DIVISION 116

USE OF RADIONUCLIDES IN THE HEALING ARTS

Purpose and Scope

333-116-0010 This Division establishes requirements and provisions ~~[for]~~ **to regulate the production, preparation, compounding and** use of radionuclides in the healing arts~~[, as defined in Division 100 of these rules,]~~ **and for issuance of licenses authorizing the medical use of this material.** ~~[and for issuance of licenses authorizing the use of this material in the healing arts.]~~ These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this Division are in addition to, and not in substitution for, others in these Rules. The requirements and provisions of these Rules apply to applicants and licensees subject to this Division unless specifically exempted.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Definitions

333-116-0020 As used in this Division, the following definitions apply:

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

(2) ~~[*"Agreement State" means any State with which the U.S. Nuclear Regulatory Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.*~~

~~*(3) "ALARA (as low as reasonably achievable)" means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical.*~~

~~*(a) Consistent with the purpose for which the licensed activity is undertaken,*~~

~~*(b) Taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and*~~

~~*(c) In relation to utilization of nuclear energy in the public interest.*~~

~~*(4)]*~~ "Area of use" means a portion of an address of use [a physical structure] that has been set aside for the purpose of receiving, using or storing radioactive material;

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

(a) Meets the requirements in OAR 333-116-0910 and 333-116-0915; or

(b) Is identified as an authorized nuclear pharmacist on an Agency, Agreement State, or U.S. Nuclear Regulatory Commission license that authorizes the use of byproduct material in the practice of nuclear pharmacy; or

(c) Is identified as an authorized nuclear pharmacist on a permit issued by an Agency, Agreement State, or U.S. Nuclear Regulatory Commission specific licensee of broad scope that is authorized to permit the use of radioactive material in the practice of nuclear pharmacy; or

(d) Is approved as an authorized nuclear pharmacist by a nuclear pharmacy licensed (authorized) by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State to approve authorized nuclear pharmacists.

(4)~~*[(5)]*~~ "Authorized user" means a practitioner of the healing arts who:

(a) Meets the requirements listed in OAR 333-116-660, 333-116-670, 333-116-680, 333-116-690, 333-116-700, 333-116-710, 333-116-720, and 333-116-740 or

(b) is identified as an authorized user on an Agency, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; **or**

(c) Is identified as an authorized user on a permit issued by an Agency, Agreement State, or U.S. Nuclear Regulatory Commission licensee of broad scope that is authorized to permit the medical use of radioactive material.

(5)~~*[(6)]*~~ "Black Box" means the radiopharmaceutical production purification system used in a PET facility.

(6)~~*[(7)]*~~ "Brachytherapy source" means an individual sealed source or a manufacturer-assembled source train **or a combination of these sources that is designed to deliver a therapeutic dose of radiation within a few centimeters, by surface, intracavitary, or interstitial application** that is not designed to be disassembled by the user.

(7)~~*[(8)]*~~ "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**. This source may also be used for other purposes.**~~*[;]*~~

(8)~~*[(9)]*~~ "Dental use" means the intentional external administration of the radiation from byproduct material to human beings in the practice of dentistry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(9)~~*[(10)]*~~ "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.

(10)~~*[(11)]*~~ "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

(11) "High dose-rate remote afterloader" means a device that remotely delivers a brachytherapy source, with a dose rate in excess of 2 gray (200 rads) per hour, to the point or surface where the dose is prescribed.

(12) "Low dose-rate remote afterloader" means a device that remotely delivers a brachytherapy source, with a dose rate of less than 2 gray (200 rads) per hour, to the point or surface where the dose is prescribed.

(13)~~*[(12)]*~~ "Management" means the chief executive officer or that individual's designee;

(14)~~*[(13)]*~~ "Medical institution" means an organization in which several medical disciplines are practiced;

(15)~~*[(14)]*~~ "Medical use" means the intentional internal or external administration of radioactive material, or the radiation therefrom, to **patients or** human~~*[s]*~~ **research subjects under the supervision of an authorized user.** ~~*[in the practice of the healing arts in accordance with a license issued by a state or territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico;]*~~

(16) ~~*[(15)]*~~ "Ministerial change" means a change that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgment about whether those requirements should apply in the case at hand.

(17)~~*[(16)]*~~ "Misadministration" means the administration of:

(a) A radiopharmaceutical dosage greater than ~~*[30 microcuries]*~~ **1.11 megabecquerels (30 µCi)** of either sodium iodide I-125 or I-131:

(A) Involving the wrong patient or wrong radiopharmaceutical, or

(B) When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceed ~~*[30 microcuries]*~~ **1.11 megabecquerels (30 µCi)** .

(b) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131;

(A) Involving the wrong patient, wrong radiopharmaceutical, or wrong route of administration; or

(B) When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

(c) A gamma stereotactic radiosurgery radiation dose:

(A) Involving the wrong patient or wrong treatment site; or

(B) When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.

(d) A teletherapy radiation dose:

(A) Involving the wrong patient, wrong mode of treatment, or wrong treatment site;

(B) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

(C) When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or

(D) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

(e) A brachytherapy radiation dose:

(A) Involving the wrong patient, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

(B) Involving a sealed source that is leaking;

(C) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

(D) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

(f) A diagnostic radiopharmaceutical dosage, other than quantities greater than ~~*[30 microcuries]*~~ **1.11 megabecquerels (30 µCi)** of either sodium iodide I-125 or I-131~~*[, both]*~~:

(A) Involving the wrong patient, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; ~~[and]~~**or**

(B) When the dose to the patient exceeds ~~[5 rems]~~ **50 millisieverts (5 rem)** effective dose equivalent or ~~[50 rems]~~ **500 millisieverts (50 rem)** dose equivalent to any individual organ.

(18)~~[(17)]~~ "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.~~[;]~~

(19) Nuclear Pharmacist means an authorized nuclear pharmacist, as defined in OAR 333-116-0020(3), who has received additional training, pursuant to 333-116-0910 and 333-116-0915 in the management and handling of radioactive drugs and is authorized by license to receive, use, transfer, and dispose of such radioactive drugs.

(20)~~[(18)]~~ "Output" means the exposure rate, dose rate or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.~~[;]~~

(21)~~[(19)]~~ "PET" means Positron Emission Tomography

(22) "Pharmacist" means an individual licensed by a State or Terrritory of the United States, The District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

(23)~~[(20)]~~ "Physician" means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

(24) "Prescribed dosage" means the quantity of radiopharmaceutical activity as documented -- (1) in a written directive; or (2) either in the diagnositic clinical procedures manual or in any appropriate record, in accordance with the directions of the authorized user for diagnostic procedures.

(25) "Prescribed dose" means -- (1) for gamma stereotactic radiosurgery, the total dose as documented in the written directive; (2) for theletherapy, the total dose and dose per fraction, as documented in the written directive; (3) for brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or (4) for remote afterloaders, the total dose as documented in the written directive.

(26)~~[(21)]~~ "Podiatric use" means the intentional external administration of the radiation from byproduct material to human beings in the practice of podiatry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(27)~~[(22)]~~ "Podiatrist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

(28)~~[(23)]~~ "Positron Emission Tomography (PET) facility" means a facility comprised of an accelerator that produces positron-emitting isotopes, a radiopharmacy that specializes in preparation of PET radiopharmaceuticals, and**/or** a clinic that uses PET isotopes for ~~[clinical]~~ **medical diagnostic** purposes.

(29)~~[(24)]~~"Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:

(a) In a written directive; or

(b) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

(30)~~[(25)]~~ "Prescribed dose" means

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

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

(c) For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; **or**~~[.]~~

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

(31) "Pulsed dose-rate remote afterloader"means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose rate" range, but is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

(32) "Radiation Safety Officer" means the individual identified as the Radiation Safety Officer on a Agency, Agreement State, or U.S. Nuclear Regulatory Commission license.

(33)~~[(26)]~~ "Recordable event" means the administration of:

(a) A radiopharmaceutical or radiation without a written directive where a written directive is required;

(b) A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

(c) A radiopharmaceutical dosage greater than ~~[30 microcuries]~~ **1.11 megabecquerels (30 µCi)** of either sodium iodide I-125 or I-131 when both:

(A) The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and

(B) The difference between the administered dosage and prescribed dosage exceed 15 microcuries;

(d) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribe dosage;

(e) A teletherapy radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose; or

(f) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

(34) "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

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

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

(37)~~[(27)]~~"Teletherapy physicist" means the individual identified as the qualified teletherapy physicist on a Agency license.~~[;]~~

(38)~~[(28)]~~"Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.~~[;]~~

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

(40) "Unit dosage" means a dosage intended for medical use in a single patient or human research subject that has been obtained from a manufacturer or preparer licensed by the Agency as a nuclear pharmacy.

(41)~~**[(29)]**~~ "Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

(42)~~**[(30)]**~~ "Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in OAR 333-116-0125(1)(e), containing the following information:

(a) For any administration of quantities greater than ~~*[30 microcuries]*~~ **1.11 megabecquerels (30 µCi)** of either sodium iodide I-125 or I-131: the dosage;

(b) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

(c) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

(d) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

(e) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

(f) For all other brachytherapy:

(A) Prior to implantation: the radioisotope, number of sources, and source strengths; and

(B) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

FDA, other Federal, and State requirements

333-116-025 Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605
Hist.: HD

License Required

333-116-0030 (1) No person shall manufacture, produce, acquire, receive, possess, use or transfer radioactive material for medical use except in accordance with a specific or general license issued pursuant to this Division or as otherwise provided in this Division.

(2) Unless prohibited by license condition an individual may receive, possess, use or transfer radioactive material in accordance with the Rules in this Division under the supervision of an authorized user as provided in OAR 333-116-0100.

(3) Notwithstanding the above requirements, any licensee licensed pursuant to this rule also is authorized to use radioactive material under the general license in OAR 333-102-0130 for the specified

in vitro uses without filing the form as required by OAR 333-102-0130(2); the licensee is subject to the other provisions of OAR 333-102-0130.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Application for license, amendment, or renewal

333-116-035 (1) An application must be signed by the management of the facility.

(2) An application for a license for medical use of radioactive material as described in OAR 333-116-200, 333-116-300, 333-116-320, 333-116-360, 333-116-400, and 333-116-420 and for medical use of remote afterloaders in 333-116-475, must be made by filing a "Radioactive Materials License Application - Medical". A request for a license amendment or renewal may be submitted in letter format.

(3) Except for medical use of remote afterloaders, a separate license application must be filed for each medical use of radioactive material as described in 333-116-480 by filing a "Radioactive Materials License Application - Medical" A request for a license amendment or renewal may be submitted in letter format.

(4) An application for a license for medical use of radioactive material as described in 333-116-900 must be made by filing a "Radioactive Materials License Application - Medical".

(a) In addition to the information required in the "Radioactive Materials License Application - Medical", the application must also include information regarding any radiation safety aspects of the medical use of the radioactive material that is not addressed in this division, as well as any specific information necessary for:

(A) Radiation safety precautions and instructions;

(B) Training and experience of proposed users;

(C) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(D) Calibration, maintenance, and repair of equipment necessary for radiation safety.

(b) The applicant of licensee shall also provide any other information requested by the Agency in its review of the application.

(5) An applicant that satisfies the requirements specified in OAR 333-102-900 may apply for a Type A specific license of broad scope.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.:

License Amendments

333-116-0040 A licensee shall apply for and shall receive a license amendment:

(1) Before using radioactive material for a method or type of medical use not permitted by the license issued under this Division;

(2) Before permitting anyone, except a visiting authorized user described in OAR 333-116-0110, to work as an authorized user, **authorized nuclear pharmacist, or authorized medical physicist** under the license **except an individual who is:**~~[,]~~

(a) An authorized user who meets the requirements of 333-116-660, 333-116-670, 333-116-680, 333-116-690, 333-116-700, 333-116-710 or 333-116-720 of these rules;

(b) An authorized nuclear pharmacist who meets the requirements in OAR 333-116-0910;

(c) Identified as an authorized user, or an authorized nuclear pharmacist on a Nuclear Regulatory Commission or Agreement State license that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively, or

(3) Before changing the Radiation Safety Officer or Teletherapy Physicist;

(4) Before receiving radioactive material in excess of the amount authorized on the license;

(5) Before adding to or changing the area of use or mailing address identified on the license; and

(6) Before changing statements, representations and procedures which are incorporated into the license.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Notifications

333-116-0050 (1) A licensee shall provide to the Agency a copy of the board certification, the Nuclear Regulatory Commission or Agreement State license, or the permit issued by a licensee of Broad Scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, pursuant to OAR 333-116-040(2)(a) through (c)

(2) A licensee shall notify the Agency by letter ~~[within]~~ **no later than** 30 days **after:**

(a)~~[when a]~~**An** authorized user, **an authorized nuclear pharmacist, a** Radiation Safety Officer or **an authorized medical** ~~[Teletherapy]~~ 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 does not constitute a transfer of control ot the license as described in OAR 333-102-305 of these rules; or

(d) The licensee has added to or changed the areas where radioactive material is used in accordance with 333-116-200 and 333-116-300.

(3) The licensee shall mail the documents required in this Division to the Agency for review.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Exemptions regarding Type A specific licenses of broad scope

333-116-055 (1) A licensee possessing a Type A specific license of broad scope for medical use is exempt from:

(a) The provisions of OAR 333-116-040(2);

(b) The provisions of 333-116-040(5) regarding additions to or changes in areas of use only at the addresses specified in the license;

(c) The provisions of 333-116-050(1);

(d) The provisions of 333-116-050(2)(a) for an authorized user, or authorized nuclear pharmacist, and

(e) The provisions of 333-116-140(1).

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.:

License issuance

333-116-057 (1) The Agency shall issue a license for the medical use of radioactive material if:

(a) The applicant has filed a "Radioactive Materials License Application - Medical" in accordance with the instructions in OAR 333-116-035;

(b) The applicant has paid any applicable fee as provided in Division 103 of these rules;

(c) The Agency finds the applicant equipped and committed to observe the safety standards established by the Agency in these rules for the protection of the public health and safety; and

(d) The applicant meets the requirements of Division 102 of these rules.

(2) The Agency shall issue a license for mobile services if the applicant:

(a) Meets the requirements in paragraph (1) above; and

(b) Assures that individuals or human research subjects to whom radiopharmaceuticals or radiation from implants will be administered may be released following treatment in accordance with 333-116-460.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.:

Specific Exemptions

333-116-059 The Agency may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in this division as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.:

General Administrative Requirements

ALARA Program

333-116-0060 (1) Each licensee shall develop and implement a written program to maintain radiation dose and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable in accordance with OAR 333-120-0020.

(2) To satisfy the requirement of section (1) of this rule:

(a) The management, Radiation Safety Officer and all authorized users shall participate in the establishment, implementation and operation of the program as required by these Rules or required by the Radiation Safety Committee;

(b) For licensees that are not medical institutions, management and all authorized users shall participate in the program as requested by the Radiation Safety Officer.

(3) The ALARA program shall include an annual review by the Radiation Safety Committee for medical institutions or by management and the Radiation Safety Officer for licensees which are not medical institutions. The review shall include a summary of the types and amounts of radioactive material used, occupational dose reports and a summary of the continuing education and training for all personnel who work with or in the vicinity of radioactive material.

(4) The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public and releases of radioactive material as low as reasonably achievable, taking into account the state of technology and the cost of improvements in relation to benefits.

(5) The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description must include:

(a) A commitment by management to keep occupational doses as low as reasonably achievable;

(b) A requirement that the Radiation Safety Officer brief management once each year on the radiation safety program;

(c) Personnel exposure investigational levels that, when exceeded, will initiate an investigation by the Radiation Safety officer of the cause of the exposure; and

(d) Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Radiation Safety Officer

333-116-0070 (1) A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

(2) The Radiation Safety Officer shall:

(a) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, ~~[and]~~ disposals, **misadministrations** and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(b) **Establish and** ~~[H]~~implement written policy and procedures for:

(A) Authorizing the purchase of radioactive material;

(B) Receiving and opening packages of radioactive material;

(C) Storing radioactive material;

(D) Keeping an inventory record of radioactive material;

(E) Using radioactive material safely;

(F) Taking emergency action if control of radioactive material is lost;

(G) Performing periodic radiation surveys;

(H) Performing checks and calibrations of survey instruments and other safety equipment;

(I) Disposing of radioactive material;

(J) Training personnel who work in or frequent areas where radioactive material is used or stored; and

(K) Keeping a copy of all records and reports required by the Agency Rules, a copy of these Rules, a copy of each licensing request and license and amendments and the written policy and procedures required by the Rules.

(c) Brief management once each year on the byproduct material program;

(d) Establish personnel exposure investigational levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure;

(e) Establish personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence;

(~~[c]~~**f**) For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to ~~[submittal]~~ **submission** to the Agency for licensing action;

(~~[d]~~**g**) For medical use sited at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Radiation Safety Committee

333-116-0080 (1) Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of radioactive material which shall meet the following administrative requirements:

(a) Membership must consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate;

(b) The Committee shall meet a least once each calendar quarter;

(c) To establish a quorum and to conduct business, one-half of the Committee's membership shall be present, including the Radiation Safety Officer and the management's representative;

(d) The minutes of each Radiation Safety Committee meeting shall include:

(A) The date of the meeting;

(B) Members present;

(C) Members absent;

(D) Summary of deliberations and discussions;

(E) Recommended actions and the numerical results of all ballots; and

(F) Document any reviews required in OAR 333-116-0060(2) and ~~[section]~~ **333-116-0080**(2) ~~[of this rule]~~.

(e) The Committee shall provide each member with a copy of the meeting minutes and retain one copy until the Agency authorizes its disposition.

(2) To oversee the use of licensed material, the Committee shall:

(a) Be responsible for monitoring the institutional program to maintain individual and collective doses as low as reasonably achievable;

(b) Review, on the basis of safety and with regard to the training and experience standards of this division, and approve or disapprove any individual who is to be listed as an authorized user, the Radiation Safety Officer or Teletherapy Physicist before submitting a license application or request for amendment or renewal;

(c) Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;

(d) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and radiation safety program changes prior to ~~[submittal]~~ **submission** to the Agency for licensing action;

(e) Review quarterly, with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with radioactive material;

(f) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;

(g) Review annually, with the assistance of the Radiation Safety Officer, the radioactive material program; and

(h) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Statement of Authorities and Responsibilities

333-116-0090 (1) A licensee shall provide the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, sufficient authority and organizational freedom to:

(a) Identify radiation safety problems;

(b) Initiate, recommend or provide solutions; and

(c) Verify implementation of corrective actions.

(2) A licensee shall establish in writing the authorities, duties, responsibilities and radiation safety activities of the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee.

(3) In addition to the radiation protection program requirements of OAR 333-120-0020, a licensee's management shall approve in writing:

(a) Requests for license application, renewal, or amendments before submission to the Agency;

(b) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, authorized medical physicist; and

(c) Radiation protection program changes that do not require a license amendment and are permitted under 333-116-023;

(4) A license with multiple modalities or multiple users shall also develop, implement, and maintain written administrative procedures for interdepartmental/interdisciplinary coordination of the licensee's radiation protection program.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Supervision

333-116-0100 (1) A licensee who permits the receipt, possession, use or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by OAR 333-116-0030 shall:

(a) Instruct the supervised individual in the **licensee's written radiation protection procedures, written directive procedures, the licensee's written quality management program, the Oregon Rules for the Control of Radiation and the institutions radioactive materials license conditions** ~~*[principles of radiation safety]*~~ appropriate to that individual's use of radioactive material; and

(b) Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;

(c) Require the authorized user to be immediately available to communicate with the supervised individual;

(d) Require the authorized user to be able to be physically present and available to the supervised individual (on one hour notice); and

~~*[NOTE: The supervising authorized user need not be present for each use of radioactive material.]*~~

(e) Require that only those individuals specifically trained and designated by the authorized user, shall be permitted to administer radionuclides or radiation to patients.

(2) A licensee **that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by OAR 333-116-030(3),**shall

(a) Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's use of radioactive material, and

(b) R*[r]*equire the supervised individual **to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures established by the licensee and this Division, and license conditions.***[receiving, possessing, using or transferring radioactive material under OAR 333-116-0030 to:]*

(3) A licensee shall establish, implement and maintain a policy for all supervised individuals to request clarification, as needed, from:

(a) The authorized user, before initiating or continuing any procedure that requires a written directive, if the supervised individual has any question about what should be done or how it should be done; and

(b) The authorized user or authorized nuclear pharmacist about the instructions and requirements provided to the the supervised individual in accordance with paragraphs (1) and (2).

(4) A licensee that permits supervised activities under paragraph (1) and (2) is responsible for the acts and omissions of the supervised individual.

[(a) Follow the instructions of the supervising authorized user;
(b) Follow the procedures established by the Radiation Safety Officer; and
(c) Comply with the Rules of this Division and the license conditions with respect to the use of radioactive material.]

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Written Directives

333-116-0105 (1) A written directive must be prepared, dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 Megabequerels (Mbq)(30 microcuries (uCi)), any therapeutic dosage of a radiopharmaceutical, or any therapeutic dose of radiation from radioactive material.

Note 1: If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in writing in the patient's record. (i.e. written directive is prepared within 48 hours of the oral directive)

Note 2: If, because of a patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize a patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48

hours of the oral revision. Also, a written revision to an existing written directive may be made by any diagnostic or therapeutic procedure provided that the revision is dated and signed by the authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic dose, the teletherapy dose, or the next teletherapy fractional dose.

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

(a) For any administration of quantities greater than 1.11 Mbq (30 uCi) of sodium iodide I-131; the dosage;

(b) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-131: the radiopharmaceutical dosage, and route of administration;

(c) For gamma stereotactic radiosurgery: target coordinates (including gamma angle), collimator size, plug pattern, total dose for the treatment, and the total treatment volume;

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

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

(f) For all other brachytherapy:

(A) Prior to implantation: treatment site, the radionuclide, number of sources and source strengths or dose; and

(B) After implantation but prior to completion of the procedure: the radionuclide, treatment site, and total source strength and exposure time (or equivalently, the total dose).

(3) The licensee shall retain the written directive until records are reviewed by Agency inspectors.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.:

Procedures for administrations requiring a written directive

333-116-0107 (1) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(a) The patient's or human research subject's identity is verified before each administration; and

(b) Each administration is in accordance with the written directive.

(2) The procedures required by paragraph (1) of this section shall, at a minimum, address:

(a) Verifying the identity of the patient or human research subject;

(b) Verifying that the specific details of the administration are in accordance with the written directive and treatment plan;

(c) Checking both manual and computer-generated dose calculations; and

(d) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices authorized by OAR 333-116-480.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.:

Visiting Authorized User

333-116-0110 (1) A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:

(a) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;

(b) The licensee has a copy of the Agency license or a license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, that identifies the visiting authorized user by name as an authorized user for medical use; and

(c) Only those procedures for which the visiting authorized user is specifically authorized by the Agency license are performed by that individual.

(2) A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in section (1) of this rule.

(3) A licensee shall retain copies of the records specified in this rule until inspection by the Agency.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Mobile Nuclear Medicine Service Administrative Requirements

333-116-0120 (1) The Agency will only license mobile nuclear medicine services in accordance with **OAR 333-116-300, 333-116-320, and 333-116-400 of** this Division and **OAR 333-102-130** ~~*[other applicable requirements of these Rules to serve clients who do not have an Agency license]*~~.

(2) Mobile nuclear medicine service licensees shall obtain a letter signed by the management of each client for which services are rendered that authorizes use of licensed radioactive material at the client's address of use. The mobile nuclear medicine service licensee shall retain the letter for three years after the last provision of service.

(3) If a mobile nuclear medicine service provides services that the client also is authorized to provide, the client is responsible for assuring that services are conducted in accordance with the rules in this Division while the mobile nuclear medicine service is under the client's direction.

(4) A mobile nuclear medicine service may not order radioactive material to be delivered directly from the manufacturer or the distributor to the client's address of use **unless the client has a radioactive materials license. Radioactive material delivered to the client's address of use shall be received and handled in conformance with the client's license**.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Radiation Safety Program Changes

333-116-0123 (1) A licensee may make minor changes in radiation safety procedures that are not potentially important to safety, i.e., ministerial changes, that were described in the application for license, renewal, or amendment except for those changes in OAR 333-116-0040 and OAR 333-116-0500 of this division. Examples of such ministerial changes include: editing of procedures for clarity or conformance with local drafting policy or updating names, telephone numbers, and address; adoption of model radiation safety procedures published in Oregon Licensing Guides; replacement of equipment; reassignment of tasks among employees; or assignment of service contracts for services such as personnel dosimetry, radiation safety equipment repair or calibration, waste disposal, and safety surveys. A licensee is responsible for assuring that any change made is in compliance with the requirements of the rules and the license.

(2) A licensee shall retain a record of each change until the license has been renewed or terminated. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management, or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1995, f. & cert. ef. 4-26-95

Quality Management Program

333-116-0125 (1) Each applicant or licensee under this division, as applicable, shall establish and maintain a written quality management program to provide high confidence that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:

(a) That, prior to administration, a written directive (see NOTE below) is prepared for:

(A) Any teletherapy radiation dose;

(B) Any gamma stereotactic radiosurgery radiation dose;

(C) Any brachytherapy radiation dose;

(D) Any administration of quantities greater than ~~[30 microcuries]~~ **1.11 megabecquerels (30 µCi)** of either sodium iodide I-125 or I-131; or

(E) Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;

(b) That, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive;

(c) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

(d) That each administration is in accordance with the written directive; and

(e) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

NOTE: If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

(2) The licensee shall:

(a) Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:

(A) A representative sample of patient administrations,

(B) All recordable events, and

(C) All misadministrations to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;

(b) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of paragraph (a) of this section; and

(c) Retain records of each review, including the evaluations and findings of the review, in an auditable form for three years.

(3) The licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

(a) Assembling the relevant facts including the cause;

(b) Identifying what, if any, corrective action is required to prevent recurrence; and

(c) Retaining a record, in an auditable form, for ~~[three]~~ **five** years **or until inspected by the agency**, of the relevant facts and what corrective action, if any, was taken.

(4) The licensee shall retain:

(a) Each written directive; and

(b) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in OAR 333-116-0125(1)(a), in an auditable form, for ~~[three]~~ **five** years**, or until inspected by the agency,** after the date of administration.

(5) The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modification to the Agency Office within 30 days after the modification has been made.

(6) Each applicant for a new license, as applicable, shall submit to the Agency Office in accordance with OAR 333-102-0295 a quality management program as part of the application for a license and implement the program upon issuance of the license by the agency.

~~*[(7) Each existing licensee, as applicable, shall submit to the agency in accordance with OAR 333-102-0295 by December 31, 1995, a written certification that the quality management program has been implemented along with a copy of the program.]*~~

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1995, f. & cert. ef. 4-26-95

Records and Reports of Misadministrations

333-116-0130 (1)For a misadministration:

(a) The licensee shall notify the Agency by telephone no later than the next calendar day after discovery of the misadministration.

NOTE: The 24-hour phone number of the Agency Office is (503) 731-4014.

(b) The licensee shall submit a written report to the Agency Office within 15 days after the discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the patient" in this section), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.

(c) The licensee shall notify the referring physician of the affected patient and the patient or a responsible relative or guardian, unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative or guardian would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of this.

(d) If the patient was notified, the licensee also shall furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either:

(A) A copy of the report that was submitted to the Agency; or

(B) A brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the Agency can be obtained from the licensee.

(2) Each licensee shall retain a record of each misadministration for five years. The record must contain the names of all individuals involved in the event (including the physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or

identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

(3) Aside from the notification requirement, nothing in this section shall affect any rights or duties of licensees and physicians in relation to each other, patients or responsible relatives or guardians.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Suppliers

333-116-0140 A licensee may use for medical use only:

(1) Radioactive material manufactured, **produced**, labeled, **prepared, compounded,** packaged and distributed in accordance with a license issued pursuant to these Rules or the equivalent Rules of another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission; and

(2) reagent kits**, radiopharmaceuticals, and/or radiobiologics** that have been manufactured, labeled, packaged and distributed in accordance with an approval issued by the U.S. Department of Health and Human Services, Food and Drug Administration.

(3) Radiopharmaceuticals compounded from a prescription in accordance with the regulations of the state Board of Pharmacy.

(4) Teletherapy and brachytherapy sources manufactured and distributed in accordance with a license issued pursuant to these regulations, or the equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

General Technical Requirements

Quality Control of Imaging Equipment

333-116-0150 Each licensee shall establish written quality control procedures for all **diagnostic** equipment used to obtain images from radionuclide studies. As a minimum the **quality control** procedures **and frequencies** shall include quality control procedures recommended by equipment manufacturers or procedures which have been approved by the Agency. The licensee shall conduct quality control procedures in accordance with written procedures.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Possession, Use, Calibration and Check of Dose Calibrators

333-116-0160 (1) A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity **of radionuclides prior to administration** ~~[administered]~~ to each patient **or human research subject. The licensee shall also develop, implement and maintain written procedures for proper calibration and operation of the dose calibrator.**

(2) **At a minimum, a** ~~[A]~~ licensee shall:

(a) Check each dose calibrator for constancy **and proper operation** with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check must be done on a frequently used setting with a sealed source of not less than ~~[10 µCi (370 kBq) of radium-226 or 50 µCi (1.85 MBq)]~~ **1.85 megabecquerels (50 µCi)** of any ~~[other]~~ photon-emitting radionuclide with a half-life greater than 90 days**. The results of this test must be within ±10 percent of the sources stated activity. Sources used for the daily constancy test shall be determined by the manufacturer to be within ±5 percent of the stated activity and traceable to the National Institute of Standards and Technology or other standards recognized as being equivalent by the National Institute of Standards and Technology**~~[,]~~

(b) Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least two sealed sources containing different **photon-emitting** radionuclides~~[, the activity of which the manufacturer has determined within five percent of the stated activity,]~~ with **a** minimum activity of ~~[10 µCi (370 kBq) for radium-226 and 50 µCi (1.85 MBq)]~~ **1.85 megabecquerels (50 µCi) each,** ~~[for any other photon-emitting radionuclide, and]~~ at least one of which has a principal photon energy between 100 keV and 500 keV**. All sources used to satisfy the accuracy test shall be determined by the manufacturer to be within ±5 percent of the stated activity and traceable to the National Institute of Standards and Technology or other standards recognized as being equivalent by the National Institute of Standards and Technology**;

(c) Test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range of use between ~~[10 µCi (370 kBq)]~~ **1.1 megabecquerels (30 microcuries)** and the highest dosage that will be administered; and

(d) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(3) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than ~~[10 µCi (370 kBq)]~~ **1.1 megabecquerels (30 microcuries)** and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(4) A licensee shall also perform checks and tests required by ~~[this rule]~~ **333-116-0160(2)** following adjustment or repair of the dose calibrator **and prior to use**.

(5) A licensee shall retain a record of each check and test required by ~~[this Division]~~ **333-116-0160(2)** until inspection by the Agency. The records required by ~~[this Division]~~ **333-116-0160(2)** shall include:

(a) For ~~[subsection (2)(a) of this rule]~~ **constancy**, the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings and the initials of the individual who performed the check;

(b) For ~~[subsection (2)(b) of this rule]~~ **accuracy**, the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings and the signature of the Radiation Safety Officer;

(c) For ~~[subsection (2)(c) of this rule]~~ **linearity**, the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test and the signature of the Radiation Safety Officer; and

(d) For ~~[subsection (2)(d) of this rule]~~ **geometry dependence**, the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test and the signature of the Radiation Safety Officer.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Possession, use calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.

333-116-165 (1) For other than unit dosages, a licensee shall possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. A licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radionuclides prior to administration to each patient or human research subject.

(2) A licensee shall develop, implement, and maintain written procedures for use of the instrumentation. At a minimum, a licensee shall:

(a) Perform tests before initial use, and following repair, on each instrument for accuracy, linearity, and geometry dependence, unless it is not appropriate for the use of the instrument; and make adjustments when necessary;

(b) Perform accuracy annually;

(c) Perform linearity tests annually over the range of medical use; and

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

(3) Accuracy tests shall be performed with source(s) that are traceable to National Institute of Standards and Technology (NIST) or by a supplier who has compared the source to a source that was calibrated by NIST.

(4) A licensee shall retain a record of each check and test required by this section until inspection by the Agency.

Calibration and Check of Survey Instrument

333-116-0170 (1) A licensee shall ensure that the survey instruments used to show compliance with this Division have been calibrated before first use, annually and following repair.

(2) To satisfy the requirements of section (1) of this rule the licensee shall:

(a) Calibrate all required scale readings up to ~~*[1000 mrem (10 mSv)]*~~ **10 millisieverts (1000 mrem)** per hour with a radiation source;

(b) For each scale that shall be calibrated, calibrate two readings separated by at least 50 percent of scale reading; and

(c) Conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(3) To satisfy the requirements of section (2) of this rule, the licensee shall:

(a) Consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 10 percent; and

(b) Consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent if a correction chart or graph is conspicuously attached to the instrument.

(4) A licensee shall check each survey instrument for proper operation with the dedicated check source before each use. The licensee is not required to keep records of these checks.

(5) The licensee shall retain a record of each calibration required in section (1) of this rule until inspection by the Agency. The record shall include:

(a) A description of the calibration procedure; and

(b) A description of the source used and the certified exposure rates from the source and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration and the date of calibration.

(6) To meet the requirements of sections (1), (2) and (3) of this rule, the licensee may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by section (5) of this rule, shall be maintained by the licensee.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Assay of Radiopharmaceutical Doses

333-116-0180 A licensee shall:

(1) Assay, within 30 minutes before medical use, the activity of each radiopharmaceutical dosage that contains more than ~~*[10 µCi (370 kBq)]*~~ **370 kilobecquerels (10 µCi)** of a **alpha-, beta-, or** photon-emitting radionuclide;

(2) Assay, before medical use, the activity of each radiopharmaceutical dosage ~~[with a desired activity of 10 µCi (370 kBq) or less of a photon-emitting radionuclide to verify that the dosage does not exceed 10 µCi (370 kBq);]~~ **emitting alpha and/or beta radiation as the radiation of principal interest, unless such radiopharmaceutical has been obtained:**

(a) In unit dose form, calibrated by the supplier for individual patients; and

(b) From a supplier which participates in a measurement quality assurance program with the National Institute of Standards and Technology, and which is designed to ensure that unit doses have a calibration traceable to a national standard;

(3) For a dosage of a alpha- or beta-emitting radionuclide prepared by the licensee, this determination shall be made by direct measurement or by a combination of measurements and calculations.

(4) A licensee shall not use a dosage if the dosage differs from the prescribed dosage by more than 20 percent, unless authorized in writing by an authorized user.

(5)~~[(3)]~~ Retain a record of the assays required by this section until inspection by the Agency. To satisfy this requirement, the record shall contain the:

(a) Generic name, trade name or abbreviation of the radiopharmaceutical, its lot number and expiration dates and the radionuclide;

(b) Patient's name and identification number if one has been assigned;

(c) Prescribed dosage and activity of the dosage at the time of assay or a notation that the total activity is less than ~~[10 µCi (370 kBq)]~~ **370 kilobecquerels (10 µCi)**;

(d) Date and time of the assay; and

(e) Date and time of administration; and

(f)~~[(e)]~~ Initials of the individual who performed the assay.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Authorization for Calibration and Reference Source

333-116-0190 Any person authorized by OAR 333-116-0030 for medical use of radioactive material may receive, possess and use the following radioactive material for check, calibration and reference use:

(1) Sealed sources manufactured and distributed by persons specifically licensed pursuant to ~~[Division 102 of these Rules]~~ **OAR 333-102-XXX** or equivalent provisions of the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State and that do not exceed ~~[15 mCi (555 MBq)]~~ **555 MBq (15 mCi)** each;

(2) Any radioactive material listed in OAR 333-116-0300, ~~[or]~~ 333-116-0320 **or 333-116-360** with a half-life of 100 days or less in individual amounts not to exceed ~~[15 mCi (555 MBq)]~~ **555 MBq (15 mCi), except Y-90 sources not to exceed 2.8 GBq (75 mCi)**;

(3) Any radioactive material listed in 33-116-0300, ~~[or]~~ 333-116-0320 **or 333-116-360** with a half life greater than 100 days in individual amounts not to exceed ~~[200 µCi (7.4 MBq)]~~ **7.4 MBq (200 µCi)** each; and

(4) Technetium-99m in individual amounts to exceed ~~[50 mCi (1.85 GBq)]~~ **1.85 GBq (50 mCi).**

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Requirements for Possession of Sealed Sources and Brachytherapy Sources

333-116-0200 (1) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Agency, and shall maintain the instructions for the duration of source use in a legible form convenient to users.

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

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

(b) The source is tested for leakage at intervals not to exceed six months or at intervals approved by the Agency, another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission **in the Sealed Source and Device Registry (SS&D).**

(3) To satisfy the leak test requirements of this Division, the licensee shall assure that:

(a) Leak tests are capable of detecting the presence of ~~[0.005 µCi (185 Bq)]~~ **185 Bq (0.005 µCi)** of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of ~~[0.001 µCi (37 Bq)]~~ **37 Bq (0.001 µCi)** per 24 hours;

(b) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

(c) For teletherapy units, test samples are taken when the source is in the "off" position.

(4) A licensee shall retain leak test records until inspected by the Agency. The records shall contain the model number and serial number if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (Bq), a description of the method used to measure each test sample, the date of the test and the signature of the Radiation Safety Officer.

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

(a) Immediately withdraw the sealed source from use and store it in accordance with the requirements of these Rules; and

(b) File a report within five days of receiving the leakage test results with the Agency describing the equipment involved, the test results and the action taken.

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

(a) Sources containing only radioactive material with a half-life of less than 30 days;

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

(c) Sources containing ~~[100 µCi (3.7 MBq)]~~ **3.7 MBq (100 µCi)** or less of beta or photon-emitting material or ~~[10 µCi (370 kBq)]~~ **370 kBq (10 µCi)** or less of alpha-emitting material;

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

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

(7) A licensee in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at intervals not to exceed three months. The licensee shall retain each inventory record until inspected by the Agency. The inventory records must contain the model number of each source and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory and the signature of the Radiation Safety Officer.

(8) A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed three months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units**, gamma stereotactic radiosurgery sources,** or sealed sources in diagnostic devices.

(9) A licensee shall retain a record of each survey required in section (8) of this rule until inspection by the Agency. The record must include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in ~~*[mrem (μSv)]*~~ **μSv mrem** per hour, the model number and serial number of the survey instrument used to make the survey and the signature of the Radiation Safety Officer.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Syringe Shields

333-116-0210 (1) A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.

(2) A licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Syringe Labels

333-116-0220 Unless utilized immediately a licensee shall conspicuously label each syringe or syringe radiation shield that contains a syringe with a radiopharmaceutical, with the radiopharmaceutical name or its abbreviation, the type of diagnostic study or therapy procedure to be performed or the patient's name.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665

Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Vial Shields

333-116-0230 A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Vial Shield Labels

333-116-0240 A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Surveys for Contamination and Ambient Radiation Dose Rate

333-116-0250 (1) A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

(2) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

(3) A licensee shall conduct the surveys required by section (1) and (2) of this rule so as to be able to measure dose rates as low as ~~*[0.1 mrem (one μSv)]*~~ **1 μSv (0.1 mrem)** per hour.

(4) A licensee shall establish dose rate action levels for the surveys required by section (1) and (2) of this rule and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

(5) A licensee shall survey for removable contamination each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.

(6) A licensee shall conduct the surveys required by section (5) of this rule so as to be able to detect contamination on each wipe sample of ~~*[2,000 disintegrations per minute (33.3 Bq)]*~~ **33.3 Bq (2000 dpm)**.

(7) A licensee shall establish removable contamination action levels for the surveys required by section (5) of this rule and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

(8) A licensee shall retain a record of each survey required by this rule until inspection by the Agency. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in ~~*[mrem*~~

~~(μSv)]~~ **μSv mrem** per hour or the removable contamination in each area expressed in ~~[disintegrations (Bq) per minute]~~ **Bq (dpm)** per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples and the initials of the individual who performed the survey.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Release of Patients Containing Therapeutic Quantities of Radiopharmaceuticals or Permanent Implants

333-116-0260 (1) A licensee shall not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either:

(a) The dose rate from the patient is less than ~~[five mrem (50 μSv)]~~ **50 μSv (5 mrem)** per hour at a distance of one meter; or

(b) The activity in the patient is less than ~~[30 mCi (1.11 GBq)]~~ **1.11 GBq (30 millicuries)**.

