Washington State Register

WSR 24-15-097 PROPOSED RULES DEPARTMENT OF HEALTH

[Filed July 21, 2024, 1:56 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 24-03-145. Title of Rule and Other Identifying Information: Radioactive materials licensing fees in chapter 246-254 WAC. The department of health (department) is proposing to increase radioactive material licensing fees to cover operating costs for the following: WAC 246-254-030 Small business discount provision and optional fee payment schedule applicable to radioactive materials licensees, 246-254-070 Fees for specialized radioactive material licenses, 246-254-080 Fees for medical and veterinary radioactive material use, 246-254-090 Fees for industrial radioactive material licenses, 246-254-100 Fees for laboratory radioactive material licenses, and 246-254-120 Fees for licensing and compliance actions.

The department is proposing a 31 percent fee increase across the board to all of the licenses but not proposing any new license categories. The department is proposing to remove the 50 percent discount for additional sites and the 25 percent small business discount because they are unfunded.

Hearing Location(s): On September 3, 2024, at 3:00 p.m., at the Department of Health, Town Center 2, Room 166, 111 Israel Road S.E., Tumwater, WA 98501; or virtual. Register in advance for this webinar https://us02web.zoom.us/webinar/register/WN_U-FZoZdUR5ylwaHX2jpF4A. After registering, you will receive a confirmation email containing information about joining the webinar. Individuals may attend the rules hearing either in person or virtually.

Date of Intended Adoption: September 10, 2024.

Submit Written Comments to: Peter Beaton, Department of Health, P.O. Box 47820 Olympia, WA 98504-7820, email peter.beaton@doh.wa.gov, https://fortress.wa.gov/doh/policyreview, beginning date and time of filing, by September 3, 2024, at midnight.

Assistance for Persons with Disabilities: Contact Samantha Mendez, phone 360-236-3215, TTY 711, email samantha.mendez@doh.wa.gov, by August 27, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The department is required to charge a fee for each operating license issued to radioactive material license holders regulated by the department. The fees must cover the cost of administering a license and enforcing the program. The department completed an initial assessment of the radioactive materials program and determined the fees are not generating sufficient revenue to cover the costs of the program.

Reasons Supporting Proposal: RCW 43.70.250 requires the department to charge a fee for each operating license issued to owners of radioactive material licenses regulated by the department. Rule making is the only available approach for setting or changing fees that are enforceable. The department anticipates costs for the program to increase by four percent in biennium 2027 and then three percent each year thereafter. Cost increases are primarily due to inflation in personnel-related costs. A one-time higher than normal cost increase on salaries is expected to occur due to statewide class and compensation review. The department also anticipates a one-time database replacement cost increase of \$600,000. This data system is 15 years old and

cannot perform the duties and functions required for an efficient workflow process.

Statutory Authority for Adoption: RCW 43.70.110, 43.70.250, and 70A.388.050.

Statute Being Implemented: RCW 43.70.110, 43.70.250, and 70A.388.050.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Department of Health, governmental.

Name of Agency Personnel Responsible for Drafting: Peter Beaton, Department of Health, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-4031; Implementation and Enforcement: Earl Fordham, Department of Health, 309 Bradley Boulevard, Suite 201, Richland, WA 99352, 509-628-7628.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is not required under RCW 34.05.328. This rule is exempt per RCW 34.05.328 (5)(b)(vi).

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(3) as the rules set or adjust fees under the authority of RCW 19.02.075 or that set or adjust fees or rates pursuant to legislative standards, including fees set or adjusted under the authority of RCW 19.80.045. Explanation of exemptions: The proposed rule changes amend fees. Scope of exemption for rule proposal:

Is fully exempt.

July 21, 2024
Kristin Peterson, JD
Chief of Policy
for Umair A. Shah, MD, MPH
Secretary

OTS-5366.1

 $\underline{\text{AMENDATORY SECTION}}$ (Amending WSR 91-22-027, filed 10/29/91, effective 11/29/91)

WAC 246-254-030 ((Small business discount provision and)) Optional fee payment schedule applicable to radioactive materials licensees. (1) ((Small business may receive a twenty-five percent discount on radioactive materials license fees specified in WAC 246-254-070, 246-254-080, 246-254-090, and 246-254-100.

