AMENDATORY SECTION (Amending WSR 07-14-131, filed 7/3/07, effective 8/3/07)

WAC 246-240-010 Definitions. 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.

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.

Authorized medical physicist means an individual who:

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

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

(a) A specific medical use license issued by the department, the U.S. Nuclear Regulatory Commission or an agreement state;

(b) A medical use permit issued by a U.S. NRC master material licensee;

(c) A permit issued by a U.S. NRC or agreement state broad scope medical use licensee; or

(d) A permit issued by a U.S. NRC master material license broad scope medical use permittee.

Authorized nuclear pharmacist means a pharmacist who:

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

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

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

(b) A permit issued by a U.S. NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(c) A permit issued by a U.S. NRC or agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(d) A permit issued by a U.S. NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

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

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

Authorized user means a physician, dentist, or podiatrist who:

(1) 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

(2) Is identified as an authorized user on:

(a) A department, U.S. NRC, or agreement state license that authorizes the medical use of radioactive material;

(b) A permit issued by a U.S. NRC master material licensee that is authorized to permit the medical use of radioactive material;

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

(d) A permit issued by a U.S. NRC master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

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.

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.

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.

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 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

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.

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.

High dose-rate remote afterloader, as used in this chapter, 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.

Low dose-rate remote afterloader, as used in this chapter, means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

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.

Manual brachytherapy, as used in this chapter, 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.

Medical event means an event that meets the criteria in WAC 246-240-651.

Medical institution means an organization in which more than

one medical discipline is practiced.

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.

Medium dose-rate remote afterloader, as used in this chapter, means a brachytherapy device that remotely delivers a dose rate of greater than 2 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.

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

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.

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.

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.

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

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, or a radiation safety officer.

Prescribed dosage means the specified activity or range of activity of unsealed radioactive material as documented:

(1) In a written directive; or

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

Prescribed dose means:

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

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

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

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

Pulsed dose-rate remote afterloader, as used in this chapter, 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:

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

(2) Is used to simulate the radiobiology of a low dose-rate

treatment by inserting the source for a given fraction of each hour.

Radiation safety officer means an individual who:

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

(2) Is identified as a radiation safety officer on a specific medical use license issued by the department prior to October 5, 2005, the U.S. NRC or an agreement state; or

(3) A medical use permit issued by a commission master material licensee.

Sealed source and device registry means the national registry that contains all the registration certificates, generated by both the U.S. 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.

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.

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

Teletherapy, as used in this chapter, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

Temporary job site means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

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.

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.

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

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.

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.

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 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-060 Written directives. (1) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels ((~~(MBq)~~)) (30 microcuries ((~~(μCi)~~))), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within forty-eight hours of the oral directive.

(2) The written directive must contain the patient or human research subject's name and the following information:

(a) For any administration of quantities greater than 1.11 ((~~MBq~~)) megabecquerels (30 ((~~μCi~~)) microcuries) of sodium iodide I-131: The dosage;

(b) For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide I-131: The radioactive drug, dosage, and route of administration;

(c) For gamma stereotactic radiosurgery: The total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(d) For teletherapy: The total dose, dose per fraction, number of fractions, and treatment site;

(e) For high dose-rate remote afterloading brachytherapy: The radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(f) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(i) Before implantation: Treatment site, the radionuclide, and dose; and

(ii) After implantation but before completion of the procedure: The radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

(3) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within forty-eight hours of the oral revision.

(4) The licensee shall retain a copy of the written directive in accordance with WAC 246-240-557.

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-107 Determination of dosages of unsealed radioactive material for medical use. (1) A licensee shall determine and record the activity of each dosage before medical use.

(2) For a unit dosage, this determination must be made by:

(a) Direct measurement of radioactivity; or

(b) A decay correction, based on the activity or activity concentration determined by:

(i) A manufacturer, producer, or preparer licensed under WAC 246-235-100 or equivalent U.S. NRC or agreement state requirements; or

(ii) An agreement state or U.S. NRC licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug (IND) protocol accepted by FDA.