(2) A licensee shall not authorize release from confinement for medical care any patient administered a permanent implant until the dose rate from the patient is less than ~~[five mrem (50 μSv)]~~ **50 μSv (5 mrem)** per hour at a distance of one meter.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Release of individuals containing radiopharmaceuticals or implants

333-116-0265 (1) A licensee may authorize the release from its control any individual who has been administered radiopharmaceuticals or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not calculated to exceed 5 mSv (0.5 rem) Note: U. S. Nuclear Regulatory Commission Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials",describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 millisieverts (0.5 rem).

(2) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a breast-feeding infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall 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) A licensee shall maintain a record of the basis for authorizing the release of an individual, until inspected by the Agency, if the total effective dose equivalent is calculated by:

(a) Using the retained activity rather than the activity administered,

(b) Using an occupancy factor less than 0.25 at 1 meter,

(c)Using the biological or effective half-life, or

(d) Considering the shielding by tissue.

(4) The licensee shall maintain a record, for 3 years after the date of release, 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 5 millisieverts (0.5 rem).

Mobile Nuclear Medicine Service Technical Requirement

333-116-0270 A licensee providing mobile nuclear medicine service shall:

(1) Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits unless authorized pertinent to other Divisions of these rules;

(2) Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

(3) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use;

(4) Check survey instruments and dose calibrators as required in OAR 333-116-0160(2)(a), (4), (5) and 333-116-0170(4), and check all other transported equipment for proper function before medical use at each location of use;

(5) Carry a calibrated survey meter in each vehicle that is being used to transport radioactive material, and before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed; and

(6) Retain a record of each survey required by section (5) of this rule until inspection by the Agency. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in mrem (μSv) per hour, the model and serial number of the instrument used to make the survey and the initials of the individual who performed the survey.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Storage of Volatiles and Gases

333-116-0280 (1) A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers radiation shield and container.

(2) A licensee shall store and use a multidose container in a properly functioning fume hood.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Decay-In-Storage

333-116-0290 (1) A licensee shall hold radioactive material **with a physical half-life of less than 65 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;

(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 a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

(c) Removes or obliterates all radiation labels; 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 the licensee shall retain a record of section (1) of this rule each disposal until inspection by the Agency. 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 disposal.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Uptake, Dilution and Excretion

Use of Radiopharmaceuticals for Uptake, Dilution or Excretion Studies

333-116-0300 (1) A licensee may use any radioactive material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution or excretion:

(a) ~~*[for w]*~~**Which** the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA); **or***[.]*

(b)Which is prepared and compounded by an authorized nuclear pharmacist, a physician who is an authorized user, or an individual under the supervision of either as specified in OAR 333-116-100.

(2) A licensee using a radiopharmaceutical specified in section (1) of this rule for a clinical procedure other than one specified in the product label or package insert instructions for use shall comply with the product label or package insert instructions regarding physical form, route of administration and dosage range.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Possession of Survey Instrument

333-116-0310 A licensee authorized to use radioactive material for uptake, dilution and excretion studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range ~~*[0.1 mrem (1.0 µSv)]*~~ **1 µSv (0.1 mrem)** per hour to ~~*[100 mrem (one mSv)]*~~ **1 mSv (100 mrem)** per hour. The instrument shall be operable and calibrated in accordance with OAR 333-116-0170.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Imaging and Localization

Use of Radiopharmaceuticals, Generators and Reagents Kits for Imaging and Localization Studies

333-116-0320 (1) A licensee may use any radioactive material in a diagnostic radiopharmaceutical, except aerosol or gaseous form, or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for:

(a) Which ~~*[which]*~~ the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA); or[.]

(b) Which is prepared and compounded by an authorized nuclear pharmacist, a physician who is an authorized user, or an individual under the supervision of either as specified in OAR 333-116-100.

(2) A licensee using radiopharmaceuticals specified in section (1) of this rule for clinical procedures other than one specified in the product label or package insert instructions shall comply with the product label or package insert regarding physical form and dosage range.

(3) A licensee shall elute generators in compliance with OAR 333-116-0330 and prepare radiopharmaceuticals from kits in accordance with the manufacturer's instructions.

**** (4) Technetium-99m pentatate as an aerosol for lung function studies is not subject to the restrictions in section (1) of this rule. Provided the conditions of OAR 333-116-0340 are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Agency.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Permissible Molybdenum-99 Concentration

333-116-0330 (1) A licensee shall not administer to humans a radiopharmaceutical containing more than ~~*[0.15 µCi (5.55 kBq)]*~~ **0.15 kBq (0.15 µCi)** of molybdenum-99 per ~~*[mCi (MBq)]*~~ **MBq (mCi)** of technetium-99m.

(2) A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract.

(3) A licensee who must measure molybdenum concentration shall retain a record of each measurement until inspection by the Agency. The record shall include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in ~~*[mCi (MBq)]*~~ **MBq (mCi)**, the measured activity of the molybdenum expressed in ~~*[µCi (kBq)]*~~ **kBq (µCi)**, the ratio of the measures expressed as **kBq** (µCi) of molybdenum per **MBq** (mCi) of technetium, the date of the test and the initials of the individual who performed the test.

(4) A licensee shall report immediately to the Agency each occurrence of molybdenum-99 concentration exceeding the limits specified in section (1) of this rule.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Control of Aerosols and Gases

333-116-0340 (1) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by OAR 333-120-0130 and 333-120-0180.

(2) The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(3) A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

(4) Before receiving, using or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in 10 CFR Part 20 Appendix B to 20.1001 to 20.2401. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

(5) A licensee shall post the time calculated in accordance with ~~*[section]*~~ **333-116-0340**(4) of this rule at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

(6) A licensee shall check the operation of collection systems before each use and measure the ventilation rates in areas of use at intervals not to exceed six months. **Records of these checks and measurements shall be maintained for 5 years or until inspected by the Agency.**

(7) A copy of the calculations required in ~~*[section]*~~ **333-116-0340**(4) of this rule shall be recorded and retained for the duration of the license.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Possession of Survey Instruments

333-116-0350 A licensee authorized to use radioactive material for imaging and localization studies shall have in its possession a portable, radiation detection survey instrument capable of detecting dose rates over the range of ~~*[0.1 mrem (one µSv)]*~~ **1 µSv (0.1 mrem)** per hour to ~~*[100 mrem (one mSv)]*~~ **1 mSv (100 mrem)** per hour and a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~*[one mrem (10 µSv)]*~~ **10 µSv (1 mrem)** per hour to ~~*[1000 mrem (10 mSv)]*~~ **10 millisieverts (1000 mrem)** per hour. The instruments shall be operable and calibrated in accordance with OAR 333-116-0170.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Radiopharmaceuticals for Therapy

Use of Radiopharmaceuticals for Therapy

333-116-0360 (1) A licensee may use ~~*[the following prepared radiopharmaceuticals:]*~~ **for therapeutic administration any unsealed byproduct material prepared for medical use that:**

(a) Has been granted acceptance or approval by the Food and Drug Administration; and

(b) Has been prepared by an authorized nuclear pharmacist, a physician who is an authorized user on a license from the Agency, other Agreement State, or the U.S. Nuclear Regulatory Commission.

~~*[(1) Iodine-131 as iodide for treatment of hyperthyroidism, cardiac dysfunction and thyroid carcinoma;*~~

~~*(2) Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases;*~~

~~*(3) Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions;*~~

~~*(4) Gold-198 as colloid for intracavitary treatment of malignant effusions;*~~

~~*(5) Any radioactive material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).]*~~

(2) The licensee shall comply with the package insert instructions regarding indications and method of administration.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Safety Instruction

333-116-0370 (1) A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients undergoing radiopharmaceutical therapy. Refresher training shall be provided at intervals not to exceed one year.

(2) To satisfy ~~*[section]*~~ **333-116-0370**(1) of this rule, the instruction shall describe the licensee's procedures for:

(a) Patient control;

(b) Visitor control;

(c) Contamination control;

(d) Waste control; and

(e) Notification of the Radiation Safety Officer or authorized user in case of the patient's death or medical emergency.

(3) A licensee shall keep until inspection by the Agency a list of individuals receiving instruction required by ~~*[section]*~~ **333-116-0370**(1) of this rule, a description of the instruction, the date of instruction and the name of the individual who gave the instruction.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Safety Precautions

333-116-0380 (1) For each patient receiving radiopharmaceutical therapy and hospitalized for compliance with OAR 333-116-0260 **or 333-116-0265**, a licensee shall:

(a) Provide a private room with a private sanitary facility;

(b) Post the patient's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's chart where and how long visitors may stay in the patient's room;

(c) Authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

(d) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of OAR 333-120-0180 of these Rules and retain until inspection by the Agency a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in mrem per hour, the instrument used to make the survey and the initials of the individual who made the survey;

(e) Either monitor material and items removed from the patient's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle materials and items as radioactive waste;

(f) ~~*[Provide]*~~ **Instruct** the patient **and, where appropriate, the patient's family, orally and in writing concerning** ~~*[with]*~~ radiation safety ~~*[guidance]*~~ **precautions** that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient;

(g) Survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than ~~[200 disintegrations per minute (3.3 Bq)]~~ **3.33 Bq (200 dpm)** per 100 square centimeters; and

(h) Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage and retain for the period required by OAR 333-120-0620 of these Rules a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured and the initials of the individual who made the measurements. **Other procedures acceptable to the Agency may be used for individuals who only prepare, but do not administer, doses of stabilized I-131.**

(2) A licensee shall notify the Radiation Safety Officer or the nuclear physician immediately if the patient dies or has a medical emergency.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Possession of Survey Instruments

333-116-0390 A licensee authorized to use radioactive material for radiopharmaceutical therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range ~~[0.1 mrem (one μSv)]~~ **1 μSv (0.1 mrem)** per hour to 100 mrem (one mSv) per hour and a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~[one mrem (10 μSv)]~~ **10 μSv (1 mrem)** per hour to ~~[1000 mrem (10 mSv)]~~ **10 mSv (1000 mrem)** per hour. The instruments shall be operable and calibrated in accordance with OAR 333-116-0170.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Sealed Sources for Diagnosis

Use of Sealed Sources for Diagnosis

333-116-0400 A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

(1) Iodine-125 as a sealed source in a device for bone mineral analysis;

(2) Americium-241 as a sealed source in a device for bone mineral analysis;

(3) Gadolinium-153 as a sealed source in a device for bone mineral analysis; and

(4) Iodine-125 as a sealed source in a portable device for imaging.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665

Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Availability of Survey Instrument

333-116-0410 A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range ~~*[0.1 mrem (one μSv)]*~~ **1 μSv (0.1 mrem)** per hour to 100 mrem (one mSv) per hour and a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~*[one mrem (10 μSv)]*~~ **10 μSv (1 mrem)** per hour to ~~*[1000 mrem (10 mSv)]*~~ **10 mSv (1000 mrem)** per hour. The instrument shall be operable and calibrated in accordance with OAR 333-116-0170.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Sources for Brachytherapy

Use of Sources for Brachytherapy

333-116-0420 A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

(1) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial and intracavitary treatment of cancer;

(2) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial and intracavitary treatment of cancer;

(3) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;

(4) Iodine-125 as a sealed source in seeds for interstitial treatment of cancer;

(5) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

(6) Radium-226 as a sealed source in needles or applicator cells for topical, interstitial and intracavitary treatment of cancer;

(7) Radon-222 as seeds for interstitial, treatment of cancer;

(8) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and

(9) Palladium-103 as a sealed source in seeds for the interstitial treatment of cancer.

(10) Any medical device or material approved for human use by the US FDA and approved for licensing purposes by the US NRC or an Agreement State.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Safety Instructions

333-116-0430 (1) The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient receiving implant therapy. Refresher training shall be provided at intervals not to exceed one year.

(2) To satisfy section (1) of this rule, the instruction shall describe:

(a) Size and appearance of the brachytherapy sources;

(b) Safe handling and shielding instructions in case of a dislodged source;

(c) Procedures for patient control;

(d) Procedures for visitor control; and

(e) Procedures for notification of the Radiation Safety Officer or authorized user if the patient dies or has a medical emergency.

(3) A licensee shall retain until inspection by the Agency a record of individuals receiving instruction required by ~~[section]~~ **333-116-0430**(1) of this rule, a description of the instruction, the date of instruction and the name of the individual who gave the instruction.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Safety Precaution

333-116-0440 (1) A licensee shall, for each patient receiving implant therapy:

(a) Not place the patient in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirement of OAR 333-120-0180 of these rules at a distance of one meter from the implant;

(b) Post the patient's door with a "Caution: Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room;

(c) Authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

(d) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with OAR 333-120-0180 of these Rules, and retain until inspection by the Agency, a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in ~~[mrem (μSv)]~~ **microsieverts (mrems)** per hour, the instrument used to make the survey and the initials of the individual who made the survey; and

(e) ~~[Provide]~~ **Instruct** the patient **and, where appropriate, the patient's family, orally and in writing concerning** ~~[with]~~ radiation safety ~~[guidance]~~ **precautions** that will help to keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.

(2) A licensee shall notify the Radiation Safety Officer or authorized user immediately if the patient dies or has a medical emergency.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Brachytherapy Sources Inventory

333-116-0450 (1) Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count the number returned to ensure that all sources taken from the storage area have been returned.

(2) A licensee shall make a record of brachytherapy source use which includes:

(a) The names of the individuals permitted to handle the sources;

(b) The number and activity of sources removed from storage, the room number of use and patient's name, the time and date they were removed from storage, the number and activity of the sources in storage after the removal and the initials of the individual who removed the sources from storage; and

(c) The number and activity of sources returned to storage, the room number of use and patient's name, the time and date they were returned to storage, the number and activity of sources in storage after the return and the initials of the individual who returned the sources to storage.

(3) Immediately after implanting sources in a patient and immediately after removal of sources from a patient the licensee shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

(4) A licensee shall retain the records required in ~~[section]~~ **333-116-0450**(2) and **333-116-0450**(3) of this rule until inspection by the Agency.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Release of Patients Treated With Temporary Implant

333-116-0460 (1) Immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed. The licensee shall not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.

(2) A licensee shall retain a record of patient surveys which demonstrate compliance with OAR 333-116-0450(1) until inspection by the Agency. Each record must include the date of the survey, the name of the patient, the dose rate from the patient expressed as ~~[mrem (μSv)]~~ **μSv (mrem)** per hour and measured within one meter from the patient and the initials of the individual who made the survey.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Possession of Survey Instruments

333-116-0470 A licensee authorized to use radioactive material for implant therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range ~~*[0.1 mrem (one μSv)]*~~ **1 μSv (0.1 mrem)** per hour to 100 mrem (one mSv) per hour and a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~*[one mrem (10 μSv)]*~~ **10 μSv (1 mrem)** per hour to ~~*[1000 mrem (10 mSv)]*~~ **10 mSv (1000 mrem)** per hour. The instruments shall be operable and calibrated in accordance with OAR 333-116-0170.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Teletherapy and X-ray Therapy (Radiation Beam Therapy)

Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit

333-116-0480 ~~*[A licensee shall only use cobalt-60 or cesium-137 as a sealed source in a teletherapy unit for medical use in accordance with the manufacturer's radiation safety and operating instructions.]*~~ **Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.**

A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Installation, Maintenance, Adjustment, and Repair ~~*[Restriction]*~~

333-116-0490 ~~*[Only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State to perform teletherapy unit maintenance and repair shall install, relocate or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or maintain, adjust or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source or result in increased radiation levels.]*~~

(a) Only a person specifically licensed by the Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving

unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Commission or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(d) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with § 35.2605.

Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

333-116-0495

(1) A licensee shall --

(a) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(b) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(c) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(d) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include --

(A) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(B) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(C) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(2) A copy of the procedures required by paragraph (a)(4) of this section must be physically located at the unit console.

(3) A licensee shall post instructions at the unit console to inform the operator of --

(a) The location of the procedures required by paragraph (a)(4) of this section; and

(b) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(4) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in --

(a) The procedures identified in paragraph (a)(4) of this section; and

(b) The operating procedures for the unit.

(5) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(6) A licensee shall retain a record of individuals receiving instruction required by paragraph (d) of this section, in accordance with § 35.2310.

(7) A licensee shall retain a copy of the procedures required by §§ 35.610(a)(4) and (d)(2) in accordance with § 35.2610.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Amendment

333-116-0500 In addition to the requirements specified in OAR 333-116-0040, a licensee shall apply for and shall receive a license amendment before:

(1) Making any change in the treatment room shielding;

(2) Making any change in the location of the teletherapy unit within the treatment room;

(3) Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

(4) Relocating the teletherapy unit; or

(5) Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Safety ~~*[Instruction]*~~ Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

333-116-0510 ~~*[(1) A licensee shall post written instructions at the teletherapy unit console. To satisfy this requirement, these instructions shall inform the operator of:*~~

~~*(a) The procedure to be followed to ensure that only the patient is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption;*~~

~~*(b) The procedure to be followed if:*~~

~~*(A) The operator is unable to turn the primary beam of radiation off with controls outside the treatment room or any other abnormal operation occurs; and*~~

~~*(B) The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.*~~

~~*(2) A licensee shall provide instruction in the topics identified in [section]* 333-116-0510*(1) [of this rule] to all individuals who operate a teletherapy unit and shall provide appropriate refresher training to individuals at intervals not to exceed one year.*~~

~~*(3) A licensee shall retain until inspection by the Agency a record of individuals receiving instruction required by [section]* 333-116-0510*(2) of this rule, a description of the instruction, the date of instruction and the name of the individual who gave the instruction.]*~~

(a) A licensee shall control access to the treatment room by a door at each entrance.

(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will --

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(2) Cause the source(s) to be shielded when an entrance door is opened; and

(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(d) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(e) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(f) In addition to the requirements specified in paragraphs (a) through (e) of this section, a licensee shall --

(1) For medium dose-rate and pulsed dose-rate remote afterloader units, require --

(i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) For high dose-rate remote afterloader units, require --

(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(4) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(g) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source --

(1) Remaining in the unshielded position; or

(2) Lodged within the patient following completion of the treatment.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit

333-116-0515 A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

(1) As approved in the Sealed Source and Device Registry; or

(2) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA.

Doors, Interlocks and Warning System

333-116-0520 (1) A licensee shall control access to the teletherapy room by a door at each entrance.

(2) A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:

(a) Prevent the operator from turning the primary beam of radiation on unless each treatment room entrance door is closed;

(b) Turn the primary beam of radiation off immediately when an entrance door is opened; and

(c) Prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

(3) A licensee shall equip each entrance to the teletherapy therapy room with a beam condition indicator light.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665

Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

333-116-0525

(1) A licensee shall control access to the treatment room by a door at each entrance.

(2) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will --

(a) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(b) Cause the source(s) to be shielded when an entrance door is opened; and

(c) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(3) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(4) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(5) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(6) In addition to the requirements specified in paragraphs (a) through (e) of this section, a licensee shall --

(a) For medium dose-rate and pulsed dose-rate remote afterloader units, require --

(A) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(B) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(b) For high dose-rate remote afterloader units, require --

(A) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(B) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(c) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(d) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(7) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source --

(a) Remaining in the unshielded position; or

(b) Lodged within the patient following completion of the treatment.

Possession of Survey Instrument

333-116-0530 A licensee authorized to use radioactive material in a teletherapy therapy unit shall have in its possession either **both** a portable radiation detection survey instrument capable of detecting dose rates over the range ~~*[0.1 mrem (one μSv)]*~~ **1 μSv (0.1 mrem)** per hour to 100 mrem (one mSv) per hour and a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~*[one mrem (10 μSv)]*~~ **10 μSv (1 mrem)** per hour to ~~*[1000 mrem (10 mSv)]*~~ **10 mSv (1000 mrem)** per hour. The instruments shall be operable and calibrated in accordance with OAR 333-116-0170.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Radiation Monitoring Device

333-116-0540 (1) A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

(2) Each radiation monitor shall be capable of providing visible ~~*[notice]*~~ **evidence** of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels must be observable by an individual prior to entering the teletherapy room.

(3) Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system **or other type of uninterruptible power supply (UPS)**.

(4) ~~*[A]*~~**Each** radiation monitor must be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.

(5) A licensee shall maintain a record of the check required by ~~*[section]*~~ **333-116-0540**(4) ~~*[of this rule]*~~ until inspection by the Agency. The record shall include the date of the check, notation that the monitor indicates when the source is exposed and the initials of the individual who performed the check.

(6) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in ~~*[section]*~~ **333-116-0540**(4) ~~*[of this rule]*~~.

(7) **If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism. The instrument or dosimeter shall be**

checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in 333-116-0540(5).

(8) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Viewing System

333-116-0550 A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient from the teletherapy unit console during irradiation.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Dosimetry Equipment

333-116-0560 (1) **Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer,** ~~*[A]*~~ **a** licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met.

(a) The system shall have been calibrated ~~*[by the]*~~ **using a system or source traceable to the** National Institute of Standards and Technology **(NIST) and published protocols accepted by nationally recognized bodies;** or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration shall have been performed within the previous two years and after any servicing that may have affected system calibration; or

(b) The system shall have been calibrated within the previous four years; 18 to 30 months after that calibration, the system shall have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the AAPM. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting must ~~*[have indicated]*~~ **show** that the calibration factor of the licensee's system had not changed by more than two percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating ~~*[cobalt-60 teletherapy]*~~ **sealed sources for therapeutic** units, the licensee shall use ~~*[a teletherapy unit with a cobalt-60 source]*~~ **a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.** ~~*[When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.]*~~

(2) The licensee shall have available for use a dosimetry system for spot-check **output** measurements**, if applicable**. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with ~~[section]~~ **333-116-0560**(1) of this rule. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in section **333-116-0560**(1) of this rule.

(3) The licensee shall retain a record of each calibration, intercomparison and comparison for the duration of the license. For each calibration, intercomparison or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared or compared as required by ~~[section]~~ **333-116-0560**(1) and **333-116-0560**(2) ~~[of this rule]~~, the correction factors that were deduced, the names **and credentials** of the individuals who performed the calibration, intercomparison or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Full Calibration Measurement

333-116-0570 (1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(a) Before the first medical use of the unit; and

(b) Before medical use under the following conditions:

(A) Whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(B) Following replacement of the **radioactive** source or following reinstallation of the teletherapy unit in a new location;

(C) Following any repair of the teletherapy unit that includes removal of the **radioactive** source or major repair of the components associated with the source exposure assembly; and

(c) At intervals not exceeding one year.

(2) To satisfy the requirement of ~~[section]~~ **333-116-0570**(1) ~~[of this rule]~~, full calibration measurements shall include determination of:

(a) The output within ±3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(b) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(c) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(d) Timer accuracy**, constancy, and linearity;**

(e) On-off error; and

(f) The accuracy of all distance measuring and localization devices in medical use.

(3) A licensee shall use the dosimetry system described in OAR 333-116-0650(1) to measure the output for one set of exposure conditions. The remaining radiation measurements required in ~~[subsection]~~ **333-116-0570**(2)(a) ~~[of this rule]~~ may then be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by ~~[section]~~ **333-116-0570**(1) ~~[of this rule]~~ in accordance with ~~[either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396 or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983, pp. 741-771 and Vol. 11, No. 2, 1984, p.213]~~ **published protocols accepted by nationally recognized bodies.**

(5) A licensee shall correct mathematically the outputs determined in ~~[subsection]~~ **333-116-0570**(2)(a) ~~[of this rule]~~ for physical decay for intervals not exceeding one month for cobalt-60 and intervals not exceeding six months for cesium-137**, or at intervals consistent with 1 percent decay for all other nuclides.**

(6) Full calibration measurements required by ~~[section]~~ **333-116-0570**(1) ~~[of this rule]~~ and physical decay corrections required by ~~[section]~~ **333-116-0570**(5) ~~[of this rule]~~ shall be performed by a teletherapy **or medical** physicist **certified to perform such measurements and named on the licensee's license or authorized by a license issued by the Nuclear Regulatory Commission or an Agreement State to perform such services.**

(7) A licensee shall retain a record of each calibration for the duration of the license. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated on-off error, the estimated accuracy of each distance measuring or localization device and the signature of the teletherapy physicist.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Full Calibration Measurements on Remote Afterloader Units

333-116-0573

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit --

(a) Before the first medical use of the unit;

(b) Before medical use under the following conditions:

(A) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(B) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(c) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(d) At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(2) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include, as applicable, determination of:

(a) The output within +/- 5 percent;

(b) Source positioning accuracy to within +/- 1 millimeter;

(c) Source retraction with backup battery upon power failure;

(d) Length of the source transfer tubes;

(e) Timer accuracy and linearity over the typical range of use;

(f) Length of the applicators; and

(g) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(3) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output.

(4) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(5) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (b) of this section, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

(6) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with paragraphs (a) through (e) of this section.

(7) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay at intervals consistent with 1 percent physical decay.

(8) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (g) of this section must be performed by the authorized medical physicist.

(9) A licensee shall retain a record of each calibration in accordance with § 35.2632.

Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units

333-116-0577

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit --

(a) Before the first medical use of the unit;

(b) Before medical use under the following conditions --

(A) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(B) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(C) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(c) At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(2) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of --

(a) The output within +/-3 percent;

(b) Relative helmet factors;

(c) Isocenter coincidence;

(d) Timer accuracy and linearity over the range of use;

(e) On-off error;

(f) Trunnion centricity;

(g) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(h) Helmet microswitches;

(i) Emergency timing circuits; and

(j) Stereotactic frames and localizing devices (trunnions).

(3) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(6) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(7) A licensee shall retain a record of each calibration in accordance with § 35.2632.

Periodic Spot-Checks

333-116-0580 (1) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit at intervals not to exceed one month.

(2) To satisfy the requirement of ~~*[section]*~~ **333-116-0580**(1) ~~*[of this rule]*~~, measurements shall include determination of:

(a) Timer constancy, accuracy, and ~~*[timer]*~~ linearity over the range of use;

(b) On-off error;

(c) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(d) The accuracy of all distance measuring and localization devices used for medical use;

(e) The output for one typical set of operating conditions **measured with the dosimetry system described in 333-116-560;** and

(f) The difference between the measurement made in ~~[subsection]~~ **333-116-0580**(2)(e) ~~[of this rule]~~ and the anticipated output, expressed as a percentage of the anticipated value obtained at last full calibration corrected mathematically for physical decay.

(3) A licensee shall use the dosimetry system described in OAR 333-116-0560 to make the measurement required in ~~[subsection]~~ **333-116-0580**(2)(e) ~~[of this rule]~~.

(4) A licensee shall perform measurements required by ~~[subsection]~~ **333-116-0580**(1) ~~[of this rule]~~ in accordance with procedures established by the teletherapy **or medical** physicist. That individual ~~[does not need]~~ **is not required** to actually perform the output spot-check measurements.

(5) A licensee shall have the teletherapy **or medical** physicist review the results of each output spot-check within 15 days **of each measurement**. The teletherapy **or medical** physicist shall promptly notify the licensee in writing of the results of each output spot-check. The licensee shall keep a copy of each written notification until inspection by the Agency.

(6) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility at intervals not to exceed one month~~[,]~~**;**

(7) To satisfy the requirement of ~~[section]~~ **333-116-0580**(5) ~~[of this rule]~~, checks shall assure proper operation of:

(a) Electrical interlocks at each teletherapy room entrance;

(b) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism;

(c) Beam condition indicator lights on the teletherapy unit, on the control console and in the facility;

(d) Viewing systems;

(e) Treatment room doors from inside and outside the treatment room; and

(f) Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".

(8) A licensee shall lock the control console in the "off" position if any door interlock malfunctions. No licensee shall use the unit until the interlock system is repaired unless specifically authorized by the Agency.

(9) A licensee shall promptly repair any system identified in ~~[section]~~ **333-116-0580**(7) ~~[of this rule]~~ that is not operating properly.

(10)A licensee shall retain a record of each spot-check required by ~~[section]~~ **333-116-0580**(1) and **333-116-0580**(6) ~~[of this rule]~~ until inspection by the Agency. The record shall include, the date of the spot-check, the manufacturer's name, model number and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, the measured timer accuracy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door

electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors and the signature of the individual who performed the periodic spot-check.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Periodic Spot-checks for Remote Afterloader Units

333-116-0583

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit--

(a) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(b) Before each patient treatment with a low dose-rate remote afterloader unit; and

(c) After each source installation.

(2) A licensee shall perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(4) To satisfy the requirements of paragraph (a) of this section, spot-checks must, at a minimum, assure proper operation of --

(a) Electrical interlocks at each remote afterloader unit room entrance;

(b) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(c) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(d) Emergency response equipment;

(e) Radiation monitors used to indicate the source position;

(f) Timer accuracy;

(g) Clock (date and time) in the unit's computer; and

(h) Decayed source(s) activity in the unit's computer.

(5) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) A licensee shall retain a record of each check required by paragraph (d) and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2643.

Additional Technical Requirements for Mobile Remote Afterloader Units

333-116-0585

(1) A licensee providing mobile remote afterloader service shall --

(a) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(b) Account for all sources before departure from a client's address of use.

(2) In addition to the periodic spot-checks required by § 35.643, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of

(a) Electrical interlocks on treatment area access points;

(b) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(c) Viewing and intercom systems;

(d) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(e) Radiation monitors used to indicate room exposures;

(f) Source positioning (accuracy); and

(g) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(3) In addition to the requirements for checks in paragraph (b), a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(4) If the results of the checks required in paragraph (b) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(5) A licensee shall retain a record of each check required by paragraph (b) of this section in accordance with § 35.2647.

Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units

333-116-0587

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit --

(a) Monthly;

(b) Before the first use of the unit on a given day; and

(c) After each source installation.

(2) A licensee shall--

(a) Perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(b) Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(3) To satisfy the requirements of paragraph (a)(1) of this section, spot-checks must, at a minimum --

(a) Assure proper operation of --

(A) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(B) Helmet microswitches;

(C) Emergency timing circuits; and

(D) Stereotactic frames and localizing devices (trunnions).

(b) Determine --

(A) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b);

(B) The difference between the measurement made in paragraph (c)(2)(i) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(C) Source output against computer calculation;

(D) Timer accuracy and linearity over the range of use;

(E) On-off error; and

(F) Trunnion centricity.

(4) To satisfy the requirements of paragraphs (a)(2) and (a)(3) of this section, spot-checks must assure proper operation of --

(a) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(b) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(c) Viewing and intercom systems;

(d) Timer termination;

(e) Radiation monitors used to indicate room exposures; and

(f) Emergency off buttons.

(5) A licensee shall arrange for the repair of any system identified in paragraph (c) of this section that is not operating properly as soon as possible.

(6) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(7) A licensee shall retain a record of each check required by paragraphs (c) and (d) and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2645.

Radiation Surveys for Teletherapy Facilities

333-116-0590 (1) Before medical use, after each installation of a teletherapy source and after making any change for which an amendment is required by OAR 333-116-0500, the licensee shall

perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with OAR 333-116-0170 to verify that:

(a) The maximum and average radiation levels at one meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field do not exceed ~~*[10 mrem (100 µSv)]*~~ **100 µSv (10 mrem)** per hour and ~~*[two mrem (20 µSv)]*~~ **20 µSv (2 mrem)** per hour, respectively; and

(b) With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

(A) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in OAR 333-120-0100 of these rules; and

(B) Radiation levels in unrestricted areas do not exceed the limits specified in OAR 333-120-0180 of these rules.

(2) If the results of the surveys required in section (1) of this rule indicate any radiation levels in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the off position and not use the unit:

(a) Except as may be necessary to repair, replace or test the teletherapy unit, the teletherapy unit shielding or the treatment room shielding; or

(b) Until the licensee has received a specific exemption from the Agency.

(3) A licensee shall retain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the off position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in mrem (µSv) per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area and the signature of the Radiation Safety Officer.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Safety Checks ~~[for Teletherapy Facilities]~~ and Five-year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units

333-116-0600 (1) A licensee shall ~~[promptly check all systems listed in OAR 333-116-0580, for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by OAR 333-116-0500(1) through (4)]~~ **have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.**

(2) **This inspection and servicing may only be performed by persons specifically licensed to do so by the Nuclear Regulatory Commission or an Agreement State.**

(~~[2]~~**3**) If the results of the checks required in section (1) of this rule indicate the malfunction of any system ~~[specified in OAR 333-116-0580]~~, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system.

(~~[3]~~**4**) A licensee shall retain until inspection by the Agency a record of the facility checks following installation of a source. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors and the signature of the Radiation Safety Officer.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Therapy-related Computer Systems

333-116-605 The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(1) The source-specific input parameters required by the dose calculation algorithm;

(2) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) The accuracy of isodose plots and graphic displays;

(4) The accuracy of the software used to determine sealed source positions from radiographic images; and

(5) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

Modification of Teletherapy Unit or Room Before Beginning a Treatment Program

333-116-0610

(1) If the survey required by 333-116-0590 indicates that any individual member of the public is likely to receive a dose in excess of the limits specified in 333-120-0180, the licensee shall, before beginning the treatment program:

(a) Either equip the unit with stops or add additional radiation shielding to ensure compliance with 333-120-0180.

(b) Perform the survey required by 333-116-0590 again; and

(c) Include in the report required by 333-116-0620 the results of the initial survey, a description of the modification made to comply with 333-116-0610(1)(a), and the results of the second survey.

(2) As an alternative to the requirements set out in 333-116-0610(a), a licensee may request a license amendment under 333-120-0180(3) that authorizes radiation levels in unrestricted areas greater than those permitted by 333-120-0180(1) of this chapter. A licensee may not begin the treatment program until the license amendment has been issued.

Reports of Teletherapy Surveys, Checks, Tests and Measurements

333-116-0620 A licensee shall furnish a copy of the records required in OAR 333-116-0590, 333-116-0600, 333-116-0610 and the output from the teletherapy source expressed as rem (Sv) per hour at one meter from the source and determined during the full calibration required in OAR 333-116-0570 to the Agency within 30 days following completion of the action that initiated the record requirement.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Five-Year Inspection

333-116-0630 (1) A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(2) This inspection and servicing shall only be performed by persons specifically licensed to do so by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission.

(3) A licensee shall keep a record of the inspection and servicing for the duration of the license. The record shall contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced and the signature of the inspector.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Training and Experience Requirements

Radiation Safety Officer

333-116-0640 Except as provided in OAR 333-116-0650, an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in this rule shall:

(1) Be certified by:

(a) American Board of Health Physics in Comprehensive Health Physics; or

(b) American Board of Radiology ~~*[in Radiological Physics, Therapeutic Radiological Physics or Medical Nuclear Physics]*~~; or

(c) American Board of Nuclear Medicine; or

(d) American Board of Science in Nuclear Medicine; or

(e) Board of Pharmaceutical Specialties in Nuclear Pharmacy or Science; or

(f) American Board of Medical Physics in radiation oncology physics; or

(g) Royal College of Physicians and Surgeons of Canada in nuclear medicine; or

(h) American Osteopathic Board of Radiology; or

(i) American Osteopathic Board of Nuclear Medicine; or

(2) ~~*[Have had]*~~ **Has completed** 200 hours of classroom and laboratory training as follows:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology;

(e) Radiopharmaceutical chemistry; and

(f) One year of full time experience in radiation safety at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on an Agency, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or

(3) Be an authorized user for those radioactive material uses that come within the Radiation Safety Officer's responsibilities.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Training for Experienced Radiation Safety Officer

333-116-0650 An individual identified as a Radiation Safety Officer on an Agency, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license on (Effective July 1, 1990) who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of OAR 333-116-0640.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Training for Uptake, Dilution or Excretion Studies

333-116-0660 Except as provided in OAR 333-116-0740 and 333-116-0750, the licensee shall require the authorized user of a radiopharmaceutical listed in OAR 333-116-0300 to be a physician who:

(1) Is certified in:

(a) Nuclear medicine by the American Board of Nuclear Medicine; or

(b) Diagnostic radiology by the American Board of Radiology; or

(c) Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or

(d) Nuclear Medicine by the American Osteopathic Board of Nuclear Medicine; or

(e) Nuclear Medicine by the Royal College of Physicians and Surgeons of Canada; or

(2) Has completed 40 hours of instruction in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals and 20 hours of supervised clinical experience:

(a) To satisfy the basic instruction requirement, 40 hours of classroom and laboratory instruction shall include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Radiation biology; and

(E) Radiopharmaceutical chemistry.

(b) To satisfy the requirement for 20 hours of supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and shall include:

(A) Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations or contraindications;

(B) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(C) Administering dosages to patients and using syringe radiation shields;

(D) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(E) Patient followup; or

(3) Has successfully completed a ~~[four]~~ **six** month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience and supervised clinical experience in all the topics identified in OAR 333-116-0660(2).

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Training for Imaging and Localization Studies

333-116-0670 Except as provided in OAR 333-116-0740 or 333-116-0750, the licensee shall require the authorized user of a radiopharmaceutical, generator or reagent kit specified in OAR 333-116-0320 to be a physician who:

(1) Is certified in:

(a) Nuclear medicine by the American Board of Nuclear Medicine; or

(b) Diagnostic radiology by the American Board of Radiology;or

(c) Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or

(d) Nuclear Medicine by the American Osteopathic Board of Nuclear Medicine; or

(e) Nuclear Medicine by the Royal College of Physicians and Surgeons of Canada; or

(2) Has completed 200 hours of instruction in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators and reagent kits, 500 hours of supervised work experience and 500 hours of supervised clinical experience:

(a) To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Radiopharmaceutical chemistry; and

(E) Radiation biology.

(b) To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

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

(B) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(C) Calculating and safely preparing patient dosages;

(D) Using administrative controls to prevent the misadministration of radioactive material;

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

(F) Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.

(c) To satisfy the requirement for 500 hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

(A) Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations or contraindications;

(B) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(C) Administering dosages to patients and using syringe radiation shields;

(D) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(E) Patient followup; or

(3) Has successfully completed a ~~[four]~~ **six** month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience and supervised clinical experience in all the topics identified in OAR 333-116-0670(2).

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Training for Therapeutic Use of Radiopharmaceuticals

333-116-0680 Except as provided in OAR 333-116-0740, the licensee shall require the authorized user of a radiopharmaceutical listed in OAR 333-116-0360 for therapy to be a physician who:

(1) Is certified by:

(a) The American Board of Nuclear Medicine; or

(b) The American Board of Radiology in radiology or therapeutic radiology**, or radiation oncology; or**

(c) The American Osteopathic Board of Radiology after 1984; or

(d) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(2) Has completed 80 hours of instruction in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals and has had supervised clinical experience:

(a) To satisfy the requirement for instruction, 80 hours of classroom and laboratory training shall include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Radiation biology;

(b) To satisfy the requirement for supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

(A) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten individuals;

(B) Use of soluble phosphorus-32 for the treatment of ascites polycythemia vera, leukemia or bone metastases in three individuals;

(C) Use of iodine-131 for treatment of thyroid carcinoma in three individuals; and

(D) Use of colloidal chromic phosphorus-32 or of colloidal gold-198 for intracavitary treatment of malignant effusions in three individuals.

(E) Use of phosphorus-32, strontium-89, or samarium-153 for treatment of pain associated with bone metastases in three individuals.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Training for Therapeutic Use of Brachytherapy Sources

333-116-0690 Except as provided in OAR 333-116-0740, the licensee shall require the authorized user using a brachytherapy source specified in OAR 333-116-0420 for therapy to be a physician who:

(1) Is certified in:

(a) Radiology, radiation oncology or therapeutic radiology by the American Board of Radiology; or

(b) Radiation oncology by the American Osteopathic Board of Radiology; or

(c) Radiology, with a specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(d) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(2) Is in the active practice of therapeutic radiology, has completed 200 hours of instruction in basic radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience and a minimum of three years of supervised clinical experience:

(a) To satisfy the requirement for instruction, 200 hours of classroom and laboratory training shall include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Radiation biology.

(b) To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at an institution and shall include:

(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 sealed sources;

(D) Using administrative controls to prevent the misadministration of radioactive material; and

(E) Using emergency procedures to control radioactive material.

