From: "Frazee, Terry (DOH)" <Terry.Frazee@DOH.WA.GOV>
To: <kxs@nrc.gov>
Date: 05/15/2007 6:50:11 PM
Subject: RATS 2006-1 Proposed Regulation

Below is a link to our rule-making order proposing a permanent change to chapters 245-235 and 246-240 of the Washington Administrative Code. The state-required red-line/strike out text is included in the order.

We believe that these revisions will satisfy the compatibility and health and safety categories established in your Procedure SA-200 for the regulation amendment described as RATS 2006-1 (SA-201).

http://www.leg.wa.gov/documents/wsr/2007/07/07-07-074.htm

If you have any questions or comments, please contact me at your earliest convenience. Thank you.

****
Public Health - Always Working for a Safer and Healthier Washington
****

This message from Terry C. Frazee
Western Regional Director
Office of Radiation Protection
Division of Environmental Health
Washington Department of Health

Quick ways to reach me:
Voice = 360-236-3213
FAX = 360-236-2255

Also, visit our Home Page at
http://www.doh.wa.gov/ehp/rp

We are located in Town Center 2 at 111 Israel Rd SE, Tumwater, WA 98501.
Our mailing address is PO Box 47827, Olympia, WA 98504-7827.

CC: <jct1@nrc.gov>, "Robertson, Gary (DOH)" <Gary.Robertson@DOH.WA.GOV>, "Scroggs, Arden (DOH)" <Arden.Scroggs@DOH.WA.GOV>

Mail Envelope Properties (464A390C.F76 : 19 : 20342)

Subject:	RATS 2006-1 Proposed Regulation
Creation Date	05/15/2007 6:49:18 PM
From:	"Frazee, Terry (DOH)" <Terry.Frazee@DOH.WA.GOV>
Created By:	Terry.Frazee@DOH.WA.GOV

Recipients

nrc.gov
TWGWPO02.HQGWDO01
KXS (Kathleen Schneider)
JCT1 CC (Jennifer Tobin)

DOH.WA.GOV
Arden.Scroggs CC (Arden (DOH) Scroggs)
Gary.Robertson CC (Gary (DOH) Robertson)

Post Office	**Route**
TWGWPO02.HQGWDO01	nrc.gov
	DOH.WA.GOV

Files	**Size**	**Date & Time**
MESSAGE	1129	05/15/2007 6:49:18 PM
TEXT.htm	2674	
Mime.822	5963	

Options

Expiration Date:	None
Priority:	Standard
ReplyRequested:	No
Return Notification:	None
Concealed Subject:	No
Security:	Standard

WSR 07-07-074

PROPOSED RULES

DEPARTMENT OF HEALTH

[Filed March 16, 2007, 8:05 a.m.]

Original Notice.

Exempt from preproposal statement of inquiry under RCW 34.05.310(4).

Title of Rule and Other Identifying Information: Chapter 246-235 WAC, Radioactive materials -- Specific licenses and chapter 246-240 WAC, Radioactive materials -- Medical use of radioactive material. This proposal makes technical corrections necessary for conformance with United States Nuclear Regulatory Commission (NRC) regulations.

Proposed changes are amending WAC 246-235-100, 246-235-102, 246-240-010, 246-240-025, 246-240-066, 246-240-069, 246-240-072, 246-240-081, 246-240-110, 246-240-151, 246-240-154, 246-240-157, 246-240-163, 246-240-210, 246-240-213, 246-240-216, 246-240-219, 246-240-269, 246-240-278 and 246-240-399; and repealing WAC 246-240-451, 246-240-454, 246-240-457, 246-240-460, 246-240-463, 246-240-466, 246-240-469, 246-240-472, 246-240-475, 246-240-478, 246-240-481, 246-240-484, and 246-240-487.

Hearing Location(s): Department of Health (DOH), Town Center 2, Room 530, 111 Israel Road S.E., Tumwater, WA 98501, on April 24, 2007, at 10:30 a.m.

Date of Intended Adoption: April 24, 2007.

Submit Written Comments to: Terry C. Frazee, Western Regional Director, DOH, Office of Radiation Protection, Box 47827, Olympia, WA 98504-7827, web site http://www3.doh.wa.gov/policyreview/, fax (360) 236-2255, by April 17, 2007.

Assistance for Persons with Disabilities: Contact C. DeMaris by April 17, 2007, TTY (800) 833-6388 or 711.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The purpose of this change is to clarify, and correct omissions in, the previous rule, as well as to remove obsolete requirements and correct certain punctuation and typographical errors consistent with technical amendments.