(3) For other than unit dosages, this determination must be made by:

(a) Direct measurement of radioactivity;

(b) Combination of measurement of radioactivity and mathematical calculations; or

(c) Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer, producer, or preparer licensed under WAC 246-235-100 or equivalent agreement state requirements.

(4) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than twenty percent.

(5) A licensee shall retain a record of the dosage determination required by this section in accordance with WAC 246-240-569.

AMENDATORY SECTION (Amending WSR 07-14-131, filed 7/3/07, effective 8/3/07)

WAC 246-240-110 Authorization for calibration, transmission, and reference sources. Any person authorized by WAC 246-240-016 for medical use of radioactive material may receive, possess, and

use any of the following radioactive material for check, calibration, transmission, and reference use:

(1) Sealed sources, not exceeding 1.11 ((~~GBq~~)) gigabecquerels (30 ((~~mCi~~)) millicuries) each, manufactured and distributed by a person licensed under WAC 246-235-102 or equivalent agreement state or U.S. NRC regulations.

(2) Sealed sources, not exceeding 1.11 ((~~GBq~~)) gigabecquerels (30 ((~~mCi~~)) millicuries) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under WAC 246-235-102, or equivalent agreement state or U.S. NRC regulations if the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

(3) Any radioactive material with a half-life not longer than one hundred twenty days in individual amounts not to exceed 0.56 ((~~GBq~~)) gigabecquerels (15 ((~~mCi~~)) millicuries).

(4) Any radioactive material with a half-life longer than one hundred twenty days in individual amounts not to exceed the smaller of 7.4 ((~~MBq~~)) megabecquerels (200 ((~~μCi~~)) microcuries) or 1000 times the quantities in Schedule B of WAC 246-232-120.

(5) Technetium-99m in amounts as needed.

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-113 Requirements for possession of sealed sources and brachytherapy sources. (1) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

(2) A licensee in possession of a sealed source shall:

(a) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(b) Test the source for leakage at intervals not to exceed six months or at other intervals approved by the department, the U.S. NRC, or an agreement state in the sealed source and device registry.

(3) To satisfy the leak test requirements of this section, the licensee shall ensure the sample is analyzed by such method that the leak test can detect the presence of 185 ((~~Bq~~)) becquerels (0.005 ((~~μCi~~)) microcuries) of radioactive material in the sample.

(4) A licensee shall retain leak test records in accordance with WAC 246-240-572(1).

(5) If the leak test reveals the presence of 185 ((~~Bq~~)) becquerels (0.005 ((~~μCi~~)) microcuries) or more of removable contamination, the licensee shall:

(a) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in chapters 246-221 and 246-232 WAC; and

(b) File a report within five days of the leak test in accordance with WAC 246-240-657.

(6) A licensee need not perform a leak test on the following sources:

(a) Sources containing only radioactive material with a half-life of less than thirty days;

(b) Sources containing only radioactive material as a gas;

(c) Sources containing 3.7 ((~~MBq~~)) megabecquerels (100 ((~~µCi~~)) microcuries) or less of beta-or gamma-emitting material or 0.37 ((~~MBq~~)) megabecquerels (10 ((~~µCi~~)) microcuries) or less of alpha-emitting material;

(d) Seeds of iridium-192 encased in nylon ribbon; and

(e) Sources stored and not being used. However, the licensee shall test each source for leakage before any use or transfer unless it has been leak tested within six months before the date of use or transfer.

(7) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a physical inventory of all the sources in its possession at intervals not to exceed six months. The licensee shall retain each inventory record in accordance with WAC 246-240-572.

AMENDATORY SECTION (Amending WSR 07-14-131, filed 7/3/07, effective 8/3/07)

WAC 246-240-151 Use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required. Except for quantities that require a written directive under WAC 246-240-060(2), a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that is:

(1) Obtained from a manufacturer, producer, or preparer licensed under WAC 246-235-100(1) or equivalent U.S. NRC or agreement state requirements; or

(2) Prepared by an authorized nuclear pharmacist, or a physician who is an authorized user and who meets the requirements specified in WAC 246-240-163, or 246-240-210 and 246-240-163 (3)(a)(ii)(G), or an individual under the supervision of either as specified in WAC 246-240-057; or

(3) Obtained from and prepared by an agreement state or U.S. NRC licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug (IND) protocol accepted by FDA; or

(4) Prepared by the licensee for use in research in accordance

with a radioactive drug research committee-approved application or an investigational new drug (IND) protocol accepted by FDA.

