrument computers) against electrical power interruptions and surges that can contribute to data loss.

(6) The laboratory must protect any internal computer systems from spyware, viruses, malware, and other attacks through the use of firewalls and by maintaining software security updates.

(7) The laboratory must validate and document changes made to computer systems, software, interfaces, calculations, and security measures prior to implementing for use on samples.

(8) Software testing must include performing manual calculations or checking against another software product that has been previously tested, or by analysis of standards.

(9) The laboratory must have a signed contract or agreement with any external service providers that includes the priority elements of physical, technical, and administrative safeguards to protect their systems and data.

NEW SECTION

WAC 16-309-250 Method approvals. (1) Laboratories must use an agency approved method for cannabinoid concentration, pesticides, residual solvents, and heavy metals testing. A list of approved analytical and preparative methods are available on the agency's website (https://agr.wa.gov/departments/cannabis/cannabis-lab-analysis-program). If a laboratory wants to use a method not currently on the approved agency list of methods, the lab can submit a method for approval.

(2) Laboratories must, at a minimum, do the following for a new method approval:

(a) Laboratories must submit a method approval form with their required method documentation and method validation data emailed to the department at cannabis@agr.wa.gov.

(b) Receive written approval from the department of the validated method for use on customer samples.

(3) The initial method review and approval may take 30 days. The department may request revisions, clarifications, and/or additional data to review the method.

(4) Laboratories will receive notification via email about the status of the method. Approved methods will be added to the agency website for public access.

(5) Laboratories with denied methods will be provided with a detailed synopsis of why the method was insufficient.

(6) Methods submitted to the WSDA for approval must include a standard operating procedure that documents the following:

(a) A title that indicates the type of procedure being conducted (i.e., pesticides, residual solvents, cannabinoid concentration, or heavy metals).

(b) A document control number, date, and revision number.

(c) Approval signatory and date.

(d) A table of contents and page numbering.

(e) A section that documents the revision history for the method.

(f) A definitions section that includes a definition of terms, acronyms, and abbreviations used in the methods.

(g) A section that outlines the purpose, range, limitations (including limit of quantitation and limit of detection), intended use of the method, and target analytes.

(h) A summary section that includes an overview of the method procedure and quality assurance.

(i) An interference section that identifies known or potential interferences that may occur during use of the method and describes ways to reduce or eliminate these interferences.

(j) A safety section that describes special precautions needed to ensure personnel safety during the performance of the method.

(k) A section for equipment, supplies, reagents, and standards that are required to perform the method.

(l) A section that provides requirements and instructions for collecting, preserving, and storing samples.

(m) A quality control section that cites the procedures and analyses required to document the quality of data generated by the method and includes corrective actions for out-of-control data. This section must also describe how to assess data for acceptance based on quality control measures.

(n) A calibration and standardization section that describes the method or instrument calibration and standardization process and the required calibration verification.

(o) A procedure section that describes the sample processing and instrumental analysis steps of the method and provides detailed instructions to analysts.

(p) A section that provides instructions for analyzing data, equations, and definitions of constants used to calculate final sample analysis results.

(q) A method performance section that provides method performance criteria, including precision or bias statements regarding detection limits and sources or limitations of data produced using the method.

(r) A pollution prevention and waste management section that describes aspects of the method that minimizes or prevents pollution and the minimization and proper disposal of waste and samples.

(s) A section for references that lists source documents and publications that contain ancillary information.

(t) A section that contains all the tables, figures, diagrams, example forms for data recording, and flowcharts. This section may also contain validation data references in the body of the method.

(7) Methods must be validated and laboratories must submit method validation documentation as detailed in WAC 16-309-260.

(8) Should the department determine a method has become obsolete or invalid, it may retire the approved method after providing six months notice.

NEW SECTION

WAC 16-309-260 Method validations. (1) Laboratories must perform method validation studies prior to implementing a new or original test method, implementing an approved method, implementing a new instrument, or modifying an existing method or instrument for each matrices tested.

(2) The records must include sufficient information to allow for a comprehensive review of the studies performed. Laboratories must have criteria for acceptance of study data, for agreement of replicate study samples, and for defining true outlier values. Study samples for quantitative methods must meet the same qualitative criteria (e.g., the same retention time, mass ratio, internal standard abundance, and chromatography criteria) used for samples. The laboratory's acceptance criteria must be described in the SOP and in the study summary.

(3) Laboratories must perform reverification studies on an annual basis at minimum on high complexity nonreagent methods. Reverification studies are designed to verify that the existing LOD, LOQ, and ULOL values are still valid and do not require laboratories to analyze the same number of samples that are required for full validation studies.

(4) If the laboratory modifies an existing test method or instrument parameter that affects the performance of the method, the revised method must be re-validated prior to use. If the modification is relatively minor, the validation studies may be focused on those parameters that have been affected.

(5) Validations must include linearity, precision, accuracy, LOD, LOQ, ULOL, carryover, selectivity/interference, and matrix effects. unless defined specifically below.

