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

**WAC 246-240-001 Purpose and scope.** This chapter contains the requirements and provisions for the medical use of radioactive material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of chapters 246-220, 246-221, 246-222, 246-232, 246-235, and 246-254 WAC, apply to applicants and licensees subject to this chapter unless specifically exempted. ((~~When a requirement in this chapter differs from the requirement in an existing license condition, the requirement in this chapter shall govern.~~))

AMENDATORY SECTION (Amending WSR 09-06-003, filed 2/18/09, effective 3/21/09)

**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; or

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

(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 07-14-131, filed 7/3/07, effective 8/3/07)

**WAC 246-240-069 Training for radiation safety officer.** Except as provided in WAC 246-240-078, the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer under WAC 246-240-051 to be an individual who:

(1) Is certified by a specialty board whose certification process has been recognized by the department, the U.S. NRC, or an agreement state, and who meets the requirements of subsections (4) and (5) of this section. (Specialty boards whose certification process has been recognized by the department, the U.S. Nuclear Regulatory Commission or an agreement state will be posted on the NRC's web page, at http://www.nrc.gov.) To be recognized, a specialty board shall require all candidates for certification to:

(a) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of twenty college credits in physical science;

(b) Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

(c) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(i) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) Have two years of full-time practical training and/or

supervised experience in medical physics:

(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the commission or an agreement state; or

(B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in WAC 246-240-078, 246-240-163 or 246-240-210; and

(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(d) Obtain written certification under oath signed by a preceptor radiation safety officer that the individual has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; or

(2)(a) Has completed 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) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on a department or agreement state license or license issued by the U.S. NRC that authorizes similar type(s) of use(s) of radioactive material involving the following:

(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 instruments used to measure radionuclides;

(C) Securing and controlling radioactive material;

(D) Using administrative controls to avoid mistakes in the administration of radioactive material;

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

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

(G) Disposing of radioactive material; or

(b) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the department, the U.S. NRC, or an agreement state under WAC 246-240-072 and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as radiation safety officer and who meets the requirements in subsections (4) and (5) of this section;

or

(3) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license or a medical physicist who has been certified by a specialty board whose certification process has been recognized by the department, the U.S. Nuclear Regulatory Commission or an agreement state under WAC 246-240-072 and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has radiation safety officer responsibilities; and

(4) Has obtained written certification under oath, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in subsection (5) of this section, and in subsection (1)(a) and (b), or (c)(i) and (ii) of this section, or subsection (2)(a) or (b) of this section, or subsection (3) of this section and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and

(5) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by an authorized medical physicist, authorized user, authorized nuclear pharmacist, or radiation safety officer, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

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

**WAC 246-240-072 Training for an authorized medical physicist.** Except as provided in WAC 246-240-078, the licensee shall require the authorized medical physicist to be an individual who:

(1) Is certified by a specialty board whose certification process has been recognized by the department, the U.S. Nuclear Regulatory Commission or an agreement state and who meets the requirements in subsections (2)(b) and (3) of this section. (Specialty boards whose certification process has been recognized by the commission or an agreement state will be posted on the NRC's web page at http://www.nrc.gov.) To be recognized, a specialty board shall require all candidates for certification to:

(a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(b) Have two years of full-time practical training and/or supervised experience in medical physics:

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the commission or an agreement state; or

(ii) In clinical radiation facilities providing high energy,

external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in WAC 246-240-078, 246-240-278 or 246-240-399;

(c) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(2)(a) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use modalities for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high energy, external beam therapy and brachytherapy services and must include:

(i) Performing sealed source leak tests and inventories;

(ii) Performing decay corrections;

(iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(b) Has obtained written certification under oath that the individual has satisfactorily completed the requirements in subsections (1)(a) and (b) and (3), or (2)(a) and (3) of this section, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification under oath must be signed by a preceptor authorized medical physicist who meets the requirements in WAC 246-240-072, 246-240-078, or equivalent U.S. NRC or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(3) Has training for the type(s) of use in the modalities for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