- (2) To qualify for the discount, the business shall:
- (a) Be a corporation, partnership, sole proprietorship, or other legal entity formed for the purpose of making a profit;
- (b) Be independently owned and operated from all other businesses (i.e., not a subsidiary of a parent company); and
 - (c) Have fifty or fewer employees.
- (3) To receive the discount, the license applicant at the time of initial license request, or the licensee at the time of annual billing shall:

- (a) Certify, on the business' letterhead or appropriate departmental form, the business meets the conditions in subsection (2) of this section;
- (b) Sign the certification as the chief executive officer of the business or as an official designee;
 - (c) Have the certification notarized;
 - (d) Enclose the payment with the certification; and
- (e) Submit the certification and payment in accordance with instructions provided by the department.
- (4))) The department may verify certifications and will suspend any radioactive materials license if the applicant/licensee:
 - (a) Failed to pay the required fee; or
 - (b) Made an invalid or false certification.
- $((\frac{5}{}))$ Upon request of any radioactive materials licensee or license applicant, the department may accept semiannual or quarterly payments in lieu of the required annual license fee, provided:
- (a) A written payment schedule setting specific due dates and payment amounts is submitted; and
- (b) The total payments per the schedule equal the fee in effect at the time such fee payment schedule is accepted by the department.

 $\underline{\text{AMENDATORY SECTION}}$ (Amending WSR 17-01-084, filed 12/16/16, effective 1/16/17)

- WAC 246-254-070 Fees for specialized radioactive material licenses. (1) Persons licensed or authorized to possess or use radioactive material in the following special categories shall forward annual fees to the department as follows:
- (a) ((\$10,721)) \$14,054 for operation of a single nuclear pharmacy.
- (b) ((\$18,284)) \$23,952 for operation of a single nuclear laundry.
- (c) ((\$18,284)) \$23,952 for a license authorizing a single facility to use more than one curie of unsealed radioactive material in the manufacture and distribution of radioactive products or devices containing radioactive material.
- (d) ((\$6,406)) \$8,392 for a license authorizing a single facility to use less than or equal to one curie of unsealed radioactive material or any quantity of previously sealed sources in the manufacture and distribution of products or devices containing radioactive material.
- (e) ((\$1,647)) \$2,158 for a license authorizing the receipt and redistribution from a single facility of manufactured products or devices containing radioactive material.
- (f) ((\$12,266)) \$16,068 for a license authorizing decontamination services operating from a single facility.
- (g) ((\$5,798)) \$7,595 for a license authorizing waste brokerage including the possession, temporary storage at a single facility, and over-packing only of radioactive waste.
- (h) $((\frac{$2,583}{}))$ $\frac{$3,384}{}$ for a license authorizing health physics services, leak testing, calibration services, equipment servicing, or possession of sealed sources for purpose of sales demonstration only.
 - (i) ((\$3,032)) \$3,972 for a civil defense license.
- (j) ((\$912)) \$1,195 for a license authorizing possession of special nuclear material as pacemakers or depleted uranium as shielding.

- (2) Persons licensed or authorized to possess and use radioactive material in the following broad scope categories shall forward annual fees to the department as follows:
- (a) ((\$36,288)) \$47,537 for a license authorizing possession of atomic numbers three through ((eighty-three)) 83 with maximum authorized possession of any single isotope greater than one curie.
- (b) ((\$16,773)) \$21,973 for a license authorizing possession of atomic numbers three through ((eighty-three)) 83 with maximum authorized possession of any single isotope greater than 0.1 curie but less than or equal to one curie.
- (c) ((\$13,478)) \$17,656 for a license authorizing possession of atomic numbers three through ((eighty-three)) 83 with maximum authorized possession less than or equal to 0.1 curie.
- (3) Persons licensed or authorized to possess or use radioactive material which are not covered by any of the annual license fees described in WAC 246-254-070 through 246-254-100, shall pay fees as follows:
 - (a) An initial application fee of ((\$1,170)) \$1,533;
- (b) Billing at the rate of ((\$189)) \$248 for each hour of direct staff time associated with issuing and maintaining the license and for the inspection of the license; and
- (c) Any fees for additional services as described in WAC 246-254-120.
- (d) The initial application fee will be considered a credit against billings for direct staff charges but is otherwise nonrefundable.
- (4) Persons licensed or authorized to possess or use radioactive material in a facility for radioactive waste processing, including resource recovery, volume reduction, decontamination activities, or other waste treatment, but not permitting commercial on-site disposal, shall pay fees as follows:
- (a) A nonrefundable initial application fee for a new license of ((\$18,720)) \$24,523 which shall be credited to the applicant's quarterly billing described in (b) of this subsection; and
- (b) Quarterly billings for actual direct and indirect costs incurred by the department including, but not limited to, license renewal, license amendments, compliance inspections, a resident inspector for time spent on the licensee's premises as deemed necessary by the department, laboratory and other support services, and travel costs associated with staff involved in the foregoing.