(6) The laboratory must characterize the linearity of a method based on replicate analysis (i.e., a minimum of three replicates at each concentration) of samples of at least six concentrations. The concentrations must be distributed above and below the cutoff for the test.

(7) The laboratory must characterize the precision of a method based on replicate analysis, at least 20 results total. Analysis must be at significant concentrations around the cutoff/decision point and expected range. At least three replicates at each concentration must be analyzed. Precision studies must be performed on multiple days and in multiple batches in order to assess intra-batch and inter-batch variability.

(8) The laboratory must characterize the accuracy (expressed as bias) of a method by calculating the percent difference between the analyzed sample results and the target concentrations. Accuracy studies must be performed on multiple days and in multiple batches to assess intra-batch and inter-batch variability.

(9) The laboratory must characterize the LOD of a method by a series of replicates with decreasing concentrations (i.e., a minimum of three replicates at each concentration). The LOD must be experimentally determined and supported by analytical data. The laboratory can choose to artificially set the LOD at the established LOQ if the LOQ is at least 25 percent below the decision point limit.

(10) The laboratory must characterize the LOQ of a method by a series of replicates with decreasing concentrations (i.e., a minimum of three replicates at each concentration). The LOQ of a method must be determined and supported by analytical data and must be at least 25 percent below the decision point limit.

(11) The laboratory must characterize the ULOL of a method by a series of replicates with increasing concentrations (i.e., a minimum of three replicates at each concentration). Laboratories may select a value at the upper end of the dynamic range for a method, but it must be determined and supported by analytical data.

(12) The laboratory must investigate the potential of carryover of a method from one sample to another during testing by analyzing highly concentrated samples followed by negative samples (i.e., without the analyte of interest) and evaluate the negative samples for carryover. Positive samples that follow a sample at carryover concentrations must be reinjected or reextracted to eliminate carryover concerns.

(13) The laboratory must investigate the day-to-day precision using positive and negative samples assuring the ruggedness of the testing method provides good reproducibility over a period of at least five days.

(14) The laboratory must investigate the selectivity and interferences of a method by testing commonly encountered compounds and compounds that are structurally similar that could potentially interfere with the method at higher concentrations. Laboratories may accept manufacturer studies of immunoassay products if the study was performed using cannabis-focused compounds.

(15) The laboratory must investigate any possible matrix effect by evaluating the potential for components of the sample matrix to either suppress or enhance the ionization of the analytes of the compound(s) of interest and internal standard(s). Studies must include the evaluation of at least five different lots of products (i.e., flower from five different plants or from five different plant lots).

(16) When dilution of a sample is necessary to keep the result concentration within the range of linearity, the laboratory must conduct dilution integrity studies to document that the dilution does not affect the method's performance. These consist of precision/accuracy studies using samples at the dilution specified in the procedure.

(17) The laboratory must perform a parallel study when a new instrument or a new/revised procedure is implemented where results from the revised/new method or new instrument are compared to results from the existing method/instrument.

(18) The laboratory must perform a positive/negative differentiation study when validating a qualitative test by analyzing positive and negative samples that have been verified by a quantitative method to assess the assay's ability to differentiate positive and negative samples. The laboratory may analyze a combination of positive and negative controls, proficiency test (PT) samples or previously tested samples. The laboratory must analyze a minimum of five positive samples at differing concentrations and five negative samples (i.e., 10 results total).

(19) The laboratory must verify extraction efficiency assuring their method can sufficiently extract out the analyte of interest from the sample matrix.

(20) Records for validation and periodic reverification studies must be organized in a format to facilitate a comprehensive review and, at a minimum, the records must include:

(a) A stated purpose;

(b) Description of test method(s);

(c) Identity of the instrument(s) used for the study;

(d) A listing of the instrument parameters used for the study;

(e) A description of the study samples;

(f) A summary of the statistical data collected to characterize the assay;

(g) A discussion;

(h) A summary with conclusions; and

(i) All raw analytical data from the samples analyzed in the study.

(21) The laboratory must use the same criteria for acceptance of study data (e.g., the same retention time, mass ratio, internal standard abundance, and chromatography criteria) as used for the daily samples.

(22) The laboratory must maintain the original assay validation study records for methods in production for an indefinite period. Validation and reverification study records must be made available at the time of inspection or upon request. Labs are required to maintain records for retired methods for five years.

(23) All immunoassay and qualitative assay methods must be properly validated prior to use with samples and supported with the following studies:

(a) Linearity;

(b) Precision and accuracy around the cutoff;

(c) Selectivity;

(d) Carryover;

(e) A parallel study using the existing and new/revised procedures;

(f) Positive/negative sample differentiation studies.