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

**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, the U.S. Nuclear Regulatory Commission or an agreement state and who meets the requirements in subsection (2)(b) of this section. (Specialty boards whose certification process has been recognized by the commission or an agreement state will be posted on the NRC's web page at http://www.nrc.gov.) To be recognized, a specialty board shall require all candidates for certification to:

(a) Have graduated from a pharmacy program accredited by the American Council On Pharmaceutical 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 four thousand hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than two thousand 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 two hundred hours in a structured educational program consisting of both:

(i) Didactic 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 certification under oath, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subsections (1)(a), (b), and (c) or (2)(a) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

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

**WAC 246-240-078 Training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.** (1) An individual identified as a radiation safety officer, a teletherapy or medical physicist, or a nuclear pharmacist on a department, U.S. NRC, or agreement state license, or a permit issued by an agreement state or U.S. NRC broad scope licensee or master material license permit, or by a master material license permittee of broad scope before October 24, 2006, need not comply with the training requirements of WAC 246-240-278, 246-240-072, or 246-240-075, respectively.

(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the department or agreement state, or U.S. NRC broad scope license, or license issued before October 24, 2006, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of WAC 246-240-151 and 246-240-399.

(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 07-14-131, filed 7/3/07, effective 8/3/07)

**WAC 246-240-154 Training for uptake, dilution, and excretion studies.** 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 246-240-151 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the department, the U.S. Nuclear Regulatory Commission or an agreement state and who

meets the requirements of subsection (3)(b) of this section. (Specialty boards whose certification process has been recognized by the department, the U.S. NRC or an agreement state will be posted on the NRC's web page at http://www.nrc.gov.) To be recognized, a specialty board shall require all candidates for certification to:

(a) Meet the requirements in subsection (3)(a) of this section; and

(b) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(2) Is an authorized user under WAC 246-240-163 or 246-240-210 or equivalent agreement state or U.S. NRC requirements; or subsection (3)(a) of this section; or

(3)(a) Has completed sixty hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. 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, 246-240-154, 246-240-163, or 246-240-210 or equivalent U.S. NRC or agreement state requirements, involving:

(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; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(b) Has obtained written certification under oath, signed by a preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-154, 246-240-163, or 246-240-210, or equivalent agreement state or U.S. NRC requirements, that the individual has satisfactorily completed the requirements in (a) of this subsection and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under WAC 246-240-151.

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

**WAC 246-240-163 Training for imaging and localization studies.** 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 246-240-157 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the department, the U.S. Nuclear Regulatory Commission or an agreement state and who meets the requirements in subsection (3)(b) of this section. (Specialty boards whose certification process has been recognized by the commission or an agreement state will be posted on the U.S. NRC's web page at http://www.nrc.gov.) To be recognized, a specialty board shall require all candidates for certification to:

(a) Satisfy the requirements in subsection (3)(a) of this section; and

(b) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(2) Is an authorized user under WAC 246-240-210 and meets the requirements in WAC 246-240-163 (3)(a)(ii)(G) and 246-240-210 or equivalent agreement state or U.S. NRC requirements; or

(3)(a) Has completed seven hundred hours of training and experience, including a minimum of eighty hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

(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;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in WAC 246-240-078, 246-240-163, or 246-240-210 and 246-240-163 (3)(a)(ii)(G), or equivalent agreement state or U.S. NRC requirements, involving:

(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 safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(b) Has obtained written certification under oath, signed by a preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-163, or 246-240-210 and 246-240-163 (3)(a)(ii)(G) or equivalent agreement state or U.S. NRC requirements, that the individual has satisfactorily completed the requirements in (a) of this subsection and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under WAC 246-240-151 and 246-240-157.