(c) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:

(A) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment and any limitations or contraindications;

(B) Selecting the proper brachytherapy sources and dose and method of administration;

(C) Calculating the dose; and

(D) Post-administration followup and review of case histories in collaboration with the authorized user.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Training for Ophthalmic Use of Strontium-90

333-116-0700 Except as provided in OAR 333-116-0740, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

(1) Is certified in radiology or therapeutic radiology by the American Board of Radiology; or

(2) Is in the active practice of therapeutic radiology or ophthalmology and has completed 24 hours of instruction in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy and a period of supervised clinical training in ophthalmic radiotherapy:

(a) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(A) Six hours of radiation physics and instrumentation;

(B) Six hours of radiation protection;

(C) Four hours of mathematics pertaining to the use and measurement of radioactivity; and

(D) Eight hours of radiation biology.

(b) To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training must be under the supervision of an authorized user at a medical institution and must include the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

(A) Examination of each individual to be treated;

(B) Calculation of the dose to be administered;

(C) Administration of the dose; and

(D) Followup and review of each individual's case history.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Training for Use of Sealed Sources for Diagnosis

333-116-0710 Except as provided in OAR 333-116-0740 the licensee shall require the authorized user using a sealed source in a device specified in OAR 333-116-0400 to be a physician, dentist or podiatrist who:

(1) Is certified in:

(a) Radiology, diagnostic radiology with special competence in nuclear radiology, radiation oncology or therapeutic radiology by the American Board of Radiology; or

(b) Nuclear medicine by the American Board of Nuclear Medicine; or

(c) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

(d) Nuclear medicine by the Royal College of Canada; or

(2) Has completed eight hours of instruction in basic radioisotope handling techniques specifically applicable to the use of the device. To satisfy the requirement for instruction, the training shall include:

(a) Three hours of radiation physics, mathematics pertaining to the use and measurement of radioactivity and instrumentation;

(b) Three hours of radiation biology; and

(c) Two hours of radiation protection and training in the use of the device for the purposes authorized by the license.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

333-116-0720 Except as provided in OAR 333-116-0740, the licensee shall require the authorized user of a sealed source specified in OAR 333-116-0480 in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit to be a physician who:

(1) Is certified in:

(a) Radiology, radiation oncology or therapeutic radiology by the American Board of Radiology; or

(b) Radiation oncology by the American Osteopathic Board of Radiology; or

(c) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(d) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(2) Is in the active practice of therapeutic radiology and has completed 200 hours of instruction in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience and a minimum of three years of supervised clinical experience:

(a) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(A) ~~*[One hundred and ten hours of r]*~~**R**adiation physics and instrumentation;

(B) ~~*[Forty hours of r]*~~**R**adiation protection;

(C) ~~*[Twenty-five hours of m]*~~**M**athematics pertaining to the use and measurement of radioactivity; and

(D) ~~*[Twenty-five hours of r]*~~**R**adiation biology.

(b) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user at an institution and shall include:

(A) Review of the full calibration measurements and periodic spot checks;

(B) Preparing treatment plans and calculating treatment times;

(C) Using administrative controls to prevent misadministrations;

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

(E) Checking and using survey meters.

(c) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:

(A) Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment and any limitations or contraindications;

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

(C) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and

(D) Post-administration followup and review of case histories.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Training for Teletherapy or Brachytherapy Physicist

333-116-0730 The licensee shall require the teletherapy physicist to:

(1) Be certified by the American Board of Radiology in:

(a) Therapeutic radiological physics; or

(b) Roentgen ray and gamma ray physics; or

(c) X-ray and radium physics; or

(d) Radiological physics; or

(2) Be certified by the American Board of Medical Physics in radiation oncology physics; or

(3)~~**((2))**~~ Hold a master's or doctor's degree in physics, biophysics, radiological physics or health physics and have completed one year of full time training in therapeutic radiological physics and also one year of full time work experience under the supervision of a teletherapy or brachytherapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in OAR 333-116-0200, 333-116-0570, 333-116-0580 and 333-116-0590 under the supervision of a teletherapy or brachytherapy physicist during the year of work experience.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Training for Experienced Authorized User

333-116-0740 Practitioners of the healing arts identified as authorized users for the human use of radioactive material on an Agency, Nuclear Regulatory Commission or Agreement State or Licensing State license on (effective July 1, 1990) who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of OAR 333-116-0640 through 333-116-0760.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Physician Training in a Three Month Program

333-116-0750 A physician who, before July 1, 1984, began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program is exempted from the requirements of OAR 333-116-0660 or 333-116-0670.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Recentness of Training

333-116-0760 The training and experience specified in OAR 333-116-0640 through 333-116-0730 must have been obtained within the five years preceding the date of application or the individual must have had continuing education and experience since the required training and experience was completed.

Stat. Auth.: ORS Ch. 453.605 - 453.7807
Stats. Implemented: ORS 453.625, 453.635, 453.665
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Specific Requirements for Positron Emission Tomography (PET) Facilities

Licensing and Registration of Positron Emission Tomography (PET) Facilities

333-116-0800 (1) Each component of a PET facility (accelerator, radiopharmacy, and clinic) shall be separately **registered or** licensed pursuant to OAR 333-101-0005, 333-102-0200, 333-103-0005 or 333-103-0010.

(2) The licensee or registrant shall receive applicable agency authorization at least thirty (30) days prior to the production of any accelerator-produced radioactive material or any change in

accelerator configuration, shielding, location, room shielding or configuration, nuclide production method, ventilation systems, rabbit or other delivery systems, operating or emergency procedures, radiation safety personnel, authorized users or operators, or other applicable provisions authorized pursuant to these rules.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.665
Hist.: HD 1-1995, f. & cert. ef. 4-26-95

Supervision of PET Facilities

333-116-0810 (1) Management shall ensure that there is a qualified Radiation Safety Officer (RSO) who shall oversee the radiation safety aspects of the PET facility and be responsible for radiation safety of the accelerator facility, pharmacy, and PET clinic.

(a) In the case of separate licenses for different components in a PET facility, there shall be a cooperative consortium of management and radiation safety personnel that acts as directors for the facility.

(b) Management, whether singular or in consortium, shall write a statement of authority and responsibility for all staff handling or controlling the production and use of PET isotopes.

(2) The RSO shall be assisted by personnel specifically trained and designated for the area of concern, whether accelerator operation, pharmaceutical production, or PET clinic.

(3) There shall be a Radiation Safety Committee (RSC) for a PET facility. The RSC can be a sub-committee of an institutional RSC or a conjoint committee of individual licenses where several licensees are cooperating in the PET facility.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.665
Hist.: HD 1-1995, f. & cert. ef. 4-26-95

Other Applicable Requirements

333-116-0820 (1) The licensee shall ensure that any radiopharmaceutical for which an Investigational New Drug (IND) status does not exist, or which shall be used for research purposes in humans, is reviewed by an Institutional Review Board (IRB) or Human Subjects Review Board or Committee. The licensee shall establish procedures, reviews, quality assurance, and emergency procedures for all procedures reviewed by the IRB. The IRB, the PET Radiation Safety Committee or subcommittee, and the PET or facility Radiation Safety Officer shall review and approve any and all PET procedures, unless otherwise authorized in a radioactive materials license pursuant to OAR 333-102-0200.

(2) Transfers of radioisotopes shall be in accordance with requirements in OAR 333-102-0330.

(3) PET facility radiation protection programs, occupational dose limits, radiation dose limits for the public, surveys and monitoring, restricted area control, storage of radioactive materials, internal

exposure control, precautionary procedures, waste disposal, records, and reports shall meet all applicable requirements of Division 120 of these rules.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.665
Hist.: HD 1-1995, f. & cert. ef. 4-26-95

Accelerator Facility Requirements

333-116-0830 (1) Accelerators shall be meet all requirements of Division 109 of this Chapter [these rules]. Shielded-room accelerators shall be equipped with interlocks and personnel control; self-shielded accelerators shall be shielded such that personnel access is prevented during operation.

(2) Non-ionizing radiation shall meet requirements of Division 112 of these rules.

(3) Target maintenance and repair, contamination control, and emergency actions shall be conducted pursuant to Division 120 of these rules.

(4) There shall be an Understanding of Transfer (UOT) when isotopes are transferred from one licensee or entity to another for processing, specifying at what point control is transferred to personnel handling radiochemical production or radiopharmacy operation.

(5) Radiation surveys shall be made prior to any accelerator operation or isotope production with a radiation survey instrument calibrated in accordance with requirements in OAR 333-116-0390. Periodic surveys shall be done throughout times of operation to ensure that radiation levels meet all applicable requirements in Division 120 (Radiation Protection Standards).

(6) Ventilation controls shall be implemented to ensure compliance with all applicable local, state, and federal requirements. Controls shall include monitoring of stacks and computer modeling of air emissions to confirm compliance with standards.

(7) Real-time (integrating) monitors shall be used to confirm requirements in OAR 333-120-0100, 333-120-0160, 333-120-0170, and 333-120-0180.

(8) Contamination wipes for radioactive material shall be made pursuant to requirements in OAR 333-116-0250;

(9) Dosimetry must address both gamma and beta doses in all areas of the facility. Licensees and registrants must monitor extremities to ensure compliance with OAR 333-120-0100. Bioassays, as defined in OAR 333-100-0005(16), are not required, but there must be evaluation of internal exposures, pursuant to OAR 333-120-0130, based on calculated releases and monitoring.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.665
Hist.: HD 1-1995, f. & cert. ef. 4-26-95

Safety Considerations and Quality Management for PET Facilities

333-116-0840 (1) The licensee shall establish and implement a Quality Management program pursuant to OAR 333-116-0125 for PET products, as well as other production and calibration products.

(2) PET instrumentation and other equipment unique to the PET process shall meet all applicable radiation protection standards pursuant to Division 120 of these rules.

(3) Area monitors must be visible and audible to accelerator operators. Monitors must be checked for proper operation daily.

(4) Wasted targets shall be treated as radioactive waste and must be properly dismantled, shielded, stored, and disposed.

(5) Accelerator shielding design and safety shall meet requirements of OAR 333-109-0025.

(6) Shielding around guide-bends, targets, hot-cells, purification manifolds, etc. shall ensure that limits in 333-120-0180 and 333-120-0190 have been met in all areas of beam and nuclide production.

(7) Security provisions for unauthorized access, janitorial services, maintenance, visitors, tours, and personnel-in-training shall conform to requirements in OAR 333-120-0180, 333-120-0250 and 333-120-0260.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.665
Hist.: HD 1-1995, f. & cert. ef. 4-26-95

Radiopharmacy and Radiochemical Production

333-116-0850 (1) All preparations used in humans shall meet the Oregon State Board of Pharmacy standards, as well as applicable federal Food and Drug Administration (FDA) requirements.

(a) All research products to be used in humans shall be reviewed and approved by the licensee's or consortium Institutional Review Board (IRB).

(b) No research radiopharmaceutical shall be used in a human being until its pyrogenicity and purity have been shown to meet applicable standards.

(2) Pharmacy or chemistry personnel shall work directly under the supervision of a physician who meets the training criteria in OAR 333-116-0670.

(3) There shall be no transfers between or among licensees unless there is a signed Memorandum or Understanding of Transfer. Such memorandum shall preclude any transfers from one licensee entity to another if there is incomplete information, purity questions, or non-approval from the IRB.

(4) There shall be a detailed description of the shielding and operation of the "black box" (hot cell).

(5) There shall be operating and emergency, training, and survey procedures for ease of movement of the product within the pharmacy production area. Emergency procedures must address potential high dose rate emergencies such as stuck rabbit (transport container), pneumatic tube contamination, manifold leak or spill, hot cell emergency, or other incident.

(6) Equipment and procedures shall include:

(a) Hood with continuous stack monitoring system and procedures to confirm air emission standards compliance;

(b) Remote handling equipment for very high dose rates (all handling must be done remotely);

(c) Dose calibration, system validation, and calibration standards, for all individual doses;

(d) Ba-133 shall not be used as a calibration source;

(e) Dose calibrator linearity check using a positron emitter (beta shield must be evaluated to prevent interference with annihilation measurement);
(f) Product delivery system design, shielding, carrier, and emergency procedures;
(g) Leak tests (hermeticity) of delivery container;
(h) Labelling requirements, transportation manifests, and packaging for outside deliveries;
(i) Transportation requirements pursuant to Division 118 of these rules;
(j) Inventory control, "cradle to grave" tracking, and communication with PET clinic;
(k) Waste disposal procedures.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.665
Hist.: HD 1-1995, f. & cert. ef. 4-26-95

PET Clinic

333-116-0860 In addition to requirements in OAR 333-116-0670, each authorized user and technologist must have at least 6 months training and experience in handling and managing PET products.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.665
Hist.: HD 1-1995, f. & cert. ef. 4-26-95

Rubidium-82 Generator

333-116-0870 Rubidium-82 generators require quality assurance procedures for equipment, patient injection, waiting area, imaging, and post-imaging care. There also must be a procedure for spills, and a handling procedure for liquid quality assurance sources for early model PET cameras. Dose calibration procedures are the same as in OAR 333-116-0850(6).

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.665
Hist.: HD 1-1995, f. & cert. ef. 4-26-95

Training and Experience for PET Personnel

333-116-0880 (1) The accelerator must be operated by a trained, certified, operator who is licensed by the Oregon Board of Radiologic Technology as a Therapeutic Radiologic Technologist (LRTT).

(2) Pharmacy or chemistry personnel must have 200 extra hours above Nuclear Pharmacy requirements and 500 hours specific to PET.
The 500 hours should be divided equally between didactic and practical applications.

(3) Authorized users must meet training requirements for human use in OAR 333-116-0670.

(4) Technical personnel working under an authorized user must have basic radiation safety training, plus 200 extra hours specific to PET.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.625, 453.665
Hist.: HD 1-1995, f. & cert. ef. 4-26-95

Training for authorized medical physicist

333-116-0905 The licensee shall require the authorized medical physicist to be an individual who:

(1) Is certified by a speciality board whose certification process includes all of the training and experience requirements in paragraph (2) of this section and whose certification has been approved by the U.S. Nuclear Regulatory Commission; or

(2)(a) Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics, or an equivalent training program approved by the U.S. Nuclear Regulatory Commission, and has completed one year of full-time training in therapeutic radiological physics and an additional year of full-time practical experience under the supervision of a medical physicist at at medical institution that includes the tasks listed in OAR 333-116-xxx//35.67//35.632//35.633//35.635// 35.642//35.643,35.644//35.645 and 35.652,// as applicable; and

(b) Has obtained a written certification, signed by a preceptor authorized medical physicist, that the requirements in paragraph (2)(a) in this section have been satifactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized medical physicist; and,

(c) Following completion of the requirements in paragraph(2)(a) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the U.S. Nuclear Regulatory Commission in accordance with appendix A of this Division.

Training for an authorized nuclear pharmacist

333-116-0910 The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(1) Is certified as a nuclear pharmacist by a speciality board whose certification process includes all of the requirements in paragraph (2) of this section and whose certification has been approved by the U.S. Nuclear Regulatory Commission, or

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

(A) Didactic 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) Supervised practical experience in a nuclear pharmacy involving:

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

(ii) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

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

(iv) Using administrative controls to avoid misadministration s in the administration of radioactive material; and

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

(b) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the requirements of paragraph (2)(a) have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Training for experienced nuclear pharmacists

333-116-0915 A licensee may apply for and shall receive a license amendment identifying an experienced nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in OAR 333-116-0910(2)(a) before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement in 333-116-0910(2)(b) and recentness of training in 333-116-0760 to qualify as an authorized nuclear pharmacist.

~~*[The following 10 CFR schedule is not part of OAR 333-0102; it is incorporated here as a convenience only.*~~

~~*10 CFR 35.100*~~
~~*SCHEDULE A*~~

~~*GROUPS OF MEDICAL USES OF RADIOACTIVE MATERIAL*~~

~~***Group I. Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution and excretion (does not include uses involving imaging and tumor localizations)***~~
~~*(1) Chromium-51 as sodium chromate or labeled human serum albumin.*~~
~~*(2) Cobalt-57 as labeled cyanocobalamin.*~~
~~*(3) Cobalt-58 as labeled cyanocobalamin.*~~
~~*(4) Cobalt-60 as labeled cyanocobalamin.*~~
~~*(5) Iodine-123 as sodium iodide.*~~
~~*(6) Iodine-125 as sodium iodide, iodinated human serum albumin, oleic acid iothalamate.*~~
~~*(7) Iodine-131 as sodium iodide, iodinated human serum albumin, labeled rose bengal, triolein, or sodium iodohippurate.*~~
~~*(8) Iron-59 as citrate.*~~
~~*(9) Potassium-42 as chloride.*~~
~~*(10) Sodium-24 as chloride.*~~
~~*(11) Technetium-99m as pertechnetate.*~~
~~*(12) Any radioactive material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution, or excretion for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or a "New Drug Application" (NDA) has been accepted by the Food and Drug Administration (FDA).*~~

~~***Group II. Use of prepared radiopharmaceuticals for diagnostic studies involving imaging and tumor localizations***~~
~~*(1) Chromium-51 as human serum albumin.*~~
~~*(2) Fluorine-18 in solution.*~~
~~*(3) Gallium-67 as citrate.*~~
~~*(4) Gold-198 in colloidal form.*~~
~~*(5) Indium-113m as chloride.*~~
~~*(6) Iodine-123 as sodium iodide.*~~
~~*(7) Iodine-125 as sodium iodide or fibrinogen.*~~
~~*(8) Iodine-131 as sodium iodide, iodinated human serum albumin, macroaggregated iodinated human serum albumin, colloidal (micro- aggregated) iodinated human serum albumin, rose bengal, or sodium iodohippurate.*~~
~~*(9) Mercury-197 as chlormerodrin.*~~
~~*(10) Mercury-203 as chlormerodrin.*~~
~~*(11) Selenium-75 as selenomethionine.*~~

~~*(12) Strontium-85 as nitrate.*~~
~~*(13) Strontium-87m as chloride.*~~
~~*(14) Technetium-99m as pertechnetate, sulfur colloid, or macroaggregated human serum albumin.*~~
~~*(15) Thallium-201 as chloride.*~~
~~*(16) Ytterbium-169 as pentatate sodium.*~~
~~*(17) Any radioactive material in a radiopharmaceutical prepared from a reagent kit listed in (3) of Group III.*~~
~~*(18) Any radioactive material in a radiopharmaceutical and for a diagnostic use involving imaging except those in gaseous forms for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or a "New Drug Application" (NDA) has been accepted by the Food and Drug Administration (FDA).*~~

~~***Group III. Use of generators and reagent kits for the preparation and use of radiopharmaceuticals containing radioactive material for certain diagnostic uses***~~
~~*(1) Molybdenum-99/technetium-99m generators for the elution of technetium-99m as pertechnetate.*~~
~~*(2) Technetium-99m as pertechnetate for use with reagent kits for preparation and use of radiopharmaceuticals containing technetium-99m as provided in (3) and (4) of this group.*~~
~~*(3) Reagent kits for preparation of technetium-99m labeled:*~~
~~*(i) sulfur colloid;*~~
~~*(ii) pentatate sodium;*~~
~~*(iii) human serum albumin microspheres;*~~
~~*(iv) polyphosphates;*~~
~~*(v) macroaggregated human serum albumin;*~~
~~*(vi) etidronate sodium;*~~
~~*(vii) stannous pyrophosphate;*~~
~~*(viii) human serum albumin;*~~
~~*(ix) medronate sodium;*~~
~~*(x) glucepate sodium;*~~
~~*(xi) oxidronate sodium;*~~
~~*(xii) disofenin;*~~
~~*(xiii) succimer; and*~~
~~*(xiv) albumin colloid.*~~
~~*(4) Tin-113/indium-113m generators for the elution of indium-113m as chloride.*~~
~~*(5) Yttrium-87/strontium-87m generators for the elution of strontium-87m.*~~
~~*(6) Any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for which generator or reagent kit a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by or a "New Drug Application" (NDA) has been approved by the Food and Drug Administration (FDA).*~~

~~***Group IV. Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety***~~
~~*(1) Iodine-131 as iodide for treatment of hyperthyroidism and cardiac dysfunction.*~~

~~*(2) Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia, and bone metastases.*~~
~~*(3) Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions.*~~
~~*(4) Any radioactive material in a radiopharmaceutical and for a therapeutic use not normally requiring hospitalization for purposes of radiation safety for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by or a "New Drug Application" (NDA) has been approved by the Food and Drug Administration (FDA).*~~

~~***Group V. Use of prepared radiopharmaceuticals for certain therapeutic uses that normally require hospitalization for our purposes of radiation safety***~~
~~*(1) Gold-198 as colloid for intracavitary treatment of malignant effusions.*~~
~~*(2) Iodine-131 as iodide for treatment of thyroid carcinoma.*~~
~~*(3) Any radioactive material in a radiopharmaceutical and for a therapeutic use normally requiring hospitalization for radiation safety reasons for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by or a "New Drug Application" (NDA) has been approved by the Food and Drug Administration (FDA).*~~

~~***Group VI. Use of sources and devices containing radioactive material for certain medical uses***~~
~~*(1) Americium-241 as a sealed source in a device for bone mineral analysis.*~~
~~*(2) Cesium-137 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer.*~~
~~*(3) Cobalt-60 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer.*~~
~~*(4) Gold-198 as seeds for interstitial treatment of cancer.*~~
~~*(5) Iodine-125 as a sealed source in a device for bone mineral analysis.*~~
~~*(6) Iodine-125 as a sealed source in a portable device for bone imaging and foreign body detection.*~~
~~*(7) Iodine-125 as seeds for interstitial treatment of cancer.*~~
~~*(8) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer.*~~
~~*(9) Radium-226 as a sealed source for topical, interstitial, and intracavitary treatment of cancer.*~~
~~*(10) Radon-222 as seeds for topical, interstitial, and intracavitary treatment of cancer.*~~
~~*(11) Strontium-90 sealed in an applicator for treatment of superficial eye conditions.]*~~

DIVISION 117

REGULATION AND LICENSING OF NATURALLY OCCURRING RADIOACTIVE MATERIALS (NORM)

Purpose

333-117-0010 This Division establishes radiation protection standards for the possession, use, transfer and disposal of naturally occurring radioactive materials (NORM) not subject to regulation under the Atomic Energy Act of 1954, as amended.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Scope

333-117-0020 (1) These rules apply to any person who engages in the extraction, mining, beneficiating, processing, use, transfer or disposal of NORM in such a manner as to technologically alter the natural sources of radiation or their potential exposure pathways to humans.

(2) The Rules in this Division address the introduction of NORM into products in which neither the NORM nor the radiation emitted from the NORM is considered to be beneficial to the products. The manufacture and distribution of products containing NORM in which the NORM and/or its associated radiation(s) is considered to be a beneficial attribute are licensed under the provisions of Division 102.

(3) This Division also addresses waste management and disposal standards which apply to both inactive and active sites and facilities.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Definitions

333-117-0030 As used in this Division, the following definitions apply:

(1) "Beneficial attribute" or "beneficial to the product" means that the radioactivity of the product is necessary to the use of the product;

(2) "Beneficiating" means the processing of materials for the purpose of altering the chemical or physical properties to improve the quality, purity or assay grade of a desired product;

(3) "General environment" means the total terrestrial, atmospheric and aquatic environments outside sites within which any activity, operation or process authorized by a general or specific license issued under this Division is performed;

(4) "Naturally occurring radioactive material (NORM)" means any nuclide which is radioactive in its natural physical state (i.e., not man-made), but does not include source or special nuclear material;

(5) "Working Level (WL)" means any combination of short-lived radon decay products in one liter of air that will result in the ultimate emission of alpha particles with a total energy of 130 billion electron volts. (2.1×10^{-8}J).

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Exemptions

333-117-0040 (1) Persons who receive, possess, use, process, transfer, distribute and dispose of NORM are exempt from the requirements of these Rules if: The materials contain or are contaminated at concentrations less than **185 Bq/kg** (five picocuries per gram) ~~[(185 Bq/kg)]~~ of radium, 0.05 percent by weight of uranium or thorium or **5.55 kBq/kg** (150 picocuries per gram) ~~[(5.55 kBq/kg)]~~ of any other NORM radionuclide, provided that these concentrations are not exceeded at any time.

(2) Persons who receive products or materials containing NORM distributed in accordance with a specific license issued by the Agency pursuant to OAR 333-117-0220(2) or an equivalent license issued by another Licensing State are exempt from these Rules.

(3) The manufacturing, distribution, use and disposal of the following products/materials are exempt from the requirements of these Rules:

(a) Potassium and potassium compounds which have not been isotopically enriched in the radionuclide K-40; and

(b) Brazil nuts.

(4) The wholesale and retail distribution (including custom blending), possession and use of the following products/material are exempt from the requirements of these:

(a) Phosphate and potash fertilizer;

(b) Phosphogypsum for agricultural uses; and

(c) Materials used for building construction if such materials contain NORM which has not been technologically enhanced.

(5) The possession and use of natural gas and natural gas products as a fuel are exempt from the requirements of these Rules. The distribution of natural gas and the manufacturing and distribution of natural gas products are exempt from the specific license requirements of this Division but are subject to the general license requirements in OAR 333-117-0100 and 333-117-0130.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Effective Date

333-117-0050 The provision and requirements of this Division shall take effect January 1990 and shall apply to all facilities or sites owned or controlled by a person on that date. Products distributed and disposals made prior to that date are not subject to the provisions of this Division.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

General License

General License

333-117-0100 (1) A general license is hereby issued to mine, extract, receive, possess, own, use, process and dispose of NORM not exempted in OAR 333-117-0040 without regard to quantity. This general license does not authorize the manufacturing or distribution of products containing NORM in concentrations greater than those specified in OAR 333-117-0040(1).

(2) Facilities and equipment contaminated with NORM in excess of the levels set forth in Table 1 of this Division shall not be released for unrestricted use. The decontamination or maintenance of such equipment and facilities shall only be performed by persons specifically licensed by the Agency or another Licensing State to conduct such work. Each general licensee shall establish written procedures for the evaluation (or screening) of equipment and components to ensure that the levels in Table 1 of this Division are not exceeded.

(3) No person shall transfer land for unrestricted use where the concentration of radium-226 or radium-228 in soil averaged over any 100 square meters exceeds the background level by more than:

(a) Five pCi/gm, averaged over the first 15 cm of soil below the surface; and

(b) Fifteen pCi/gm, averaged over 15 cm thick layers of soil more than 15 cm below the surface.

(4) Equipment contaminated with NORM in excess of the levels set forth in Table 1 of this Division may be released for maintenance and/or overhaul provided the recipient is specifically licensed to perform the activity on contaminated equipment. The decontamination or maintenance of equipment, facilities and land, as described in OAR 333-117-0200(2) shall only be performed by persons specifically licensed by the Agency or another Licensing State to conduct such work.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Protection of Workers During Operations

333-117-0110 Each person subject to the general license in OAR 333-117-0100 shall conduct operations in compliance with the standards for radiation protection set out in Division 111 and Division 120, except for releases of radioactivity in effluents, which shall be governed by OAR 333-117-0120 and disposal, which shall be governed by OAR 333-117-0130.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Protection of the General Population From Releases of Radioactivity

333-117-0120 Concentrations of radioactive material which may be released to the general environment in groundwater, surface water, air, soil, plants and animals shall not result in an annual dose

above background exceeding an equivalent of **0.25 mSv** (25 millirem) ~~[(0.25 mSv)]~~ to the whole body or **0.75 mSv** (75 millirem) ~~[(0.75 mSv)]~~ to the critical organ of any member of the public. Doses due to radon-220, radon-222 and their respective decay products, are excluded from these limits. Effort shall be made to maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Disposal and Transfer of Waste for Disposal

333-117-0130 Each person subject to the general license in OAR 333-117-0100 shall manage and dispose of wastes containing NORM in accordance with the applicable requirements of the U.S. Environmental Protection Agency for disposal of such wastes or in a manner equivalent to the requirements for uranium and thorium byproduct materials in **40 CFR 192** or shall transfer wastes for disposal to a land disposal facility licensed by the U.S. Nuclear Regulatory Commission or an Agreement State or a Licensing State. Records of disposal including manifests, shall be maintained pursuant to the provisions of Division 120 of these Rules. Transfers of waste containing NORM for disposal shall be made only to a person specifically licensed to receive such waste.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Specific License

Specific License

333-117-0200 (1) Unless otherwise exempted under the provisions of Division 102 of the Rules, the manufacturing and distribution of any material or product containing NORM shall be specifically licensed pursuant to the requirements of this Division or pursuant to equivalent regulations of another Licensing State.

(2) Persons conducting the following activities involving equipment and facilities contaminated with NORM in excess of the levels set forth in Table 1 of this Division shall be specifically licensed pursuant to the requirements of this Division:

(a) Decontamination of equipment, facilities and land;

(b) Maintenance of equipment and facilities involving the exposure of individuals to radiation or radioactive materials; or

(c) Disposal of the resulting waste.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Filing Application for Specific Licenses

333-117-0210 (1) Applications for specific licenses shall be filed in a manner and on a form prescribed by the Agency.

(2) The Agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(3) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(4) An application for a license may include a request for a license authorizing one or more activities.

(5) In an application, the applicant may incorporate by reference information contained in previous application, statements or reports filed with the Agency provided such references are clear and specific.

(6) Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Requirements for the Issuance of Specific Licenses

333-117-0220 (1) A license application will be approved if the Agency determines that:

(a) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these rules in such a manner as to minimize danger to public health and safety or property;

(b) The applicant's proposed equipment, facilities and procedures are adequate to minimize danger to public health and safety or property;

(c) The issuance of the license will not be inimical to the health and safety of the public; and

(d) The applicant satisfies any applicable special requirement in this Division.

(2) An application for a specific license to decontaminate or perform maintenance on equipment and facilities contaminated with NORM in excess of the levels set forth in Table 1 of this Division and to dispose of the resulting waste will be approved if:

(a) The applicant satisfies the general requirements specified in section (1) of this rule; and

(b) The applicant has adequately addressed the following items in the application:

(A) Procedures and equipment for protection of workers;

(B) An evaluation of the radiation levels and concentrations of contamination expected during normal operations;

(C) Operating and emergency procedures, including procedures for waste reduction and quality assurance of items released for unrestricted use; and

(D) Method of disposing of the radioactive material removed from contaminated equipment and facilities.

(3) An application for a specific license to manufacture and/or initially transfer products or materials containing NORM to persons exempted from these Rules pursuant to OAR 333-117-0040(2) will be approved if:

(a) The applicant satisfies the general requirements specified in section (1) of this rule;

(b) The NORM is not contained in any food, beverage, cosmetic, drug or other commodity designed for ingestion or inhalation by or application to, a human being; and

(c) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking and conditions of handling, storage, use and disposal of the NORM material or product to demonstrate that the material or product will meet the safety criteria set forth in OAR 333-117-0230. The information shall include:

(A) A description of the material or product and its intended use or uses;

(B) The type, quantity and concentration of NORM in each material or product;

(C) The chemical and physical form of the NORM in the material or product and changes in chemical and physical form that may occur during the useful life of the material or product;

(D) An analysis of the solubility in water and body fluids of the NORM in the material or product;

(E) The details of manufacture and design of the material or product relating to containment and shielding of the NORM and other safety features under normal and severe conditions of handling, storage, use, reuse and disposal of the material or product;

(F) The degree of access of human beings to the material or product during normal handling, use and disposal;

(G) The total quantity of NORM expected to be distributed annually in the material or product;

(H) The expected useful life of the material or product;

(I) The proposed method of labeling or marking each unit of the material or product with identification of the manufacturer and/or initial transferor of the product and the radionuclide(s) and quantity of NORM in the material or product;

(J) Procedures for prototype testing of the material or product to demonstrate the effectiveness of the containment, shielding and other safety features under both normal and severe conditions of handling, storage, use, reuse and disposal;

(K) Results of the prototype testing of the material or product, including any change in the form of the NORM contained in it, the extent to which the NORM may be released to the environment, any change in radiation levels and any other changes in safety features;

(L) The estimated external radiation doses and dose commitments relevant to the safety criteria in OAR 333-117-0230 and the basis for such estimates;

(M) A determination that the probabilities with respect to doses referred to in OAR 333-117-0230 meet the criteria;

(N) Quality control procedures to be followed in the production of production lots of material or product and the quality control standards the material or product will be required to meet; and

(O) Any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the material or product.

(4) Notwithstanding the provisions of OAR 333-117-0230(2) the Agency may deny an application for a specific license if the end uses of the product are frivolous or cannot be reasonably foreseen.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Safety Criteria

333-117-0230 An applicant for a license under OAR 333-117-0220(3) shall demonstrate that the product is designed and will be manufactured so that:

(1) In normal use and disposal it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material, excluding radon and radon decay products, in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the material or product, will exceed the doses in Column I of Table 2;

(2) In normal handling and storage of the quantities of the material or product likely to accumulate in one location during marketing, distribution, installation and servicing of the material or product it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material, excluding radon, in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the material or product, will exceed the doses in Column II of Table 2;

(3) In normal use, disposal, handling and storage, it is unlikely that the radon released from the material or product will result in an average radon concentration in air of more than **14.8 Bq/m^3** (0.4 picocurie) per liter ~~*(14.8 Bq/m^3)*~~;

(4) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding or other safety features of the material or product from wear and abuse likely to occur in normal handling and use of the material or product during its useful life.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Issuance of Specific Licenses

333-117-0240 (1) Upon a determination that an application meets the requirements of the Act and rules of the Agency, the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(2) The Agency may incorporate in any license at the time of issuance or thereafter by amendment, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this Division as it deems appropriate or necessary in order to:

(a) Minimize danger to public health and safety or property;

(b) Require such reports and the keeping of such records and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(c) Prevent loss or theft of material subject to this Division.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Conditions of Licenses Issued Under 333-117-0220

333-117-0250 (1) General Terms and Conditions.

(a) Each license issued pursuant to this Division shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations and orders of the Agency.

(b) No license issued or granted under this Division and no right to possess or utilize radioactive material granted by any license issued pursuant to this Division shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

(c) Each person licensed by the Agency pursuant to this Division shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

(d) Each person licensed by the Agency pursuant to this Division is subject to the general license provisions of OAR 333-117-0110, 333-117-0120 and 333-117-0130.

(e) Each licensee shall notify the Agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code (11 U.S.C.) by or against:

(A) A licensee;

(B) An entity (as that term is defined in 11 U.S.C. 101 (14)) controlling a licensee or listing the license of licensee as property of the estate; or

(C) An affiliate (as that term is defined in 11 U.S.C. 101 (2)) of the licensee.

(f) The notification indicated in section (1)(e) of this rule must:

(A) Indicate the bankruptcy court in which the petition for bankruptcy was filed; and

(B) The date of the filing of the petition.

(2) Quality Control, Labeling and Reports of Transfer. Each person licensed under OAR 333-117-0220(2) shall:

(a) Carry out adequate control procedures in the manufacture of the material or product to assure that each production lot meets the quality control standards approved by the Agency;

(b) Label or mark each unit so that the manufacturer, processor, producer or initial transferor of the material or product and the NORM in the material or product can be identified; and

(c) Maintain records identifying, by name and address, each person to whom NORM is transferred for use under OAR 333-117-0040(2) or the equivalent regulations of another Licensing State and stating the kinds, quantities and uses of NORM transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Agency. Each report shall cover the year ending December 31, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to OAR 333-117-0220(2) during the reporting period, the report shall so indicate.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Expiration and Termination of Licenses

333-117-0260 (1) Except as provided in OAR 333-117-0270(2) and subsection (4)(c) of this rule, each specific license shall expire at the end of the specified day in the month and year stated therein.

(2) Each licensee shall notify the Agency immediately, in writing, and request termination of the license when the licensee decides to terminate all activities involving materials authorized under the license. This notification and request for termination of the license must include the reports and information specified in paragraph (4)(a)(D) of this rule. The licensee is subject to the provisions of section (4) and (5) of this rule, as applicable.

(3) No less than 30 days before the expiration date specified in a specific license, the licensee shall either:

(a) Submit an application for license renewal under OAR 333-117-0270; or

(b) Notify the Agency in writing, under section (2) of this rule, if the licensee decides to discontinue all activities involving NORM.

(4) If a licensee does not submit an application for license renewal under OAR 333-117-0270, the licensee shall on or before the expiration date specified in the license:

(a) Terminate use of NORM;

(b) Remove radioactive contamination to the extent practicable;

(c) Properly dispose of NORM; and

(d) Submit a record of disposal of radioactive material and radiation survey(s) to confirm the absence of NORM or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual radioactive contamination in some other manner. The licensee shall, as appropriate:

(e) Report levels of radiation in units of **microsieverts** (microrad) per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces and report levels of radioactivity in units of disintegrations per minute (or **Becquerels or** microcuries) per 100 square centimeters removable and fixed on surfaces, microcuries per milliliter in water and picocuries per gram in contaminated solids such as soils or concrete; and

(f) Specify the instruments(s) used and certify that each instrument is properly calibrated and tested.

(5) If no radioactivity attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found. If the Agency determines that the information submitted under subsection (4)(b) of this rule and paragraph (4)(a)(D) of this rule is adequate and surveys confirm the findings, the Agency will notify the licensee in writing that the license is terminated.

(6) If detectable levels of residual radioactivity attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual NORM until the Agency notifies the licensee in writing that the license is terminated. During this time, the licensee is subject to the provisions of section (5) of this rule, and OAR 333-103-0010. In addition to the information submitted under paragraph (4)(a)(D) of this rule, the licensee shall submit a plan, if appropriate, for decontaminating the location(s) and disposing of the residual NORM.

(7) Each licensee who possesses residual radioactive material under subsection (4)(c) of this rule shall:

(a) Be limited to actions involving NORM related to preparing the location(s) for release for unrestricted use; and

(b) Continue to control entry to restricted areas until the location(s) are suitable for release for unrestricted use and the Agency notifies the licensee in writing that the license is terminated.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Renewal of Licenses

333-117-0270 (1) Applications for renewal of specific licenses shall be filed in accordance with OAR 333-117-0210.

(2) In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the Agency.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Amendment of Licenses at Request of Licensee

333-117-0280 Applications for amendment of a license shall be filed in accordance with OAR 333-117-0210 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Agency Action on Applications to Renew and Amend

333-117-0290 In considering an application by a licensee to renew or amend the license, the Agency will apply the criteria set forth in OAR 333-117-0220.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Modification and Revocation of Licenses

333-117-0300 (1) The terms and conditions of all licenses shall be subject to amendment, revision or modification or the license may be suspended or revoked by reason of amendments to the Act or by reason of rules, regulations and orders issued by the Agency.

(2) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act or because of conditions revealed by such application or statement of fact or any report, record or inspection or other means which would warrant the Agency to refuse to grant a license on an original application or for violation of, or failure to observe any of the terms and conditions of the Act or of the license or of any rule, regulation or order of the Agency.

(3) Except in cases of willfulness or those in which the public health, interest or safety requires, otherwise, no license shall be modified, suspended or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Reciprocity

Reciprocal Recognition of Licenses

333-117-0370 Subject to these Rules any person who holds a specific license from a Licensing State and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in any calendar year provided that:

(1) The licensing document does not limit the activity authorized by such document to specified installations or locations;

(2) The out-of-state licensee notifies the Agency in writing at least three days prior to engaging in such activity. Such notification shall indicate the location, period and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. The Agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaged in activities under the general license provided in section (1) of this rule;

(3) The out-of-state licensee complies with all applicable Rules of the Agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable Rules of the Agency;

(4) The out-of-state licensee supplies such other information as the Agency may request; and

(5) The out-of-state licensee shall not transfer or dispose of NORM possessed or used under the general license provided in section (1) of this rule except by transfer to a person:

(a) Specifically licensed by the Agency or by another Licensing State to receive such material; or

(b) Exempt from the requirements for a license for such material under OAR 333-117-0040.

