



PUBLIC HEALTH DIVISION
Radiation Protection Services

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Authority

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January 28, 2013

Pamela J. Henderson, Deputy Director
Division Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
T8-E24
Washington, D.C. 20555-0001

Dear Ms. Henderson:

Enclosed is a copy of the State of Oregon, Radiation Protections Services Section, final Administrative Rule as filed with Oregon Secretary of State. These final revisions are scheduled to go into effect January 29, 2013.

Rats ID

2007-1, Medical Use of Byproduct Material - Minor Corrections and Clarifications 10 CFR Parts 32 and 35

State Section: Oregon Administrative Rules (OAR) Chapter 333, Division 116

We believe that adoption of these rules satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-200.

If you have any questions, please feel free to contact me at (971) 673-0500 or email me @ Todd.s.carpenter@state.or.us

Sincerely,

Todd S. Carpenter
Licensing Manager

Cc: Kathleen Schneider

Enclosures: Copy of final Oregon Administrative Rules

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333-102-0285 for 32.72(b)(5)

Manufacture, Preparation, or Transfer for Commercial Distribution of Radiopharmaceutical Drugs Containing Radioactive Material for Medical Use Under Division 116

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radiopharmaceutical drugs containing radioactive material for use by persons authorized pursuant to division 116 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in OAR 333-102-0200;

(b) The applicant submits evidence that the applicant is at least one of the following:

(A) Registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);;

(B) Registered or licensed with a state agency as a drug manufacturer;

(C) Licensed as a pharmacy by a state Board of Pharmacy;

(D) Operating as a nuclear pharmacy within a federal medical institution; or.

(E) A Positron Emission Tomography (PET) drug production facility registered with a state agency.

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

(d) The applicant satisfies the following labeling requirements:

(A) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radiopharmaceutical drug to be transferred for commercial distribution. The label must include the radiation symbol and the words CAUTION, RADIOACTIVE MATERIAL or DANGER, RADIOACTIVE MATERIAL; the name of the radiopharmaceutical drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radiopharmaceutical drugs with a half life greater than 100 days, the time may be omitted.

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(B) A label is affixed to each syringe, vial, or other container used to hold a radiopharmaceutical drug to be transferred for commercial distribution. The label must include the radiation symbol and the words CAUTION, RADIOACTIVE MATERIAL or DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee described by paragraphs (1)(b)(C) or (D) of this rule:

(a) May prepare radiopharmaceutical drugs for medical use, as defined in OAR 333-116-0020, provided that the radiopharmaceutical drug is prepared either by an authorized nuclear pharmacist, as specified in subsections (2)(b) and (2)(d) of this rule, or an individual under the supervision of an authorized nuclear pharmacist as specified in OAR 333-116-0100.

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

(A) This individual qualifies as an authorized nuclear pharmacist as defined in OAR 333-116-0020;

(B) This individual meets the requirements specified in OAR 333-116-0910, 333-116-0760, 333-116-0915 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(C) This individual is designated as an authorized nuclear pharmacist in accordance with subsection (2)(d) of this rule.

(c) The actions authorized in subsections (2)(a) and (2)(b) of this rule are permitted in spite of more restrictive language in license conditions.

(d) May designate a pharmacist (as defined in OAR 333-116-0020) as an authorized nuclear pharmacist if:

(A) The individual was a nuclear pharmacist preparing only radiopharmaceutical drugs containing accelerator-produced radioactive material; and

(B) The individual practiced at a pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the Nuclear Regulator Commission.

(e) Shall provide to the Department a copy of :

(A) Each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in OAR 333-116-0910 with the written attestation signed by a preceptor as required by OAR 333-116-0680(2)(b); or

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(B) The Commission or Agreement State license; or

(C) Commission master materials licensee permit; or

(D) The permit issued by a licensee or Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

(E) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

(F) A copy of the state pharmacy licensure or registration no later than 30 days after the date that the licensee allows pursuant to paragraphs (2)(b)(A) and (2)(b)(C) of this rule, which allows the individual to work as an authorized nuclear pharmacist.

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radiopharmaceutical drugs. 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 radiopharmaceutical drugs 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 rule relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radiopharmaceutical drugs.

NOTE: Although the Department does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radio pharmaceuticals containing radioactive material as a part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material, who desires to have the reagent kits approved by the Department for use by persons licensed for medical use pursuant to OAR 333-116 or by persons authorized under a group license, or equivalent, by the U.S. Nuclear Regulatory Commission or any other Agreement State, may submit the pertinent information specified in this rule.

[Publications: Publications referenced are available from the agency.]