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

**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, the U.S. Nuclear Regulatory Commission or an agreement state. (Specialty boards whose certification process has been recognized by the commission or an agreement state will be posted on the NRC's web page at http://www.nrc.gov.) To be 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 seven hundred hours of training and experience as described in subsection (2) 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 Training of the American Osteopathic Association;

(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 by-product material; and

(c) Obtain written certification under oath that the

individual has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under WAC 246-240-201. The written certification under oath must be signed by a preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-210, or equivalent U.S. NRC or agreement state requirements. The preceptor authorized user, who meets the requirements in WAC 246-240-078 or 246-240-210 must have experience in administering dosages in the same dosage category or categories (i.e., this section) as the individual requesting authorized user status; or

(2) Has completed seven hundred hours of training and experience, including a minimum of two hundred 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:

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

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in subsection (1) or (2) of this section, or equivalent U.S. 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 (i.e., this section) as the individual requesting authorized user status. The work experience must involve:

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

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

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

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

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

(vi) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(vii) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

(A) 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;

(B) 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 (b)(vii)(A) of this subsection;

(C) Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required; and/or

(D) Parenteral administration of any other radionuclide for which a written directive is required; and

(E) Has obtained written certification under oath that the individual has satisfactorily completed the requirements in subsection (1)(a) and ((~~(b)~~)) (2)(b)(vii) of this section, WAC 246-240-078, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under WAC 246-240-201. The written certification under oath must be signed by a preceptor authorized user who meets the requirements in this section, or equivalent U.S. NRC or agreement state requirements. The preceptor authorized user, who meets the requirements in this subsection (2), must also have experience in administering dosages in the same dosage category or categories (i.e., this section) as the individual requesting authorized user status.

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

**WAC 246-240-213 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).** Except as provided in WAC 246-240-078, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in subsection (3) of this section and whose certification has been recognized by the department, the U.S. Nuclear Regulatory Commission or an agreement state. (Specialty boards whose certification process has been recognized by the commission or an agreement state will be posted on the NRC's web page at http://www.nrc.gov.); or

(2) Is an authorized user under WAC 246-240-210 for uses listed in WAC 246-240-210 (2)(b)(vii)(A) and (B), 246-240-216, or equivalent agreement state or U.S. NRC requirements; or

(3)(a) Has successfully completed eighty hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in WAC 246-240-078, 246-240-210, 246-240-213, 246-240-216, or equivalent agreement state or U.S. NRC requirements. A supervising authorized user who meets the requirements in WAC 246-240-210(2), must also have experience in administering dosages as specified in WAC 246-240-210 (2)(b)(vii)(A) or (B). The work experience must involve:

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

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

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

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

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

(vi) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Has obtained written certification under oath that the individual has satisfactorily completed the requirements in (a) and (b) of this subsection and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under WAC 246-240-201. The written certification under oath must be signed by a preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-210, 246-240-213, 246-240-216, or equivalent agreement state or U.S. NRC requirements. A preceptor authorized user, who meets the requirement in WAC 246-240-210(2), must also have experience in administering dosages as specified in WAC 246-240-210 (2)(b)(vii)(A) or (B).

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

**WAC 246-240-216 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).** Except as provided in WAC 246-240-078, the licensee shall require an

authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in subsection (3) of this section and whose certification has been recognized by the department, the U.S. NRC or an agreement state. (Specialty boards whose certification process has been recognized by the commission or an agreement state will be posted on the NRC's web page at http://www.nrc.gov.); or

(2) Is an authorized user under WAC 246-240-210 for uses listed in WAC 246-240-210 (2)(b)(vii)(B), or equivalent agreement state or U.S. NRC requirements; or

(3)(a) Has successfully completed eighty hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in WAC 246-240-078, 246-240-210, 246-240-216, or equivalent agreement state or U.S. NRC requirements. A supervising authorized user, who meets the requirements in WAC 246-240-210(2), must also have experience in administering dosages as specified in WAC 246-240-210 (2)(b)(vii)(B).

The work experience must involve:

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

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

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

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

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

(vi) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Has obtained written certification under oath that the individual has satisfactorily completed the requirements in (a) and (b) of this subsection and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under WAC 246-240-201. The written certification under oath must be signed by a preceptor authorized

user who meets the requirements in WAC 246-240-078, 246-240-210, 246-240-216, or equivalent agreement state or U.S. NRC requirements. A preceptor authorized user, who meets the requirements in WAC 246-240-210(2), must have experience in administering dosages as specified in WAC 246-240-210 (2)(b)(vii)(B).