Stat. Auth.: ORS Ch. 453.605 - 453.807
Stats. Implemented: ORS 453.605, 453.625, 453.665
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

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TABLE 1

(OAR 333-117-0100, 333-117-0200, 333-117-0220)

ACCEPTABLE SURFACE CONTAMINATION LEVELS FOR NORM

NUCLIDE[a]	AVERAGE[bcf]	MAXIMUM[bdf]	REMOVABLE[bcef]
U-nat, U-235, U-238, and associated decay products, except Ra-226, Th-230, Ac-227, Po-210 and Pa-231	5,000 dpm alpha/100 cm^2	15,000 dpm alpha/100 cm^2	1,000 dpm alpha/100 cm^2
Transuranics, Ra-226 Ra-228, Th-230, Th-228, Pa-231, Ac-227	100 dpm/100 cm^2	300 dpm/100 cm^2	20 dpm/100 cm^2
Th-nat, Th-232, Ra-223, Ra-224, U-232	1,000 dpm/ 100 cm^2	3,000 dpm/ 100 cm^2	200 dpm/ 100 cm^2
Beta-gamma emitters including Pb-210 (nuclides with decay modes other than alpha emission or spontaneous fission) except others noted above.	5,000 dpm beta, gamma/ 100 cm^2	15,000 dpm beta, gamma/ 100 cm^2	1,000 dpm beta, gamma/ 100 cm^2

[a]Where surface contamination by both alpha and beta-gamma emitting nuclides exists, the limits established for alpha and beta-gamma emitting nuclides should apply independently.

[b]As used in this table, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency and geometric factors associated with the instrumentation.

[c]Measurements of average contamination level should not be averaged over more than one square meter. For objects of less surface area, the average should be derived for each object.

[d]The maximum contamination level applies to an area of not more than 100 cm^2.

[e]The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with dry filter or soft absorbent paper, applying moderate pressure and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

[f]The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 mrad/hr (2μGy/hr) at one cm and 1.0 mrad/hr (10μGy/hr) at one cm, respectively, measured through not more than seven milligrams per square centimeter of total absorber.

TABLE 2

(OAR 333-117-0230)

Table of Organ Doses

Part of Body	Column I Dose in Rem	Column II Dose in Rem
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.005 (0.05mSv)	0.5(5mSv)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter	0.075(0.75mSv)	7.5(75mSv)
Other organs	0.015(0.15mSv)	1.5(15mSv)

Division 118
Transportation of Radioactive Material

Purpose and Scope

333-118-0010 The rules in this Division establish requirements for packaging, preparation for shipment, and transportation of radioactive material and apply to any person who transports radioactive material or delivers radioactive material to a carrier for transport.

Stat. Auth.: ORS Ch. 453.605 - 453.755
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Definitions

333-118-0020 As used in this Division, the following definitions apply:

(1) "Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

(2) "Closed transport vehicle" means a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the radioactive material. The enclosure may be either temporary or permanent but shall limit access from top, sides, and ends. In the case of packaged materials, it may be of the "see-through" type.

(3) "Exclusive use" means the sole use of a conveyance by a single consignor and for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. **The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.**

NOTE: The term "exclusive use" is used interchangeably with the terms "sole use" or "full load" in other regulations, such as Title 49 of the Code of Federal Regulations.

(4) "Fissile material" means any special nuclear material consisting of or containing one or more fissile radionuclides. Fissile radionuclides are plutonium-238, plutonium-239, plutonium-241, uranium-233, and uranium-235, **or any combination of these radionuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only, are not included in this definition.** Neither natural nor depleted uranium is fissile material.

NOTE: Agency jurisdiction **is limited** ~~*[extends only]*~~ to special nuclear material ~~*[if]*~~ **in** quantities ~~*[are]*~~ not sufficient to form a critical mass as defined in Division 100 of these rules.

~~*[(a) Fissile Class I: A package which may be transported in unlimited numbers and in any arrangement, and which requires no nuclear criticality safety controls during transportation. A transport index is not assigned for purposes of nuclear criticality safety but may be required because of external radiation levels.]*~~

~~*[(b) Fissile Class II: A package which may be transported together with other packages in any arrangement but, for criticality control, in numbers which do not exceed an aggregate transport index of 50. These shipments require no other nuclear criticality safety control during transportation. Individual packages may have a transport index not less than 0.1 and not more than 10.]*~~

(5) "Fissile material package" means a fissile material packaging together with its fissile material

contents.

(6) "Low specific activity (LSA) material" means ~~[any of the following:~~

~~(a) Uranium or thorium ores and physical or chemical concentrates of those ores;~~

~~(b) Unirradiated natural or depleted uranium or unirradiated natural thorium;~~

~~(c) Tritium oxide in aqueous solutions provided the concentration does not exceed 5.0 millicuries (185 MBq) per milliliter;~~

~~(d) Material in which the radioactivity is essentially uniformly distributed and in which the estimated average concentration per gram of contents does not exceed:~~

~~(A) 0.0001 millicurie (3.7 kBq) of radionuclides for which the A_2 quantity in 10 CFR Part 71 Appendix A is not more than 0.05 curie (1.85 GBq);~~

~~(B) 0.005 millicurie (185 kBq) of radionuclides for which the A_2 quantity in Appendix 1 of this Division is more than 0.05 curie (1.85 GBq) but not more than one curie (37 GBq); or~~

~~(C) 0.3 millicurie (11.1 MBq) of radionuclides for which the A_2 quantity in 10 CFR Part 71 Appendix A is more than one curie (37 GBq); or~~

~~(e) Objects of nonradioactive material externally contaminated with radioactive material, provided that the radioactive material is not readily dispersible, and the surface contamination, when averaged over an area of one square meter, does not exceed 0.0001 millicurie per square centimeter (3.7 kBq/cm^2) of radionuclides for which the A_2 quantity in 10 CFR Part 71 Appendix A is not more than 0.05 curie (1.85 GBq) or 0.001 millicurie per square centimeter (37 kBq/cm^2) for other radionuclides.]~~ **radioactive material that satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups:**

(a) LSA-I.

(A) Ores containing only naturally occurring radionuclides (e.g., uranium, thorium) and uranium or thorium concentrates of such ores; or

(B) Solid unirradiated natural uranium, depleted uranium, natural thorium, or their solid or liquid compounds or mixtures; or

(C) Radioactive material, other than fissile material, for which the A_2 value is unlimited; or

(D) Mill tailings, contaminated earth, concrete, rubble, other bulk debris, and activated material in which the radioactive material is essentially uniformly distributed, and the average specific activity does not exceed 10^{-6} A_2/g.

(b) LSA-II.

(A) Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or

(B) Material in which the radioactive material is distributed throughout, and the average specific activity does not exceed 10^{-4} A_2/g for solids and gases, and 10^{-5} A_2/g for liquids.

(c) LSA-III. Solids (e.g., consolidated wastes, activated materials) in which:

(A) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.); and

(B) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for 7 days, would not exceed 1E-1 A2; and

(C) The average specific activity of the solid does not exceed 2E-3 A2 per gram.

(7) "Low toxicity alpha emitters" means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates; or alpha emitters with a half-life of less than 10 days.

(68) "Normal form radioactive material" means radioactive material which has not been demonstrated to qualify as special form radioactive material.

( )"Nuclear waste" means a quantity of source, byproduct or special nuclear material required to be in U.S. Nuclear Regulatory Commission approved specification packaging while transported to, through or across a state boundary to a disposal site, or to a collection point for transport to a disposal site.

NOTE: The definition of nuclear waste in this Part is used in the same way as in 49 CFR 173.403.

(79) "Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of ~~[this Division]~~ **49 CFR Part 173 Subpart I.** It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

(810) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189 **and Parts 390-397.**

(11) "Regulations of the U.S. Nuclear Regulatory Commission" means the regulations in 10 CFR 71.

(12) "Special form radioactive material" means radioactive material that satisfies the following conditions:

(a) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(b) The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch.); and

(c) It satisfies the test requirements specified by the Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on March 31, 1996, and constructed prior to April 1, 1998, may continue to be used. A special form encapsulation either designed or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.

(912) Specific activity" of a radionuclide means the radioactivity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

(14) "Surface contaminated object" (SCO) means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the following limits:

(a) SCO-I: a solid object on which:

(A) The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 4 Bq/cm^2 (10^{-4} microcurie/cm^2) for beta, gamma and low toxicity alpha emitters, or 0.4 Bq/cm^2 (10^{-5} microcurie/cm^2) for all other alpha emitters;

(B) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $4x10^4$ Bq/cm^2 (1.0 microcurie/cm^2) for beta, gamma and low toxicity alpha emitters, or $4x10^3$ Bq/cm^2 (0.1 microcurie/cm^2) for all other alpha emitters; and

(C) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $4x10^4$ Bq/cm^2 (1 microcurie/cm^2) for beta, gamma and low toxicity alpha emitters, or $4x10^3$ Bq/cm^2 (0.1 microcurie/cm^2) for all other alpha emitters.

(b) SCO-II: a solid object on which the limits for SCO-I are exceeded and on which:

(A) The non-fixed contamination on the accessible surface averaged over 300 square centimeters (or the area of the surface if less than 300 square centimeters) does not exceed 400 bequerel per square centimeter (Bq/cm2) (1E-2 microcurie per square centimeter) for beta, gamma and low toxicity alpha emitters or 40 bequerel per square centimeter (Bq/cm2) (1E-3 microcurie per square centimeter) for all other alpha emitters;

(B) The fixed contamination on the accessible surface averaged over 300 square centimeters (or the area of the surface if less than 300 square centimeters) does not exceed 8E5 bequerel per square centimeter (Bq/cm2) (20 microcuries square centimeter) for beta, gamma and low toxicity alpha emitters, or 8E4 bequerel per square centimeter (Bq/cm2) (2 microcuries per square centimeter) for all other alpha emitters; and

(C) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 square centimeters (or the area of the surface if less than 300 square centimeters) does not exceed 8E5 bequerel per square centimeter (Bq/cm2) (20 microcuries per square centimeter) for beta, gamma and low toxicity alpha emitters, or $8x10^4$ Bq/cm^2 (2 microcuries/cm^2) for all other alpha emitters.

(~~10~~15) "Transport index" means the dimensionless number, rounded up to the first decimal place, placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number expressing the maximum radiation level in millirem per hour at one meter from the external surface of the package **in millisievert (mSv) per hour multiplied by 100 (equivalent to the maximum radiation level in millirem per hour at 1 meter)**.

(~~11~~16)"Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A1 and A2 are given in 10 CFR Part 71 Appendix A or may be determined by procedures described in 10 CFR Part 71 Appendix A.

(17) "Type A package" means a packaging that, together with its radioactive contents limited to A_1 or A_2 as appropriate, meets the requirements of 49 CFR 173.410 and 173.412 and is designed to retain the integrity of containment and shielding under normal conditions of transport as demonstrated by the tests set forth in 173.465 or 173.466, as appropriate.

(~~12~~18)"Type B package" means a Type B packaging together with its radioactive contents.

NOTE: A type B package design is designated as B(U) or B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, refer to 49 CFR Part 173. A Type B package approved prior to September 6, 1983, was designated only as Type B. Limitations on its use are specified in **OAR 333-118-035**.

(~~13~~19)"Type B packaging" means a packaging designed to retain the integrity of containment and shielding when subjected to the normal conditions of transport and hypothetical accident test conditions set forth in 10 CFR Part 71.

(~~14~~20)"Type B quantity" means a quantity of radioactive material greater than Type A quantity.

ED NOTE: 10 CFR Part 71 Appendix A referred to or incorporated by reference in this rule is

attached to this Division or available from the Health Division.

( ) "Uranium - natural, depleted, enriched"

(a) "Natural uranium" means uranium isotopes with the naturally occurring distribution of uranium, isotopes (which is approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).

(b) "Depleted uranium" means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(c) "Enriched uranium" means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

Stat. Auth.: ORS Ch. 453.605 - 453.755
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

General Regulatory Provisions

Requirement for License

333-118-0030 No person shall transport radioactive material or deliver radioactive material to a carrier for transport except as authorized in a general or specific license issued by the Agency or as exempted in **OAR 333-118-040**.

Stat. Auth.: ORS Ch. 453.605 - 453.755
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Exemptions

333-118-0040 (1) Common and contract carriers, freight forwarders, and warehouse workers ~~*[which]*~~ **that** are subject to the requirements of the U.S. Department of Transportation in 49 CFR 170 through 189 or the U.S. Postal Service in the **U.S.** Postal Service Manual ~~*[(]*~~Domestic Mail Manual~~*[)]*~~ **(DMM), section C-023.9.0,** ~~*[Section 124.3 incorporated by reference, 39 CFR 111.11 (1974),]*~~ are exempt from the ~~*[requirements]*~~ **rules in** ~~*[of this]*~~ Divisions **102, 105, 113, 115, 116, 117, and 121 of this Chapter and the requirements for a license** to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to OAR 333-118-030 and other applicable requirements of these rules.

(2) Any licensee is exempt from the requirements of this Division to the extent that the licensee delivers to a carrier for transport a package containing radioactive material having a specific activity not greater than **70 bequerel per gram (Bq/g)** (0.002 microcurie per gram ~~*[(74 Bq/gm)]*~~.

~~*[(3) With the exception of OAR 333-118-050 and 333-118-160, a licensee is exempt from all requirements of this Division, with respect to shipment or carriage of the following:*~~

~~*(a) A package containing no more than a Type A quantity of radioactive material if the package contains no fissile material; or*~~

~~*(b) Packages transported between locations within the United States which contain only americium or plutonium in special form with an aggregate radioactivity not to exceed 20 curies (740 Gbq).]*~~

Stat. Auth.: ORS Ch. 453.605 - 453.755
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Transportation of Licensed Material

333-118-0050 (1) Each licensee who transports licensed material outside ~~[of the confines of the licensee's plant or other place of use]~~ **the site of usage, as specified in the Agency license, or where transport is on public highways**, or who delivers licensed material to a carrier for transport shall:

(a) Comply with the applicable requirements, appropriate to the mode of transport, of the regulations of the U.S. Department of Transportation **in 49 CFR 170-189, particularly the regulations of U.S. Department of transportation in the following areas:**

(A) Packaging - 49 CFR Part 173: Subparts A and B and I.

(B) Marking and labeling - 49 CFR Part 172: Subpart D, §§ 172.400 through 172.407, §§ 172.436 through 172.440, and Subpart E.

(C) Placarding - 49 CFR Part 172: Subpart F, especially §§ 172.500 through 172.519, 172.556, and Appendices B and C.

(D) Accident reporting - 49 CFR Part 171: §§ 171.15 and 171.16.

(E) Shipping papers and emergency information - 49 CFR Part 172: Subparts C and G.

(F) Hazardous material employee training - 49 CFR Part 172: Subpart H.

(H) Hazardous material shipper/carrier registration - 49 CFR Part 107: Subpart G.

~~[; and]~~

(b) The licensee also shall comply with applicable U.S. Department of Transportation regulations pertaining to the following modes of transportation:

(A) Rail - 49 CFR Part 174: Subparts A through D and K.

(B) Air - 49 CFR Part 175.

(C) Vessel - 49 CFR Part 176: Subparts A through F and M.

(D) Public highway - 49 CFR Part 177 and Parts 390 through 397.

(~~[b]~~**c**) Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.

(2) If, for any reason, the regulations of the U.S. Department of Transportation are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of ~~[those regulations to the same extent]~~ **49 CFR Parts 170 through 189 appropriate to the mode of transport and to the same extent** as if the shipment ~~[was]~~ **were** subject to the regulations.

Stat. Auth.: ORS Ch. 453.605 - 453.755
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

General Licenses

General Licenses for Carriers

333-118-0060 (1) A general license is hereby issued to any common or contract carrier not exempt under **OAR 333-118-040** to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation, insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.*

Note: Notification of an incident shall be filed with, or made to, the Department as prescribed in 49 CFR, regardless of and in addition to the notification made to the U.S.

Department of Transportation or other agencies.

(2) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation, insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.*

***Note: Notification of an incident shall be filed with, or made to, the Department as prescribed in 49 CFR, regardless of and in addition to the notification made to the U.S. Department of Transportation or other agencies.**

(3) Persons who transport radioactive material pursuant to the general licenses in ~~[section]~~ **333-118-060(1)** or **333-118-060(2)** ~~[this rule;]~~ are exempt from the requirements of Divisions 111 and 120 of these rules to the extent that they transport radioactive material.

~~[*NOTE: Any notification of incidents referred to in those U.S. Department of Transportation requirements shall be filed with, or made to, the Agency.]~~

Stat. Auth.: ORS Ch. 453.605 - 453.755
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

General License: Nuclear Regulatory Commission-Approved Packages

333-118-0070 (1) A general license is hereby issued to any licensee of the Agency to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by the U.S. Nuclear Regulatory Commission.

(2) This general license applies only to a licensee who:

(a) Has a copy of the specific license, certificate of compliance, or other approval **by the Nuclear Regulatory Commission** of the package and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

(b) Complies with the terms and conditions of the license, certificate, or other approval **by the Nuclear Regulatory Commission**, as applicable, and the applicable requirements of ~~[this]~~ Division **118**;

(c) Prior to the licensee's first use of the package, has registered with the U.S. Nuclear Regulatory Commission; and

(d) Has a quality assurance program required by **OAR 333-118-200** and approved by the Agency.

(3) The general license in ~~[section]~~ **OAR 333-118-070**(1) ~~[of this rule]~~ applies only when the package approval authorizes use of the package under this general license.

(4) For previously approved Type B packages which are not designated as either B(U) or B(M) in the Certificate of Compliance, this general license is subject to additional restrictions in **OAR 333-118-080. For a Type B or fissile material package, the design of which was approved by Nuclear Regulatory Commission before April 1, 1996, the general license is subject to additional restrictions of OAR 333-118-080.**

Stat. Auth.: ORS Ch. 453.605 - 453.755
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

General License: Previously Approved ~~[Type B]~~ Packages

333-118-0080 (1) A Type B package previously approved by the U.S. Nuclear Regulatory Commission, but not designated as B(U) or B(M) in the Certificate of Compliance, may be used under the general license of **OAR 333-118-070** with the following additional limitations:

(~~1~~) **a**) Fabrication of the packaging was satisfactorily completed before August 31, 1986, as demonstrated by application of its model number in accordance with U.S. Nuclear Regulatory Commission regulations **at 10 CFR 71.85(c)**; and

(~~2~~) **b**) The package may not be used for a shipment to a location outside the United States ~~[after August 31, 1986,]~~ except **when approved** under special arrangement ~~[approved by Department of Transportation (DOT)]~~ in accordance with 49 CFR 173.471. **A package used for a shipment to a location outside the United States is subject to multilateral approval, as defined in U.S. Department of Transportation regulations at 49 CFR 173.403**; and

(c)A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.

(2) A Type B(U) package, a Type B(M) package, a low specific activity (LSA) material package or a fissile material package, previously approved by the Nuclear Regulatory Commission but without the designation "-85" in the identification number of the Nuclear Regulatory Commission certificate of compliance, may be used under the general license of 333-118-070 with the following additional conditions:

(a) Fabrication of the package is satisfactorily completed by April 1, 1999, as demonstrated by application of its model number in accordance with Nuclear Regulatory Commission regulations at 10 CFR 71.85(c);

(b) A package used for a shipment to a location outside the United States is subject to multilateral approval except approved under special arrangement in accordance with U.S. Department of Transportation regulations at 49 CFR 173.403; and

(c) A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.

Stat. Auth.: ORS Ch. 453.605 - 453.755
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

General License: ~~[DOT]~~ U.S. Department of Transportation Specification Container

333-118-0090 (1) A general license is issued to any licensee of the Agency to transport, or to deliver to a carrier for transport, licensed material in a specification container ~~[for]~~ **containing** a **fissile material or a** Type B quantity of radioactive material as specified in 49 CFR Parts 173 and 178.

(2) This general license applies only to a licensee who has a quality assurance program required by OAR 333-118-200 and approved by the Agency.

(a) Has a copy of the specification;

(b) Complies with the terms and conditions of the specification and the applicable requirements of Division 118; and

(c) Has a quality assurance program required by OAR 333-118-200

(3) ~~[This]~~ **The** general license **in OAR 333-118-090 is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States except by multilateral approval as defined in 49 CFR 173.403.** ~~[applies only to a licensee who:~~

~~(a) Has a copy of the specification; and~~

~~(b) Complies with the terms and conditions of the specification and the applicable requirements~~

~~*of this Division.*~~

~~*(4) The general license in section (1) of this rule is subject to the limitation that the specification container may not be used for shipment to a location outside the United States after August 31, 1986, except under special arrangements approved by Department of Transportation (DOT) in accordance with 49 CFR 173.472.]*~~

Stat. Auth.: ORS Ch. 453.605 - 453.755
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

General License: Use of Foreign Approved Package

333-118-0100 (1) A general license is issued to any licensee of the Agency to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate which has been revalidated by the U.S. Department of Transportation as meeting the applicable requirements of 49 CFR 171.12.

(2) This general license applies only to international shipments.

(3) This general license applies only to a licensee who:

(a) Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment; ~~and~~

(b) Complies with the terms and conditions of the certificate and revalidation and with the applicable requirements of this Division.

(c) Has a quality assurance program approved by the Nuclear Regulatory Commission.

Stat. Auth.: ORS Ch. 453.605 - 453.755
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

General License: ~~Type A,~~ Fissile ~~Class II Package~~ Material, Limited Quantity per Package.

333-118-0110 (1) A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped as a Fissile Class II package **in accordance with Division 333-118.**

(2) This general license applies only when a package contains no more than a Type A quantity of radioactive material, including only one of the following:

(a) Up to 40 grams of uranium-235; or

(b) Up to 30 grams of uranium-233; or

(c) Up to 25 grams of the fissile radionuclides of plutonium, except that for encapsulated plutonium-beryllium neutron sources in special form, an A_1 quantity of plutonium may be present; or

(d) A combination of fissile radionuclides in which the sum of the ratios of the amount of each radionuclide to the corresponding maximum amounts in ~~*[subsections (2)(a)(b) and (c) of this rule]*~~ **333-118-110(2)(a), 333-118-110(2)(b), and 333-118-110(2)(c)** does not exceed unity.

(3) ~~*[Except as specified in section (4) of this rule, this general license applies only when a package containing more than 15 grams of fissile radionuclides is labeled with a transport index not less than the number given by the following equation:*~~

~~*Minimum Transport Index = (0.4x + 0.67y + z) (1 - 15)*~~
~~*x+y+z*~~

~~*where the package contains x grams of uranium-235, y grams of uranium-233, and z grams of the fissile*~~

~~*radionuclides of plutonium.]*~~ **Except as specified in 333-118-110(3)(b), this general license applies only when all of the following requirements are met:**

(a) A package containing fissile radionuclides is labeled with a transport index not less than the number given by the following equation:

Minimum Transport Index =

(0.25x + 0.33y + 0.4z)

where the package contains x grams of uranium-235, y grams of uranium-233, and z grams of the fissile radionuclides of plutonium;

(b) For a package in which the only fissile material is encapsulated plutonium-beryllium neutron sources in special form, the transport index based on criticality considerations may be taken as 0.025 times the number of grams of the fissile radionuclides of plutonium.

(c) In all cases, the transport index must be rounded up to one decimal place and shall not exceed 10.0.

(d) Except for the beryllium contained within the special form plutonium-beryllium sources authorized in 333-118-110(2), beryllium, graphite, or hydrogenous material enriched in deuterium is not present in quantities exceeding 0.1% of the fissile material mass.

(e) The licensee has a quality assurance program approved by the nuclear regulatory commission.

~~*[(4) For a package in which the only fissile material is in the form of encapsulated plutonium-beryllium neutron sources in special form, the transport index based on criticality considerations may be taken as 0.026 times the number of grams of the fissile radionuclides of plutonium in excess of 15 grams]*~~

~~*[(5) In all cases, the transport index must be rounded up to one decimal place and may not exceed 10.0.]*~~

Stat. Auth.: ORS Ch. 453.605 - 453.755

Hist.: HD 1-1991, f. & cert. ef. 1-8-91

General License: ~~*[Restricted, Fissile Class II]*~~ **Fissile Material, Limited Moderator per** Package

333-118-0120 (1) A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped as a Fissile Class II package **in accordance with Division 333-118.**

(2) This general license applies only when all of the following requirements are met.

(a) The package contains no more than a Type A quantity of radioactive material.

(b) Neither beryllium nor hydrogenous material enriched in deuterium is present.

(c) The total mass of graphite present does not exceed ~~*[150]*~~ **7.7** times the total mass of uranium-235 plus plutonium.

(d) Substances having higher hydrogen density than water**, for example certain hydrocarbon oils,** are not present, except that polyethylene may be used for packing or wrapping.

(e) Uranium-233 is not present, and the amount of plutonium does not exceed one percent of the amount of uranium-235.

(f) The amount of uranium-235 is limited as follows:

(A) If the fissile radionuclides are not uniformly distributed, the maximum amount of uranium-235 per package may not exceed the value given in **the following** Table 1.

(B) If the fissile radionuclides are distributed uniformly, **for example, they cannot form a lattice arrangement within the packaging, and** the maximum amount of uranium-235 per package

may not exceed the value given in Table 2.

(g) The transport index of each package based on criticality considerations is taken as 10 times the number of grams of uranium-235 in the package divided by the maximum allowable number of grams per package in accordance with Table 1 or 2 of this section as applicable.

Uranium enrichment in grams of uranium-235 per package	Permissible weight percent of maximum uranium-235 not exceeding
24	40
20	42
15	45
11	48
10	51
9.5	52
9	54
8.5	55
8	57
7.5	59
7	60
6.5	62
6	65
5.5	68
5	72
4.5	76
4	80
3.5	88
3	100
2.5	120
2	164
1.5	272
1.35	320
1	680*
0.92	1200*

TABLE 2: PERMISSIBLE MASS OF URANIUM-235 PER FISSILE MATERIAL PACKAGE [UNIFORM DISTRIBUTION]

Uranium enrichment in weight percent of uranium-235 not exceeding	Permissible maximum grams of uranium-235 per package
4	84
3.5	
92	
3	
112	
2.5	148
2	240

1.5
560*
1.35
800*

* Pursuant to the Department's agreement with the Nuclear Regulatory Commission, jurisdiction extends only to 350 grams of uranium-235.

TABLE 3 NON-FIXED (REMOVABLE) EXTERNAL RADIOACTIVE CONTAMINATION WIPE LIMITS			
Contaminant	Maximum Permissible Limits		
	Bq/cm^2	uCi/cm^2	dpm/cm^2
Beta and gamma emitters and low toxicity alpha emitters	0.4	10^{-5}	22
All other alpha emitting radionuclides	0.04	10^{-6}	2.2

Appendix A to Division 118 - Determination of A_1 and A_2

I. Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations are given in Table A-1. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) figure. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is one tenth of one percent or less. Where values of A_1 or A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

II. For individual radionuclides whose identities are known, but which are not listed in Table A-1, the determination of the values of A_1 and A_2 requires Department approval, except that the values of A_1 and A_2 in Table A-2 may be used without obtaining Agency approval.

III. In the calculations of A_1 and A_2 for a radionuclide not in Table A-1, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter nuclide has a half-life either longer than 10 days, or longer than that of the parent nuclide, shall be considered as a single radionuclide, and the activity to be taken into account, and the A_1 or A_2 value to be applied shall be those corresponding to the parent nuclide of that chain. In the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than 10 days, or greater than that of the parent nuclide, the parent and those daughter nuclides shall be considered as mixtures of different nuclides.

IV. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:

(a) For special form radioactive material, the maximum quantity transported in a Type A package:

$$\sum_i \frac{B(i)}{A_1(i)} \text{ less than or equal to } 1$$

(b) For nor mal form radioactive material, the maximum quantity transported in a Type A package:

$$\sum_i \frac{B(i)}{A_2(i)} \text{ less than or equal to } 1$$

where B(i) is the activity of radionuclide I and $A_1(i)$ and $A_2(i)$ are the A_1 and A_2 values for radionuclide respectively.

Alternatively, an A1 value for mixtures of special form material may be determined as follows:

$$A_1 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where f(i) is the fraction of activity of nuclide i in the mixture and $A_1(i)$ is the appropriate A_1 value for nuclide i.

An A2 value for mixtures of normal form material may be determined as follows:

$$A_2 \text{ for mixture} = \frac{1}{\sum_I \frac{f(i)}{A_2(i)}}$$

where f(i) is the fraction of activity of nuclide I in the mixture and $A_2(i)$ is the appropriate A_2 value for nuclide I.

V. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not

known, the radionuclides may be grouped and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

TABLE 1

Uranium enrichment in weight percent of uranium-235 not exceeding:	Permissible maximum grams of uranium-235 per package:
24	40
20	42
15	45
11	48
10	51
9.5	52
9	54
8.5	55
8	57
7.5	59
7	60
6.5	62
6	65
5.5	68
5	72
4.5	76
4	80
3.5	88
3	100
2.5	120
2	164
1.5	272
1.35	320
1	680 *
0.92	1200 *

* **NOTE:** Pursuant to the Agency's agreement with the U.S. Nuclear Regulatory Commission, jurisdiction extends only to 350 grams of uranium-235.

(g) The transport index of each package based on criticality considerations is taken as 10 times the number of grams of uranium-235 in the package divided by the maximum allowable number of grams per package in accordance with Table 1 or 2 as applicable.

TABLE 2

Uranium enrichment in weight percent of uranium-235 not exceeding:	Permissible maximum grams of uranium-235 per package:
4	84
3.5	92
3	112
2.5	148
2	240
1.5	560
*	

* **NOTE**: Pursuant to the Agency's agreement with the U.S. Nuclear Regulatory Commission, jurisdiction extends only to 350 grams of uranium-235.

Stat. Auth.: ORS Ch. 453.605 - 453.755
Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Operating Controls and Procedures

Fissile Material: Assumptions as to Unknown Properties <u>of Fissile Material</u>

333-118-0130 When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties had credible values that would cause the maximum ~~*[nuclear reactivity]*~~ **neutron multiplication**.

Stat. Auth.: ORS Ch. 453.605 - 453.755
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Preliminary Determinations

333-118-0140 Prior to the first use of any packaging for the shipment of radioactive material:

(1) The licensee shall ~~*[ascertain]*~~ **show** that there are no defects ~~*[which]*~~ **that** could significantly reduce the effectiveness of the packaging;

(2) Where the maximum normal operating pressure will exceed ~~*[34.3]*~~ **35** kilopascals (five **pounds per square inch** (psi)) gauge, the licensee shall test the containment system at an internal pressure at least 50 percent higher than the maximum normal operating pressure to ~~*[verify]*~~ **show** ~~*[the capability of]*~~ that **the** system ~~*[to]*~~ **will** maintain its structural integrity at that pressure;

(3) The licensee shall determine that the packaging has been fabricated in accordance with the design approved by the U.S. Nuclear Regulatory Commission; and

(4) The licensee shall conspicuously and durably mark the packaging with its model number, **serial number,** gross weight, and a package identification number **as** assigned by the U.S. Nuclear Regulatory Commission.

Stat. Auth.: ORS Ch. 453.605 - 453.755
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Routine Determinations

333-118-0150 Prior to each shipment of licensed material, the licensee shall determine that:

(1) The package is proper for the contents to be shipped;

(2) The package is in unimpaired physical condition except superficial defects such as marks or dents;

(3) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

(4) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

(5) Any pressure relief device is operable and set in accordance with written procedures;

(6) The package has been loaded and closed in accordance with written procedures;

(7) Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified ~~*[by the U.S. Nuclear Regulatory Commission]*~~ **in 10 CFR 71.45**;

(8) The level of **non-fixed** (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable.

(a) The level of **non-fixed** (removable) radioactive contamination may be determined by wiping an area of 300 square centimeters of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the

wiping material. Sufficient measurements must be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. Except as provided in ~~[section 8]~~ **OAR 333-118-150(8)(b)** ~~[of this rule]~~, the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, must not exceed the limits given in Table 3 below at any time during transport. Other methods of assessment of equal or greater efficiency may be used. When other methods are used, the detection efficiency of the method used must be taken into account and in no case may the removable contamination on the external surfaces of the package exceed 10 times the limits listed in Table 3.

(9b) In the case of packages transported as exclusive use shipments by rail or highway only, the **non-fixed** (removable) radioactive contamination at any time during transport must not exceed 10 times the levels prescribed in ~~[section 8]~~ **OAR 333-118-150(8)(a)** ~~[of this rule]~~. The levels at the beginning of transport must not exceed the levels in ~~[section 8]~~ **OAR 333-118-150(8)(a)** ~~[of this rule]~~;

(~~[10]~~**9**) External radiation levels around the package and around the vehicle, if applicable, will not exceed **2 mSv/hr** (200 millirem~~[s]~~ per hour) ~~[(two mSv/h)]~~ at any point on the external surface of the package at any time during the transportation. The transport index shall not exceed 10;

~~(11) For a package transported in exclusive use by rail, highway or water, radiation levels external to the package may exceed the limits specified in section (10) of this rule but shall not exceed any of the following:~~

~~(a) 200 millirems per hour (two mSv/h) on the accessible external surface of the package unless the following conditions are met, in which case the limit is 1000 millirems per hour (10 Sv/h);~~

TABLE 3
REMOVABLE EXTERNAL RADIOACTIVE CONTAMINATION WIPE LIMITS

Contaminant	Maximum Permissible Limits $\mu Ci/cm^2$	dpm/cm^2
Beta-gamma emitting radionuclides; all radionuclides with half-lives less than ten days; natural uranium; natural thorium; uranium-235; uranium-238; thorium-232; thorium-228 and thorium-230 when contained in ores or physical concentrates	10^{-5}	22
All other alpha emitting radionuclides.....	10^{-6}	2.2

(10) For a package transported in exclusive use by rail, highway, or water, radiation levels external to the package may exceed the limits specified in ~~[section]~~ **OAR 333-118-150(10)** ~~[of this rule]~~ but shall not exceed any of the following:

(a) **2 milliSieverts per hour (mSv/h)** (200 millirems per hour) ~~[(two mSv/h)]~~ on the accessible external surface of the package unless the following conditions are met, in which case the limit is **10 milliSieverts per hour (mSv/h)** (1000 millirems per hour) ~~[(10 Sv/h)]~~;

(A) The shipment is made in a closed transport vehicle,

(B) Provisions are made to secure the package so that its position within the vehicle remains fixed during transportation, and

(C) There are no loading or unloading operations between the beginning and end of the transportation.

(b) **2 milliSieverts per hour (mSv/h)** (200 millirems per hour) ~~[(two mSv/h)]~~ at any point on the outer surface of the vehicle, including the upper and lower surfaces, or, in the case of a flat-bed style vehicle, with a personnel barrier*, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load (or enclosure, if used), and on the lower external surface of the vehicle;

***NOTE:** A flat-bed style vehicle with a personnel barrier shall have radiation levels determined at vertical planes. If no personnel barrier, the package cannot exceed 200 millirems per hour (two mSv/h) at the surface.

(c) **0.1 milliSieverts per hour (mSv/h)**(10 millirems per hour) ~~[(0.1 mSv/h)]~~ at any point two (2) meters from the vertical planes represented by the outer lateral surfaces of the vehicle, or, in the case of a flat-bed style vehicle, at any point

two (2) meters from the vertical planes projected from the outer edges of the vehicle; and

(d) **0.02 milliSieverts per hour (mSv/h)** (~~[Two]~~ **2** millirems per hour) ~~[(0.02 mSv/h)]~~ in any normally occupied positions of the vehicle, except that this provision does not apply to private motor carriers when persons occupying these positions are provided with special health supervision, personnel radiation exposure monitoring devices, and training in accordance with OAR 333-111-005; and

(~~[12]~~**11**) A package must be prepared for transport so that in still air at 100 degrees Fahrenheit (38 degrees Celsius) and in the shade, no accessible surface of a package would have a temperature exceeding 122 degrees Fahrenheit (50 degrees Celsius) in a nonexclusive use shipment or ~~[180]~~ **185** degrees Fahrenheit (~~[82]~~ **85** degrees Celsius) in an exclusive use shipment. Accessible package surface temperatures shall not exceed these limits at any time during transportation.

(12) A package may not incorporate a feature intended to allow continuous venting during transport.

(13) Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee.

NOTE: * A flat-bed style vehicle with a personnel barrier shall have radiation levels determined at vertical planes. If no personnel barrier is in place, the package cannot exceed 2 mSv/h (200 millirems per hour) at any accessible surface.

Stat. Auth.: ORS Ch. 453.605 - 453.755

Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Air Transport of Plutonium

333-118-0160 Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this Division or included indirectly by citation of the U.S. Department of Transportation regulations, as may be applicable, the licensee shall assure that plutonium in any form is not transported by air, or delivered to a carrier for air transport, unless:

(1) The plutonium is contained in a medical device designed for individual human application; or

(2) The plutonium is contained in a material in which the specific activity is not greater than **70 Bq/g** (0.002 microcuries per gram) ~~[(74 Bq/gm)]~~ of material and in which the radioactivity is essentially uniformly distributed; or

(3) The plutonium is shipped in a single package containing no more than an A2 quantity of plutonium in any isotope or form and is shipped in accordance with **OAR 333-118-050**; or

(4) The plutonium is shipped in a package specifically authorized **(in the certificate of compliance issued by the Nuclear Regulatory Commission for that package)** for the shipment of plutonium by air **and the licensee requires, through special arrangement with the carrier, compliance with 49 CFR 175.704, the U.S. Department of Transportation regulations applicable to the air transport of plutoniium.** ~~[in the Certificate of Compliance for that package issued by the U.S. Nuclear Regulatory Commission].~~

Stat. Auth.: ORS Ch. 453.605 - 453.755

Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Shipment Records

333-118-0170 ~~[After shipment of]~~**Each** licensee shall maintain **for a period of 3 years after shipment, or** until inspected by the Agency, a record of each shipment of licensed material not exempt under OAR 333-118-040, showing, where applicable:

(1) Identification of the packaging by model **and serial** number;

(2) Verification that ~~[there were]~~ **the packaging, as shipped, had** no significant defects ~~[in the packaging, as shipped]~~;

(3) Volume and identification of coolant;

(4) Type and quantity of licensed material in each package, and the total quantity of each shipment;

(5) Date of the shipment;

(6) Name and address of the transferee;

(7) Address to which the shipment was made; and

(8) Results of the determinations required by **OAR 333-118-150**.

Stat. Auth.: ORS Ch. 453.605 - 453.755

Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Reports

333-118-180 The licensee shall report to the Agency within 30 days:

(1) Any instance in which there is significant reduction in the effectiveness of any ~~[authorized]~~ **approved Type B or fissile** packaging during use; and

(2) Details of any defects with safety significance in the **Type B or fissile** packaging after first use, with the means employed to repair the defects and prevent their recurrence **or**

(3) Instances in which the conditions of approval in the certificate of compliance were not observed in making a shipment.

Stat. Auth.: ORS Ch. 453.605 - 453.755
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Advance Notification of Transport of Nuclear Waste

333-118-0190 (1) Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport to the governor, or governor's designee, of each state**within or** through which the waste will be transported.

NOTE: A list of the mailing addresses of the governors and governors' designees is available upon request from the Director, Office of State, Local, and Indian Tribe Programs, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(2) Advance notification is required only when:

(a) The nuclear waste is required to be in Type B packaging for transportation;

(b) The nuclear waste is being transported **into, within, or** through, ~~[or across]~~ **a** state **en route** ~~[boundaries]~~ to a disposal ~~[site]~~ **facility** or to a collection point for transport to a disposal ~~[site]~~ **facility**; and

(c) The quantity of licensed material in a single package exceeds **any one of the following**:

(A) ~~[5,000 curies (185 TBq) of]~~ **3000 times the A1 value of the radionuclides as specified in Appendix A, Table A-1 for** special form ~~[radionuclides]~~ **radioactive material**;

(B) ~~[5,000 curies (185 TBq) of uncompressed gases of argon-41, krypton-85m, krypton-87, xenon-131$_m$, or xenon-135]~~ **3000 times the A_2 value of the radionuclides as specified in Appendix A, Table A-1 for normal form radioactive material**;

(C) **1000 TBq (27,000 Ci)** ~~[50,000 curies (1.85 PBq) of argon-37, or of uncompressed gases of krypton-85 or xenon-133, or of hydrogen-3 as a gas, as luminous paint, or absorbed on solid material~~

~~(D) 20 curies (740 GBq) of other non-special form radionuclides for which A_2 is less than or equal to four curies (148 GBq); or~~

~~(E) 200 curies (7.4 TBq) of other non-special form radionuclides for which A_2 is greater than four curies (148 Gbq).]~~

(3) Each advance notification required by ~~[section]~~ **333-118-190**(1) ~~[of this rule]~~ shall contain the following information:

(a) The name, address, and telephone number of the shipper, carrier and receiver of the shipment;

(b) A description of the nuclear waste contained in the shipment as required by **49 CFR 172.202 and 172.203 (d)**;

(c) The point of origin of the shipment and the 7-day period during which departure of the shipment is estimated to occur;

(d) The 7-day period during which arrival of the shipment at state boundaries is estimated to occur;

(e) The destination of the shipment, and the 7-day period during which arrival of the shipment is estimated to occur; and

(f) A point of contact with a telephone number for current shipment information.