AMENDATORY SECTION (Amending WSR 07-14-131, filed 7/3/07, effective 8/3/07)

WAC 246-240-157 Use of unsealed radioactive material for imaging and localization studies for which a written directive is not required. Except for quantities that require a written directive under WAC 246-240-060(2), a licensee may use any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

(1) Obtained from a manufacturer, producer, or preparer licensed under WAC 246-235-100(1) or equivalent agreement state or U.S. NRC requirements; or

(2) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in WAC 246-240-163, or 246-240-210 and 246-240-163 (3)(a)(ii)(G), or an individual under the supervision of either as specified in WAC 246-240-057;

(3) Obtained from and prepared by an agreement state or U.S. NRC licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug (IND) protocol accepted by FDA; or

(4) Prepared by the licensee for use in research in accordance with a radioactive drug research committee-approved application or an investigational new drug (IND) protocol accepted by FDA.

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-160 Permissible molybdenum-99 concentration. (1) A licensee may not administer to humans a radiopharmaceutical that contains more than:

(a) 5.55 kilobecquerel of molybdenum-99 per 37 megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or

(b) 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection, (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or

(c) 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

(2) A licensee that uses molybdenum-99/technetium-99m

generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with subsection (1) of this section.

(3) A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of strontium-82 and strontium-85 to demonstrate compliance with subsection (1)(a) of this section.

(4) If a licensee is required to measure the molybdenum-99 concentration, or strontium-82 and strontium-85 concentrations the licensee shall retain a record of each measurement in accordance with WAC 246-240-587.

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-201 Use of unsealed radioactive material for which a written directive is required. A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:

(1) Obtained from a manufacturer, producer, or preparer licensed under WAC 246-235-100(1) or equivalent agreement state or U.S. NRC requirements; or

(2) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in WAC 246-240-163 or 246-240-210, or an individual under the supervision of either as specified in WAC 246-240-057; or

(3) Obtained from and prepared by an agreement state or U.S. NRC licensee for use in research in accordance with an investigational new drug (IND) protocol accepted by FDA; or

(4) Prepared by the licensee for use in research in accordance with an investigational new drug (IND) protocol accepted by FDA.

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-569 Records of dosages of unsealed radioactive material for medical use. (1) A licensee shall maintain a record of dosage determinations required by WAC 246-240-107 for three years.

(2) The record must contain:

(a) The radiopharmaceutical;

(b) The patient's or human research subject's name, or

identification number if one has been assigned;

(c) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 ((~~MBq~~)) megabecquerels (30 ((~~µCi~~)) microcuries);

(d) The date and time of the dosage determination; and

(e) The name of the individual who determined the dosage.

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-587 Records of molybdenum-99, strontium-82, and strontium-85 concentrations. A licensee shall maintain a record of the molybdenum-99, strontium-82, and/or strontium-85 concentration tests required by WAC 246-240-160(2) for three years.

(1) The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerels of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement.

(2) For each measured elution of rubidium-82, the ratio of the measures expressed as kilobecquerels of strontium-82 per megabecquerel of rubidium-82 (or microcuries of strontium-82 per millicurie of rubidium), and/or kilobecquerels of strontium-85 per megabecquerel of rubidium-82 (or microcuries of strontium-85 per millicurie of rubidium), the time and date of the measurement, and the name of the individual who made the measurement.

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-657 Report of a leaking source. A licensee shall file a report within five days if a leak test required by WAC 246-240-113 reveals the presence of 185 ((~~Bq~~)) becquerels (0.005 ((~~µCi~~)) microcuries) or more of removable contamination. The report must be filed with the department, and sent to the department at P.O. Box 47827, Olympia WA 98504-7827, (phone 360-236-3300). The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.