Reasons Supporting Proposal: The state of Washington, as an agreement state, must keep its rules compatible with those of the NRC.

Statutory Authority for Adoption: RCW 70.98.050.

Statute Being Implemented: RCW 70.98.050.

Rule is necessary because of federal law, final amendments to 10 C.F.R. as published in 71 F.R. 15005.

Name of Proponent: Washington department of health, governmental.

Name of Agency Personnel Responsible for Drafting: Curt DeMaris, 111 Israel Road S.E., Tumwater, WA, (360)

236-3223; Implementation and Enforcement: Arden Scroggs, 111 Israel Road S.E., Tumwater, WA, (360) 236-3221.

No small business economic impact statement has been prepared under chapter 19.85 RCW. This rule adopts NRC regulations without material change. Under RCW 19.85.025, 19.85.061, and 34.05.3150(4), a small business economic impact statement is not required for rules that adopt federal regulations without material change. The revisions to chapters 246-235 and 246-240 WAC are necessary to conform DOH rules to recent NRC amendments to 10 C.F.R. Parts 20, 32, 35 and 73. See 71 Fed. Reg. 15005 (March 27, 2006). The amendments will maintain compatibility of DOH rules with those of the NRC.

A cost-benefit analysis is not required under RCW 34.05.328. These rules adopt NRC regulations without material change and the DOH is required adopt them in order to maintain compatibility under agreement with the NRC. Under RCW 34.05.328 (5)(b)(iii), the cost-benefit requirement does not apply to rules adopting federal regulations without material change.

March 15, 2007

B. White

for M. C. Selecky

Secretary

OTS-9129.1

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

WAC 246-235-100 Manufacture, preparation, or commercial transfer of radiopharmaceuticals for medical use. (1) An application for a specific license to manufacture and, prepare, or transfer for commercial distribution radiopharmaceuticals containing radioactive material for use by persons licensed under chapter 246-240 WAC for medical use in humans will be approved if:

(a) The applicant satisfies the general requirements specified in WAC 246-235-020;

(b) The applicant submits evidence that:

(i) The applicant is registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer; or

(ii) The applicant is licensed as a nuclear pharmacy by the state board of pharmacy;

(c) The applicant submits information on the radionuclide, chemical and physical form, maximum activity per vial, syringe, generator, or other container of the radiopharmaceutical, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by medical use licensees; and

(d) The applicant satisfies the labeling requirements specified by the state board of pharmacy in WAC 246-903-020. For a drug manufacturer, the labels required by this subsection are in addition to the labeling required by the Food and Drug Administration (FDA) and may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(2) A nuclear pharmacy licensee:

(a) May prepare radiopharmaceuticals for medical use provided the radiopharmaceutical is prepared by or under the supervision of an authorized nuclear pharmacist.

(b) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(i) This individual qualifies as an authorized nuclear pharmacist as defined in WAC 246-240-010;

(ii) This individual meets the state board of pharmacy requirements in WAC 246-903-030, Nuclear pharmacists, and the requirements of WAC 246-240-081 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(iii) This individual is designated as an authorized nuclear pharmacist in accordance with (d) of this subsection.

(c) The actions authorized in (a) and (b) of this subsection are permitted in spite of more restrictive language in license conditions.

(d) May designate a pharmacist as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the department, the U.S. NRC, or an agreement state.

(e) Shall provide to the department a copy of each individual's letter of notification from the state board of pharmacy recognizing the individual as a nuclear pharmacist, within thirty days of the date the licensee allows the individual to work as an authorized nuclear pharmacist under (b) of this subsection.

(3) A manufacturer or nuclear pharmacy licensee shall possess and use instrumentation to measure the radioactivity of radiopharmaceuticals. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radiopharmaceuticals, prior to transfer for commercial distribution. In addition, the licensee shall:

(a) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(b) Check each instrument for constancy and proper operation at the beginning of each day of use.

(4) Nothing in this section relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radiopharmaceuticals.

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-235-100, filed 2/6/06, effective 3/9/06; 98-13-037, § 246-235-100, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. 91-15-112 (Order 184), § 246-235-100, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. 91-02-049 (Order 121), recodified as § 246-235-100, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.050. 81-01-011 (Order 1570), § 402-22-110, filed 12/8/80. Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-22-110, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-076.]