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

**WAC 246-240-219 Training for the parenteral administration of unsealed radioactive material requiring a written directive.** Except as provided in WAC 246-240-078, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

(1) Is an authorized user under WAC 246-240-210 for uses listed in WAC 246-240-210 (2)(b)(vii)(C) or (D), or equivalent agreement state or U.S. NRC requirements; or

(2) Is an authorized user under WAC 246-240-278 or 246-240-399, or equivalent agreement state or U.S. NRC requirements and who meets the requirements in subsection (4) of this section; or

(3) Is certified by a medical specialty board whose certification process has been recognized by the U.S. NRC or an agreement state under WAC 246-240-278 or 246-240-399, and who meets the requirements in subsection (4) of this section.

(4)(a) Has successfully completed eighty hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in WAC 246-240-078, 246-240-210, 246-240-219, or equivalent agreement state or U.S. NRC requirements, in the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in WAC 246-240-210 must have experience in administering dosages as specified in WAC 246-240-210 (2)(b)(vii)(C) and/or (D). The work experience must involve:

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

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

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

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

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

(vi) Administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least three cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(5) Has obtained written certification under oath that the individual has satisfactorily completed the requirements in subsection (2) or (3) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written certification under oath must be signed by a preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-210, 246-240-219, or equivalent agreement state or U.S. NRC requirements. A preceptor authorized user, who meets the requirements in WAC 246-240-210, must have experience in administering dosages as specified in WAC 246-240-210 (2)(b)(vii)(C) and/or (D).

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

**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, the U.S. NRC, or an agreement state. (Specialty boards whose certification process has been recognized by the commission or an agreement state will be posted on the NRC's web page at http://www.nrc.gov.) To be 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 Training of the American Osteopathic Association;

(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 high and low dose-rate brachytherapy; and

(c) Obtain written certification under oath, signed by a preceptor authorized user who meets the requirements in WAC 246-240-278 or equivalent U.S. NRC or agreement state requirements, that the individual has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized in WAC 246-240-251; 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 U.S. NRC requirements at a medical institution, 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 U.S. 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 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 certification under oath, signed by a preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-278 or equivalent agreement state or U.S. NRC

requirements, that the individual has satisfactorily completed the requirements in subsection (1)(a) of this section, or (a) and (b) of this subsection and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under WAC 246-240-251.

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

**WAC 246-240-281 Training for ophthalmic use of strontium-90.** Except as provided in WAC 246-240-078, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

(1) Is an authorized user under WAC 246-240-278 or equivalent agreement state or U.S. NRC requirements; or

(2)(a) Has completed twenty-four hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals.

This supervised clinical training must involve:

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow up and review of each individual's case history; and

(c) Has obtained written certification under oath, signed by a preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-278, 246-240-281, or equivalent agreement state or U.S. NRC requirements, that the individual has satisfactorily completed the requirements in subsections (1) and (2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

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

**WAC 246-240-399 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.** Except as provided in WAC 246-240-078, the licensee shall require an authorized user of a sealed source for a use authorized under WAC 246-240-351 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the department, the U.S. NRC, or an agreement state. (Specialty boards whose certification process has been recognized by the NRC or an agreement state will be posted on the NRC's web page at http://www.nrc.gov.) To be 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 therapy 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 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 stereotactic radiosurgery, high and low dose-rate brachytherapy, and external beam therapy; or

(2)(a) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit 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, 246-240-399 or equivalent agreement state or U.S. NRC requirements at a medical institution, involving:

(A) Reviewing full calibration measurements and periodic spot-checks;

(B) Preparing treatment plans and calculating treatment doses and times;

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

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(E) Checking and using survey meters; and

(F) Selecting the proper dose and how it is to be administered; and

(b) Has completed three years of supervised clinical

experience in radiation therapy, under an authorized user who meets the requirements in WAC 246-240-078, 246-240-399 or equivalent U.S. 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 Royal College of Physicians and Surgeons of Canada or the Committee 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 certification under oath that the individual has satisfactorily completed the requirements in subsection (1)(a) of this section, or (a) and (b), and (d) of this subsection and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification under oath must be signed by a preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-399 or equivalent U.S. NRC or agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(d) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.