WAC 246-254-080 Fees for medical and veterinary radioactive material use. $((\frac{1}{1}))$ Licensees authorized possession or use of radioactive material in the following medical or veterinary categories shall forward annual fees to the department as follows:

 $((\frac{a)}{9,065}))$ (1) \$11,875 for operation of a mobile nuclear medicine program from a single base of operation;

 $((\frac{b)}{56,608}))$ $\underline{(2)}$ \$8,656 for the use of unsealed radioactive material for imaging and localization studies for which a written directive is not required as defined in WAC 246-240-157, at a single facility (diagnostic imaging and localization nuclear medicine);

- (((c) \$5,723)) (3) \$7,497 for the use of unsealed radioactive material for which a written directive is required as defined in WAC 246-240-201 at a single facility (radiopharmaceutical therapy);
- $((\frac{d})$ \$9,126)) (4) \$11,955 for the use of unsealed radioactive material for imaging and localization studies for which a written directive is not required as defined in WAC 246-240-157, the use of unsealed radioactive material for which a written directive is required as defined in WAC 246-240-201, and/or the use of sealed sources for manual brachytherapy as defined in WAC 246-240-251 at a single facility (combination diagnostic nuclear medicine and/or radiopharmaceutical therapy), and/or sealed source (manual or machine) therapy;
- $((\frac{(e)}{54,904}))$ <u>(5)</u> \$6,424 for the use of sealed sources for manual brachytherapy as defined in WAC 246-240-251 at a single facility (manual brachytherapy);
- $((\frac{(f)}{3,032}))^{\frac{1}{6}}$ \$3,972 for the use of sealed sources in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit, as defined in WAC 246-240-351, at a single facility (machine brachytherapy);
- $((\frac{g)}{\$4,605}))$ (7) \$6,033 for a license authorizing medical or veterinary possession of greater than $(\frac{wo hundred}{200})$ $(\frac{200}{200})$ millicuries total possession of radioactive material at a single facility;
- $((\frac{h)}{\$3,664}))$ (8) \$4,800 for a license authorizing medical or veterinary possession of greater than $(\frac{thirty}{\$30})$ millicuries but less than or equal to $(\frac{two hundred}{\$100})$ 200 millicuries total possession of radioactive material at a single facility;
- $((\frac{1}{2}, \frac{52,681}{681}))$ (9) \$3,512 for a license authorizing medical or veterinary possession of less than or equal to $(\frac{1}{2})$ millicuries total possession of radioactive material at a single facility;
- $((\frac{1}{2}), \frac{2}{363}))$ (10) $\frac{3}{3096}$ for the use of unsealed radioactive material for uptake, dilution and/or excretion studies for which a written directive is not required, as defined in WAC 246-240-151, at a single facility (diagnostic uptake, dilution, and excretion nuclear medicine);
- $((\frac{k}{k}) \frac{1,474}{474}))$ (11) $\frac{1}{k}$ for a license authorizing medical or veterinary possession of a sealed source for diagnostic use at a single facility.
- (((2) The fee for a license authorizing multiple locations shall be increased by fifty percent of the annual fee for each additional location.))

- WAC 246-254-090 Fees for industrial radioactive material licenses. (1) Persons licensed or authorized to possess or use radioactive material in the following industrial categories shall forward annual fees to the department as follows:
- (a) ((\$10,675)) \$13,984 for a license authorizing the use of radiographic exposure devices in one or more permanent radiographic vaults in a single facility.
- (b) ((\$14,311)) \$18,747 for a license authorizing the use of radiographic exposure devices at temporary job sites but operating from a single storage facility.

- (c) ((\$7,010)) \$9,183 for a license authorizing well-logging activities including the use of radioactive tracers operating from a single storage facility.
- (d) ((\$1,511)) \$1,979 for a license authorizing possession of portable sealed sources including moisture/density gauges and excluding radiographic exposure devices operating from a single storage facility.
- (e) ((\$1,647)) \$2,158 for a license authorizing possession of any nonportable sealed source, including special nuclear material and excluding radioactive material used in a gas chromatograph at a single facility.
- (f) ((\$1,038)) \$1,360 for a license authorizing possession of gas chromatograph units containing radioactive material at a single facility.
- (g) ((\$2,878)) \$3,770 for a license authorizing possession of any self-shielded or pool type irradiator with sealed source total quantity greater than ((one hundred)) 100 curies at a single facility.
- (h) ((\$15,298)) \$20,040 for a license authorizing possession of sealed sources for a walk-in type irradiator at a single facility.
- (i) ((\$13,323)) \$17,453 for a license authorizing possession of greater than one gram of unsealed special nuclear material or greater than ((\$ive hundred)) 500 kilograms of source material at a single facility.
- (j) ((\$4,263)) \$5,585 for a license authorizing possession of less than or equal to one gram of unsealed special nuclear material or ((five hundred)) 500 kilograms of source material at a single facility.
- (k) ((\$673)) \$882 for a license authorizing possession of static elimination devices not covered by a general license.
- (2) Persons with licenses authorizing multiple locations of permanent storage shall increase the annual fee by ((fifty)) 100 percent for each additional location.
- (3) Depleted uranium registrants required to file Form RHF-20 shall forward an annual fee of ((\$135)) \$177 to the department.
- (4) General licensees required to register in accordance with WAC 246-233-020 (3)(k) shall forward an annual fee of ((\$402)) \$527 to the department.