(4) The notification required by ~~[section]~~ **333-118-190**(1) ~~[of this rule]~~ shall be made in writing to the office of each appropriate governor, or governor's designee, and to the Agency. A notification delivered by mail must be postmarked at least seven days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A notification delivered by the messenger must reach the office of the governor, or governor's designee, at least four**(4)** days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for ~~[one]~~ **3** years **or until inspected by the agency**.

(5) The licensee shall notify each appropriate governor, or governor's designee, and the Agency of any changes to schedule information provided pursuant to ~~[section]~~ **333-118-190**(1) ~~[of this rule]~~. Such notification shall be by telephone to a

responsible individual in the office of the governor, or governor's designee, of the appropriate state or states. The licensee shall maintain for ~~[one]~~ **3** years a record of the name of the individual contacted.

(6) Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice to the governor, or governor's designee, of each appropriate state and to the Agency. A copy of the notice shall be retained by the licensee for ~~[one]~~ **3** years.

Stat. Auth.: ORS Ch. 453.605 - 453.755
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Quality Assurance

Quality Assurance Requirements

333-118-0200 (1) **Unless otherwise authorized by the agency, e**~~[E]~~ach licensee shall establish, maintain, and execute a quality assurance program to verify by procedures such as checking, auditing, and inspection, that deficiencies, deviations, and defective material and equipment relating to the shipment of packages containing radioactive material are promptly identified and corrected.

(2) The licensee shall identify the material and components to be covered by the quality assurance program.

(3) Each licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which packaging is used.

(4) Prior to the use of any package for the shipment of radioactive material, each licensee shall obtain approval by the Agency of its quality assurance program.

(5) The licensee shall maintain sufficient written records to demonstrate compliance with the quality assurance program. Records of quality assurance pertaining to the use of a package for shipment of radioactive material shall be maintained **for a period of 3 years after shipment or** until inspected by the Agency.

Stat. Auth.: ORS Ch. 453.605 - 453.755
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Referenced Materials

333-118-0800(1) This Division of Chapter 333 of the Oregon Administrative Rules incorporates by reference material originally published elsewhere. Certified copies of the complete text of incorporated materials referenced are available for public inspection during regular business hours at the Radiation Protection Services Office. Copies of referenced material will be provided at cost upon request. Information regarding how the incorporated material may be obtained or examined is available from Radioactive Materials Program, Radiation Protection Services, 800 NE Oregon Street Suite 260, Portland, Oregon 97232.

(2) Material referenced in this Division does not include amendments to or revised editions of the material published later than the effective date of the relevant section.

Appendix A to ~~[Division 118-]~~10 CFR Part 71 Determination of A_1 and A_2

I. Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations are given in Table A-1. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) figure. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is one tenth of one percent or less. Where values of A_1 or A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

II. For individual radionuclides whose identities are known, but which are not listed in Table A-1, the determination of the values of A_1 and A_2 requires Department approval, except that the values of A_1 and A_2 in Table A-2 may be used without obtaining Agency approval.

III. In the calculations of A_1 and A_2 for a radionuclide not in Table A-1, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter nuclide has a half-life either longer than 10 days, or longer than that of the parent nuclide, shall be considered as a single radionuclide, and the activity to be taken into account, and the A_1 or A_2 value to be applied shall be those corresponding to the parent nuclide of that chain. In the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than 10 days, or greater than that of the parent nuclide, the parent and those daughter nuclides shall be considered as mixtures of different nuclides.

IV. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:

(a) For special form radioactive material, the maximum quantity transported in a Type A package:

$$\sum_i \frac{B(i)}{A_1(i)}$$ less than or equal to 1

(b) For normal form radioactive material, the maximum quantity transported in a Type A package:

$$\sum_i \frac{B(i)}{A_2(i)}$$ less than or equal to 1

where B(i) is the activity of radionuclide I and $A_1(i)$ and $A_2(i)$ are the A_1 and A_2 values for radionuclide respectively.

Alternatively, an A1 value for mixtures of special form material may be determined as follows:

$$A_1 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where f(i) is the fraction of activity of nuclide i in the mixture and $A_1(i)$ is the appropriate A1 value for nuclide i.

An A2 value for mixtures of normal form material may be determined as follows:

$$A_2 \text{ for mixture} = \frac{1}{\sum_I \frac{f(i)}{A_2(i)}}$$

where f(i) is the fraction of activity of nuclide I in the mixture and $A_2(i)$ is the appropriate A_2 value for nuclide I.

V. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

Table A-1: A_1 and A_2 Values for Radionuclides

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
Ac-225	Actinium(89)	0.6	16.2	$1x10^{-2}$	0.270	$2.1x10^{3}$	$5.8x10^{4}$
Ac-227	40	1080	$2x10^{-5}$	$5.41x10^{-4}$	2.7	$7.2x10^{1}$	
Ac-228	0.6	16.2	0.4	10.8	$8.4x10^{4}$	$2.2x10^{6}$	
Ag-105	Silver(47)	2	54.1	2	54.1	$1.1x10^{3}$	$3.0x10^{4}$
Ag-108m		0.6	16.2	0.6	16.2	$9.7x10^{-1}$	$2.6x10^{1}$
Ag-110m		0.4	10.8	0.4	10.8	$1.8x10^{2}$	$4.7x10^{3}$
Ag-111	0.6	16.2	0.5	13.5	$5.8x10^{3}$	$1.6x10^{5}$	
Al-26	Aluminum(13)	0.4	10.8	0.4	10.8	$7.0x10^{-4}$	$1.9x10^{-2}$
Am-241	Americium(95)	2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$1.3x10^{-1}$	3.4
Am-242m		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$3.6x10^{-1}$	$1.0x10^{1}$
Am-243		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$7.4x10^{-3}$	$2.0x10^{-1}$
Ar-37	Argon(18)	40	1080	40	1080	$3.7x10^{3}$	$9.9x10^{4}$
Ar-39		20	541	20	541	1.3	$3.4x10^{1}$
Ar-41		0.6	16.2	0.6	16.2	$1.5x10^{6}$	$4.2x10^{7}$
Ar-42		0.2	5.41	0.2	5.41	9.6	$2.6x10^{2}$
As-72	Arsenic(33)	0.2	5.41	0.2	5.41	$6.2x10^{4}$	$1.7x10^{6}$
As-73		40	1080	40	1080	$8.2x10^{2}$	$2.2x10^{4}$
As-74		1	27.0	0.5	13.5	$3.7x10^{3}$	$9.9x10^{4}$
As-76		0.2	5.41	0.2	5.41	$5.8x10^{4}$	$1.6x10^{6}$
As-77		20	541	0.5	13.5	$3.9x10^{4}$	$1.0x10^{6}$
At-211	Astatine(85)	30	811	2	54.1	$7.6x10^{4}$	$2.1x10^{6}$
Au-193	Gold(79)	6	162	6	162	$3.4x10^{4}$	$9.2x10^{5}$
Au-194	1	27.0	1	27.0	$1.5x10^{4}$	$4.1x10^{5}$	
Au-195	10	270	10	270	$1.4x10^{2}$	$3.7x10^{3}$	
Au-196	2	54.1	2	54.1	$4.0x10^{3}$	$1.1x10^{5}$	
Au-198	3	81.1	0.5	13.5	$9.0x10^{3}$	$2.4x10^{5}$	
Au-199	10	270	0.9	24.3	$7.7x10^{3}$	$2.1x10^{5}$	

Table A-1 (Cont.)

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
Ba-131	Barium(56)	2	54.1	2	54.1	$3.1x10^{3}$	$8.4x10^{4}$
Ba-133m		10	270	0.9	24.3	$2.2x10^{4}$	$6.1x10^{5}$
Ba-133	3	81.1	3	81.1	9.4	$2.6x10^{2}$	
Ba-140	0.4	10.8	0.4	10.8	$2.7x10^{3}$	$7.3x10^{4}$	
Be-7	Beryllium(4)	20	541	20	541	$1.3x10^{4}$	$3.5x10^{5}$
Be-10		20	541	0.5	13.5	$8.3x10^{-4}$	$2.2x10^{-2}$
Bi-205	Bismuth(83)	0.6	16.2	0.6	16.2	$1.5x10^{3}$	$4.2x10^{4}$
Bi-206		0.3	8.11	0.3	8.11	$3.8x10^{3}$	$1.0x10^{5}$
Bi-207		0.7	18.9	0.7	18.9	1.9	$5.2x10^{1}$
Bi-210m		0.3	8.11	$3x10^{-2}$	0.811	$2.1x10^{-5}$	$5.7x10^{-4}$
Bi-210		0.6	16.2	0.5	13.5	$4.6x10^{3}$	$1.2x10^{5}$
Bi-212		0.3	8.11	0.3	8.11	$5.4x10^{5}$	$1.5x10^{7}$
Bk-247	Berkelium(97)	2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$3.8x10^{-2}$	1.0
Bk-249	40	1080	$8x10^{-2}$	2.16	$6.1x10^{1}$	$1.6x10^{3}$	
Br-76	Bromine(35)	0.3	8.11	0.3	8.11	$9.4x10^{4}$	$2.5x10^{6}$
Br-77		3	81.1	3	81.1	$2.6x10^{4}$	$7.1x10^{5}$
Br-82		0.4	10.8	0.4	10.8	$4.0x10^{4}$	$1.1x10^{6}$
C-11	Carbon(6)	1	27	0.5	13.5	$3.1x10^{7}$	$8.4x10^{8}$
C-14		40	1080	2	54.1	$1.6x10^{-1}$	4.5
Ca-41	Calcium(20)	40	1080	40	1080	$3.1x10^{-3}$	$8.5x10^{-2}$
Ca-45		40	1080	0.9	24.3	$6.6x10^{2}$	$1.8x10^{4}$
Ca-47		0.9	24.3	0.5	13.5	$2.3x10^{4}$	$6.1x10^{5}$
Cd-109	Cadmium(48)	40	1080	1	27.0	$9.6x10^{1}$	$2.6x10^{3}$
Cd-113m		20	541	$9x10^{-2}$	2.43	$8.3x10^{4}$	$2.2x10^{2}$
Cd-115m		0.3	8.11	0.3	8.11	$9.4x10^{2}$	$2.5x10^{4}$
Cd-115	4	108	0.5	13.5	$1.9x10^{4}$	$5.1x10^{5}$	
Ce-139	Cerium(58)	6	162	6	162	$2.5x10^{2}$	$6.8x10^{3}$
Ce-141	10	270	0.5	13.5	$1.1x10^{3}$	$2.8x10^{4}$	
Ce-143	0.6	16.2	0.5	13.5	$2.5x10^{4}$	$6.6x10^{5}$	
Ce-144	0.2	5.41	0.2	5.41	$1.2x10^{2}$	$3.2x10^{3}$	
Cf-248	Californium(98)	30	811	$3x10^{-3}$	$8.11x10^{-2}$	$5.8x10^{1}$	$1.6x10^{3}$
Cf-249		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$1.5x10^{-1}$	4.1
Cf-250		5	135	$5x10^{-4}$	$1.35x10^{-2}$	4.0	$1.1x10^{2}$
Cf-251		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$5.9x10^{-2}$	1.6
Cf-252		0.1	2.70	$1x10^{-3}$	$2.70x10^{-2}$	$2.0x10^{1}$	$5.4x10^{2}$
Cf-253		40	1080	$6x10^{-2}$	1.62	$1.1x10^{3}$	$2.9x10^{4}$
Cf-254		$3x10^{-3}$	$8.11x10^{-2}$	$6x10^{-4}$	$1.62x10^{-2}$	$3.1x10^{2}$	$8.5x10^{3}$
Cl-36	Chlorine(17)	20	541	0.5	13.5	$1.2x10^{-3}$	$3.3x10^{-2}$
Cl-38		0.2	5.41	0.2	5.41	$4.9x10^{6}$	$1.3x10^{8}$
Cm-240	Curium(96)	40	1080	$2x10^{-2}$	0.541	$7.5x10^{2}$	$2.0x10^{4}$
Cm-241		2	54.1	0.9	24.3	$6.1x10^{2}$	$1.7x10^{4}$
Cm-242		40	1080	$1x10^{-2}$	0.270	$1.2x10^{2}$	$3.3x10^{3}$
Cm-243		3	81.1	$3x10^{-4}$	$8.11x10^{-3}$	1.9	$5.2x10^{1}$
Cm-244		4	108	$4x10^{-4}$	$1.08x10^{-2}$	3.0	$8.1x10^{1}$
Cm-245		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$6.4x10^{-3}$	$1.7x10^{-1}$
Cm-246		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$1.1x10^{-2}$	$3.1x10^{-1}$
Cm-247		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$3.4x10^{-6}$	$9.3x10^{-5}$
Cm-248		$4x10^{-2}$	1.08	$5x10^{-5}$	$1.35x10^{-3}$	$1.6x10^{-4}$	$4.2x10^{-3}$

Table A-1 (Cont.)

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
Co-55	Cobalt(27)	0.5	13.5	0.5	13.5	$1.1x10^5$	$3.1x10^6$
Co-56		0.3	8.11	0.3	8.11	$1.1x10^3$	$3.0x10^4$
Co-57		8	216	8	216	$3.1x10^2$	$8.4x10^3$
Co-58m		40	1080	40	1080	$2.2x10^5$	$5.9x10^6$
Co-58		1	27.0	1	27.0	$1.2x10^3$	$3.2x10^4$
Co-60		0.4	10.8	0.4	10.8	$4.2x10^1$	$1.1x10^3$
Cr-51	Chromium(24)	30	811	30	811	$3.4x10^3$	$9.2x10^4$
Cs-129	Cesium(55)	4	108	4	108	$2.8x10^4$	$7.6x10^5$
Cs-131	40	1080	40	1080	$3.8x10^3$	$1.0x10^5$	
Cs-132	1	27.0	1	27.0	$5.7x10^3$	$1.5x10^5$	
Cs-134m		40	1080	9	243	$3.0x10^5$	$8.0x10^6$
Cs-134	0.6	16.2	0.5	13.5	$4.8x10^1$	$1.3x10^3$	
Cs-135	40	1080	0.9	24.3	$4.3x10^{-5}$	$1.2x10^{-3}$	
Cs-136	0.5	13.5	0.5	13.5	$2.7x10^3$	$7.3x10^4$	
Cs-137	2	54.1	0.5	13.5	3.2	$8.7x10^1$	
Cu-64	Copper(29)	5	135	0.9	24.3	$1.4x10^5$	$3.9x10^6$
Cu-67		9	243	0.9	24.3	$2.8x10^4$	$7.6x10^5$
Dy-159	Dysprosium(66)	20	541	20	541	$2.1x10^2$	$5.7x10^3$
Dy-165	0.6	16.2	0.5	13.5	$3.0x10^5$	$8.2x10^6$	
Dy-166	0.3	8.11	0.3	8.11	$8.6x10^3$	$2.3x10^5$	
Er-169	Erbium(68)	40	1080	0.9	24.3	$3.1x10^3$	$8.3x10^4$
Er-171		0.6	16.2	0.5	13.5	$9.0x10^4$	$2.4x10^6$
Es-253	Einsteinium(99)[a]	200	5400	$2.1x10^{-2}$	$5.4x10^{-1}$	--	--
Es-254	30	811	$3x10^{-3}$	$8.11x10^{-2}$	--	--	
Es-254m		0.6	16.2	0.4	10.8	--	--
Es-255	--	--	--	--	--	--	
Eu-147	Europium(63)	2	54.1	2	54.1	$1.4x10^3$	$3.7x10^4$
Eu-148	0.5	13.5	0.5	13.5	$6.0x10^2$	$1.6x10^4$	
Eu-149	20	541	20	541	$3.5x10^2$	$9.4x10^3$	
Eu-150	0.7	18.9	0.7	18.9	$6.1x10^4$	$1.6x10^6$	
Eu-152m		0.6	16.2	0.5	13.5	$8.2x10^4$	$2.2x10^6$
Eu-152	0.9	24.3	0.9	24.3	6.5	$1.8x10^2$	
Eu-154	0.8	21.6	0.5	13.5	9.8	$2.6x10^2$	
Eu-155	20	541	2	54.1	$1.8x10^1$	$4.9x10^2$	
Eu-156	0.6	16.2	0.5	13.5	$2.0x10^3$	$5.5x10^4$	
F-18	Fluorine(9)	1	27.0	0.5	13.5	$3.5x10^6$	$9.5x10^7$
Fe-52	Iron(26)	0.2	5.41	0.2	5.41	$2.7x10^5$	$7.3x10^6$
Fe-55		40	1080	40	1080	$8.8x10^1$	$2.4x10^3$
Fe-59		0.8	21.6	0.8	21.6	$1.8x10^3$	$5.0x10^4$
Fe-60		40	1080	0.2	5.41	$7.4x10^{-4}$	$2.0x10^{-2}$
Fm-255	Fermium(100)[b]	40	1080	0.8	21.6	--	--
Fm-257	10	270	$8x10^{-3}$	$21.6x10^{-1}$	--	--	
Ga-67	Gallium(31)	6	162	6	162	$2.2x10^4$	$6.0x10^5$
Ga-68		0.3	8.11	0.3	8.11	$1.5x10^6$	$4.1x10^7$
Ga-72		0.4	10.8	0.4	10.8	$1.1x10^5$	$3.1x10^6$
Gd-146	Gadolinium(64)	0.4	10.8	0.4	10.8	$6.9x10^2$	$1.9x10^4$
Gd-148	3	81.1	$3x10^{-4}$	$8.11x10^{-3}$	1.2	$3.2x10^1$	
Gd-153	10	270	5	135	$1.3x10^2$	$3.5x10^3$	

Table A-1 (Cont.)

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
Gd-159	4	108	0.5	13.5	$3.9x10^4$	$1.1x10^6$	
Ge-68	Germanium(32)	0.3	8.11	0.3	8.11	$2.6x10^2$	$7.1x10^3$
Ge-71		40	1080	40	1080	$5.8x10^3$	$1.6x10^5$
Ge-77		0.3	8.11	0.3	8.11	$1.3x10^5$	$3.6x10^6$
H-3	Hydrogen(1) See T-Tritium						
Hf-172	Hafnium(72)	0.5	13.5	0.3	8.11	$4.1x10^1$	$1.1x10^3$
Hf-175		3	81.1	3	81.1	$3.9x10^2$	$1.1x10^4$
Hf-181		2	54.1	0.9	24.3	$6.3x10^2$	$1.7x10^4$
Hf-182		4	108	$3x10^{-2}$	0.811	$8.1x10^{-6}$	$2.2x10^{-4}$
Hg-194	Mercury(80)	1	27.0	1	27.0	$1.3x10^{-1}$	3.5
Hg-195m		5	135	5	135	$1.5x10^4$	$4.0x10^5$
Hg-197m		10	270	0.9	24.3	$2.5x10^4$	$6.7x10^5$
Hg-197	10	270	10	270	$9.2x10^3$	$2.5x10^5$	
Hg-203	4	108	0.9	24.3	$5.1x10^2$	$1.4x10^4$	
Ho-163	Holmium(67)	40	1080	40	1080	2.7	$7.6x10^1$
Ho-166m		0.6	16.2	0.3	8.11	$6.6x10^{-2}$	1.8
Ho-166	0.3	8.11	0.3	8.11	$2.6x10^4$	$7.0x10^5$	
I-123	Iodine(53)	6	162	6	162	$7.1x10^4$	$1.9x10^6$
I-124		0.9	24.3	0.9	24.3	$9.3x10^3$	$2.5x10^5$
I-125		20	541	2	54.1	$6.4x10^2$	$1.7x10^4$
I-126		2	54.1	0.9	24.3	$2.9x10^3$	$8.0x10^4$
I-129		Unlimited	Unlimited	Unlimited	Unlimited	$6.5x10^{-6}$	$1.8x10^{-4}$
I-131		3	81.1	0.5	13.5	$4.6x10^3$	$1.2x10^5$
I-132		0.4	10.8	0.4	10.8	$3.8x10^5$	$1.0x10^7$
I-133		0.6	16.2	0.5	13.5	$4.2x10^4$	$1.1x10^6$
I-134		0.3	8.11	0.3	8.11	$9.9x10^5$	$2.7x10^7$
I-135		0.6	16.2	0.5	13.5	$1.3x10^5$	$3.5x10^6$
In-111	Indium(49)	2	54.1	2	54.1	$1.5x10^4$	$4.2x10^5$
In-113m		4	108	4	108	$6.2x10^5$	$1.7x10^7$
In-114m		0.3	8.11	0.3	8.11	$8.6x10^2$	$2.3x10^4$
In-115m		6	162	0.9	24.3	$2.2x10^5$	$6.1x10^6$
Ir-189	Iridium(77)	10	270	10	270	$1.9x10^3$	$5.2x10^4$
Ir-190		0.7	18.9	0.7	18.9	$2.3x10^3$	$6.2x10^4$
Ir-192		1	27.0	0.5	13.5	$3.4x10^2$	$9.2x10^3$
Ir-193m		10	270	10	270	$2.4x10^3$	$6.4x10^4$
Ir-194		0.2	5.41	0.2	5.41	$3.1x10^4$	$8.4x10^5$
K-40	Potassium(19)	0.6	16.2	0.6	16.2	$2.4x10^{-7}$	$6.4x10^{-6}$
K-42		0.2	5.41	0.2	5.41	$2.2x10^5$	$6.0x10^6$
K-43		1.0	27.0	0.5	13.5	$1.2x10^5$	$3.3x10^6$
Kr-81	Krypton(36)	40	1080	40	1080	$7.8x10^{-4}$	$2.1x10^{-2}$
Kr-85m		6	162	6	162	$3.0x10^5$	$8.2x10^6$
Kr-85		20	541	10	270	$1.5x10^1$	$3.9x10^2$
Kr-87		0.2	5.41	0.2	5.41	$1.0x10^6$	$2.8x10^7$
La-137	Lanthanum(57)	40	1080	2	54.1	$1.6x10^{-3}$	$4.4x10^{-2}$
La-140	0.4	10.8	0.4	10.8	$2.1x10^4$	$5.6x10^5$	
Lu-172	Lutetium(71)	0.5	13.5	0.5	13.5	$4.2x10^3$	$1.1x10^5$
Lu-173	8	216	8	216	$5.6x10^1$	$1.5x10^3$	

Table A-1 (Cont.)

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
Lu-174m		20	541	8	216	2.0×10^{2}	5.3×10^{3}
Lu-174	8	216	4	108	2.3×10^{1}	6.2×10^{2}	
Lu-177	30	811	0.9	24.3	4.1×10^{3}	1.1×10^{5}	
MFP	For mixed fission products, use formula for mixtures or Table A-2.						
Mg-28	Magnesium(12)	0.2	5.41	0.2	5.41	2.0×10^{5}	5.4×10^{6}
Mn-52	Manganese(25)	0.3	8.11	0.3	8.11	1.6×10^{4}	4.4×10^{5}
Mn-53		Unlimited	Unlimited	Unlimited	Unlimited	6.8×10^{-5}	1.8×10^{-3}
Mn-54		1	27.0	1	27.0	2.9×10^{2}	7.7×10^{3}
Mn-56		0.2	5.41	0.2	5.41	8.0×10^{5}	2.2×10^{7}
Mo-93	Molybdenum(42)	40	1080	7	189	4.1×10^{-2}	1.1
Mo-99		0.6	16.2	0.5	13.5[c]	1.8×10^{4}	4.8×10^{5}
N-13	Nitrogen(7)	0.6	16.2	0.5	13.5	5.4×10^{7}	1.5×10^{9}
Na-22	Sodium(11)	0.5	13.5	0.5	13.5	2.3×10^{2}	6.3×10^{3}
Na-24		0.2	5.41	0.2	5.41	3.2×10^{5}	8.7×10^{6}
Nb-92m	Niobium(41)	0.7	18.9	0.7	18.9	5.2×10^{3}	1.4×10^{5}
Nb-93m		40	1080	6	162	8.8	2.4×10^{2}
Nb-94		0.6	16.2	0.6	16.2	6.9×10^{-3}	1.9×10^{-1}
Nb-95		1	27.0	1	27.0	1.5×10^{3}	3.9×10^{4}
Nb-97		0.6	16.2	0.5	13.5	9.9×10^{5}	2.7×10^{7}
Nd-147	Neodymium(60)	4	108	0.5	13.5	3.0×10^{3}	8.1×10^{4}
Nd-149	0.6	16.2	0.5	13.5	4.5×10^{5}	1.2×10^{7}	
Ni-59	Nickel(28)	40	1080	40	1080	3.0×10^{-3}	8.0×10^{-2}
Ni-63		40	1080	30	811	2.1	5.7×10^{1}
Ni-65		0.3	8.11	0.3	8.11	7.1×10^{5}	1.9×10^{7}
Np-235	Neptunium(93)	40	1080	40	1080	5.2×10^{1}	1.4×10^{3}
Np-236	7	189	1×10^{-3}	2.70×10^{-2}	4.7×10^{-4}	1.3×10^{-2}	
Np-237	2	54.1	2×10^{-4}	5.41×10^{-3}	2.6×10^{-5}	7.1×10^{-4}	
Np-239	6	162	0.5	13.5	8.6×10^{3}	2.3×10^{5}	
Os-185	Osmium(76)	1	27.0	1	27.0	2.8×10^{2}	7.5×10^{3}
Os-191m		40	1080	40	1080	4.6×10^{4}	1.3×10^{6}
Os-191	10	270	0.9	24.3	1.6×10^{3}	4.4×10^{4}	
Os-193	0.6	16.2	0.5	13.5	2.0×10^{4}	5.3×10^{5}	
Os-194	0.2	5.41	0.2	5.41	1.1×10^{1}	3.1×10^{2}	
P-32	Phosphorus(15)	0.3	8.11	0.3	8.11	1.1×10^{4}	2.9×10^{5}
P-33		40	1080	0.9	24.3	5.8×10^{3}	1.6×10^{5}
Pa-230	Protactinium(91)	2	54.1	0.1	2.70	1.2×10^{3}	3.3×10^{4}
Pa-231	0.6	16.2	6×10^{-5}	1.62×10^{-3}	1.7×10^{-3}	4.7×10^{-2}	
Pa-233	5	135	0.9	24.3	7.7×10^{2}	2.1×10^{4}	
Pb-201	Lead(82) 1	27.0	1	27.0	6.2×10^{4}	1.7×10^{6}	
Pb-202	40	1080	2	54.1	1.2×10^{-4}	3.4×10^{-3}	
Pb-203	3	81.1	3	81.1	1.1×10^{4}	3.0×10^{5}	
Pb-205	Unlimited	Unlimited	Unlimited	Unlimited	4.5×10^{-6}	1.2×10^{-4}	
Pb-210	0.6	16.2	9×10^{-3}	0.243	2.8	7.6×10^{1}	
Pb-212	0.3	8.11	0.3	8.11	5.1×10^{4}	1.4×10^{6}	
Pd-103	Palladium(46)	40	1080	40	1080	2.8×10^{3}	7.5×10^{4}
Pd-107	Unlimited	Unlimited	Unlimited	Unlimited	1.9×10^{-5}	5.1×10^{-4}	
Pd-109	0.6	16.2	0.5	13.5	7.9×10^{4}	2.1×10^{6}	
Pm-143	Promethium(61)	3	81.1	3	81.1	1.3×10^{2}	3.4×10^{3}

Table A-1 (Cont.)

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
Pm-144		0.6	16.2	0.6	16.2	$9.2x10^{1}$	$2.5x10^{3}$
Pm-145		30	811	7	189	5.2	$1.4x10^{2}$
Pm-147		40	1080	0.9	24.3	$3.4x10^{1}$	$9.3x10^{2}$
Pm-148m		0.5	13.5	0.5	13.5	$7.9x10^{2}$	$2.1x10^{4}$
Pm-149		0.6	16.2	0.5	13.5	$1.5x10^{4}$	$4.0x10^{5}$
Pm-151		3	81.1	0.5	13.5	$2.7x10^{4}$	$7.3x10^{5}$
Po-208	Polonium(84)	40	1080	$2x10^{-2}$	0.541	$2.2x10^{1}$	$5.9x10^{2}$
Po-209	40	1080	$2x10^{-2}$	0.541	$6.2x10^{-1}$	$1.7x10^{1}$	
Po-210	40	1080	$2x10^{-2}$	0.541	$1.7x10^{2}$	$4.5x10^{3}$	
Pr-142	Praseodymium(59)	0.2	5.41	0.2	5.41	$4.3x10^{4}$	$1.2x10^{6}$
Pr-143		4	108	0.5	13.5	$2.5x10^{3}$	$6.7x10^{4}$
Pt-188	Platinum(78)	0.6	16.2	0.6	16.2	$2.5x10^{3}$	$6.8x10^{4}$
Pt-191		3	81.1	3	81.1	$8.7x10^{3}$	$2.4x10^{5}$
Pt-193m		40	1080	9	243	$5.8x10^{3}$	$1.6x10^{5}$
Pt-193		40	1080	40	1080	1.4	$3.7x10^{1}$
Pt-195m		10	270	2	54.1	$6.2x10^{3}$	$1.7x10^{5}$
Pt-197m		10	270	0.9	24.3	$3.7x10^{5}$	$1.0x10^{7}$
Pt-197		20	541	0.5	13.5	$3.2x10^{4}$	$8.7x10^{5}$
Pu-236	Plutonium(94)	7	189	$7x10^{-4}$	$1.89x10^{-2}$	$2.0x10^{1}$	$5.3x10^{2}$
Pu-237	20	541	20	541	$4.5x10^{2}$	$1.2x10^{4}$	
Pu-238	2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$6.3x10^{-1}$	$1.7x10^{1}$	
Pu-239	2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$2.3x10^{-3}$	$6.2x10^{-2}$	
Pu-240	2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$8.4x10^{-3}$	$2.3x10^{-1}$	
Pu-241	40	1080	$1x10^{-2}$	0.270	3.8	$1.0x10^{2}$	
Pu-242	2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$1.5x10^{-4}$	$3.9x10^{-3}$	
Pu-244	0.3	8.11	$2x10^{-4}$	$5.41x10^{-3}$	$6.7x10^{-7}$	$1.8x10^{-5}$	
Ra-223	Radium(88)	0.6	16.2	$3x10^{-2}$	0.811	$1.9x10^{3}$	$5.1x10^{4}$
Ra-224	0.3	8.11	$6x10^{-2}$	1.62	$5.9x10^{3}$	$1.6x10^{5}$	
Ra-225	0.6	16.2	$2x10^{-2}$	0.541	$1.5x10^{3}$	$3.9x10^{4}$	
Ra-226	0.3	8.11	$2x10^{-2}$	0.541	$3.7x10^{-2}$	1.0	
Ra-228	0.6	16.2	$4x10^{-2}$	1.08	$1.0x10^{1}$	$2.7x10^{2}$	
Rb-81	Rubidium(37)	2	54.1	0.9	24.3	$3.1x10^{5}$	$8.4x10^{6}$
Rb-83		2	54.1	2	54.1	$6.8x10^{2}$	$1.8x10^{4}$
Rb-84		1	27.0	0.9	24.3	$1.8x10^{3}$	$4.7x10^{4}$
Rb-86		0.3	8.11	0.3	8.11	$3.0x10^{3}$	$8.1x10^{4}$
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	$3.2x10^{-9}$	$8.6x10^{-8}$
Rb (natural)		Unlimited	Unlimited	Unlimited	Unlimited	$6.7x10^{6}$	$1.8x10^{8}$
Re-183	Rhenium(75)	5	135	5	135	$3.8x10^{2}$	$1.0x10^{4}$
Re-184m		3	81.1	3	81.1	$1.6x10^{2}$	$4.3x10^{3}$
Re-184	1	27.0	1	27.0	$6.9x10^{2}$	$1.9x10^{4}$	
Re-186	4	108	0.5	13.5	$6.9x10^{3}$	$1.9x10^{5}$	
Re-187	Unlimited	Unlimited	Unlimited	Unlimited	$1.4x10^{-9}$	$3.8x10^{-8}$	
Re-188	0.2	5.41	0.2	5.41	$3.6x10^{4}$	$9.8x10^{5}$	
Re-189	4	108	0.5	13.5	$2.5x10^{4}$	$6.8x10^{5}$	
Re (natural)		Unlimited	Unlimited	Unlimited	Unlimited	--	$2.4x10^{-8}$
Rh-99	Rhodium(45)	2	54.1	2	54.1	$3.0x10^{3}$	$8.2x10^{4}$
Rh-101	4	108	4	108	$4.1x10^{1}$	$1.1x10^{3}$	
Rh-102m		2	54.1	0.9	24.3	$2.3x10^{2}$	$6.2x10^{3}$

Table A-1 (Cont.)

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
Rh-102	0.5	13.5	0.5	13.5	$4.5x10^{1}$	$1.2x10^{3}$	
Rh-103m		40	1080	40	1080	$1.2x10^{6}$	$3.3x10^{7}$
Rh-105	10	270	0.9	24.3	$3.1x10^{4}$	$8.4x10^{5}$	
Rn-222	Radon(86)	0.2	5.41	$4x10^{-3}$	0.108	$5.7x10^{3}$	$1.5x10^{5}$
Ru-97	Ruthenium(44)	4	108	4	108	$1.7x10^{4}$	$4.6x10^{5}$
Ru-103	2	54.1	0.9	24.3	$1.2x10^{3}$	$3.2x10^{4}$	
Ru-105	0.6	16.2	0.5	13.5	$2.5x10^{5}$	$6.7x10^{6}$	
Ru-106	0.2	5.41	0.2	5.41	$1.2x10^{2}$	$3.3x10^{3}$	
S-35	Sulfur(16)	40	1080	2	54.1	$1.6x10^{3}$	$4.3x10^{4}$
Sb-122	Antimony(51)	0.3	8.11	0.3	8.11	$1.5x10^{4}$	$4.0x10^{5}$
Sb-124	0.6	16.2	0.5	13.5	$6.5x10^{2}$	$1.7x10^{4}$	
Sb-125	2	54.1	0.9	24.3	$3.9x10^{1}$	$1.0x10^{3}$	
Sb-126	0.4	10.8	0.4	10.8	$3.1x10^{3}$	$8.4x10^{4}$	
Sc-44	Scandium(21)	0.5	13.5	0.5	13.5	$6.7x10^{5}$	$1.8x10^{7}$
Sc-46		0.5	13.5	0.5	13.5	$1.3x10^{3}$	$3.4x10^{4}$
Sc-47		9	243	0.9	24.3	$3.1x10^{4}$	$8.3x10^{5}$
Sc-48		0.3	8.11	0.3	8.11	$5.5x10^{4}$	$1.5x10^{6}$
Se-75	Selenium(34)	3	81.1	3	81.1	$5.4x10^{2}$	$1.5x10^{4}$
Se-79		40	1080	2	54.1	$2.6x10^{-3}$	$7.0x10^{-2}$
Si-31	Silicon(14)	0.6	16.2	0.5	13.5	$1.4x10^{6}$	$3.9x10^{7}$
Si-32		40	1080	0.2	5.41	3.9	$1.1x10^{2}$
Sm-145	Samarium(62)	20	541	20	541	$9.8x10^{1}$	$2.6x10^{3}$
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	$8.5x10^{-1}0$	$2.3x10^{-8}$
Sm-151		40	1080	4	108	$9.7x10^{-1}$	$2.6x10^{1}$
Sm-153		4	108	0.5	13.5	$1.6x10^{4}$	$4.4x10^{5}$
Sn-113	Tin(50) 4	108	4	108	$3.7x10^{2}$	$1.0x10^{4}$	
Sn-117m		6	162	2	54.1	$3.0x10^{3}$	$8.2x10^{4}$
Sn-119m		40	1080	40	1080	$1.4x10^{2}$	$3.7x10^{3}$
Sn-121m		40	1080	0.9	24.3	2.0	$5.4x10^{1}$
Sn-123	0.6	16.2	0.5	13.5	$3.0x10^{2}$	$8.2x10^{3}$	
Sn-125	0.2	5.41	0.2	5.41	$4.0x10^{3}$	$1.1x10^{5}$	
Sn-126	0.3	8.11	0.3	8.11	$1.0x10^{-3}$	$2.8x10^{-2}$	
Sr-82	Strontium(38)	0.2	5.41	0.2	5.41	$2.3x10^{3}$	$6.2x10^{4}$
Sr-85m	5	135	5	135	$1.2x10^{6}$	$3.3x10^{7}$	
Sr-85		2	54.1	2	54.1	$8.8x10^{2}$	$2.4x10^{4}$
Sr-87m	3	81.1	3	81.1	$4.8x10^{5}$	$1.3x10^{7}$	
Sr-89		0.6	16.2	0.5	13.5	$1.1x10^{3}$	$2.9x10^{4}$
Sr-90		0.2	5.41	0.1	2.70	5.1	$1.4x10^{2}$
Sr-91		0.3	8.11	0.3	8.11	$1.3x10^{5}$	$3.6x10^{6}$
Sr-92		0.8	21.6	0.5	13.5	$4.7x10^{5}$	$1.3x10^{7}$
T	Tritium(1)	40	1080	40	1080	$3.6x10^{2}$	$9.7x10^{3}$
Ta-178	Tantalum(73)	1	27.0	1	27.0	$4.2x10^{6}$	$1.1x10^{8}$
Ta-179	30	811	30	811	$4.1x10^{1}$	$1.1x10^{3}$	
Ta-182	0.8	21.6	0.5	13.5	$2.3x10^{2}$	$6.2x10^{3}$	
Tb-157	Terbium(65)	40	1080	10	270	$5.6x10^{-1}$	$1.5x10^{1}$
Tb-158	1	27.0	0.7	18.9	$5.6x10^{-1}$	$1.5x10^{1}$	
Tb-160	0.9	24.3	0.5	13.5	$4.2x10^{2}$	$1.1x10^{4}$	
Tc-95m	Technetium(43)	2	54.1	2	54.1	$8.3x10^{2}$	$2.2x10^{4}$

Table A-1 (Cont.)

