AMENDATORY SECTION (Amending WSR 22-19-084, filed 9/20/22, effective 10/21/22)

WAC 246-240-010 Definitions, abbreviations, and acronyms. The definitions, abbreviations, and acronyms in this section and in WAC 246-220-010 apply throughout this chapter unless the context clearly indicates otherwise.

(1) "Address of use" means the building or buildings that are identified on the license and where radioactive material may be received, prepared, used, or stored.

(2) "Area of use" means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing radioactive material.

(3) "Associate radiation safety officer" means an individual who:

(a) Meets the requirements in WAC 246-240-069 and 246-240-081; and

(b) Is currently identified as an associate radiation safety officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the radiation safety officer on:

(i) A specific medical use license issued by the department, NRC, or an agreement state; or

(ii) A medical use permit issued by an NRC master material licensee.

(4) "Attestation" means written certification under oath.

(5) "Authorized medical physicist" means an individual who:

(a) Meets the requirements in WAC 246-240-072 and 246-240-081; or

(b) Is identified as an authorized medical physicist or teletherapy physicist on:

(i) A specific medical use license issued by the department, NRC, or an agreement state;

(ii) A medical use permit issued by an NRC master material licensee;

(iii) A permit issued by an NRC or agreement state broad scope medical use licensee; or

(iv) A permit issued by an NRC master material license broad scope medical use permittee.

(6) "Authorized nuclear pharmacist" means a pharmacist who:

(a) Meets the requirements in WAC 246-240-075 and 246-240-081; or

(b) Is identified as an authorized nuclear pharmacist on:

(i) A specific license issued by the department, NRC, or an agreement state, that authorizes medical use or the practice of nuclear pharmacy;

(ii) A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(iii) A permit issued by an NRC or agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(iv) A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

(c) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(d) Is designated as an authorized nuclear pharmacist in accordance with WAC 246-235-100(2).

(7) "Authorized user" means a physician, dentist, or podiatrist who:

(a) Meets the requirements in WAC 246-240-081 and 246-240-154, 246-240-163, 246-240-210, 246-240-213, 246-240-216, 246-240-278, 246-240-301, or 246-240-399; or

(b) Is identified as an authorized user on:

(i) A department, NRC, or agreement state license that authorizes the medical use of radioactive material; or

(ii) A permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material; or

(iii) A permit issued by a department, NRC, or agreement state specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

(iv) A permit issued by an NRC master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

(8) "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

(9) "Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(10) "Client's address" means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with WAC 246-240-125.

(11) "Cyclotron" means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 mega-electron volts and is commonly used for production of short half-life radionuclides for medical use.

(12) "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

(13) "Dentist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

(14) "FDA" means the U.S. Food and Drug Administration.

(15) "High dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

(16) "Low dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of less than or equal to two gray (200 rads) per hour at the point or surface where the dose is prescribed.

(17) "Management" means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or that person's delegate or delegates.

(18) "Manual brachytherapy" means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

(19) "Medical event" means an event that meets the criteria in WAC 246-240-651.

(20) "Medical institution" means an organization in which more than one medical discipline is practiced.

(21) "Medical use" means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

(22) "Medium dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of greater than two gray (200 rads), but less than or equal to 12 grays (1200 rads) per hour at the point or surface where the dose is prescribed.

(23) "Mobile medical service" means the transportation of radioactive material to and its medical use at the client's address.

(24) "Ophthalmic physicist" means an individual who:

(a) Meets the requirements in WAC 246-240-272 (1)(b) and 246-240-081; and

(b) Is identified as an ophthalmic physicist on a:

(i) Specific medical use license issued by the NRC or an agreement state;

(ii) Permit issued by an NRC or agreement state broad scope medical use licensee;

(iii) Medical use permit issued by an NRC master material licensee; or

(iv) Permit issued by an NRC master material licensee broad scope medical use permittee.

(25) "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

(26) "Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

(27) "Podiatrist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

(28) "Positron emission tomography (PET) radionuclide production facility" means a facility operating an accelerator for the purpose of producing positron emission tomography radionuclides.

(29) "Preceptor" means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, an authorized radiation safety officer, or an associate radiation safety officer.

(30) "Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented:

(a) In a written directive; or

(b) In accordance with the directions of the authorized user for procedures performed under WAC 246-240-151 and 246-240-157.

(31) "Prescribed dose" means:

(a) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(b) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(c) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(d) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

(32) "Pulsed dose-rate remote afterloader" means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

(a) Is approximately ((~~one-tenth~~)) 1/10th of the activity of typical high dose-rate remote afterloader sources; and

(b) Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

(33) "Sealed source and device registry" means the national registry that contains all the registration certificates, generated by NRC and the agreement states, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

(34) "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

(35) "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

(36) "Teletherapy" means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

(37) "Temporary job site" means a location where mobile medical services are conducted at other than those fixed locations of use authorized by the license.