- WAC 246-254-100 Fees for laboratory radioactive material licenses. (1) Persons licensed or authorized to possess or use unsealed radioactive material in the following laboratory categories shall forward annual fees to the department as follows:
- (a) ((\$7,300)) \$9,563 for a license authorizing possession at a single facility of unsealed sources in amounts greater than:
 - (i) One millicurie of I-125 or I-131; or
 - (ii) One hundred millicuries of H-3 or C-14; or
 - (iii) Ten millicuries of any single isotope.
- (b) ((\$3,603)) \$4,720 for a license authorizing possession at a single facility of unsealed sources in amounts:
- (i) Greater than 0.1 millicurie and less than or equal to one millicurie of I-125 or I-131; or

- (ii) Greater than ((ten)) <u>10</u> millicuries and less than or equal to ((ten)) 100 millicuries of H-3 or C-14; or
- (iii) Greater than one millicurie and less than or equal to ((ten)) 10 millicuries of any single isotope.
- (c) ((\$3,032)) \$3,972 for a license authorizing possession at a single facility of unsealed sources in amounts:
- (i) Greater than 0.01 millicurie and less than or equal to 0.1 millicurie of I-125 or I-131; or
- (ii) Greater than one millicurie and less than or equal to ((ten)) 10 millicuries of H-3 or C-14; or
- (iii) Greater than 0.1 millicurie and less than or equal to one millicurie of any other single isotope.
- (d) ((\$1,038)) \$1,360 for a license authorizing possession at a single facility of unsealed or sealed sources in amounts:
 - (i) Less than or equal to 0.01 millicurie of I-125 or I-131; or
 - (ii) Less than or equal to one millicurie of H-3 or C-14; or
- (iii) Less than or equal to 0.1 millicurie of any other single isotope.
- (e) ((\$1,399)) \$1,833 for a license authorizing possession at a single facility of large quantities of naturally occurring radioactive material in total concentration not exceeding 0.002 microcurie per gram.
- (2) Persons with licenses authorizing multiple locations of use shall increase the annual fee by $((\frac{\text{fifty}}{}))$ percent for each additional location.
- (3) Persons registered to perform in vitro testing pursuant to Form RHF-15 shall forward an annual fee of ((\$135)) \$177 to the department.

- WAC 246-254-120 Fees for licensing and compliance actions. (1) In addition to the fee for each radioactive material license as described under WAC 246-254-070, 246-254-080, 246-254-090, and 246-254-100, a licensee shall pay a service fee for each additional licensing and compliance action as follows:
- (a) For a second follow-up inspection, and each follow-up inspection thereafter, a fee of ((\$189)) \$248 per hour of direct staff time associated with the follow-up inspection, not to exceed ((\$1,901)) \$2,480 per follow-up inspection. Hours are calculated in half-hour increments.
- (b) For each environmental cleanup monitoring visit, a fee of ((\$189)) \$248 per hour of direct staff time associated with the environmental cleanup monitoring visit, not to exceed ((\$4,753)) \$6,226 per visit. Hours are calculated in half-hour increments.
- (c) For each new license application, the fee of ((\$304)) \$398 in addition to the required annual fee.
- (d) For each sealed source and device evaluation, a fee of ((\$189)) \$248 per hour of direct staff time associated with each sealed source and device evaluation, not to exceed ((\$5,703)) \$7,471 per evaluation.
- (e) For review of air emission and environmental programs and data collection and analysis of samples, and review of decommissioning activities by qualified staff in those work units, a fee of ((\$189))

- $\frac{$248}{}$ per hour of direct staff time associated with the review. The fee does not apply to reviews conducted by the radioactive materials section staff and does not apply unless the review time would result in a special service charge exceeding ((ten)) $\underline{10}$ percent of the licensee's annual fee.
- (f) For expedited licensing review, a fee of ((\$189)) \$248 per hour of direct staff time associated with the review. This fee only applies when, by the mutual consent of licensee and affected staff, a licensing request is taken out of date order and processed by staff during nonwork hours and for which staff is paid overtime.
- (2) The licensee or applicant shall pay any additional service fees at the time of application for a new license or within ((thirty)) 30 days of the date of the billing for all other licensing and compliance actions.
- (3) The department shall process an application only upon receipt of the new application fee and the annual fee.
- (4) The department may take action to modify, suspend, or terminate the license or sealed source and device registration if the licensee fails to pay the fee for additional licensing and compliance actions billed by the department.