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333-102-0290 for CFR 32.74(a)

Manufacture and Distribution of Sources or Devices Containing Byproduct Material for Medical Use

(1) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to division 116 of this chapter for use as a calibration, transmission, or reference source or for the uses listed in OAR 333-116-0400, 333-116-0420, 333-116-0480 and 333-116-0485 will be approved if:

- (a) The applicant satisfies the general requirements in OAR 333-102-0200.
- (b) 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 that are too lengthy for such a label may be summarized on the label and printed in detail on a brochure that is referenced on the label.
- (c) 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, date of assay and a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source or device) to persons licensed to use radioactive material identified in

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OAR 333-116-0190, 333-116-0400, or 333-116-0420, as appropriate, and to persons who hold an equivalent license issued by an Agreement State or the US Nuclear Regulatory Commission. However, labels worded in accordance with requirements that were in place on March 30, 1987 may be used until March 30, 1989.

(2) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months:

(a) The applicant must include in the application sufficient information to demonstrate that such 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; and

(b) 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 or 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 similarly designed and constructed sources or devices.

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Release of Patients Containing Therapeutic Quantities of Byproduct material or Permanent Implants

(1) The licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed five millisieverts (0.5 rem).

Note: The current revision of NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses" describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

(2) The licensee must provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain radiation exposures to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed one millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed one millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include:

- (a) Guidance on the interruption or discontinuation of breast-feeding; and
 - (b) Information on the potential consequences, if any, of failure to follow the guidance.
- (3) The licensee must maintain a record of the basis for authorizing the release of an individual, for a minimum of five years after the date of release in accordance with OAR 333-100-0057.
- (4) The licensee must maintain a record, for a minimum of five years after the date of release, in accordance with OAR 333-100-0057, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding five millisieverts (0.5 rem).

333-116-0290 for CFR 35.92

Decay-In-Storage

(1) A licensee may hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of OAR 333-120-0500 of these rules if the licensee:

- (a) Holds radioactive material for decay a minimum of 10 half-lives;

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(b) Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument for the radiation being monitored, set on its most sensitive scale and with no interposed shielding;

(c) Removes or obliterates all radiation labels, except radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

(d) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

(2) For radioactive material disposed in accordance with these rules the licensee must retain a record of each disposal until inspection by the Department. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container and the name of the individual who performed the survey.

333-116-0660 for CFR 35.190

Training for Uptake, Dilution or Excretion Studies

Except as provided in OAR 333-116-0740 and 333-116-0750, the licensee must require the authorized user of a radiopharmaceutical listed in OAR 333-116-0300 to be a physician who: Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in section (6) of this rule (The names of board certifications recognized by the NRC or an Agreement State are posted on the NRC's web site). To have its certification process recognized, a specialty board shall require all candidates for certification to:

(2) Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include subsections (5)(a) through (b):

(3) Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in radiation safety, radionuclide handling and quality control; or
(4) Is an authorized user under OAR 333-116-0670 and 333-116-0680 or equivalent Nuclear Regulator Commission or Agreement State requirements; or

(5) Has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques

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applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include subsections (a) through (b):

(a) 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 byproduct material for medical use; and

(E) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in this rule, OAR 333-116-0670 and 333-116-0680 or Nuclear Regulatory Commission or equivalent 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 byproduct material;

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

(F) Administering dosages of radiopharmaceutical drugs to patients or human research subjects; and (6) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this rule, OAR 333-116-0670 and 333-116-0680 or Nuclear Regulatory Commission or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in section (2) or (5) of this rule and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under OAR 333-116-0300.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 5-

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2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10

333-116-0670 for CFR 35.290

Training for Imaging and Localization Studies

Except as provided in OAR 333-116-0740 or 333-116-0750, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under OAR 333-116-0320 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in section (6) of this rule. (The names of board certifications which have been recognized by the Commission or an Agreement State are posted on the NRC's web site) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(2) Complete 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include paragraphs (5)(A) through (B)(vii) of this rule; and

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

(4) Is an authorized user under OAR 333-116-0680 or equivalent Agreement State requirements; or

(5) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include at a minimum::

(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;

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

(v) Radiation biology; and

(B) Work experience, under the supervision of an authorized user, who meets the requirements in this rule or OAR 333-116-0680 or equivalent Nuclear Regulatory commission or Agreement State requirements, involving:

(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 byproduct material;

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

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

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

(6) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this rule or OAR 333-116-0680 or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in subsections (2) or (5) of this rule and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under this rule or OAR 333-116-0680.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10

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