(38) "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

(39) "Therapeutic dose" means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

(40) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(41) "Type of use" means use of radioactive material under WAC 246-240-151, 246-240-157, 246-240-201, 246-240-251, 246-240-301, 246-240-351, or 246-240-501.

(42) "Unit dosage" means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

(43) "Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in WAC 246-240-060.

AMENDATORY SECTION (Amending WSR 22-19-084, filed 9/20/22, effective 10/21/22)

WAC 246-240-075 Training for an authorized nuclear pharmacist. Except as provided in WAC 246-240-078, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(1) Is certified by a specialty board whose certification process has been recognized by the department, NRC, or an agreement state. The names of board certifications that have been recognized by the department, NRC, or an agreement state are posted on the NRC's medical uses licensee toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Have graduated from a pharmacy program accredited by the ((~~American~~)) Accreditation Council ((~~on Pharmaceutical~~)) for Pharmacy Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(b) Hold a current, active license to practice pharmacy;

(c) Provide evidence of having acquired at least 4,000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience; and

(d) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, which assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(2)(a) Has completed 700 hours in a structured educational program consisting of both:

(i) Two hundred hours of classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of radioactive material for medical use; and

(E) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving:

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha-or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid medical events in the administration of radioactive material; and

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(b) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in (a) of this subsection and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

AMENDATORY SECTION (Amending WSR 22-19-084, filed 9/20/22, effective 10/21/22)

WAC 246-240-078 Training for experienced radiation safety officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist. (1)(a) An individual identified on a department, NRC, or an agreement state license; or a permit issued by a department, NRC, or an agreement state broad scope licensee or master material license permit; or by a master material license permittee of broad scope as a radiation safety officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or authorized nuclear pharmacist on or before January 14, 2019, need not comply with the training requirements of WAC 246-240-069, 246-240-072, or 246-240-075, respectively except the radiation safety officers and authorized medical physicists identified in this subsection must meet the training requirements in WAC 246-240-069(4) or 246-240-072(3), as appropriate, for any material or uses for which they were not authorized prior to this date.

(b) Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of WAC 246-240-069 to be identified as a radiation safety officer or as an associate radiation safety officer on a department, NRC, or an agreement state license or NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

(c) Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, X-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in WAC 246-240-072, for those materials and uses that these individuals performed on or before October 24, 2005.

(d) A radiation safety officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of WAC 246-240-069, 246-240-072 or 246-240-075, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and during the time period identified in this subsection, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of this chapter.

(2)(a) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the department, NRC, or an agreement state, a permit issued by an NRC master material license, a permit issued by a department, NRC, or an agreement state broad scope licensee, or permit issued by an NRC master material license broad scope permittee on or before January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of WAC 246-240-151 through 246-240-399.

(b) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the department, NRC, or an agreement state, a permit issued by an NRC master material licensee, a permit issued by the department, NRC, or an agreement state broad scope licensee, or a permit issued in accordance with ((~~an NRC~~)) a commission master material broad scope license on or before October 24, 2005, need not comply with the training requirements of WAC 246-240-151 through 246-240-399 for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

(i) For uses authorized under WAC 246-240-151 or 246-240-157, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(ii) For uses authorized under WAC 246-240-201, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(iii) For uses authorized under WAC 246-240-251 or 246-240-351, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(iv) For uses authorized under WAC 246-240-301, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(c) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of WAC 246-240-151 through 246-240-399 of this chapter when performing the same medical uses. A physician, dentist, or podiatrist, who used only

accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this subsection, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this chapter.

(3) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on state of Washington radioactive materials licenses for the same uses for which these individuals are authorized.

AMENDATORY SECTION (Amending WSR 22-19-084, filed 9/20/22, effective 10/21/22)

WAC 246-240-210 Training for use of unsealed radioactive material for which a written directive is required. Except as provided in WAC 246-240-078, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under WAC 246-240-201 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the department, NRC, or an agreement state and who meets the requirements in subsection (2)(a)(ii)(G) of this section. The names of board certifications that have been recognized by the department, NRC, or an agreement state are posted on the NRC's medical uses licensee toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty that includes 700 hours of training and experience as described in subsection (2)(a)(i) through (ii)(E) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the ((~~Committee on Postgraduate~~)) Council on Postdoctoral Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

(2)(a) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

(i) Classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of radioactive material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in WAC 246-240-078, or this section, or equivalent NRC or agreement state requirements. A supervising authorized user, who meets the requirements in this subsection, must also have experience in administering dosages in the same dosage category or categories (as in (a)(ii)(G) of this subsection) as the individual requesting authorized user status. The work experience must involve:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(E) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(F) (Reserved);

(G) Administering dosages of radioactive drugs to patients or human research subjects from the three categories in this subsection. Radioactive drugs containing radionuclides in categories not included in this subsection are regulated under WAC 246-240-501. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

(I) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for which a written directive is required;

(II) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131. Experience with at least three cases in this also satisfies the requirement in (a)(ii)(G)(I) of this subsection;

(III) Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy less than 150 keV for which a written directive is required; and

(b) Has obtained written attestation that the individual has satisfactorily completed the requirements in (a) of this subsection, and is able to independently fulfill at radiation safety-related duties as an authorized user for the medical uses authorized under WAC 246-240-201 for which the individual is requesting authorized user status. The written attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in this section, WAC 246-240-078, 246-240-210, or equivalent NRC or agreement state requirements, and has experience in administering dosages in the same dosage category or categories (as in (a)(ii)(G) of this subsection) as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in WAC 246-240-078, 246-240-210, or equivalent NRC or agreement state requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by

the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in (a) of this subsection.