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
Tc-96m		0.4	10.8	0.4	10.8	$1.4x10^{6}$	$3.8x10^{7}$
Tc-96		0.4	10.8	0.4	10.8	$1.2x10^{4}$	$3.2x10^{5}$
Tc-97m		40	1080	40	1080	$5.6x10^{2}$	$1.5x10^{4}$
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	$5.2x10^{-5}$	$1.4x10^{-3}$
Tc-98		0.7	18.9	0.7	18.9	$3.2x10^{-5}$	$8.7x10^{-4}$
Tc-99m		8	216	8	216	$1.9x10^{5}$	$5.3x10^{6}$
Tc-99		40	1080	0.9	24.3	$6.3x10^{-4}$	$1.7x10^{-2}$
Te-118	Tellurium(52)	0.2	5.41	0.2	5.41	$6.8x10^{3}$	$1.8x10^{5}$
Te-121m		5	135	5	135	$2.6x10^{2}$	$7.0x10^{3}$
Te-121	2	54.1	2	54.1	$2.4x10^{3}$	$6.4x10^{4}$	
Te-123m		7	189	7	189	$3.3x10^{2}$	$8.9x10^{3}$
Te-125m		30	811	9	243	$6.7x10^{2}$	$1.8x10^{4}$
Te-127m		20	541	0.5	13.5	$3.5x10^{2}$	$9.4x10^{3}$
Te-127	20	541	0.5	13.5	$9.8x10^{4}$	$2.6x10^{6}$	
Te-129m		0.6	16.2	0.5	13.5	$1.1x10^{3}$	$3.0x10^{4}$
Te-129	0.6	16.2	0.5	13.5	$7.7x10^{5}$	$2.1x10^{7}$	
Te-131m		0.7	18.9	0.5	13.5	$3.0x10^{4}$	$8.0x10^{5}$
Te-132	0.4	10.8	0.4	10.8	$1.1x10^{4}$	$3.0x10^{5}$	
Th-227	Thorium(90)	9	243	$1x10^{-2}$	0.270	$1.1x10^{3}$	$3.1x10^{4}$
Th-228	0.3	8.11	$4x10^{-4}$	$1.08x10^{-2}$	$3.0x10^{1}$	$8.2x10^{2}$	
Th-229	0.3	8.11	$3x10^{-5}$	$8.11x10^{-4}$	$7.9x10^{-3}$	$2.1x10^{-1}$	
Th-230	2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$7.6x10^{-4}$	$2.1x10^{-2}$	
Th-231	40	1080	0.9	24.3	$2.0x10^{4}$	$5.3x10^{5}$	
Th-232	Unlimited	Unlimited	Unlimited	Unlimited	$4.0x10^{-9}$	$1.1x10^{-7}$	
Th-234	0.2	5.41	0.2	5.41	$8.6x10^{2}$	$2.3x10^{4}$	
Th (natural)		Unlimited	Unlimited	Unlimited	Unlimited	$8.1x10^{-9}$	$2.2x10^{-7}$
Ti-44	Titanium(22)	0.5	13.5	0.2	5.41	6.4	$1.7x10^{2}$
Tl-200	Thallium(81.1)	0.8	21.6	0.8	21.6	$2.2x10^{4}$	$6.0x10^{5}$
Tl-201		10	270	10	270	$7.9x10^{3}$	$2.1x10^{5}$
Tl-202		2	54.1	2	54.1	$2.0x10^{3}$	$5.3x10^{4}$
Tl-204		4	108	0.5	13.5	$1.7x10^{1}$	$4.6x10^{2}$
Tm-167	Thulium(69)	7	189	7	189	$3.1x10^{3}$	$8.5x10^{4}$
Tm-168		0.8	21.6	0.8	21.6	$3.1x10^{2}$	$8.3x10^{3}$
Tm-170		4	108	0.5	13.5	$2.2x10^{2}$	$6.0x10^{3}$
Tm-171		40	1080	10	270	$4.0x10^{1}$	$1.1x10^{3}$
U-230	Uranium(92)	40	1080	$1x10^{-2}$	0.270	$1.0x10^{3}$	$2.7x10^{4}$
U-232		3	81.1	$3x10^{-4}$	$8.11x10^{-3}$	$8.3x10^{-1}$	$2.2x10^{1}$
U-233		10	270	$1x10^{-3}$	$2.70x10^{-2}$	$3.6x10^{-4}$	$9.7x10^{-3}$
U-234		10	270	$1x10^{-3}$	$2.70x10^{-2}$	$2.3x10^{-4}$	$6.2x10^{-3}$
U-235		Unlimited	Unlimited	Unlimited	Unlimited	$8.0x10^{-8}$	$2.2x10^{-6}$
U-236		10	270	$1x10^{-3}$	$2.70x10^{-2}$	$2.4x10^{-6}$	$6.5x10^{-5}$
U-238		Unlimited	Unlimited	Unlimited	Unlimited	$1.2x10^{-8}$	$3.4x10^{-7}$
U (natural)		Unlimited	Unlimited	Unlimited	Unlimited	$2.6x10^{-8}$	$7.1x10^{-7}$
U (enriched 5% or less)		Unlimited	Unlimited	Unlimited	Unlimited	--	(Table A-3)
U (enriched more than 5%)		10	270	$1x10^{-3}$	$2.70x10^{-2}$	--	(Table A-3)
U (depleted)		Unlimited	Unlimited	Unlimited	Unlimited	--	(Table A-3)
V-48	Vanadium(23)	0.3	8.11	0.3	8.11	$6.3x10^{3}$	$1.7x10^{5}$
V-49		40	1080	40	1080	$3.0x10^{2}$	$8.1x10^{3}$

Table A-1 (Cont.)

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
W-178	Tungsten(74)	1	27.0	1	27.0	$1.3x10^3$	$3.4x10^4$
W-181		30	811	30	811	$2.2x10^2$	$6.0x10^3$
W-185		40	1080	0.9	24.3	$3.5x10^2$	$9.4x10^3$
W-187		2	54.1	0.5	13.5	$2.6x10^4$	$7.0x10^5$
W-188		0.2	5.41	0.2	5.41	$3.7x10^2$	$1.0x10^4$
Xe-122	Xenon(54)	0.2	5.41	0.2	5.41	$4.8x10^4$	$1.3x10^6$
Xe-123	0.2	5.41	0.2	5.41	$4.4x10^5$	$1.2x10^7$	
Xe-127	4	108	4	108	$1.0x10^3$	$2.8x10^4$	
Xe-131m		40	1080	40	1080	$3.1x10^3$	$8.4x10^4$
Xe-133	20	541	20	541	$6.9x10^3$	$1.9x10^5$	
Xe-135	4	108	4	108	$9.5x10^4$	$2.6x10^6$	
Y-87	Yttrium(39)	2	54.1	2	54.1	$1.7x10^4$	$4.5x10^5$
Y-88		0.4	10.8	0.4	10.8	$5.2x10^2$	$1.4x10^4$
Y-90		0.2	5.41	0.2	5.41	$2.0x10^4$	$5.4x10^5$
Y-91m		2	54.1	2	54.1	$1.5x10^6$	$4.2x10^7$
Y-91		0.3	8.11	0.3	8.11	$9.1x10^2$	$2.5x10^4$
Y-92		0.2	5.41	0.2	5.41	$3.6x10^5$	$9.6x10^6$
Y-93		0.2	5.41	0.2	5.41	$1.2x10^5$	$3.3x10^6$
Yb-169	Ytterbium(70)	3	81.1	3	81.1	$8.9x10^2$	$2.4x10^4$
Yb-175	30	811	0.9	24.3	$6.6x10^3$	$1.8x10^5$	
Zn-65	Zinc(30)	2	54.1	2	54.1	$3.0x10^2$	$8.2x10^3$
Zn-69m		2	54.1	0.5	13.5	$1.2x10^5$	$3.3x10^6$
Zn-69		4	108	0.5	13.5	$1.8x10^6$	$4.9x10^7$
Zr-88	Zirconium(40)	3	81.1	3	81.1	$6.6x10^2$	$1.8x10^4$
Zr-93		40	1080	0.2	5.41	$9.3x10^{-5}$	$2.5x10^{-3}$
Zr-95		1	27.0	0.9	24.3	$7.9x10^2$	$2.1x10^4$
Zr-97		0.3	8.11	0.3	8.11	$7.1x10^4$	$1.9x10^6$

Table A-2: General Values for A_1 and A_2				
Contents	A_1		A_2	
	(TBq)	(Ci)	(TBq)	(Ci)
Only beta- or gamma-emitting nuclides are known to be present.	0.2	5	0.02	0.5
Alpha-emitting nuclides are known to be present, or no relevant data are available.	0.10	2.70	$2x10^{-5}$	$5.4x10^{-4}$

Table A-3: Activity-mass Relationships for Uranium

Uranium Enrichment* wt % U-235 present	Specific Activity	
	TBq/g	Ci/g
0.45	$1.8x10^{-8}$	$5.0x10^{-7}$
0.72	$2.6x10^{-8}$	$7.1x10^{-7}$
1.0	$2.8x10^{-8}$	$7.6x10^{-7}$
1.5	$3.7x10^{-8}$	$1.0x10^{-6}$
5.0	$1.0x10^{-7}$	$2.7x10^{-6}$
10.0	$1.8x10^{-7}$	$4.8x10^{-6}$
20.0	$3.7x10^{-7}$	$1.0x10^{-5}$
35.0	$7.4x10^{-7}$	$2.0x10^{-5}$
50.0	$9.3x10^{-7}$	$2.5x10^{-5}$
90.0	$2.2x10^{-6}$	$5.8x10^{-5}$
93.0	$2.6x10^{-6}$	$7.0x10^{-5}$
95.0	$3.4x10^{-6}$	$9.1x10^{-5}$

*The figures for uranium include representative values for the activity of the uranium-235 which is concentrated during the enrichment process.

DIVISION 119

REGISTRATION OF TANNING FACILITIES

Purpose and Scope

333-119-001 (1) The purpose of this Division is to regulate tanning facilities to minimize the risks associated with tanning by artificial Ultraviolet light. These risks include, but may not be limited to:

(a) Sunburn;

(b) Premature aging of the skin;

(c) Skin cancer;

(d) Retinal damage;

(e) Formation of cataracts;

(f) Suppression of the immune system;

(g) Damage to the vascular system; and

(h) Improper sanitation of tanning devices.

(2) The requirements of this Division apply to any tanning facility that operates any tanning devices. Physicians' phototherapy devices are exempted, see OAR 333-119-0130(2).

(3) In addition to the requirements of this Division, all registrants are subject to the applicable provisions of other parts of these rules.

Stat. Auth.: ORS Ch. 431.925 - 431.955
Stats. Implemented: ORS 431.925 - 431.955
Hist.: HD 15-1991, f. & Cert. ef. 10-1-91

Definitions

333-119-010 As used in this Division, these terms have the definitions set forth below:

(1) "Agency" means the Radiation Protection Services of the Oregon Health Division.

(2) "Consumer" means any member of the public who is provided access to a tanning device in exchange for a fee or other compensation, or any individual who, in exchange for a fee or other compensation, is afforded use of a tanning device as a condition or benefit of membership or access.

(3) "EPA" means the United States Environmental Protection Agency.

(4) "FDA" means the United States Food and Drug Administration.

(5) "Formal training" means a course of instruction reviewed and approved by the Agency and which is conducted or presented under formal classroom conditions by a qualified expert possessing adequate knowledge and experience to offer a curriculum, associated training, and certification testing pertaining to and associated with the correct use of tanning equipment. Operator training shall cover ultraviolet radiation and effects on the skin, photosensitivity, FDA and State of Oregon regulations, eye protection, and equipment maintenance.

(6) "Handrails" means a suitable physical aid that will help to maintain proper exposure distance.

(7) "Individual" means any human being.

(8) "Minor" means any individual under the age of eighteen.

(9) "Operator" means the person who has been designated by the registrant to operate or to assist and instruct the consumer in the operation and use of tanning devices. Under this definition, the term "operator" means any individual who conducts one or more of the following activities:

(a) determining consumers' skin type;

(b) determining the suitability for use of a tanning device by prospective consumers;

(c) informing the consumer of the dangers of ultraviolet radiation exposure including photoallergic reactions and photosensitizing agents;

(d) assuring that the consumer reads and properly signs all forms required by these rules;

(e) maintaining required consumer exposure records;

(f) recognizing and reporting consumer injuries or alleged injuries to the registrant;

(g) determining the consumers' exposure schedule;

(h) setting timers which control the duration of exposure; and

(i) instructing the consumer in the proper use of protective eyewear.

(10) "Other compensation" means the payment or exchange of goods, services or anything of value for use of the tanning device or devices.

(11) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of these entities.

(12) "Phototherapy device" means equipment that emits Ultraviolet radiation used by a health care professional in the treatment of disease or illness.

(13) "Protective eyewear" means suitable eyewear that protects the eye from Ultraviolet radiation and allows adequate vision.

(14) "Registrant" means any person who is registered with the Agency as required by provisions of this Division.

(15) "Registration" means registration with the Agency in accordance with provisions of this Division.

(16) "Safe level" means not more than 50 colonies of microorganisms per four square inches of equipment surface.

17) "Sanitize" means the effective bactericidal treatment of surfaces of equipment and devices by an EPA or FDA registered product which provides a sufficient concentration of chemicals, and enough time to reduce the bacterial count, including pathogens, to a safe level. Chemical germicides that are registered with EPA as hospital disinfectants when used at recommended dilutions and directions, may be approved for sanitizing of tanning devices.

(18) "Tanning device" means any equipment used for tanning of the skin, that emits electromagnetic radiation with wavelengths in the air between 200 and 400 nanometers including, but not limited to, a sunlamp, Ultraviolet Lamp, tanning booth, facial unit, UVA wand, or tanning bed. "Tanning device" also means any accompanying equipment, including, but not limited to, protective eyewear, timers, ballasts, starters, lamps, reflectors, cooling fans, acrylics, comfort pillows and handrails.

(19) "Tanning facility" means any location, place, area, structure, or business which provides persons access to any tanning device.

(20) "Timers" means a device provided to terminate the exposure at a preset time interval.

(21) "Ultraviolet radiation" means radiation that has a wavelength between two hundred nanometers and four hundred nanometers.

Stat. Auth.: ORS Ch. 431.925 - 431.955
Stats. Implemented: ORS 431.925
Hist.: HD 15-1991, f. & ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94

Registration

333-119-020 (1) Prior to the operation of any tanning device used by the public for a fee or other compensation, the owner or operator shall file an application with the Agency and pay applicable fee(s) specified in OAR 333-103-0025 to register each tanning device.

(2) If the owner or operator owns or operates more than one such tanning facility, the owner or operator shall file a separate application for each such facility owned or operated.

(3) Registration application shall be made on forms furnished by the Agency.

(4) A validation certificate or acknowledgement of validation will be issued by the Agency.

(5) The certificate issued by the Agency shall be effective for one year beginning October 1 and continuing through September 30 of the following year.

(6) The certificate shall be displayed in a conspicuous place on the premises of the tanning facility.

(7) The Agency will provide an identification number which will be affixed by an Agency inspector to each tanning device during the initial or follow-up facility inspection:

(a) Identification numbers shall not be removed without written permission of the Agency; and

(b) Identification numbers shall not be defaced.

(8) The registrant shall notify the Agency in writing before making any change which would render the information contained in the application for registration or the validation of registration no longer accurate.

(9) No registration may be transferred from one person to another person, from one tanning facility to another tanning facility, or from one tanning device to another tanning device.

(10) In the event of a change in ownership, the new owner will be required to apply for a registration of the tanning device within 30 days after taking possession of the property.

(11) Tanning facilities already in existence at the time of the effective date of this rule may continue to operate. Such facility shall be given priority in the inspection process by the Agency. However, should those tanning facilities fail to meet the standards, they may be prohibited from continuing to operate until such time as they have met those standards through evaluation by the Agency's inspectors or through a hearing held by the Agency.

Stat. Auth.: ORS Ch. 431.925 - 431.955
Stats. Implemented: ORS 431.940
Hist.: HD 15-1991, f. & ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94

GENERAL REQUIREMENTS

Administrative Responsibilities

333-119-030 (1) The registrant shall be responsible for directing the operation of the tanning facility which has been registered with the Agency. That individual, or individual's agent shall assure that the provisions of these rules are met in the operation of tanning devices.

(2) A tanning device which does not meet the provisions of these rules shall not be operated and may be tagged "Out of Service for Non-compliance with OAR 333-119 Requirements" by Agency inspectors. Devices tagged as non-compliant shall not be operated until written authorization is received by the registrant from the Agency.

(3) The registrant shall assure that the tanning facility will comply with all applicable federal laws and regulations.

(4) In addition to the requirements of this Division, all registrants are subject to the applicable

requirements of Divisions 100, 103 and 111 of these rules.

(5) The Agency Inspection Findings report and facility response letter(s) shall be conspicuously posted in public view until all items of non-compliance have been corrected and a written Agency release from this requirement is received by the registrant.

(6) The registrant shall post in a conspicuous place the Agency "Notice To The Public".

Stat. Auth.: ORS Ch. 431.925 - 431.955
Stats. Implemented: ORS 431.930, 431.935
Hist.: HD 15-1991, f. & ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94

Construction and Operation of Tanning Facilities

333-119-040 Unless otherwise ordered or approved by the Agency, each tanning facility shall be constructed, operated and maintained to meet the following minimum requirements:

(1) Physical facilities:

(a) All tanning facilities shall be equipped with convenient toilet facilities and dressing rooms. Such toilet facilities shall include a water closet and hand-washing sinks. Such toilet and dressing rooms shall be properly maintained, as well as meet all state and local codes.

(b) All areas of the tanning facility shall be ventilated with at least six air changes per hour or as required by local code.

(c) Tanning booth temperature shall be maintained below 100 degrees Fahrenheit (38 degrees Centigrade) during booth operation.

(d) The tanning device shall meet the National Fire Protection Association's National Electrical Code, or be approved by the Underwriter Laboratories (UL) or Electrical Testing Laboratories (ETL).

(e) Except as otherwise noted by the Agency, each tanning facility shall be constructed, operated and maintained in accordance with applicable city, county and state codes.

(2) Cleaning and maintenance:

(a) All areas of the tanning facility, including tanning devices, equipment and apparatus, shall be maintained in a clean and sanitary manner by the facility operator and in accordance with manufacturer's instructions.

(b) The tanning device(s) and protective eyewear shall be cleaned with an approved sanitizer after each use by the facility operator. [~~or;~~]

[~~(A) Facilities are required to may provide sanitary disposable clear plastic sheets for application and disposal after each consumer use of a tanning device. Suitable written instructions are also required to be posted to provide adequate guidance to consumers using sanitary sheets; and;~~]

[~~(B)~~] (A) [~~Facilities are required to clean and sanitize tanning devices periodically throughout each day tanning devices are being used by consumers.~~] A listing of approved sanitizers is maintained by the Agency and is available upon request of registrants. This listing may change at any time due to updating of state or federal sanitation guidelines. The operator shall use a sanitizer that sanitizes to a safe level of microorganisms as required by these rules. A clean paper or cloth towel shall be used each time the tanning device is cleaned and sanitized. The sanitizer, as described in these rules, is one specifically manufactured for sanitizing ultraviolet-light-emitting equipment and protective eyewear, and that does not damage the acrylic lamp covers of the device. The Ultraviolet Light produced by the tanning device itself is not considered an adequate sanitizing agent.

(c) Protective eyewear and tanning devices shall be sanitized after each use with a sanitizing agent

which is registered by EPA **and approved by the Agency** using the following procedures:

(A) Immerse protective eyewear for at least one minute in a clean solution (or spray tanning device acrylic surfaces and allow at least one to two minutes of surface contact time with a solution) containing at least 400 ppm (parts per million) of available quaternary ammonium compound at a temperature of at least 75 degrees Fahrenheit; or

(B) Immerse protective eyewear for at least one minute in a clean solution (or spray tanning device acrylic surfaces and allow at least one to two minutes of surface contact time with the solution) containing at least 100 ppm (parts per million) of available chlorine as a hypochlorite and at a temperature of at least 75 degrees Fahrenheit; or

(C) Immerse protective eyewear for at least one minute in a clean solution (or spray tanning device acrylic surfaces and allow at least one to two minutes of surface contact time with the solution) containing at least 25 ppm (parts per million) of available iodine and at a pH of which the efficacy has been demonstrated to be effective by the manufacturer and at temperature of at least 75 degrees Fahrenheit; **or**

(D) Immerse protective eyewear for at least one minute in a clean solution (or spray tanning device acrylic surfaces and allow at least one to two minutes of surface contact time with the solution) containing any other chemical sanitizing agent registered with the EPA or FDA, and specifically manufactured for use with protective eyewear and/or tanning devices that will provide the equivalent bactericidal effect of a solution containing at least 100 ppm (parts per million) of available chlorine as a hypochlorite at temperature of at least 75 degrees Fahrenheit.

(d) A test kit or other device that accurately measures the concentration of the sanitizing solution in parts per million (ppm) shall be used to measure the strength of the sanitizing solution when the concentrate and water dilution is initially prepared and at least weekly thereafter to ensure sufficient strength of the sanitizing solution. If a suitable test kit is not available for an approved sanitizer, the laboratory analysis data shall be provided by the product manufacturer, and a copy be on file with the Agency. Written procedures at the facility using sanitizer shall include proper mixing and handling instructions to assure proper concentration of the sanitizer.

(e) Clean sanitary towels shall be provided to all patrons using tanning facilities.

(f) A hamper or receptacle must be provided for all soiled towels and linen.

(g) No pets or animals are permitted in tanning facilities other than seeing eye dogs or hearing assistance dogs.

Stat. Auth.: ORS Ch. 431.925 - 431.955
Stats. Implemented: ORS 431.930
Hist.: HD 15-1991, f. & ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94

SPECIFIC REQUIREMENTS

Warning Statement

333-119-050 At each consumer's initial visit to a tanning facility, and at least annually thereafter, the consumer shall be provided the following written statement to review and sign which warns the consumer that (an Agency approved tanning client card may be used to satisfy this requirement):

(1) Not wearing the protective eyewear provided to each customer by the tanning facility may cause damage to the eyes; and

(2) Overexposure to the tanning process may cause burns; and

(3) Repeated exposure to the tanning process may cause skin cancer or premature aging of the skin

or both; and

(4) Abnormal skin sensitivity or burning may result from the tanning process if the customer is also consuming or using certain:

(a) Foods;

(b) Cosmetics; or

(c) Medications such as tranquilizers, antibiotics, diuretics, high blood pressure medication, antineoplastics or birth control pills; and

(5) Any person taking a prescription or over-the-counter drug should consult a physician before using a tanning device.

Stat. Auth.: ORS Ch. 431.925 - 431.955
Stats. Implemented: ORS 431.945
Hist.: HD 15-1991, f. & ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94

Warning Sign

333-119-060 (1) The registrant shall conspicuously post the warning sign described in section (2) of this rule within one meter (39.37 inches) of each tanning device and in such a manner that the sign is clearly visible, not obstructed by any barrier, equipment or other object, and can be easily viewed by the consumer before operating the tanning device.

(2) The warning sign in section (1) of this rule shall use upper and lower case letters which are at least 10 millimeters and five millimeters in height, respectively, and shall have the following wording:

DANGER - ULTRAVIOLET RADIATION

-- Follow instructions.

-- Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and/or skin cancer.

-- Wear protective eyewear.

FAILURE TO USE PROTECTIVE EYEWEAR
MAY RESULT IN SEVERE BURNS OR

LONG-TERM INJURY TO THE EYES.

-- Medications or cosmetics may increase your sensitivity to the Ultraviolet radiation. Consult a physician before using sunlamp or tanning device if you are using medications or have a history of skin problems or believe yourself to be especially sensitive to sunlight.

-- If you do not tan in the sun, you are unlikely to tan from the use of this product.

Stat. Auth.: ORS Ch. 431.925 - 431.955
Stats. Implemented: ORS 431.945
Hist.: HD 15-1991, f. & ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94

Protective Eyewear

333-119-070 (1) The registrant shall provide protective eyewear to each consumer for use during any use of tanning devices.

(2) The protective eyewear in section (1) of this rule shall meet the requirements of 21 Code of Federal Regulations (CFR) Part 1040, Section 1040.20(c)(4).

(3) Tanning facility operators shall ensure that consumers wear the protective eyewear required by this Rule.

Stat. Auth.: ORS Ch. 431.925 - 431.955
Stats. Implemented: ORS 431.945
Hist.: HD 15-1991, f. & ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94

Training of Personnel

333-119-080 (1) The registrant shall certify that all tanning device operators are adequately trained in the following:

(a) The requirements of this Division; and

(b) Procedures for correct operation of the tanning facility and tanning devices; and

(c) Recognition of injury or overexposure to Ultraviolet radiation; and

(d) The tanning device manufacturer's procedures for operation and maintenance of the tanning devices; and

(e) The determination of skin type of customers and appropriate determination of duration of exposure to registered tanning devices; and

(f) Emergency procedures to be followed in case of injury; and

(g) Potential photosensitizing foods, cosmetics, and medications.

(2) The registrant shall ensure that tanning devices are operated only while an adequately trained operator is present at the tanning facility.

(3) [~~Prior to October 1, 1994,~~] **A**[a]ll currently registered tanning facilities in the State of Oregon must have completed the following staff training requirements **within one (1) year of registering with the agency:**

(a) At least one owner, manager or operator from each tanning facility with [~~less than~~] four **or less** tanning devices, shall successfully complete one of the vendor-provided formal training courses authorized by the Agency.

(b) At least two operators from each tanning facility with **five or** more [~~than four~~] tanning devices shall successfully complete one of the vendor provided formal training courses authorized by the Agency.

(c) Training of other full or part-time operators shall be by means of an Agency-authorized and vendor-provided training course, or by materials received by an owner or primary operator from an Agency-authorized and vendor-provided training course, or by an Agency-authorized correspondence course.

(4) Staff training shall be documented by the facility owner or operator and include date and time with subjects covered in the training session for all operators [~~by October 1, 1994~~].

Stat. Auth.: ORS Ch. 431.925 - 431.955
Stats. Implemented: ORS 431.930
Hist.: HD 15-1991, f. & ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94

Protection of Consumers

333-119-090 The registrant shall establish and use a procedure manual that will aid in the protection of the consumer to excessive or unnecessary exposure to Ultraviolet Light. This manual shall include, but not be limited to, the following instructions:

(1) Only one consumer per tanning room at a time, or

(a) When two or more tanning devices are used in the same room, only those consumers using tanning devices should be present in the room, and

(b) In the case of a consumer using a tanning device who may need the aid or assistance from another person, that individual must also be provided with and wear protective eyewear.

(2) No consumer under the age of 18, without written parental consent, shall be allowed to use a tanning device. Written consent must be provided on the premises in the presence of an owner/operator, with the parent's understanding of the potential risks involved in overexposure.

(3) A sign shall be posted in conspicuous view at or near the reception area with the following text: "PERSONS UNDER AGE 18 ARE REQUIRED TO HAVE PARENT OR LEGAL GUARDIAN SIGN AUTHORIZATION TO TAN, IN THE PRESENCE OF A TANNING FACILITY OPERATOR. OAR 333-119-0090(2)."

(4) Each person using a tanning device shall be instructed by the operator on the maximum exposure time and proper exposure distance, as recommended by the manufacturer of the device. The operator shall also instruct the consumer as to the location and proper operation of the tanning device's emergency shut off switch.

(5) Infants and minors are not permitted to be in the tanning device room during exposure by parents or guardians.

(6) Tanning operators shall limit exposure time to the exposure time recommendation provided by the device manufacturer on the tanning device or in the device operating manual. The maximum exposure time recommended by the manufacturer of the device shall not be exceeded in any 24-hour period.

(7) Tanning operators shall keep a list of emergency contact numbers in view at each tanning facility. This list shall include the emergency contact numbers appropriate for the community where the facility is located. Example of emergency contacts:

(a) Nearest hospital;

(b) Nearest fire department;

(c) Emergency medical services or emergency 911 service, if available;

(d) Oregon Radiation Protection Services at (503) 731-4014.

(8) Tanning operators shall maintain a list of the common photosensitizing agents as provided by the Oregon Health Division, FDA, or other appropriate authorities, available for review by consumers.

(9) Tanning facilities are prohibited from controlling the use of tanning devices solely with token timer systems[~~, in the absence of a trained operator~~].

[~~(10) Tanning facilities using token timer control systems shall ensure that consumer is not provided with a number of tokens so as to allow an overexposure based on consumer's skin type.~~]

Stat. Auth.: ORS Ch. 431.925 - 431.955
Stats. Implemented: ORS 431.930
Hist.: HD 15-1991, f. & ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94

Equipment

333-119-100 (1) The registrant shall use only tanning devices manufactured in accordance with the specifications set forth in 21 CFR Part 1040, Section 1040.20, "Sunlamp Products and Ultraviolet Lamps Intended for Use in Sunlamp Products."

(2) Each sunlamp product or Ultraviolet Lamp used in these facilities shall not emit measurable Ultraviolet C radiation.

(3) Each Ultraviolet Lamp contained within the sunlamp product shall be shielded so as to not come into contact with the consumer. A transparent acrylic cover shall be used for this purpose.

(4) Tanning booths in which the consumer is in a standing position shall be provided with a handrail for the consumer to hold onto during operation of the booth.

(a) The construction of the booth shall be such that it will have the strength to withstand the stress of use and the impact of a falling person.

(b) Entry to stand-up booths shall be of rigid construction with doors which are non-latching and open outwardly.

(5) Each tanning device shall have, clearly marked, the appropriate position the consumer is to assume prior to operation.

(6) Each tanning device shall prominently display the following label or equivalent warning/information label:

DANGER - ULTRAVIOLET RADIATION.
FOLLOW INSTRUCTIONS CAREFULLY
DO NOT ENTER WITHOUT PROTECTIVE EYEWEAR

(7) Adequate means shall be provided to enable a consumer to summon assistance from the exposure position.

(8) All persons hired for servicing and repair of tanning devices shall be an Agency licensed service technician or State of Oregon licensed electrician.

(9) Original Equipment Manufacturer (OEM) replacement parts (or equivalent) shall be used, if available, to prevent UL/ETL de-listing of tanning devices. All local, State of Oregon, and National Electrical Codes must be observed during service and repair actions.

(10) Defective or burned out tanning lamps or bulbs shall be replaced with a type intended for use in the device and shall be of the same Ultraviolet range (A or B) as the manufacturer specifies, and shall be the original lamp type as specified by the manufacturer, or certified as an equivalent lamp per 21 CFR 1040.20.

(11) If equivalent lamps are used instead of the Original Equipment Manufacturer (OEM) required lamps, a copy of the equivalency certification, provided by the lamp supplier, shall be maintained on file for review by Agency inspectors.

(12) Defective or burned out tanning lamps and tanning lamps which have been operated in a tanning device for the manufacturer's maximum rated lamp hour life, shall be disposed of in a safe and proper manner to prevent unauthorized and unsafe use as lighting devices. Used tanning lamps are prohibited from being resold for any purpose.

(13) If the Ultraviolet tanning device is not in an individual cubicle, then a suitable screen, curtain, or other shield shall be provided, maintained, and used to prevent unnecessary exposure to Ultraviolet radiation of persons not using the device.

(14) The facility operator shall ensure that consumers do not exceed the exposure time indicated by the manufacturer.

(15) Each tanning device shall have a timer which complies with the requirements of 21 CFR Part 1040, Section 1040.20 (c)(2).

(a) The maximum timer interval shall not exceed the manufacturer's maximum recommended exposure time.

(b) Tanning device timers shall be controlled by a properly trained operator. **A remote timer control system shall be used for this purpose.** [~~New facilities (including existing facilities with change of ownership) shall install remote timer controls prior to operation of tanning devices. Existing tanning devices not equipped with a remote timer control system are required to have remote timer controls (outside of tanning device room) installed not later than October 1, 1995.~~]

(c) Each tanning device shall be equipped with an emergency shut-off mechanism to allow manual termination of the UV exposure by the consumer, as required by 21 CFR 1040.20(c)(3).

(16) Each timer must be functional and accurate to within ± 10%.

(17) The registrant shall ensure that the timer is checked annually for accuracy.

(18) All tanning devices shall be maintained to the minimum requirements of the manufacturer.

(19) Each tanning device shall be equipped with an hour meter to accurately determine lamp hour use and recording of maintenance service on each device.

Stat. Auth.: ORS Ch. 431.925 - 431.955
Stats. Implemented: ORS 431.655, 431.930, 431.945
Hist.: HD 15-1991, f. & ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94

Records and Reports

333-119-110 (1) The registrant shall maintain a record of each consumer's total number of tanning visits, dates and durations of tanning exposures.

(2) The registrant shall maintain a record of each consumer's signature and acknowledgement that they understand the potential risks involved with exposure to Ultraviolet radiation and overexposure, and that they have reviewed a photosensitizing drug list.

(3) The registrant shall maintain all records of parental consent regarding minors.

(4) The registrant shall submit to the Agency a written report of injury for which medical attention was sought or obtained from the use of registered tanning devices within five working days after occurrence. The report shall include:

(a) The name, address and phone number of the affected individual;

(b) The name, location and phone number of the tanning facility involved;

(c) The nature of the actual or alleged injury, and

(d) Any other information relevant to the actual or alleged injury to include the date and duration of exposure and any documentation of medical attention sought or obtained.

(5) The registrant shall maintain records showing the results of annual timer tests.

(6) The registrant shall maintain a record of operator training as required in OAR 333-119-0090.

(7) The registrant shall maintain the following information for each tanning device:

(a) Manufacturer's equipment manual and any other service related material or instruction; and

(b) The exposure schedule developed by the manufacturer; and

(c) Records of surveys, inspections, maintenance, and modifications performed on the tanning device with names of persons performing such services, the date of service, and the hour meter reading of the device serviced.

(8) Records shall be maintained showing the receipt, transfer, repair and disposal of all tanning

devices and lamps.

(9) All required records shall be maintained until inspected by the Agency and shall be so filed as to be readily available for review.

Stat. Auth.: ORS Ch. 431.925 - 431.955
Stats. Implemented: ORS 431.930
Hist.: HD 15-1991, f. & ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94

Advertising

333-119-120 (1) No person or facility shall advertise the use of any Ultraviolet A or Ultraviolet B tanning device using wording such as "Safe", "Safe Tanning", "No Harmful Rays", "No Adverse Effect", or similar wording or concepts.

(2) No person, in any advertisement, shall refer to the fact that such person, or such person's facility, is registered with the Agency pursuant to the provisions of this Division, and no person shall state or imply that any activity under such registration has been approved by the Agency.

(3) No person or facility shall advertise or promote tanning packages labeled as "unlimited". [~~unless tanning frequency limits are included in advertisements.~~] **(4)** Tanning packages shall include the following written tanning guidelines for all clients:

(a) Initial tanning sessions (three to five) are limited to intervals of at least 48 hours between sessions to allow adequate time for melanin activation and transit to occur prior to subsequent exposures. The manufacturer's recommended exposure schedule posted on tanning devices or listed in the operating manual for the tanning device shall be followed by tanning operators advising new clients during initial tanning sessions.

(b) After the initial (three to five) tanning exposures, tanning sessions are limited to one tanning session per 24-hour period (or one tanning session per 48 hours on tanning devices so labeled) with consumers being properly advised of the manufacturer's recommended exposure schedule posted on tanning devices or listed in the operating manual for the tanning device.

(c) Promotion of annual tanning packages shall include a written statement listing the total number of sessions allowed per person, per year (recommendations should generally not exceed two sessions per week and the maximum of 30-50 sessions per year as recommended by the International Radiation Protection Association (IRPA) and other authorities).

Stat. Auth.: ORS Ch. 431.925 - 431.955
Stats. Implemented: ORS 431.930
Hist.: HD 15-1991, f. & ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94

Exemptions

333-119-130 (1) The Agency may, upon application therefore or upon its own initiative, grant such exemptions or exceptions from the requirements of the rules in this section as it determines are authorized by law and will not result in undue hazard to public health and safety.

(2) A phototherapy device used by or under the direct supervision of a physician licensed under ORS Chapter 677 is exempt from the requirements of this Division.

(3) Any individual is exempt from the provisions of this Division to the extent that such individual owns a tanning device exclusively for personal use.

(4) Tanning devices, while in transit or storage incidental thereto, are exempt from the provisions of this Division.

(5) Tanning devices located in any facility having public access, are required to have the power supply physically disconnected from the device and lamps removed in order to qualify for a-no-fee-required storage designation. Tanning devices with lamps installed and power active to the device are required to be registered with the Agency and pay applicable fees.

Stat. Auth.: ORS Ch. 431.925 - 431.955
Stats. Implemented: ORS 431.930, 431.935
Hist.: HD 15-1991, f. & ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94

Denial, Revocation, Termination of Registration

333-119-140 (1) The Agency may deny, suspend or revoke registration issued pursuant to this Division:

(a) For any written false statement in the application for registration or in any statement of fact as required by provisions of this Division; or

(b) Because of conditions revealed by the application or any report, record, inspection or other means which would warrant the Agency to refuse to grant a registration; or

(c) For operation of the tanning facility in a manner that causes or threatens to cause hazard to the public health or safety; or

(d) For failure to allow authorized representatives of the Agency to enter the tanning facility at reasonable times for the purpose of determining compliance with the provisions of this Division, or an order of the Agency; or

(e) For violation of, or failure to observe any of the terms and conditions of the rules in this Division, or an order of the Agency; or

(f) For failure to properly dispose of used tanning lamps and thus allowing possible use in an unauthorized or hazardous manner.

(2) Except in cases of willfulness or cases in which the public health, interest or safety requires otherwise, prior to the institution of proceedings for suspension or revocation of a registration, the Agency shall:

(a) Call to the attention of the registrant, in writing, the facts or conduct which may warrant such actions, and

(b) Provide reasonable opportunity for the registrant to demonstrate or achieve compliance with all lawful requirements.

(3) Any person aggrieved by a decision by the Agency to deny a registration or to suspend or revoke a registration after issuance may request a hearing.

(4) The Agency may terminate a registration upon receipt of a written request for termination from the registrant.

(5) The Agency may, by rule, regulation, or order, impose upon any registrant such requirements in addition to those established in this regulation as it deems appropriate or necessary to minimize danger to public health and safety or property.

Stat. Auth.: ORS Ch. 431.925 - 431.955
Stats. Implemented: ORS 431.930
Hist.: HD 15-1991, f. & ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94

Vendor Responsibilities

333-119-200 (1) Any person who sells, leases, transfers, or lends tanning devices in this state shall notify the Agency of the following within 30 days after each sale or installation:

(a) Name and address of persons who have received these devices;

(b) The manufacturer model and serial numbers of each device, and

(c) The date of transfer.

(2) No person shall make, sell, lease, transfer, lend or install tanning devices or the supplies used in connection with such devices unless such supplies and equipment when placed in operation and use, will meet the requirements of these rules.

(3) State of Oregon identification numbers shall not be removed, altered or defaced by any vendor doing business in this state, without written permission of the Agency.

(4) Vendors of tanning devices, replacement lamps, sanitizers, protective eyewear, UV light measurement devices, calibration of measurement equipment, remote timer systems, computer control systems, repair or cleaning services, parts supplies, or operator training are required to apply for a license for sales, services and servicing as specified in OAR 333-101-0020. Vendor License application forms will be furnished by the Agency. Vendors are prohibited from providing tanning equipment installation, servicing and/or services prior to the Agency issuing a licensing certificate to the vendor.

(5) Vendors providing operator training services are required to apply for a license for services as specified in OAR 333-101-0020. Training-services vendors are required to furnish a copy of all training materials (including a sample examination) to the Agency for review and comment prior to offering operator training courses. Vendors shall maintain records of course completion and test results for a period of at least three years from the date of the operator training course. A copy of the list of persons successfully completing operator training shall be furnished to the Agency including the following:

(a) A copy of the training materials used for the specific course offered; and

(b) A list of qualified training personnel including training experience; and

(c) A list of persons trained with test scores listed and tanning facility name and address provided; and

(d) At least one Agency staff member shall be invited to attend any operator training course offered within the State of Oregon without charge.

(6) Not-for-profit industry sponsored training organizations are permitted to utilize recognized industry qualified experts as adjunct instructors for specific modules of training course materials that have been reviewed and authorized by the Agency.

Stat. Auth.: ORS Ch. 431.925 - 431.955
Stats. Implemented: ORS 431.655, 431.930
Hist.: HD 15-1991, f. & ef. 10-1-91; HD 15-1994, f. & ef. 5-6-94; HD 24-1994, f. & Cert. ef. 9-6-94

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DIVISION 120

STANDARDS FOR PROTECTION AGAINST RADIATION

GENERAL PROVISIONS

Purpose

333-120-0001 (1) This Division establishes standards for protection against ionizing radiation resulting from activities conducted under licenses and registrations issued by the Agency. These rules are issued under the Oregon Revised Statutes 453.605 to 453.807, and the State of Oregon's Agreement with the U.S. Nuclear Regulatory Commission.