(24) All quantitative assays must be properly validated prior to use with samples and supported with the following studies:

(a) Determination of LOQ, LOD, and ULOL;

(b) Precision/accuracy around the cutoff;

(c) Carryover;

(d) Selectivity/interference;

(e) For an assay validation: Method parameters including ion selection;

(f) For full instrument validation: Instrument parameter optimization;

(g) For LC-MS, and LC-MS/MS methods: Matrix effects;

(h) For assays using a new technology: Parallel studies of PT samples and customer samples (e.g., when validating a technology different from the existing method);

(i) For assays using an extraction: Extraction efficiency must be determined; and

(j) Hydrolysis efficiency (if sample preparation includes a hydrolysis step).

(25) An abbreviated instrument validation must be performed prior to implementing an additional instrument of an exact model that has been validated by the laboratory. The laboratory must perform the following studies:

(a) Determination of the LOQ, LOD, and ULOL;

(b) Carryover evaluation;

(c) Instrument parameter optimization; and

(d) For LC, LC-MS, and LC-MS/MS methods: Evaluation of matrix effects.

NEW SECTION

WAC 16-309-270 Proficiency testing. The laboratory must participate in an approved proficiency testing (PT) program that reflects the best available science as determined by the accrediting authority.

NEW SECTION

WAC 16-309-280 Reports. (1) All sample test results must be supported by analytical data and all analytical data must have a documented review, once reviewed by an analyst, and once reviewed by a certifying scientist prior to being reported.

(2) Laboratories must report results as either "negative," "none detected," "pass/fail," or the numeric concentration equal to or above

the decision point or cutoff of the required analytes tested as indicated in rules.

(3) For the purpose of reporting, decision points or cutoff limits have been written in chapter 314-55 WAC to the number or significant digits that laboratories are expected to use when reporting results.

(4) If the result is above the established ULOL, the laboratory must dilute the sample and retest to bring the results within the linear range of the test, unless allowed differently in the guidelines.

(5) The concentration of a diluted primary sample prior to applying the dilution factor must be above the concentration of the lowest calibrator or control in the batch.

(6) At a minimum, the computer generated COA reports for samples going to the customer must contain:

(a) A title: "Certificate of Analysis" or "Test Report";

(b) Laboratory name, lab ID number, and address;

(c) Unique identification of the test report certificate and on each page an identification in order to ensure that the page is recognized as a part of the COA, and a clear identification of the end of the report;

(d) The name, address, and license number of the customer;

(e) Date of sample collection;

(f) Sample identification number from transportation manifest;

(g) Sample/matrix type (flower, concentrate etc.);

(h) Product/sample name and category;

(i) Amount of sample received;

(j) Date received by laboratory;

(k) Name of certifying scientist;

(l) Date reported by the laboratory;

(m) Results of each test performed to include name of test, results, measurands (i.e., mg/g), cutoffs, and instrument/method of testing used;

(n) A statement to the effect that the results relate only to the items tested.

(7) Laboratories must use the analyte terminology and abbreviations specified by rules to ensure consistency in reporting and interpretation of test results.

(8) Laboratories must not release any cumulative or individual test result prior to the completion of all analysis by the lab for that sample.

(9) Any amendments to a COA after the original issuance must include a statement for the reason issued like "Corrected Report," "Supplement to COA (to include COA number)," or an equivalent form of wording.

(10) When it is necessary to issue a completely new COA, it must be uniquely identified and contain a reference to the original that it replaces (i.e., reprint).

(11) All records must include the identity of personnel performing the aliquoting, sample preparation, calibration, testing of samples and controls, and review of results.

(12) Observations, data, and calculations must be recorded at the time they are made and must be identifiable to the specific task.

(13) When mistakes occur in records, each mistake must be lined out, not erased, or made illegible or deleted, and the correct value entered alongside. All such alterations or corrections to records must be signed or initialed and dated by the person making the correction.

(14) All entries to hard copy laboratory records must be made using indelible ink. No correction fluid or tape may be used on laboratory data records.

NEW SECTION

WAC 16-309-290 Procurement controls. (1) The laboratory must have procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures covering reagents and laboratory consumables must exist for the purchase, receipt, storage, and disposition of expired materials.

(2) The laboratory must ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned.

(3) New lots or materials received outside of expected environmental conditions must be documented and validated before use.

(4) Reagents and standards must be inspected, dated, and initialed upon receipt, and upon opening.

(5) Calibration standards and analytical reagents must have an expiration or reevaluation date assigned.

(6) Standards and solutions must be identified with lot number or other assigned unique identifier to trace back to preparation documentation.

(7) Prospective suppliers must be evaluated and selected on the basis of specified criteria.

(8) Processes to ensure that approved suppliers continue to provide acceptable items and services must be established and implemented.

NEW SECTION

WAC 16-309-300 Subcontracting. (1) The laboratory must notify the customer of the subcontract arrangement in writing, including the subcontractors' accreditation credentials under chapters 69.50 RCW and 314-55 WAC.

(2) The laboratory must maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with chapter 314-55 WAC for the work in question.

(3) When there are indications that subcontractors knowingly supplied items or services of substandard quality, this information must be forwarded to laboratory management for corrective action.