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

WAC 246-235-102 Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing

radioactive material to persons licensed under chapter 246-240 WAC for use as a calibration, transmission, or reference source or for the uses listed in WAC 246-240-251, 246-240-301, and 246-240-351 will be approved if:

(1) The applicant satisfies the general requirements in WAC 246-235-020;

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(a) The radioactive material contained, its chemical and physical form and amount;

(b) Details of design and construction of the source or device;

(c) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

(d) For devices containing radioactive material, the radiation profile of a prototype device;

(e) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

(f) Procedures and standards for calibrating sources and devices;

(g) Legend and methods for labeling sources and devices as to their radioactive content; and

(h) Instructions for handling and storing the source or device from the radiation safety standpoint, these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device: Provided that instructions which are too lengthy for the label may be summarized on the label and printed in detail on a brochure which is referenced on the label.

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the named source or device is licensed by the department for distribution to persons licensed under chapter 246-240 WAC or under equivalent regulations of the United States Nuclear Regulatory Commission, an agreement state or a licensing state: Provided that the labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source.

(4) If the applicant desires that the source or device be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(5) In determining the acceptable interval for test of leakage of radioactive material, the department will consider information that includes, but is not limited to:

(a) Primary containment (source capsule);

(b) Protection of primary containment;

(c) Method of sealing containment;

(d) Containment construction materials;

(e) Form of contained radioactive material;

(f) Maximum temperature withstood during prototype tests;

(g) Maximum pressure withstood during prototype tests;

(h) Maximum quantity of contained radioactive material;

(i) Radiotoxicity of contained radioactive material; and

(j) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-235-102, filed 2/6/06, effective 3/9/06; 98-13-037, § 246-235-102, filed 6/8/98, effective 7/9/98.]

OTS-9130.4

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

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 ((~~prior to October 5, 2005.~~

~~(3)~~));

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

(c) A permit issued by a ((~~commission~~)) U.S. NRC or agreement state broad scope medical use licensee ((~~prior to October 5, 2005~~)); or

(((~~4~~))) (d) A permit issued by a ((~~commission~~)) U.S. NRC master material license broad scope medical use permittee ((~~prior to October 5, 2005~~)).

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 ((~~prior to October 5, 2005~~)), 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) ((~~A permit issued by a commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;~~

~~(5) A permit issued by a commission or agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or~~

~~(6) A permit issued by a commission master material license board scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or~~

~~(7)~~)) 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 ((~~prior to October 5, 2005,~~)) that authorizes the medical use of radioactive material((~~:~~));

(((~~(3)~~))) (b) A permit issued by a ((~~commission~~)) U.S. NRC master material licensee that is authorized to permit the medical use of ((~~by-product~~)) radioactive material;

(((~~(4)~~))) (c) A permit issued by a ((~~commission~~)) department, U.S. NRC, or agreement state specific licensee of broad scope that is authorized to permit the medical use of ((~~by-product~~)) radioactive material; or

(((~~(5)~~))) (d) A permit issued by a ((~~commission~~)) U.S. NRC master material license broad scope permittee that is authorized to permit the medical use of ((~~by-product~~)) 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.

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.

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.

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-240-010, filed 2/6/06, effective 3/9/06; 98-13-037, § 246-240-010, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. 92-06-008 (Order 245), § 246-240-010, filed 2/21/92, effective 3/23/92.]

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

WAC 246-240-025 Notifications. (1) A licensee shall notify the department no later than thirty days after:

(a) An authorized user, an authorized nuclear pharmacist, a radiation safety officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(b) The licensee's mailing address changes;

(c) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in WAC 246-232-050(2); ((~~or~~))

(d) The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used under either WAC 246-240-151 or 246-240-157; or

(e) The licensee permits an authorized user or an individual qualified to be a radiation safety officer, under WAC 246-240-069 and 246-240-081, to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer in accordance with WAC 246-240-051(3).

(2) The licensee shall send the documents required in this section to the department at P.O. Box 47827, Olympia WA 98504-7827.

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-240-025, filed 2/6/06, effective 3/9/06; 98-13-037, § 246-240-025, filed 6/8/98,

effective 7/9/98.]

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

WAC 246-240-066 Suppliers for sealed sources or devices for medical use. For medical use, a licensee may only use:

(1) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under WAC 246-235-102.

(2) Sealed sources or devices noncommercially transferred from a U.S. NRC or agreement state medical use licensee; or

(3) Teletherapy sources manufactured and distributed in accordance with a license issued under chapter 246-232 WAC.

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-240-066, filed 2/6/06, effective 3/9/06.]

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

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 ((~~under these rules before October 24, 2005~~)) in WAC 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 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, 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.

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-240-069, filed 2/6/06, effective 3/9/06.]

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

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 246-240-278 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 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 must be signed by a preceptor authorized medical physicist who meets the requirements in WAC 246-240-072 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.

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-240-072, filed 2/6/06, effective 3/9/06.]