(2) It is the purpose of the rules in this Division to control the receipt, possession, use, transfer, and disposal of licensed radioactive material and sources of radiation by any licensee or registrant in such a manner that the total dose to an individual (including doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation) does not exceed the standards for protection against radiation prescribed in this Division. However, nothing in this Division shall be construed as limiting actions that may be necessary to protect health and safety.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.625, 453.635
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Scope

333-120-0010 The rules in this Division apply to persons licensed or registered by the Agency to receive, possess, use, transfer, or dispose of licensed radioactive material or registered devices. The limits in this Division do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.635, 453.655, 453.665
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Definitions
333-120-0015

(1) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.
(2) "Activity" is the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the becquerel (Bq) and the Curie (Ci). The becquerel is equal to one disintegration per second (dps) and the Curie is equal to 3.7×10^{10} dps.
(3) "Adult" means an individual 18 or more years of age.
(4) "Airborne radioactive material" means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.
(5) "Airborne radioactivity area" means a room, enclosure, or area in which the airborne

radioactive materials, composed wholly or partly of licensed material, exist in concentrations:
(a) In excess of the derived air concentrations (DACs) specified in 10 CFR 20 Appendix B, or
(b) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours present in a week, and intake of 0.6 percent of the annual limit of intake (ALI) or 12 DAC hours.
(6) "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B.
(7) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive material, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. ``Background radiation'' does not include radiation from source, byproduct, or special nuclear materials regulated by the Agency.
(8) "Bioassay" (radiobioassay) means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.
(9) "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days , and for Class Y, Years, of greater than 100 days. For purposes of these regulations, "lung class" and "inhalation class" are equivalent terms.
(10) "Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.
(11) "Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \Sigma W_T H_{T,50}$).
(12) "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.
(13) "Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.
(14) "Decommission means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:
(a) Release of the property for unrestricted use and termination of the license; or
(b) Release of the property under restricted conditions and termination of the license.
(15) "Deep-dose equivalent (H_d), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of 1 cm (1000 mg/cm^2).
(16) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC

values are given in Table I, Column 3, of 10 CFR 20 Appendix B.
(17) "Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).
(18) "Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.
(19) "Dose or radiation dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in other paragraphs of 333-120-0015.
(20) "Dose equivalent" (H_T) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).
(21) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.
(22) "Embryo/fetus" means the developing human organism from conception until the time of birth.
(23) "Entrance or access point" means any location through which an individual could gain access to radiation areas or to radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.
(24) "Exposure" means being exposed to ionizing radiation or to radioactive material.
(25) "External dose" means that portion of the dose equivalent received from radiation sources outside the body.
(26) "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.
(27) "Eye dose equivalent" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm 2).
(28) "Generally applicable environmental radiation standards" means standards issued by the Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.
(29) "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.
(30) "Individual" means any human being.
(31) "Individual monitoring" means --
(a) The assessment of dose equivalent by the use of devices designed to be worn by an individual;
(b) The assessment of committed effective dose equivalent by bioassay (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or
(c) The assessment of dose equivalent by the use of survey data.

(32) "Individual monitoring devices" (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.
(33) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.
(34) "Lens dose equivalent (LDE)" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm 2).
(35) "Member of the public" means any individual except when that individual is receiving an occupational dose.
(36) "Minor" means an individual less than 18 years of age.
(37) "Monitoring (radiation monitoring, radiation protection monitoring)" means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.
(38) "Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these regulations, "deterministic effect" is an equivalent term.
(39) "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material for medical purposes and released, from voluntary participation in medical research programs, or as a member of the public.
(40) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.
(41) "Public dose" means the dose received by a member of the public from exposure to radiation or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material for medical purposes and released, or from voluntary participation in medical research programs.
(42) "Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.
(43) "Radiation" (ionizing radiation) means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Radiation, as used in this part, does not include non-ionizing radiation, such as radio- or microwaves, or visible, infrared, or ultraviolet light.
(44) "Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.
(45) "Reference man" means a hypothetical aggregation of human physical and physiological

characteristics determined by international consensus. These characteristics may be used by researchers and public health employees to standardize results of experiments and to relate biological insult to a common base. A description of the reference man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."

(46) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site.
(47) "Restricted area" means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.
(48) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.
(49) "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.
(50) "Shallow-dose equivalent (H_s)", which applies to the external exposure of the skin or an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of 1 square centimeter.
(51) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.
(52) "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these regulations, "probabilistic effect" is an equivalent term.
(53) "Survey means an evalulation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.
(54) "Total Effective Dose Equivalent (TEDE)" means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).
(55) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee.
(56) "Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation or from any surface that the radiation penetrates.[1/]
(57) "Weighting factor" w_T for an organ or tissue (T) means the proportion of the risk of

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[1/] *At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.*

stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

Organ Dose Weighting Factors

Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[a/]
Whole Body	1.00[b/]

[a/] 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

[b/] For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

(58) "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.
(59) "Working level (WL)" is any combination of short-lived radon daughters (for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212) in 1 liter of air that will result in the ultimate emission of 1.3x10 5 MeV of potential alpha particle energy.
(60) "Working level month (WLM) means an exposure to 1 working level for 170 hours (2,000 working hours per year/12 months per year equals approximately 170 hours per month).

Implementation.
333-120-0017
(1) Any existing license or registration condition that is more restrictive than OAR 333-120 remains in force until there is an amendment or renewal of the license or registration.

(2) If a license or registration condition exempts a licensee or registrant from a provision of OAR 333-120 in effect on or before September 1, 2002, it also exempts the licensee or registrant from the corresponding provision of OAR 333-120.

(3) If a license or registration condition cites provisions of OAR 333-120 in effect prior to September 1, 2002, which do not correspond to any provisions of OAR 333-120, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

Radiation Protection Programs

333-120-0020 (1) Each licensee or registrant shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed or registered activities and sufficient to ensure compliance with the provisions of this Division. (See OAR 333-120-0610 for recordkeeping requirements relating to these programs.)

(2) Each licensee or registrant shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

(3) Each licensee or registrant shall periodically (at least annually) review their radiation protection program content and implementation.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.625, 453.635
Hist.: HD 15-1994, f. & ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95

Radiation Dose Limits

Occupational Dose Limits For Adults

333-120-0100 (1) Each licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures under OAR 333-120-0150, to the following dose limits:

(a) An annual limit, which is the more limiting of:

(A) The total effective dose equivalent being equal to ~~*[5 rem (0.05 Sv)]*~~ **0.05 Sv (5 rem)**; or

(B) The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to ~~*[50 rem (0.5 Sv)]*~~ **0.5 Sv (50 rem)**.

(b) The annual limits to the lens of the eye, to the skin, and to the extremities which are:

(A) An eye dose equivalent of ~~*[15 rem (0.15 Sv)]*~~ **0.15 Sv (15 rem)**, and

(B) A shallow-dose equivalent of ~~*[50 rem (0.50 Sv)]*~~ **0.50 Sv (50 rem)** to the skin or to any of the extremities.

(2) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, must be subtracted from the limits for planned special exposures, as defined in OAR 333-100-0005(93), that the individual may receive during the current year (OAR 333-120-0150(5)(a) and during the individual's lifetime (OAR 333-120-0150(5)(b)).

Note: A licensee or registrant may permit a radiation worker to receive more than ~~*[5 rem]*~~ **0.05 Sv (5 rem)** per year TEDE or ~~*[50 rem]*~~ **0.5 Sv (50 rem)** to the skin, extremities, or organ, or ~~*[15 rem]*~~ **0.15 Sv (15 rem)** to the lens of the eye during a planned special exposure (PSE) only if: (a) there are no other alternatives available or practical; (b) the PSE is authorized in writing before it occurs; (c) the individuals who will be exposed are told the reason for the PSE, the dose they are expected to receive, the risks from that dose and the conditions under which they will be working (e.g., radiation or contamination levels), and how to keep their doses ALARA; (d) the licensee or registrant determines the worker's prior doses (lifetime history); (e) the total dose expected from the PSE plus any previous doses over the annual limit do not exceed the standard annual dose limits [**0.05 Sv/yr** (5 rem/yr) whole body, **0.5 Sv/yr** (50 rem/yr) skin, extremities or organ, **0.15 Sv/yr** (15 rem/yr) lens of eye], or five times the standard limits in the worker's lifetime; (f) the licensee or registrant maintains the appropriate records and files the appropriate reports; and (g)

after the PSE, the licensee or registrant records the dose received and notifies the worker in writing of the dose received within 30 days after the PSE. The dose received from the PSE does not affect the worker's ability to receive the standard annual doses but is included in the worker's lifetime history and added to any future PSEs.

(3) The assigned deep-dose equivalent and shallow-dose equivalent must be for the part of the body receiving the highest exposure:

(a) The deep-dose equivalent, eye dose equivalent and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable; **or**

(b) When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in 333-120-0210(1)(d)., the effective dose equivalent for external radiation shall be determined as follows:

(A) When only one individual monitoring device is used and it is located at the neck outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent for external radiation; or

(B) When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in D.201a., the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

(C) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

(4) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in 10 CFR Part 20 Table 1 of Appendix B to 20.1001 to 20.2401 and may be used to determine the individual's dose (OAR 333-120-0650) and to demonstrate compliance with the occupational dose limits.

(5) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity (see 10 CFR Part 20 footnote 3 of Appendix B to 20.1001 to 20.2401).

(6) When monitoring is required by OAR 333-120-0210 each licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person (OAR 333-120-0630(5)).

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.625, 453.635, 453.695
Hist.: HD 15-1994, f. & ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95

Compliance With Requirements For Summation of External and Internal Doses

333-120-0110 (1) If the licensee is required to monitor under OAR 333-120-0210 (1) and (2), the licensee shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee is required to monitor only under OAR 333-120-0210(1) or only under OAR 333-120-0210(2), then summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses by meeting one of the conditions specified in ~~[section]~~ **333-120-0110**(2) ~~[of this rule]~~ and the conditions in ~~[section]~~s **333-120-0110**(3) and **333-120-0110**(4) ~~[of this rule]~~.

Note: The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

(2) Intake by Inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep-dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(a) The sum of the fractions of the inhalation ALI for each radionuclide, or

(b) The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or

(c) The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit.

Note: An organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T, and the committed dose equivalent, $H_{T,50,}$ per unit intake is greater than 10 percent of the maximum weighted value of H_{T50} (i.e., $w_T H_{T,50}$) per unit intake for any organ or tissue.

(3) Intake by Oral Ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

(4) Intake Through Wounds or Absorption Through Skin. The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be further evaluated.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Determination of External Dose From Airborne Radioactive Material

333-120-0120 Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep-dose equivalent, eye dose equivalent, and shallow-dose equivalent from external exposure to the radioactive cloud (10 CFR Part 20 Appendix B footnotes 1 and 2 to 20.1001 to 20.2401).

Note: Airborne radioactivity measurements and DAC values should not be used as the primary means to assess the deep-dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep-dose equivalent to an individual should be based upon measurements using instruments or individual monitoring devices.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615,.635, 453.695
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Determination of Internal Exposure

333-120-0130 (1) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required under OAR 333-120-0210, take suitable and timely measurements of:

(a) Concentrations of radioactive materials in air in work areas; or

(b) Quantities of radionuclides in the body; or

(c) Quantities of radionuclides excreted from the body; or

(d) Combinations of these measurements.

(2) Unless respiratory protective equipment is used, as provided in OAR 333-120-0320 or the assessment of intake is based in bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

(3) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior or the material in an individual is known, the licensee may:

(a) Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record; and

(b) Upon prior approval of the Agency, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material (e.g., aerosol size distribution or density); and

(c) Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of given radionuclide (see 10 CFR Part 20 Appendix B to 20.1001 to 20.2401) to the committed effective dose equivalent.

(4) If the licensee chooses to assess intakes of Class Y material using the measurements given in ~~[section]~~s **333-120-0130**(1), **333-120-0130**(2) or **333-120-0130**(3) ~~[of this rule]~~, the licensee may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by OAR 333-120-0710 or 333-120-0720, in order to permit the licensee to make additional measurements basic to the assessments.

(5) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours must be either:

(a) The sum of the ratios of the concentration to the appropriate DAC value (e.g., D, W, Y) from 10 CFR Part 20 Appendix B to 20.1001 to 20.2401 for each radionuclide in the mixture; or

(b) The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

(6) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture must be the most restrictive DAC of any radionuclide in the mixture.

(7) When a mixture of radionuclides in air exists, licensees may disregard certain radionuclides in the mixture if:

(a) The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in OAR 333-120-0100 and in complying with the monitoring requirements in OAR 333-120-0210(2), and

(b) The concentration of any radionuclide disregarded is less than 10 percent of its DAC, and

(c) The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

(8) **When determining the committed effective dose equivalent, the following information may be considered:**

(a) In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of ~~[5 rem (0.05 Sv)]~~ **0.05 Sv (5 rem)** for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

(b) When the ALI (and the associated DAC) is determined by the nonstochastic organ dose limit of ~~[50 rem (0.5 Sv)]~~ **0.50 Sv (50 rem)**, the intake of radionuclides that would result in a committed effective dose equivalent of ~~[5 rem (0.05 Sv)]~~ **0.05 Sv (5 rem)** (the stochastic ALI) is listed in parentheses in 10 CFR Part 20 Table 1 of Appendix B to 20.1001 to 20.2401. In this case, the licensee may, as a simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALIs, the licensee also must demonstrate that the limit in OAR 333-120-0100(1)(a)(B) is met.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

(Reserved)
333-120-0140

Planned Special Exposures

333-120-0150 A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in OAR 333-120-0100 provided that each of the following conditions is satisfied:

(1) The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical.

(2) The licensee or registrant (and employer if the employer is not the licensee or registrant) specifically authorizes the planned special exposure, in writing, before the exposure occurs.

(3) Before a planned special exposure, the licensee or registrant ensures that the individuals involved are:

(a) Informed of the purpose of the planned operation;

(b) Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

(c) Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

(4) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses, as required by OAR 333-120-0630(2), during the lifetime of the individual for each individual involved.

(5) Subject to OAR 333-120-0100(2), the licensee or registrant does not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

(a) The numerical values of any of the dose limits in OAR 333-120-0100(1) in any year; and

(b) Five times the annual dose limits in OAR 333-120-0100(1) during the individual's lifetime.

(6) The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with OAR 333-120-0640 and submits a written report in accordance with OAR 333-120-0730.

(7) The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures is not to be considered in controlling future occupational dose of the individual under OAR 333-120-0100(1) but is to be included in evaluations required by OAR 333-120-0100(4) and (5).

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Occupational Dose Limits For Minors

333-120-0160 The annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adult workers in OAR 333-120-0100.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Dose To An Embryo/Fetus

333-120-0170 (1) The licensee or registrant shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, as defined in OAR 333-100-0005(30), does not exceed ~~[0.5 rem (5 mSv)]~~ **5 mSv (0.5 rem)**. Records shall be kept in accordance with OAR 333-120-0650.

NOTE: A woman is not a declared pregnant woman unless she says so in writing without being coerced. Unless a woman, who also is a radiation worker, has declared her pregnancy as required, she is to be treated as any other radiation worker. Pursuant to Title VII of the Civil Rights Act of 1964, as amended, no employer may restrict a fertile female's job because of concern for the health of the fetus that a woman might conceive. The court held that sex-specific fetal-protection policies are forbidden. Additionally, a female worker legally can declare pregnancy if she does not yet have documented medical proof. The document, "Instruction Concerning Prenatal Radiation Exposure", discusses declared pregnancy. It is available from ~~[the]~~ Oregon Health ~~[Division]~~ **Services**, Radiation Protection Services ~~[STE 705]~~ **Suite 260**, 800 N.E. Oregon St. ~~[#21]~~, Portland, OR 97202, phone 503/731-4014.

(2) The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman, as defined in OAR 333-100-0005(30), so as to satisfy the limit in ~~[section]~~ **333-120-0170**(1) ~~[of this rule]~~.

(3) The dose to an embryo/fetus shall be taken as the sum of:

(a) The deep-dose equivalent to the declared pregnant woman, as defined in OAR 333-100-0005(30); and

(b) The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman, as defined in OAR 333-100-0005(30).

(4) If the dose to the embryo/fetus is found to have exceeded ~~[0.5 rem (5 mSv)]~~ **4.5 mSv (0.45 rem)**~~[, or is within 0.05 rem (0.5 mSv) of this dose,]~~ by the time the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with ~~[section]~~ **333-120-0170**(1) ~~[of this rule]~~ if the additional dose to the embryo/fetus does not exceed ~~[0.05 rem (0.5 mSv)]~~ **0.5 mSv (0.05 rem)** during the remainder of the pregnancy.

Note: If a pregnant radiation worker declares in writing to the licensee that she is pregnant, the dose limit to the embryo/fetus is **5 mSv** (0.5 rem) during the entire pregnancy. The dose that is controlled is the dose to the embryo/fetus, not the dose to the woman, although for external penetrating radiation, the two are virtually synonymous.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95

Dose Limits For Individual Members of the Public

333-120-0180 (1) Each licensee or registrant shall conduct operations so that:

(a) The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed ~~[0.1 rem (1 mSv)]~~ **1 mSv (0.1 rem)** in a year, exclusive of the dose contribution from the licensee's disposal of radioactive material into sanitary sewerage in accordance with OAR 333-120-0520; and

(b) The dose in any unrestricted area from external sources does not exceed ~~[0.002 rem (0.02 mSv)]~~ **0.02 mSv (0.002 rem)** in any one hour.

(2) If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

(3) A licensee, registrant or applicant may apply for prior Agency authorization to operate up to an annual dose limit for an individual member of the public of ~~[0.5 rem (5 mSv)]~~ **5 mSv (0.5 rem)** . The licensee, registrant or applicant shall include the following information in this application:

(a) Demonstration of the need for and the expected duration of operations in excess of the limit in ~~[section]~~ **333-120-0180**(1) ~~[of this rule]~~; and

(b) The licensee's or registrant's program to assess and control dose within the ~~[0.5 rem (5 mSv)]~~ **5 mSv (0.5 rem)** annual limit; and

(c) The procedures to be followed to maintain the dose as low as is reasonably achievable.

(4) In addition to the requirements of this Division, a licensee or registrant subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR Part 190 shall comply with those standards.

(5) The Agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Compliance With Dose Limits For Individual Members of the Public

333-120-0190 (1) The licensee or registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in OAR 333-120-0180.

(2) A licensee or registrant shall show compliance with the annual dose limit in OAR 333-120-0180 by:

(a) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

(b) Demonstrating that:

(A) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in 10 CFR Part 20 Table 2 of Appendix B to 20.1001 to 20.2401; and

(B) If an individual were continually present in an unrestricted area, the dose from external sources would not exceed ~~*[0.002 rem (0.02 mSv)]*~~ **0.02 mSv (0.002 rem)** in an hour and ~~*[0.05 rem (0.5 mSv)]*~~ **0.5 mSv (0.05 rem)** in a year.

(3) Upon approval from the Agency, the licensee or registrant may adjust the effluent concentration values in 10 CFR Part 20 Table 2 of Appendix B to 20.1001 to 20.2401 for members of the public, to take into account the actual physical and chemical characteristics of the effluents (e.g., aerosol size distribution, solubility, density, radioactive decay equilibrium, chemical form).

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95

Surveys and Monitoring

General

333-120-0200 (1) Each licensee or registrant shall make or cause to be made, surveys that:

(a) ~~*[May be]*~~ **Are** necessary for the licensee or registrant to comply with the rules in this Division; and

(b) Are reasonable under the circumstances to evaluate:

(A) The **magnitude and** extent of radiation levels; and

(B) The ~~*[dose rate, kerma, or intensity of radiation or]*~~ concentrations or quantities of radioactive material; and

(C) The potential radiological hazards that could be present.

(2) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated ~~*[periodically]*~~ **at intervals not to exceed 12 months** for the radiation measured**, except when a more frequent interval is specified in another applicable Division or a license condition.**

(3) All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees or registrants to comply with OAR 333-120-0100, with

other applicable provisions of this Division or with conditions specified in a license must be processed and evaluated by a dosimetry processor:

(a) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(b) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(4) The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

Stat. Auth.: ORS 453.605 - 453.807

Stat. Imp.: ORS 453.615, 453.625, 453.635

Hist.: HD 15-1994, f. & ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95

Conditions Requiring Individual Monitoring of External and Internal Occupational Dose

333-120-0210 Each licensee or registrant shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this Division. As a minimum:

(1) Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

(a) Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in OAR 333-120-0100(1); and

(b) Minors and declared pregnant women likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in Division OAR 333-120-0160 or 333-120-0170; and

(c) Individuals entering a high or very high radiation area.

(d) Individuals working with medical fluoroscopic equipment.

(A) An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to 333-120-0170(1), shall be located under the protective apron at the waist.

(B) An individual monitoring device used for eye dose equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron.

(C) When only 1 individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to 333-120-100(3)(b)., it shall be located at the neck outside the protective apron. When a second individual monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.

(2) Each licensee or registrant shall monitor (OAR 333-120-0130) the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(a) Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) in 10 CFR Part 20 Table 1, Columns 1 and 2, of Appendix B to 20.1001 to 20.2401; and

(b) Minors and declared pregnant women likely to receive, in 1 year, a committed effective dose equivalent in excess of ~~*[0.05 rem (0.5 mSv)]*~~ **0.5 mSv (0.05 rem)**.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Location of Individual Monitoring Devices

333-120-0215 Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with 333-120-0210(1). wear individual monitoring devices as follows:

(1) An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar);

(2) An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman, pursuant to 333-120-0170(1), shall be located at the waist under any protective apron being worn by the woman;

(3) An individual monitoring device used for monitoring the eye dose equivalent, to demonstrate compliance with 333-120-0100(1)(b)(A), shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye;

(4) An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with 333-120-0100(1)(b)(B), shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

Control of Exposure From External Sources in Restricted Areas

Control of Access To High Radiation Areas

333-120-0220 (1) The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

(a) A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep-dose equivalent of ~~*[0.1 rem (1 mSv)]*~~ **1 mSv (0.1 rem)** in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates;

(b) A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(c) Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(2) In place of the controls required by ~~*[section]*~~ **333-120-0220**(1) ~~*[of this rule]*~~ for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(3) A licensee or registrant may apply to the Agency for approval of alternative methods for controlling access to high radiation areas.

(4) The licensee or registrant shall establish the controls required by ~~[sections]~~ **333-120-0220**(1) and **333-120-0220**(3) ~~[of this rule]~~ in a way that does not prevent individuals from leaving a high radiation area.

(5) Control is not required for each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation (49 CFR) provided that:

(a) The packages do not remain in the area longer than 3 days; and

(b) The dose rate at 1 meter from the external surface of any package does not exceed ~~[0.01 rem (0.1 mSv)]~~ **0.1 mSv (0.01 rem)** per hour.

(6) Control of entrance or access to rooms or other areas in hospitals is not required solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the limits established in this Division and to operate within the ALARA provisions of the licensee's or registrant's radiation protection program.

(7) The licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in 333-120-0220 if the licensee or registrant has met all the specific requirements for access and control specified in other applicable Divisions of Chapter 333, such as, 333-105 for industrial radiography, 333-106 for x-rays in the healing arts, and 333-109 for particle accelerators.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Control of Access To Very High Radiation Areas
333-120-0230

(1) In addition to the requirements in OAR 333-120-0220, the licensee or registrant shall institute additional measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rad (5 grays) or more in 1 hour at 1 meter from a radiation source or any surface through which the radiation penetrates.

(2) The licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in 333-120-0220 if the licensee or registrant has met all the specific requirements for access and control specified in other applicable Divisions of Chapter 333, such as, 333-105 for industrial radiography, 333-106 for x-rays in the healing arts, and 333-109 for particle accelerators.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Control of Access To Very High Radiation Areas - Irradiators
333-120-0240

This section applies to licensees or registrants with sources of radiation in non-self-shielded

irradiators. It does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

(1) Each area in which there may exist radiation levels in excess of ~~[500 rad (5 grays)]~~ **5 Gy (500 rad)** in 1 hour at 1 meter from a sealed radioactive source that is used to irradiate materials must meet the following requirements.

(a) Each entrance or access point must be equipped with entry control devices which:

(A) Function automatically to prevent any individual from inadvertently entering the area when very high radiation levels exist; and

(B) Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the sealed source, to be reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of ~~[0.1 rem (1 mSv)]~~ **1 mSv (0.1 rem)** in 1 hour; and

(C) Prevent operation of the source if the source would produce radiation levels in the area that could result in a deep-dose equivalent to an individual in excess of ~~[0.1 rem (1 mSv)]~~ **1 mSv (0.1 rem)** in 1 hour.

NOTE: This rule applies to radiation from accelerators, and byproduct, source, NARM, or special nuclear radioactive materials that are used in sealed sources in non-self-shielded irradiators. This rule does not apply to radioactive or x-ray sources that are used in teletherapy or medical accelerators, in radiography, or in completely self-shielded irradiators in which the source is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual. This rule also does not apply to sources from which the radiation is incidental to some other use.

(b) Additional control devices must be provided so that, upon failure of the entry control devices to function as required by ~~[section]~~ **333-120-0240**(1)(a) ~~[of this rule]~~:

(A) The radiation level within the area, from the sealed source, or radiation source is reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of ~~[0.1 rem (1 mSv)]~~ **1 mSv (0.1 rem)** in 1 hour; and

(B) Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

(c) The licensee or registrant shall provide control devices so that, upon failure or removal of physical radiation barriers other than the radiation source's shield or shielded storage container:

(A) The radiation level from the radiation source is reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of ~~[0.1 rem (1 mSv)]~~ **1 mSv (0.1 rem)** in 1 hour; and

(B) Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee/registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

(d) When the shield for the stored source is a liquid, the licensee or registrant shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

(e) Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of ~~[section]~~s **333-120-0240**(1)(c) and **333-120-0240**(d) ~~[of this rule]~~.

(f) Each area must be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source can be put into operation and in sufficient time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source from being put into operation.

(g) Each area must be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the radiation source.

(h) Each area must be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source, the radiation level from the source in the area is below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of ~~[0.1 rem (1 mSv)]~~ **1 mSv (0.1 rem)** in 1 hour.

(i) The entry control devices required in ~~[section]~~ **333-120-0240**(1)(a) ~~[of this rule]~~ must have been tested for proper functioning. Records of required testing shall be maintained in accordance with OAR 333-120-0680.

(A) Testing must be conducted prior to initial operation with the source of radiation on any day (unless operations were continued uninterrupted from the previous day); and

(B) Testing must be conducted prior to resumption of operation of the source of radiation after any unintended interruption; and

(C) The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

(j) The licensee or registrant may not conduct operations, other than those necessary to place the source in safe condition or to effect repairs on controls, unless control devices are functioning properly.

(k) Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, must be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for processed materials must be equipped to detect and signal the presence of any loose radiation sources that are carried toward such an exit and to automatically prevent loose radiation sources from being carried out of the area.

(2) Persons holding licenses or registrations or applicants for licenses or registrations for radiation sources that are within the purview of ~~[section]~~ **333-120-0240**(1) ~~[of this rule]~~ and that will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of ~~[section]~~ **333-120-0240**(1) ~~[of this rule]~~, such as those for the automatic control of radiation levels, may apply to the Agency for approval of the use of alternative safety measures. Any alternative safety measures must provide a degree of personnel protection at least equivalent to those specified in ~~[section]~~**333-120-0240** (1) ~~[of this rule]~~. At least one of the alternative measures must include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such radiation sources are used.

(3) The entry control devices required by ~~[section]~~s **333-120-0240**(1) and **333-120-0240**(2) ~~[of this rule]~~ must be established in such a way that no individual will be prevented from leaving the area.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.625, 453.635, 453.695
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Storage and Control of Licensed Material

Security of Stored Material

333-120-0250

(1) The licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

(2) The registrant shall secure registered radiation machines from unauthorized removal.

(3) The registrant shall use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Control of Material Not In Storage

333-120-0260 The licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas

Use of Process or Other Engineering Controls

333-120-0300 The licensee shall use, to the extent practicable, process or other engineering controls (e.g., containment or ventilation) to control the concentrations of radioactive material in air.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Use of Other Controls

333-120-0310 When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

(1) Control of access;
(2) Limitation of exposure times;
(3) Use of respiratory protection equipment; or
(4) Other controls.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Use of Individual Respiratory Protection Equipment

333-120-0320 (1) If the licensee uses respiratory protection equipment to limit intakes pursuant to OAR 333-120-0310:

(a) The licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health/Mine Safety and Health Administration (NIOSH/MSHA).

(b) ~~*[If the licensee wishes to]*~~ **The licensee may** use equipment that has not been tested or certified by NIOSH/MSHA, has not had certification extended by NIOSH/MSHA, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

(c) The licensee shall implement and maintain a respiratory protection program that includes:

(A) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures; and

(B) Surveys and bioassays, as appropriate, to evaluate actual intakes; and

(C) Testing of respirators for operability immediately prior to each use; and

(D) Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and

(E) Determination by a physician prior to initial fitting of respirators, and at least every 12 months thereafter, that the individual user is physically able to use the respiratory protection equipment.

(d) The licensee shall issue a written policy statement on respirator usage covering:

(A) The use of process or other engineering controls, instead of respirators; and

(B) The routine, nonroutine, and emergency use of respirators; and

(C) The periods of respirator use and relief from respirator use.

(e) The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(f) The licensee shall use equipment within limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities (such as adequate skin protection) when needed.

(2) In estimating exposure of individuals to airborne radioactive materials, the licensee or registrant may make allowance for respiratory protection equipment used to limit intakes pursuant to OAR 333-120-0310, provided that the following conditions, in addition to those in ~~*[section]*~~ **333-120-0320**(1) ~~*[of this rule]*~~, are satisfied:

(a) The licensee selects respiratory protection equipment that provides a protection factor (10 CFR Part 20 Appendix A to 20.1001 to 20.2401) greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in 10 CFR Part 20 Table 1, Column 3 of Appendix B to 20.1001 to 20.2401. If the selection of a respiratory

protection device with a protection factor greater than the peak concentration is inconsistent with the goal specified in OAR 333-120-0310 of keeping the total effective dose equivalent ALARA, the licensee or registrant may select respiratory protection equipment with a lower protection factor only if such a selection would result in keeping the total effective dose equivalent ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than estimated, the corrected value must be used; if the exposure is later found to be less than estimated, the corrected value may be used; and

(b) The licensee shall obtain authorization from the Agency before assigning respiratory protection factors in excess of those specified in 10 CFR Part 20 Appendix A to 20.1001 to 20.2401. The Agency may authorize a licensee to use higher protection factors on receipt of an application that:

(A) Describes the situation for which a need exists for higher protection factors; and

(B) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

(3) The licensee shall use as emergency devices only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by NIOSH/MSHA.

(4) The licensee shall notify the Agency, in writing, at least 30 days before the date that respiratory protection equipment is first used under the provisions of either ~~*[section]*~~s **333-120-0320**(1) or **333-120-0320**(2) ~~*[of this rule]*~~.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Further Restrictions On the Use of Respiratory Protection Equipment

333-120-0330 The Agency may impose restrictions in addition to those in OAR 333-120-0310 and 333-120-0320, and 10 CFR Part 20 Appendix A to 20.1001 to 20.2401 to:

(1) Ensure that the respiratory protection program of the licensee is adequate to limit exposures of individuals to airborne radioactive materials; and

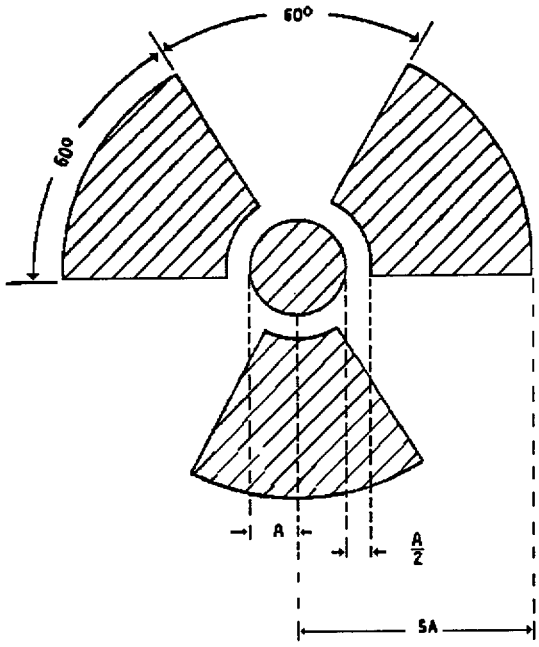
(2) Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Precautionary Procedures

Caution Signs

333-120-0400 (1) Standard radiation symbol: Unless otherwise authorized by the Agency, the symbol prescribed by this Division shall use the colors magenta, purple, or black on yellow background. The symbol prescribed by this Division is the three-bladed design:



RADIATION SYMBOL

(a) Cross-hatched area is to be magenta, or purple, or black; and

(b) The background is to be yellow.

(2) Exception To Color Requirements For Standard Radiation Symbol. Notwithstanding the requirements of ~~[section]~~ **333-120-0400**(1) ~~[of this rule]~~, licensees and registrants are authorized to label sources, source holders, or device components containing sources of licensed materials that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

(3) Additional Information On Signs and Labels. In addition to the contents of signs and labels prescribed in this Division, the licensee may provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.625, 453.635, 453.695
Hist.: HD 15-1994, f. & ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94

Posting Requirements

333-120-0410 (1) Posting of radiation areas: The licensee shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

(2) Posting of high radiation areas: The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

(3) Posting of very high radiation areas: The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

(4) Posting of airborne radioactivity areas: The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

(5) Posting of areas or rooms in which licensed material is used or stored: The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in 10 CFR Part 20 Appendix C to 20.1001 to 20.2401 with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94

Exceptions To Posting Requirements

333-120-0420 (1) A licensee is not required to post caution signs in areas or rooms containing radioactive materials for periods of less than 8 hours, if each of the following conditions is met:

(a) The materials are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to radiation or radioactive materials in excess of the limits established in this Division; and

(b) The area or room is subject to the licensee's control.

(2) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to OAR 333-120-0410 provided that:

(a) A patient being treated with a permanent implant or therapeutic radiopharmaceutical could be released from confinement pursuant to 333-116-0260 and 333-116-0265 of this Chapter;

~~*[(a) The patient is being treated with sealed sources or has been treated with unsealed radioactive material in quantities less than [30 millicuries (110 MBq)] 110 MBq (30 millicuries), or the measured dose rate at 1 meter from the patient is less than [0.005 rem (0.05 mSv)] 0.05 mSv (0.005 rem) per hour;]*~~ and

(b) There are personnel in attendance who will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the limits established in this Division and to operate within the ALARA provisions of the licensee's radiation protection program.

(3) ~~*[A room or area]*~~ **A caution sign** is not required to be posted **in a room or area containing** ~~*[with a caution sign because of the presence of]*~~ a sealed source, provided the radiation level at 30 centimeters from the surface of the source container or housing does not exceed~~*[0.005 rem (0.05 mSv)]*~~ **0.05 mSv (0.005 rem)** per hour.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Labeling Containers

333-120-0430 (1) The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(2) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

(3) Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.625, 453.635
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Exemptions To Labeling Requirements

333-120-0440 A licensee is not required to label:

(1) Containers holding licensed material in quantities less than the quantities listed in 10 CFR Part 20 Appendix C to 20.1001 to 20.2401; or

(2) Containers holding licensed material in concentrations less than those specified in 10 CFR Part 20 Table 3 of Appendix B to 20.1001 to 20.2401; or

(3) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this Division; or

(4) Containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation (49 CFR); or

NOTE: Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation (DOT) if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by DOT regulations 49 CFR 173.403(m) and (w) and 173.421-424.

(5) Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record (examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells). The record must be retained as long as the containers are in use for the purpose indicated on the record; or

(6) Installed manufacturing or process equipment, such as reactor components, piping, and tanks.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.625, 453.635, 453.665
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Procedures For Receiving and Opening Packages

333-120-0450 (1) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in ~~*[10 CFR Part 71.4 and 10 CFR Part 71 Appendix A]*~~ **49 CFR 173.435 Table of A1 and A2 Values for Radionuclides**, shall make arrangements to receive:

(a) The package when the carrier offers it for delivery; or

(b) Notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

(2) Each licensee shall:

(a) Monitor the external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in ~~*[10 CFR 71.4]*~~ **333-118-020**;

(b) Monitor the external surfaces of a labeled package for radiation levels~~*[unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Appendix A to 10 CFR Part 71]*~~; and

Note: Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 and 172.436-440

(c) Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

(3) The licensee shall perform the monitoring required by ~~*[section]*~~ **333-120-0450**(2) ~~*[of this rule]*~~ as soon as practicable after receipt of the package, but not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

(4) The licensee shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the Agency when:

(a) Removable radioactive surface contamination exceeds the limits of ~~*[10 CFR Part 71.87(i) or]*~~ OAR 333-118-0150 Table 3;

(b) External radiation levels exceed the limits of ~~*[10 CFR Part 71.47 or]*~~ OAR 333-118-0150(11).

(5) Each licensee shall:

(a) Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

(b) Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

(6) Licensees transferring special form sources in licensee-owned or licensee-operated vehicles to and from a work site are exempt from the contamination monitoring requirements of ~~*[section]*~~ (2) ~~*[of this rule]*~~, but are not exempt from the survey requirement in ~~*[section]*~~**333-120-0450** (2) ~~*[of this rule]*~~ for measuring radiation levels, which is required to ensure that the source is still properly lodged in its shield.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.625, 453.635
Hist: HD 15-1994, f. & ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95

Testing for Leakage or Contamination of Sealed Sources

333-120-0460 (1) The licensee in possession of any sealed source shall assure that:

(a) Each sealed source, except as specified in ~~[section]~~] **333-120-0460**(2) ~~[of this rule]~~, is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee; and

(b) Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission; and

(c) Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission; and

(d) For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee shall assure that the sealed source is tested for leakage or contamination before further use; and

(e) Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium-226, shall be capable of detecting the presence of 185 Bq (0.005 μCi) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position; and

(f) The test for leakage for brachytherapy sources manufactured to contain radium-226 shall be capable of detecting an absolute leakage rate of 37 Bq (0.001 μCi) of radon-222 in a 24 hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time; and

(g) Tests for contamination from radium-226 daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 185 Bq (0.005 μCi) of a radium daughter which has a half-life greater than 4 days.

(2) A licensee need not perform test for leakage or contamination on the following sealed sources:

(a) Sealed sources containing only radioactive material with a half-life of less than 30 days; or

(b) Sealed sources containing only radioactive material as a gas; or

(c) Sealed sources containing 3.7 MBq (100 μCi) or less of beta or photon-emitting material or 370 kBq (10 μCi) or less of alpha-emitting material; or

(d) Sealed sources containing only hydrogen-3; or

(e) Seeds of iridium-192 encased in nylon ribbon; or

(f) Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used, and identified as in storage. The licensee shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for

leakage or contamination within 6 months before the date of use or transfer.

(3) Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.

(4) Test results shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency.

(5) The following shall be considered evidence that a sealed source is leaking:

(a) The presence of 185 Bq (0.005 μCi) or more of removable contamination on any test sample; or

(b) Leakage of 37 Bq (0.001 μCi) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium-226; or

(c) The presence of removable contamination resulting from the decay of 185 Bq (0.005 μCi) or more of radium-226.

(6) The licensee shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this Division.

(7) Reports of test results for leaking or contaminated sealed sources shall be made pursuant to OAR 333-120-0720(1)(e).

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.625, 453.635
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Waste Disposal

General Requirements

333-120-0500 (1) A licensee shall dispose of licensed radioactive material only:

(a) By transfer to an authorized recipient as provided in OAR 333-102-0330; or

(b) By decay in storage; or

(c) By release in effluents within the limits in OAR 333-120-0520; or

(d) As authorized under OAR 333-120-0520, 333-120-0530, 333-120-0540.

(2) A person must be specifically licensed to receive waste containing licensed material from other persons for:

(a) Treatment prior to disposal; or

(b) Treatment or disposal by incineration; or

(c) Decay in storage; or

(d) Disposal at a land disposal facility licensed under 10 CFR Part 61 (U.S. Nuclear Regulatory Commission) or equivalent Agreement State regulations; or

(e) Storage until transferred to a storage or disposal facility authorized to receive the waste.