AMENDATORY SECTION (Amending WSR 22-19-084, filed 9/20/22, effective 10/21/22)

WAC 246-240-278 Training for use of manual brachytherapy sources. Except as provided in WAC 246-240-078, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under WAC 246-240-251 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the department, NRC, or an agreement state. The names of board certifications that have been recognized by the department, NRC, or an agreement state are posted on the NRC's medical uses licensee toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the ((~~Committee on Postgraduate~~)) Council on Postdoctoral Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(2)(a) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(i) Two hundred hours of classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) Five hundred hours of work experience, under the supervision of an authorized user who meets the requirements in WAC 246-240-078, 246-240-278 or equivalent agreement state or NRC requirements at a medical institution authorized to use radioactive materials under WAC 246-240-251, involving:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Checking survey meters for proper operation;

(C) Preparing, implanting, and removing brachytherapy sources;

(D) Maintaining running inventories of material on hand;

(E) Using administrative controls to prevent a medical event involving the use of radioactive material;

(F) Using emergency procedures to control radioactive material; and

(b) Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in WAC 246-240-078, 246-240-278, or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ((~~Committee~~)) Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by (a)(ii) of this subsection; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in (a) and (b) of this subsection and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under WAC 246-240-251. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-278, or equivalent agreement state or NRC requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in WAC 246-240-078, 246-240-278, or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in (a) and (b) of this subsection.

AMENDATORY SECTION (Amending WSR 22-19-084, filed 9/20/22, effective 10/21/22)

WAC 246-240-651 Report and notification of a medical event. (1) A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which:

(a) The administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:

(i) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (five rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(A) The total dose delivered differs from the prescribed dose by 20 percent or more;

(B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(C) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(ii) A dose that exceeds 0.05 Sv (five rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

(A) An administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;

(B) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(C) An administration of a dose or dosage to the wrong individual or human research subject;

(D) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(E) A leaking sealed source.

(iii) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

(A) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

(B) Fifty percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

(b) For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

(i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(ii) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(iii) An administration that includes any of the following:

(A) The wrong radionuclide;

(B) The wrong individual or human research subject;

(C) Sealed sources implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

(D) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

(2) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(3) The licensee shall notify by telephone (360-236-3300) the department no later than the next calendar day after discovery of the medical event.

(4) By an appropriate method listed in WAC 246-221-250, the licensee shall submit a written report to the department at P.O. Box 47827, Olympia WA 98504-7827 within 15 days after discovery of the medical event.

(a) The written report must include:

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the individuals who received the administration;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(5) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that they will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this subsection, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide a written description if requested.

(6) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(7) A licensee shall:

(a) Annotate a copy of the report provided to the department with the:

(i) Name of the individual who is the subject of the event; and

(ii) Identification number or if no other identification number is available, the Social Security number ((~~or other identification number, if one has been assigned,~~)) of the individual who is the subject of the event; and

(b) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

AMENDATORY SECTION (Amending WSR 22-19-084, filed 9/20/22, effective 10/21/22)

WAC 246-240-654 Report and notification of a dose to an embryo/fetus or a nursing child. (1) A licensee shall report to the department at P.O. Box 47827, Olympia WA 98504-7827, (phone 360-236-3300), any dose to an embryo/fetus that is greater than 50 mSv (five rem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individ-

ual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

(a) Is greater than 50 mSv (five rem) total effective dose equivalent; or

(b) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee shall notify by telephone the department no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in subsection (1) or (2) of this section.

(4) By an appropriate method listed in WAC 246-221-250, the licensee shall submit a written report to the department within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in subsection (1) or (2) of this section.

(a) The written report must include:

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the embryo/fetus or the nursing child;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(b) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(5) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under subsection (1) or (2) of this section, unless the referring physician personally informs the licensee either that they will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subsection, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide a written description if requested.

(6) A licensee shall:

(a) Annotate a copy of the report provided to the department with the:

(i) Name of the pregnant individual or the nursing child who is the subject of the event; and

(ii) Identification number or if no other identification number is available, the Social Security number ((~~or other identification number, if one has been assigned, of the pregnant individual or the nursing child~~)) of the individual who is the subject of the event; and

(b) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.