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

WAC 246-240-081 Recentness of training. Training and experience specified in WAC 246-240-069, 246-240-072, 246-240-075, 246-240-078, 246-240-154, 246-240-163, 246-240-210, 246-240-213, 246-240-216, 246-240-278, 246-240-281, and 246-240-399((~~, and 246-240-451 through 246-240-487 (inclusive)~~)), must have been obtained within the seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-240-081, filed 2/6/06, effective 3/9/06.]

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

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 (30 mCi) 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 (30 mCi) 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 (15 mCi).

(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 (200 μCi) or 1000 times the quantities in Schedule B of WAC 246-232-120.

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

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-240-110, filed 2/6/06, effective 3/9/06.]

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

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 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.

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-240-151, filed 2/6/06, effective 3/9/06.]

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

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 246-240-154, 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, signed by a preceptor authorized user who meets the requirements in WAC 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.

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-240-154, filed 2/6/06, effective 3/9/06.]

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

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 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.

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-240-157, filed 2/6/06, effective 3/9/06.]

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

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;

(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 ((~~prior to October 24, 2005~~)); 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 246-240-163, 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, signed by a preceptor authorized user who meets the requirements in WAC 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.

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-240-163, filed 2/6/06, effective 3/9/06.]

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

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 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 must be signed by a preceptor authorized user who meets the requirements in WAC 246-240-210 or equivalent U.S. NRC or agreement state requirements. The preceptor authorized user, who meets the requirements in WAC 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 that the individual has satisfactorily completed the requirements in subsection (1)(a) and (b) of this section 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 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.

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-240-210, filed 2/6/06, effective 3/9/06.]

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

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), ((~~or~~)) 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 246-240-210, 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 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 must be signed by a preceptor authorized user who meets the requirements in WAC 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).

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-240-213, filed 2/6/06, effective 3/9/06.]

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

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 246-240-210, 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 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 must be signed by a preceptor authorized user who meets the requirements in WAC 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).

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-240-216, filed 2/6/06, effective 3/9/06.]

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

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 246-240-210 ((~~or~~)), 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 ((~~or 246-240-460~~)) 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 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 must be signed by a preceptor authorized user who meets the requirements in WAC 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 ((~~or 246-240-219~~)), must have experience in administering dosages as specified in WAC 246-240-210 (2)(b)(vii)(C) and/or (D).

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-240-219, filed 2/6/06, effective 3/9/06.]

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

WAC 246-240-269 Calibration measurements of brachytherapy sources. (1) Before the first medical use of a brachytherapy source on or after ((~~October 24~~)) March 9, 2006, a licensee shall have:

(a) Determined the source output or activity using a dosimetry system that meets the requirements of WAC 246-240-366(1);

(b) Determined source positioning accuracy within applicators; and

(c) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of (a) and (b) of this subsection.

(2) A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with subsection (1) of this section.

(3) A licensee shall mathematically correct the outputs or activities determined in subsection (1) of this section for physical decay at intervals consistent with one percent physical decay.

(4) A licensee shall retain a record of each calibration in accordance with WAC 246-240-599.

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-240-269, filed 2/6/06, effective 3/9/06.]

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

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, 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 246-240-278 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 246-240-278 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, signed by a preceptor authorized user who meets the requirements in WAC 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.

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-240-278, filed 2/6/06, effective 3/9/06.]

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

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 ((~~commission~~)) 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;

(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 246-240-399 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 246-240-399 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 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 must be signed by a preceptor authorized user who meets the requirements in WAC 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.

[Statutory Authority: RCW 70.98.050. 06-05-019, § 246-240-399, filed 2/6/06, effective 3/9/06.]

REPEALER

The following sections of the Washington Administrative Code are repealed:
WAC 246-240-451 Radiation safety officer.
WAC 246-240-454 Training for uptake, dilution, and excretion studies.
WAC 246-240-457 Training for imaging and localization studies.
WAC 246-240-460 Training for therapeutic use of unsealed radioactive material.
WAC 246-240-463 Training for treatment of hyperthyroidism.
WAC 246-240-466 Training for treatment of thyroid carcinoma.
WAC 246-240-469 Training for use of brachytherapy sources.
WAC 246-240-472 Training for ophthalmic use of strontium-90.
WAC 246-240-475 Training for use of sealed sources for diagnosis.
WAC 246-240-478 Training for use of therapeutic medical devices.
WAC 246-240-481 Training for authorized medical physicist.
WAC 246-240-484 Training for an authorized nuclear pharmacist.
WAC 246-240-487 Training for experienced nuclear pharmacists.