(3) As authorized under the provisions of Oregon Revised Statues.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.655
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Method For Obtaining Approval of Proposed Disposal Procedures

333-120-0510 A licensee or applicant for a license may apply to the Agency for approval of proposed procedures, not otherwise authorized in the rules of this Division, to dispose of licensed material generated in the licensee's activities. Each application shall include:

(1) A description of the waste containing licensed material to be disposed of, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal; and

(2) An analysis and evaluation of pertinent information on the nature of the environment; and

(3) The nature and location of other potentially affected licensed and unlicensed facilities; and

(4) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this Division.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.655
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Disposal By Release Into Sanitary Sewerage

333-120-0520 (1) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

(a) The material is readily soluble (or is readily dispersible biological material) in water; and

(b) The quantity of licensed or other radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in 10 CFR Part 20 Table 3 of Appendix B to 20.1001 to 20.2401; and

(c) If more than one radionuclide is released, the following conditions also must be satisfied:

(A) The licensee shall determine the fraction of the limit in 10 CFR Part 20 Table 3 of Appendix B to 20.1001 to 20.2401 represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in 10 CFR Part 20 Table 3 of Appendix B to 20.1001 to 20.2401; and

(B) The sum of the fractions for each radionuclide required by ~~[section]~~ **333-120-0520**(1)(c)(A) ~~[of this rule]~~ does not exceed unity; and

(d) The total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage system in a year does not exceed ~~[5 curies (185 GBq)]~~ **185 GBq (5 Curies)** of hydrogen-3, ~~[1 curie (37 GBq)]~~ **37 GBq (1 Curie)** of carbon-14, and ~~[1 curie (37 GBq)]~~ **37 GBq (1 Curie)** of all other radioactive materials combined.

(2) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material is not subject to the limitations contained in ~~[section]~~ **333-120-0520**(1) ~~[of this rule]~~.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.655
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Treatment or Disposal By Incineration

333-120-0530 A licensee may treat or dispose of licensed material by incineration only in the amounts and forms specified in OAR 333-120-0540 or as specifically approved by the Agency pursuant to OAR 333-120-0510.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.655
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Disposal of Specific Wastes

333-120-0540 (1) A licensee may dispose of the following licensed material as if it were not radioactive:

(a) ~~*[0.05 microcurie (1.85 kBq)]*~~ **1.85 kBq (0.05 μCi)**, or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

(b) ~~*[0.05 microcurie (1.85 kBq)]*~~ **1.85 kBq (0.05 μCi)**, or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

(2) A licensee may not dispose of tissue under ~~*[section]*~~ **333-120-0540**(1)(b) ~~*[of this rule]*~~ in a manner that would permit its use either as food for humans or as animal feed.

(3) The licensee shall maintain records in accordance with OAR 333-120-0670.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.655, 453.665
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Transfer For Disposal and Manifests

333-120-0550 (1) The requirements ~~*[of this rule]*~~ **333-120-0550** and 10 CFR Part 20 Appendix F to 20.1001 to 20.2401 are designed to control transfers of low-level radioactive waste intended for disposal at a land disposal facility (as defined in 10 CFR Part 61), establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.

(2) Each shipment of radioactive waste intended for disposal at a licensed land disposal facility must be accompanied by a shipment manifest as specified in 10 CFR Part 20 section I of Appendix F to 20.1001 to 20.2401.

(3) Each shipment manifest must include a certification by the waste generator as specified in 10 CFR Part 20 section II of Appendix F to 20.1001 to 20.2401.

(4) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in 10 CFR Part 20 section III of Appendix F to 20.1001 to 20.2401.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.655
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Compliance With Environmental and Health Protection Regulations

333-120-0560 Nothing in ~~[this]~~ **Chapter 333** Divisions **100 through 121** relieves the licensee from complying with other applicable Federal, State, and local regulations or rules governing any other toxic or hazardous properties of materials that may be disposed of under ~~[this]~~ Division **333-120.**

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Records

General Provisions

333-120-0600 (1) Each licensee shall use the **SI units Becquerel, Gray, Sievert and coulomb per kilogram, or the special** units~~[.]~~ curie, rad, rem, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Division.

(2) The licensee shall make a clear distinction among the quantities entered on the records required by this Division (e.g., total effective dose equivalent, shallow-dose equivalent, eye dose equivalent, deep-dose equivalent, committed effective dose equivalent).

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635
Hist.: HD 15-1994, f. & ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94

Records of Radiation Protection Programs

333-120-0610 (1) Each licensee shall maintain records of the radiation protection program, including:

(a) The provisions of the program; and

(b) Audits and other reviews of program content and implementation.

(2) The licensee shall retain the records required by ~~[section]~~ **333-120-0610**(1)(a) ~~[of this rule]~~ until the Agency terminates each pertinent license or registration requiring the record. The licensee shall retain the records required by ~~[section]~~ **333-120-0610**(1)(b) ~~[of this rule]~~ for five years or until inspected by the Agency.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.625, 453.635
Hist.: HD 15-1994, f. & ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94

Records of Surveys and Leak Tests

333-120-0620 (1) Each licensee shall maintain records showing the results of surveys, sealed source leak tests, and calibrations required by OAR 333-120-0200, 333-120-0460 and 333-120-0450(2). The licensee shall retain these records for five years or until inspected by the Agency.

(2) The licensee shall retain each of the following records until the Agency terminates each

pertinent license or registration requiring the record:

(a) Records of the results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

(b) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

(c) Records showing the results of air sampling, surveys, and bioassays required pursuant to OAR 333-120-0320(1)(c)(A) and (B); and

(d) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

(3) Records of Tests for Leakage or Contamination of Sealed Sources. Records of tests for leakage or contamination of sealed sources required by OAR 333-120-0460, shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency for five years or until inspected by the agency.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94

Determination of Prior Occupational Dose

333-120-0630 (1) For each individual who may enter the licensee's restricted or controlled area and is likely to receive, in a year, an occupational dose requiring monitoring pursuant to OAR 333-120-0210, the licensee shall ~~[:~~

~~*(a) D]*~~determine the occupational radiation dose received during the current year~~[; and~~

~~*(b) Attempt to obtain the records of lifetime cumulative occupational radiation dose]*~~.

(2) Prior to permitting an individual to participate in a planned special exposure, the licensee shall determine:

(a) The internal and external doses from all previous planned special exposures; and

(b) All doses in excess of the limits (including doses received during accidents and emergencies) received during the lifetime of the individual.

(3) In complying with the requirements of ~~[section]~~ **333-120-0630**(1) ~~[of this rule]~~, a licensee may:

(a) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual may have received during the current year; or

(b) Accept, as the record of lifetime cumulative radiation dose, an up-to-date Agency Form Y, or equivalent, signed by the individual and counter-signed by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee); and

(c) Obtain reports of the individual's dose equivalent(s) from the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee) by telephone, telegram, electronic media, or letter. The licensee shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(4) The licensee or registrant shall record the exposure history, as required by ~~[section]~~ **333-120-**

0630(1) ~~*[of this rule]*~~, on Agency Form Y, or other clear and legible record, of all the information required on Form Y. The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed by the individual who received the exposure. For each period for which the licensee obtains reports, the licensee shall use the dose shown in the report in preparing Agency Form Y. For any period in which the licensee does not obtain a report, the licensee shall place a notation on Agency Form Y indicating the periods of time for which data are not available.

Note: Licensees are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed under OAR 333-104 (repealed 1994). Further, occupational exposure histories obtained and recorded on Agency Form Y before January 1, 1994, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

(5) If the licensee is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee shall assume:

(a) In establishing administrative controls under OAR 333-120-0100(6) for the current year, that the allowable dose limit for the individual is reduced by 1.25 rem (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

(b) That the individual is not available for planned special exposures.

(6) The licensee shall retain the records on Agency Form Y or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee shall retain records used in preparing Agency Form Y for five years or until inspected by the Agency.

(7) Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94

Records of Planned Special Exposures

333-120-0640 (1) For each use of the provisions of OAR 333-120-0150 for planned special exposures, the licensee shall maintain records that describe:

(a) The exceptional circumstances requiring the use of a planned special exposure; and

(b) The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

(c) What actions were necessary; and

(d) Why the actions were necessary; and

(e) How doses were maintained ALARA; and

(f) What individual and collective doses were expected to result, and the doses actually received in the planned special exposure.

(2) The licensee shall retain the records until the Agency terminates each pertinent license or registration requiring these records.

(3)Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the

Agency for transfer to the Agency.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94

Records of Individual Monitoring Results

333-120-0650 (1) Recordkeeping Requirement. Each licensee shall maintain records of doses received by all individuals for whom monitoring was required pursuant to OAR 333-120-0210 and records of doses received during planned special exposures, accidents, and emergency conditions. These records must include, when applicable:

(a) The deep-dose equivalent to the whole body, eye dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities; and

(b) The estimated intake or body burden of radionuclides (OAR 333-120-0110); and

(c) The committed effective dose equivalent assigned to the intake or body burden of radionuclides; and

(d) The specific information used to calculate the committed effective dose equivalent pursuant to OAR 333-120-0130(3); and

(e) The total effective dose equivalent when required by OAR 333-120-0110; and

(f) The total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose.

Note: Assessments of dose equivalent and records made using units in effect before the licensee's adoption of this Division need not be changed.

(2) Recordkeeping Frequency: The licensee shall make entries of the records specified in ~~[section]~~ **333-120-0650**(1) ~~[of this rule]~~ at least annually.

(3) Recordkeeping Format. The licensee shall maintain the records specified in ~~[section]~~ **333-120-0650**(1) ~~[of this rule]~~ on Agency Form Z, in accordance with the instructions for Agency Form Z, or in clear and legible records containing all the information required by Agency Form Z.

(4) Privacy Protection. The records required under this rule are protected from public disclosure because of their personal privacy nature. These records are protected and if transferred to the Agency, are protected under ORS 192.

(5) The licensee shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman, as defined in OAR 333-100-0005(30). The declaration of pregnancy shall also be kept on file, but may be maintained separately from the dose records.

(6) The licensee shall retain each required form or record until the Agency authorizes disposition.

Note: The following information is required on Form Z, Occupational Exposure Record for a Monitoring Period: Name; identification number and type (Social Security Number (SSN), Passport Number (PPN), Canadian Social Insurance Number (CSI), Work Permit Number (WPN), INDEX Identification Number (IND), or Other (OTH)); sex; date of birth; monitoring period; licensee name; license or registration number; is dose is official record or estimate; if dose is routine or planned special exposure; intake, list radionuclide, class, mode, total intake (μCi); external dose(s), DDE (Deep Dose Equivalent in rems), LDE (Lens Dose Equivalent in rems), SDE(WB) (Shallow Dose Equivalent Whole Body in rems), SED(ME) (Shallow Dose Equivalent Maximum Extremity in rems), CEDE (Committed Effective Dose Equivalent in rems), CDE (Committed Dose Equivalent in rems), TEDE (Total Effective Dose Equivalent in

rems) and TODE Total Organ Dose Equivalent in rems).

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & ef. 5-6-94; HD 24-1994, f. & ef. 9-6-94; HD 1-1995, f. & cert. ef. 4-26-95

Records of Dose To Individual Members of the Public

333-120-0660 (1) Each licensee shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public (OAR 333-120-0180).

(2) The licensee shall retain the records required by ~~[section]~~ **333-120-0660**(1) ~~[of this rule]~~ until the Agency terminates each pertinent licensee requiring the record.

Note: The following information is required on Form Z, Occupational Exposure Record for a Monitoring Period: Name; identification number and type of number, such as SSN; sex; date of birth; monitoring period; licensee name; license or registration number; if dose is official record or estimate; if dose is routine or planned special exposure; intakes, list radionuclide, class, mode, and total intake (μCi); external dose(s), DDE, LDE, SDE(WB), SDE(ME), CEDE, CDE, TEDE and TODE; signature of monitored individual and date signed; certifying organization and signature.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & ef. 5-6-94; HD 24-1994, f. & ef. 9-6-94; HD 1-1995, f. & cert. ef. 4-26-95

Records of Waste Disposal

333-120-0670 (1) Each licensee shall maintain records of the disposal of licensed materials made under Divisions OAR 333-120-0510, 333-120-0520, 333-120-0530, 333-120-0540, 10 CFR Part 61, and disposal by burial in soil, including burials authorized before January 28, 1981.

(2) The licensee shall retain the records required by ~~[section]~~ **333-120-0670**(1) ~~[of this rule]~~ until the Agency terminates each pertinent license requiring the record.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.655, 453.695
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Records of Testing Entry Control Devices for Very High Radiation Areas

333-120-0680 (1) Each licensee shall maintain records of tests made under OAR 333-120-0240(1)(i) on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

(2) The licensee shall retain the records required by ~~[section]~~ **333-120-0680**(1) ~~[of this rule]~~ for five years or until inspected by the Agency.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.625, 453.635, 453.695
Hist.: HD 15-1994, f. & ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94

Form of Records

333-120-0690 Each record required by this Division must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94

Reports

Reports of Theft or Loss of Licensed Material

333-120-0700 (1) Telephone reports: Each licensee **or registrant** shall report by telephone to the Agency as follows:

(a) Immediately after its occurrence becomes known to the licensee **or registrant**, any lost, stolen, or missing **licensed or registered** device, or licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in 10 CFR Part 20 Appendix C to 20.1001 to 20.2401, under such circumstances that it appears to the licensee **or registrant** that an exposure could result to persons in unrestricted areas; or

(b) Within 30 days after the occurrence of any lost, stolen, or missing **licensed or registered** device, or licensed radioactive material, becomes known to the licensee **or registrant**, all licensed **or registered** material in a quantity greater than 10 times the quantity specified in 10 CFR Part 20 Appendix C to 20.1001 to 20.2401 that is still missing at this time.

(2) Written Reports: Each licensee **or registrant** required to make a report under ~~*[section]*~~ **333-120-0700**(1) ~~*[of this rule]*~~ shall make a written report to the Agency, within 30 days after making the telephone report, setting forth the following information:

(a) A description of the device or licensed material involved, including kind, quantity, and chemical and physical form; and

(b) A description of the circumstances under which the loss or theft occurred; and

(c) A statement of disposition, or probable disposition, of the device or licensed material involved; and

(d) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

(e) Actions that have been taken, or will be taken, to recover the material; and

(f) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of a device or licensed material; and

(g) Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

(3) The licensee shall prepare any report filed with the Agency pursuant to ~~[this section]~~ **333-120-0700** so that names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.750
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Notification of Incidents

333-120-0710 (1) Immediate notification: Notwithstanding any other requirements for notification, each licensee shall immediately report any event involving a device or licensed radioactive material possessed by the licensee that may have caused or threatens to cause any of the following conditions:

(a) An individual to receive:

(A) A total effective dose equivalent of ~~[25 rem (0.25 Sv)]~~ **0.25 Sv (25 rem)** or more; or

(B) An eye dose equivalent of ~~[75 rem (0.75 Sv)]~~ **0.75 Sv (75 rem)** or more; or

(C) A shallow-dose equivalent to the skin or extremities of ~~[250 rad (2.5 Gy)]~~ **2.5 Gy (250 rad)** or more; or

(b) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational annual limit on intake (the provisions of ~~[this section]~~ **333-120-0710** do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures)~~[; or~~

~~(c) A loss of one working week or more of the operation of any facilities affected; or~~

~~(d) Damage to property in excess of $200,000].~~

(2) Twenty-four hour notification: Each licensee or registrant shall, within 24 hours of discovery of the event, report any event involving loss of control of a device or licensed material possessed by the licensee that may have caused, or threatens to cause, any of the following conditions:

(a) An individual to receive in a period of 24 hours:

(A) A total effective dose equivalent exceeding ~~[5 rem (0.05 Sv)]~~ **0.05 Sv (5 rem)**; or

(B) An eye dose equivalent exceeding ~~[15 rem (0.15 Sv)]~~ **0.15 Sv (15 rem)**; or

(C) A shallow-dose equivalent to the skin or extremities exceeding ~~[50 rem (0.5 Sv)]~~ **0.15 Sv (15 rem)**; or

(b) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit on intake (the provisions of ~~[this section]~~ **333-120-0710** do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures)~~[; or~~

~~(c) A loss of 1 day or more of the operation of any facilities affected; or~~

~~(d) Damage to property in excess of $2,000].~~

(3) The licensee shall prepare any report filed with the Agency pursuant to ~~[this section]~~ **333-120-0710** so that names of individuals who have received exposure to radiation or radioactive material are stated in a separate and detachable part of the report.

(4) Reports made by licensees in response to the requirements of ~~[this section]~~ **333-120-0710** must be made as follows:

(a) Licensees having an installed Emergency Notification System shall make the reports required by paragraphs (a) and (b) of ~~[this section]~~ **333-120-0710** to the NRC Operations Center in accordance with 10 CFR 50.72; and

(b) All other licensees shall make the reports required by paragraphs (a) and (b) of ~~[this section]~~ **333-120-0710** by telephone to the NRC Operations Center and by telegram, mailgram, or facsimile to the Administrator of the appropriate NRC Regional Office listed in appendix D to part 20.1001-20.2401.

(5) The provisions of ~~[this section]~~ **333-120-0710** do not include doses that result from planned special exposures, that are within the limits for planned special exposures, and that are reported under OAR 333-120-0730.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.750
Hist.: HD 15-1994, f. & cert. ef. 5-6-94

Reports of Exposures, Radiation Levels, Leak Tests, and Concentrations of Radioactive Material Exceeding the Limits

333-120-0720 (1) Reportable events: In addition to the notification required by OAR 333-120-0710, each licensee shall submit a written report within 30 days after learning of any of the following occurrences:

(a) Any incident for which notification is required by OAR 333-120-0710; or

(b) Doses in excess of any of the following:

(A) The occupational dose limits for adults in OAR 333-120-0100; or

(B) The occupational dose limits for a minor in OAR 333-120-0160; or

(C) The limits for an embryo/fetus of a declared pregnant woman (as defined in OAR 333-100-0005(30)) in OAR 333-120-0170; or

(D) The limits for an individual member of the public in OAR 333-120-0180; or

(E) Any applicable limit in the license; or

(c) Levels of radiation or concentrations of radioactive material in:

(A) A restricted area in excess of any applicable limit in the license; or

(B) An unrestricted area in excess of 10 times any applicable limit set forth in this Division or in the license (whether or not involving exposure of any individual in excess of the limits in OAR 333-120-0180); or

(d) For licensee subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR Part 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

(e) Leaking or contaminated sealed sources in excess of limits in OAR 333-120-0460, shall be reported within five days to the Agency describing the equipment involved, the test results and the corrective action taken.

(f) Erroneous overexposure dosimetry reports that resulted from non-personnel exposures;

(2) Contents of reports: Each report required by ~~[section]~~ **333-120-0720**(1) ~~[of this rule]~~ must

describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(a) Estimates of each individual's dose; and

(b) The levels of radiation and concentrations of radioactive material involved; and

(c) The cause of the elevated exposures, dose rates, or concentrations; and

(d) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, generally applicable environmental standards, and associated license conditions; and

(e) For each individual exposed: the name, Social Security account number, and date of birth. The report must be prepared so that this information is stated in a separate and detachable part of the report.

Note: With respect to the limit for the embryo/fetus (OAR 333-120-0170) the identifiers should be those of the declared pregnant woman, as defined in OAR 333-100-0005(30).

(3) All licensees who make reports under ~~*[section]*~~ **333-120-0720**(1) ~~*[of this rule]*~~ shall submit the report in writing to the Agency.

(4) The Agency shall prohibit the removal or expungement of any permanent dosimetry report submitted to the licensee or registrant. Evaluated erroneous personnel dose record changes to licensee or registrant records shall be recorded only on Form Z and retained by the licensee or registrant.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95

Reports of Planned Special Exposures and Individual Monitoring

333-120-0730 (1) The licensee shall submit a written report to the Agency within 30 days following any planned special exposure conducted in accordance with OAR 333-120-0150 informing the Agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by OAR 333-120-0640.

(2) The following licensees shall submit a written report to the Agency on or before April 30 of each year, documenting results of individual monitoring carried out by the licensee for each individual for whom monitoring was required pursuant to OAR 333-120-0210 during that year.

(a) Licensees authorized to possess or use radioactive material for purposes of radiography pursuant to Division 102 and 105 of these rules; or

(b) Licensees who receive radioactive waste from other persons for disposal pursuant to 10 CFR Part 61; or

(c) Licensees who possess or use at any time, for processing or manufacturing for distribution pursuant to Division 102 or 116 these rules, radioactive material in quantities exceeding any one of the following quantities:

	Quantity of Radionuclide[a] in curies
Cesium-137	1
Cobalt-60	1
Gold-19	100

Iodine-131	1
Iridium-192	10
Krypton-85	1,000
Promethium-147	10
Technetium-99m	1,000

[a] The Agency may require as a license condition, or by rule, regulation, or order pursuant to OAR 333-100-0030, reports from licensees who are licensed to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

NOTE: The licensee may include additional data for individuals for whom monitoring was provided but not required. The licensee shall use Oregon Form Z or electronic media containing all the information required by Oregon Form Z.

Stat. Auth.: ORS 453.605 - 453.807
Stat. Imp.: ORS 453.615, 453.635, 453.695
Hist.: HD 15-1994, f. & ef. 5-6-94; HD 24-1994, f. & ef. 9-6-94; HD 1-1995, f. & cert. ef. 4-26-95

LIST OF ELEMENTS

Name	Symbol	Atomic Number
Actinium	Ac	89
Aluminum	Al	13
Americium	Am	95
Antimony	Sb	51
Argon	Ar	18
Arsenic	As	33
Astatine	At	85
Barium	Ba	56
Berkelium	Bk	97
Beryllium	Be	4
Bismuth	Bi	83
Bromine	Br	35
Cadmium	Cd	48
Calcium	Ca	20
Californium	Cf	98
Carbon	C	6
Cerium	Ce	58
Cesium	Cs	55
Chlorine	Cl	17
Chromium	Cr	24
Cobalt	Co	27
Copper	Cu	29
Curium	Cm	96
Dysprosium	Dy	66
Einsteinium	Es	99
Erbium	Er	68
Europium	Eu	63
Fermium	Fm	100
Fluorine	F	9
Francium	Fr	87
Gadolinium	Gd	64
Gallium	Ga	31
Germanium	Ge	32
Gold	Au	79
Hafnium	Hf	72
Holmium	Ho	67
Hydrogen	H	1
Indium	In	49
Iodine	I	53
Iridium	Ir	77
Iron	Fe	26
Krypton	Kr	36
Lanthanum	La	57
Lead	Pb	82
Lutetium	Lu	71
Magnesium	Mg	12
Manganese	Mn	25
Mendelevium	Md	101
Mercury	Hg	80
Molybdenum	Mo	42
Neodymium	Nd	60
Neptunium	Np	93
Nickel	Ni	28
Niobium	Nb	41
Osmium	Os	76
Palladium	Pd	46
Phosphorus	P	15
Platinum	Pt	78
Plutonium	Pu	94
Polonium	Po	84
Potassium	K	19
Praseodymium	Pr	59
Promethium	Pm	61
Protactinium	Pa	91
Radium	Ra	88
Radon	Rn	86
Rhenium	Re	75
Rhodium	Rh	45
Rubidium	Rb	37
Ruthenium	Ru	44
Samarium	Sm	62
Scandium	Sc	21
Selenium	Se	34
Silicon	Si	14
Silver	Ag	47
Sodium	Na	11
Strontium	Sr	38
Sulfur	S	16
Tantalum	Ta	73
Technetium	Tc	43
Tellurium	Te	52
Terbium	Tb	65
Thallium	Tl	81
Thorium	Th	90
Thulium	Tm	69
Tin	Sn	50
Titanium	Ti	22
Tungsten	W	74
Uranium	U	92
Vanadium	V	23
Xenon	Xe	54
Ytterbium	Yb	70
Yttrium	Y	39
Zinc	Zn	30
Zirconium	Zr	40

DIVISION 121
LICENSING AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

General Provisions

Purpose and Scope

333-121-0001

(1) This Division contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive material in irradiators used to irradiate objects or materials using gamma radiation. This Division also contains radiation safety requirements for operating irradiators. The requirements of this Division are in addition to other requirements of these regulations. In particular, the provisions of Divisions 333-100, 333-102, 333-120, and 333-111 of these regulations apply to applications and licenses subject to this Division. Nothing in this Division relieves the licensee from complying with other applicable federal, state and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

(2) The regulations in this Division apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this Division.

(3) The regulations in this Division do not apply to self-contained dry-source-storage irradiators in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel; medical radiology or teletherapy; radiography for the irradiation of materials for nondestructive testing purposes; gauging; or open-field, agricultural, irradiations.

Definitions

333-121-0010 (1) "Annually" means at intervals not to exceed one year.

(2) "Doubly encapsulated sealed source" means a sealed source in which the radioactive material is sealed within an inner capsule and that capsule is sealed within an outer capsule.

(3)"Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

(4) "Irradiator operator" means an individual who has successfully completed the training and testing described in Q.19 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

(5) "Irradiator operator supervisor" means an individual who meets the requirements for an irradiator operator and who physically oversees operation of the irradiator by an individual who is currently receiving training and testing described in Q.19.

(6) "Panoramic dry-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

(7) "Panoramic irradiator" means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

(8) "Panoramic wet-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

(9) "Pool irradiator" means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

(10) "Product conveyor system" means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

(11) "Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

(12) "Sealed source" means any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the byproduct material.

(13) "Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10%, as designated by the US Geological Survey.

(14) "Underwater irradiator" means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

Specific Licensing Requirements

Application for a Specific License

333-121-0020 (1) Applications for specific licenses shall be filed on a form prescribed by the Agency.

(2) The Agency may at any time after the filing of the original application, and before the

expiration of the license, require further statements in order to enable the Agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(3) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(4) An application for a license may include a request for a license authorizing one or more activities.

(5) In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Agency provided such references are clear and specific.

(6) Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

Specific Licenses for Irradiators

333-121-0030 The Agency will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

(1) The applicant shall satisfy the general requirements specified in Division C of these regulations and the requirements contained in this Division.

(2) The application must describe the training provided to irradiator operators including:

(A) Classroom training;

(B) On-the-job or simulator training;

(C) Safety reviews;

(D) Means employed by the applicant to test each operator's understanding of the Agency's regulations and licensing requirements and the irradiator operating, safety, and emergency procedures; and

(E) Minimum training and experience of personnel who may provide training.

(3) The application must include an outline of the written operating and emergency procedures listed in Q.20 that describes the radiation safety aspects of the procedures.

(4) The application must describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

(5) The application must include a description of the access control systems required by Q.9., the radiation monitors required by Q.12., the method of detecting leaking sources required by Q.23., including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

(6) If the applicant intends to perform leak testing, the applicant shall establish procedures for performing leak testing of dry-source-storage sealed sources and submit a description of these procedures to the Agency. The description must include the:

(A) Methods of collecting the leak test samples;

(B) Qualifications of the individual who collects the samples;

(D) Instruments to be used; and

(E) Methods of analyzing the samples.

(7) If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by a person specifically authorized by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to load or unload irradiator sources.

(8) The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by Q.24.

Start of Construction

333-121-0040 The applicant may not begin construction of a new irradiator prior to the submission to the Agency of both an application for a license for the irradiator and any fee required by the applicable state requirement or statute. As used in this Division, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: engineering and design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the appropriate state

statute, rules, regulations, and orders issued under the appropriate state statute.

Applications for Exemptions

333-121-0050 Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this Division. The Agency will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

Request for Written Statements

333-121-0060 Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the Agency's request, submit a written statement to enable the Agency to determine whether the license should be modified, suspended, or revoked.

Design and Performance Requirements for Irradiators

Performance Criteria for Sealed Sources

333-121-0100 (1) Requirements for sealed sources installed after [the effective date of the rule]:

(a) Must have been evaluated in accordance with 10 CFR 32.210 or the equivalent state regulation;

(b) Must be doubly encapsulated;

(c) Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

(d) Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and

(e) In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in Q.8b through Q.8g.

(2) Temperature. The test source must be held at -40°C for 20 minutes, 600°C for one hour, and then be subjected to thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.

(3) Pressure. The test source must be twice subjected for at least five minutes to an absolute external pressure of 2 million newtons per square meter.

(4) Impact. A 2 kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.

(5) Vibration. The test source must be subjected three times for ten minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of five times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.

(6) Puncture. A 50 gram weight and pin, 0.3 centimeter pin diameter, must be dropped from a height of 1 meter onto the test source.

(7) Bend. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2000 newtons at its center equidistant from two support cylinders, the distance between which is ten times the minimum cross-sectional dimension of the source.

Access Control

333-121-0110 (1) Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to the shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The control panel lock must be designed so that the key cannot be removed unless the sources have been returned to the shielded position. The doors and barriers must not prevent any individual in the radiation room from leaving.

(2) In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is on-site of the entry. That individual shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

(3) A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels must activate the alarm described in Q.9b. The monitor may be located in the entrance, normally referred to as the maze, but not in the direct radiation beam.

(4) Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

(5) Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully

shielded position.

(6) Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

(7) Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must have a sign bearing the radiation symbol and the words, "Caution (or danger) radioactive material." Panoramic irradiators must also have a sign stating "Grave danger, very high radiation area," but the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

(8) If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. The requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

(9) Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators or facility management shall have access to keys that operate the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual who is not necessarily on-site but who is prepared to respond or summon assistance.

Shielding

333-121-0120 (1) The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (2 mrem) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 centimeters. Any area where the radiation dose rate exceeds 0.02 millisievert (2 mrem) per hour must be locked, roped off, or posted.

(2) The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 0.02 millisievert (2 mrem) per hour when the sources are in the fully shielded position.

(3) The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 0.02 millisievert (2 mrem) per hour and at 5 centimeters from the shield may not exceed 0.2 millisievert (20 mrem) per hour.

Fire Protection

333-121-0130 (1)The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully

shielded if a fire is detected.

(2) The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

Radiation Monitors

333-121-0140 (1) Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.

(2) Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

Control of Source Movement

333-121-0150 (1) The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

(2) The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

(3) The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

(4) Each control for a panoramic irradiator must be clearly marked as to its function.

Irradiator Pools

333-121-0160 (1) For licenses initially issued after [the effective date of the rule], irradiator pools must either:

(a) Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or

(b) Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.

(2) For licenses initially issued after [the effective date of the rule], irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.

(3) A means must be provided to replenish water losses from the pool.

(4) A visible indicator must be provided in a clearly observable location to indicate if the pool water level is below the normal low water level or above the normal high water level.

(5) Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.

(6) A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

(7) If long-handled tools or poles are used in irradiator pools, the radiation dose rate to the operator at the handling areas of the tools may not exceed 0.02 millisievert (2 mrem) per hour.

Source Rack Protection

333-121-0170 If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a carrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

Power Failures

333-121-0180 If electrical power at a panoramic irradiator is lost for longer than ten seconds, the sources must automatically return to the shielded position.

(2) The lock on the door of the radiation room of a panoramic irradiator must remain locked in the event of a power failure.

(3) During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

Design Requirements

333-121-0190 Irradiators whose construction begins after [the effective date of the rule], must meet the design requirements of this section.

(1) Shielding. For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall

penetrations, and entranceways to meet the radiation shielding requirements of Q.10. If the irradiator will use more than 2 x 1017 becquerels (5 million Ci) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

(2) Foundations. For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

(3) Pool integrity. For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of Q.14b., and that metal components are metallurgically compatible with other components in the pool.

(4) Water handling system. For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of Q.14e. The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

(5) Radiation monitors. For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by Q.12a. The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under Q.23b., the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

(6) Source rack. For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables, or alternate means of support, will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

(7) Access control. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of Q.9.

(8) Fire protection. For panoramic irradiators, the licensee shall verify that the number, locations, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

(9) Source return. For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if power is lost for more than ten seconds.

(10) Seismic. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as the American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.

(11) Wiring. For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

Construction Monitoring and Acceptance Testing

333-121-0200 The requirements of this section must be met for irradiators whose construction begins after [the effective date of the rule]. The requirements must be met prior to loading sources.

(1) Shielding. For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

(2) Foundations. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

(3) Pool integrity. For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of Q.14b.

(4) Water handling system. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

(5) Radiation monitors. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by Q.12a. For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet Q.23b. For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by Q.12b.

(6) Source rack. For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in Q.15 are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves that rack from moving product carriers.

(7) Access control. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

(8) Fire protection. For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing system.

(9) Source return. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without power.

(10) Computer systems. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when the system is required to be operable.

(11) Wiring. For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

Operation of Irradiators

Training

333-121-0300 (1) Before an individual is permitted to act as an irradiator operator without a supervisor present, the individual must be instructed in:

(a) The fundamentals of radiation protection applied to irradiators. This must include the differences between external radiation and radioactive contamination, units of radiation dose, dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator;

(b) The requirements of Divisions J and Q of these regulations that are relevant to the irradiator;

(c) The operation of the irradiator;

(d) Those operating and emergency procedures listed in Q.20 that the individual is responsible for performing; and

(e) Case histories of accidents or problems involving irradiators.

(2) Before an individual is permitted to act as an irradiator operator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

(3) Before an individual is permitted to act as an irradiator operator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

(4) The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:

(a) Changes in operating and emergency procedures since the last review, if any;

(b) Changes in regulations and license conditions since the last review, if any;

(c) Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;

(d) Relevant results of inspections of operator safety performance;

(e) Relevant results of the facility's inspection and maintenance checks; and

(f) A drill to practice an emergency or abnormal event procedure.

(5) The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating, safety, and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

(6) Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in Q.20 that they are expected to perform or comply with, and their proper response to alarms required in this Division. Tests may be oral.

(7) Individuals who must be prepared to respond to alarms required by Q.9b. and i., Q.11a., Q.12a. and b., and Q.23b. shall be trained and tested on how to respond. Each individual shall be retested at least annually. Tests may be oral.

Operating and Emergency Procedures

333-121-0310 (1) The licensee shall have and follow written operating procedures for:

(a) Operation of the irradiator, including entering and leaving the radiation room;

(b) Use of personnel dosimeters;

(c) Surveying the shielding of panoramic irradiators;

(d) Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

(e) Leak testing of sources;

(f) Inspection and maintenance checks required by Q.24.;

(g) Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and

(h) Inspection of movable shielding required by Q.9h., if applicable.

(2) The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:

(a) Sources stuck in the unshielded position;

(b) Personnel overexposures;

(c) A radiation alarm from the product exit portal monitor or pool monitor;

(d) Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;

(e) A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;

(f) A prolonged loss of electrical power;

(g) A fire alarm or explosion in the radiation room;

(h) An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;

(i) Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and

(j) The jamming of automatic conveyor systems.

(3) The licensee may revise operating and emergency procedures without Agency approval only if all of the following conditions are met:

(a) The revisions do not reduce the safety of the facility;

(b) The revisions are consistent with the outline or summary of procedures submitted with the

license application;

(c) The revisions have been reviewed and approved by the radiation safety officer; and

(d) The users or operators are instructed and tested on the revised procedures before they are put into use.

Personnel Monitoring

333-121-0320 (1) Irradiator operators shall wear either a film badge or a thermoluminescent dosimeter (TLD) while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The film badge or TLD processor must be accredited by the National Voluntary Laboratory Accreditation Program for high energy photons in the normal and accident dose ranges [see Division D.501.c]. Each film badge or TLD must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and TLDs must be processed at least quarterly.

(2) Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of the paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within ±20% of the true radiation dose.

Radiation Surveys

333-121-0330 91) A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed [three years] and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

(2) If the radiation levels specified in Q.10. are exceeded, the facility must be modified to comply with the requirements in Q.10.

(3) Portable radiation survey meters must be calibrated at least annually to an accuracy of ±20% for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

(4) Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in Division D, Table II, Column 2 or Table III of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DAC) of

Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sanitary Sewerage."

Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.5 microsievert (0.05 mrem) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.5 microsievert (0.05 mrem) per hour.

Detection of Leaking Sources

333-121-0340 (1) Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed six months using a leak test kit or method approved by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 μCi) of radioactive material and must be performed by a person approved by the Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform the test.

(2) For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test has been done within the six months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clear up contamination in the pool if specifically provided for in written emergency procedures.

(3) If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by an Agency, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2, Appendix B of Division D of these regulations. See 10 CFR 30.50, or the equivalent state regulations, for reporting requirements.

Inspection and Maintenance

333-121-0350 (1) The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

(a) Operability of each aspect of the access control system required by Q.9.

(b) Functioning of the source position indicator required by Q.13b.

(c) Operability of the radiation monitor for radioactive contamination in pool water required by Q.23b. using a radiation check source, if applicable.

(d) Operability of the over-pool radiation monitor at underwater irradiators as required by Q.12b.

(e) Operability of the product exit monitor required by Q.12a.

(f) Operability of the emergency source return control required by Q.13c.

(g) Visual inspection of leak-tightness of systems through which pool water circulates.

(h) Operability of the heat and smoke detectors and extinguisher system required by Q.11, without turning extinguishers on.

(i) Operability of the means of pool water replenishment required by Q.14c.

(j) Operability of the indicators of high and low pool water levels required by Q.14d.

(k) Operability of the intrusion alarm required by Q.9i., if applicable.

(l) Functioning and wear of the system, mechanisms, and cables used to raise and lower sources.

(m) Condition of the barrier to prevent products from hitting the sources or source mechanism as required by Q.15.

(n) Amount of water added to the pool to determine if the pool is leaking.

(o) Electrical wiring on required safety systems for radiation damage.

(p) Pool water conductivity measurements and analysis as required by Q.25b.

(2) Malfunctions and defects found during inspection and maintenance checks must be repaired within time frames specified in the license or license application.

Pool Water Purity

333-121-0360 (1) Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee shall take prompt

actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

(2) The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

Attendance During Operation

333-121-0370 (1) Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present on site:

(a) Whenever the irradiator is operated using an automatic product conveyor system; and

(b) Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

(2) At a panoramic irradiator at which static irradiations with no movement of the product are occurring, a person who has received the training on how to respond to alarms described in Q.19g. must be on site.

(3) At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in Q.19f. and Q.19g. Static irradiations may be performed without a person present at the facility.

Entering and Leaving the Radiation Room

333-121-0380 (1) Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

(2) Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

(a) Visually inspect the entire radiation room to verify that no one else is in it; and

(b) Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

(3) During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by Q.12b. is operating with backup power.

Irradiation of Explosive or Flammable Materials

333-121-0390 (1) Irradiation of explosive material is prohibited unless the licensee has received

prior written authorization from the Agency. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

(2) Irradiation of more than small quantities of flammable material with a flash point below 140°F is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Agency. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

Records

Records and Retention Periods

333-121-0500 The licensee shall maintain the following records at the irradiator for the periods specified.

(1) A copy of the license, the license conditions, documents incorporated into the license by reference, and amendments thereto until superseded by new documents or until the Agency terminates the license for documents not superseded.

(2) Records of each individual's training, tests, and safety reviews provided to meet the requirements of Q.19a., b., c., d., f., and g. until [three years] after the individual terminates work.

(3) Records of the annual evaluations of the safety performance of irradiator operators required by Q.19e. for [three years] after the evaluation.

(4) A copy of the current operating and emergency procedures required by Q.20 until superseded or the Agency terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by Q.20c.iii. retained for [three years] from the date of the change.

(5) Film badge and TLD results required by Q.21 until the Agency terminates the license.

(6) Records of radiation surveys required by Q.22 for [three years] from the date of the survey.

(7) Records of radiation survey meter calibrations required by Q.22 and pool water conductivity meter calibrations required by Q.25.b until [three years] from the date of calibration.

(8) Records of the results of leak tests required by Q.23a. and the results of contamination checks required by Q.23b. for [three years] from the date of each test.

(9) Records of inspection and maintenance checks required by Q.24. for [three years].

(10)Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for [three years] after

repairs are completed.

(11) Records of the receipt, transfer and disposal, of all licensed sealed sources as required by Division C.40 of these regulations and 10 CFR 30.51 or the equivalent state regulations.

(12) Records on the design checks required by Q.17 and the construction control checks as required by Q.18 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

(13) Records related to decommissioning of the irradiator as required by 10 CFR 30.35(g) or the equivalent state regulation.

Reports

333-121-0510 (1) In addition to the reporting requirements in other parts of these regulations, the licensee shall report the following events if not reported under other parts of these regulations:

(a) Source stuck in an unshielded position.

(b) Any fire or explosion in a radiation room.

(c) Damage to the source racks.

(d) Failure of the cable or drive mechanism used to move the source racks.

(e) Inoperability of the access control system.

(f) Detection of radiation source by the product exit monitor.

(g) Detection of radioactive contamination attributable to licensed radioactive material.

(h) Structural damage to the pool liner or walls.

(i) Water loss or leakage from the source storage pool, greater than the irradiator pool design parameters submitted by the licensee or applicant.

(j) Pool water conductivity exceeding 100 microsiemens per centimeter.

(2) The report must include a telephone report within 24 hours as described in 10 CFR 30.50(c)(1), or the equivalent state regulation, and a written report within 30 days as described in 10 CFR 30.50(c)(2) or the equivalent state regulation.