For Parts 20.1003

333-120-0015

Definitions

(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 3.7x1010 dps.

(3) "Accelerator produced radioactive material" means any material made active by a particle accelerator.

(~~4~~3) "Adult" means an individual 18 or more years of age.

(~~5~~4) "Airborne radioactive material" means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

(~~6~~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.

(~~7~~6) "Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

(~~8~~7) "ALARA" (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this division as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the use of licensed materials in the public interest.

(~~9~~8) "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.

(10~~9~~) "Assigned protection factor (APF)" means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

(11~~0~~) "Atmosphere supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

(12~~1~~) "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 radioactive or special nuclear materials regulated by the Department.

(13~~12~~) "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.

(14) “Byproduct Material” means:

(1) Any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or using special nuclear material.

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute ‘‘byproduct material’’ within this definition.

(3) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity. Any material that has been made radioactive by use of a particle

accelerator and is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity.

(4) Any discrete source of naturally occurring radioactive material, other than source material. The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency determines a threat to the public health and safety or the common defense, is similar to the threat posed by a discrete source of radium-226 material; and

(a) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical or research activity.

(15~~13~~) "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.

(16~~14~~) "Collective dose" is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(17~~15~~) "Committed dose equivalent" (HT,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.

(18~~16~~) "Committed effective dose equivalent" (HE,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 (HE,50) = The Sum of WTHT,50.

(19~~17~~) "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.

(20) “Consortium” means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radiopharmaceutical drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

(21~~18~~) Constraint (dose constraint) means a value above which specified licensee actions are required.

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(22~~19~~) "Critical Group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

(23~~20~~) "Declared pregnant woman" means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

(24~~21~~) "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.

(25~~22~~) "Deep-dose equivalent" (Hd), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of one cm (1000 mg/cm2).

(26~~23~~) "Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

(27~~24~~) "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.

(28~~25~~) "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).

(29) “Discrete Source” means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical or research activities.

(30~~26~~) "Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

(31~~27~~) "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.

(32~~28~~) "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 this rule.

(33~~29~~) "Dose equivalent" (HT) 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).

(34~~30~~) "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.

(35~~31~~) "Effective Dose Equivalent" (HE) is the sum of the products of the dose equivalent to the organ or tissue (HT) and the weighting factor (WT) applicable to each of the body organs or tissues that are irradiated (HE = The Sum of WTHT).

(36~~32~~) "Embryo/fetus" means the developing human organism from conception until the time of birth.

(37~~33~~) "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.

(38~~34~~) "Exposure" means being exposed to ionizing radiation or to radioactive material.

(39~~35~~) "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

(40~~36~~) "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

(41~~37~~) "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). (See "lens dose equivalent").

(42~~38~~) "Filtering facepiece (dust mask)" means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

(43~~39~~) "Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

(44~~40~~) "Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

(45~~41~~) "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.

(46~~42~~) "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

(47~~43~~) "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 one mSv (0.1 rem) in one hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

(48~~44~~) "Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

(49~~45~~) "Individual" means any human being.

(50~~46~~) "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.

(51~~47~~) "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.

(52~~48~~) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

(53~~49~~) "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).

(54~~50~~) "Loose fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

(55~~51~~) "Member of the public" means any individual except when that individual is receiving an occupational dose.

(56~~52~~) "Minor" means an individual less than 18 years of age.

(57~~53~~) "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.

(58~~54~~) "Nationally Tracked Source" means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of radioactive material listed in 10 CFR Part 20, Appendix E. . In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded in a solid form and that is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel rod, or fuel pellet.

(a) Category 1 nationally traced sources are those containing radioactive material at a quantity equal to or greater than Category 1 threshold.

(b) Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

(59~~55~~) "Negative pressure respirator (tight fitting)" means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

(60~~56~~) "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.

(61~~57~~) "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 under OAR 333-116-0260, from voluntary participation in medical research programs, or as a member of the public.

(62) “Particle Accelerator” means any machine capable of accelerating electrons, protons, deuterons or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, “accelerator” is an equivalent term.

(63~~58~~) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

(64~~59~~) "Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

(65~~60~~) “Powered air purifying respirator” (PAPR) means an air purifying respirator that uses a blower to force the ambient air through air purifying elements to the inlet covering.

(66~~61~~) "Pressure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

(67~~62~~) "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 under OAR 333-116-0260, or from voluntary participation in medical research programs.

(68~~63~~) "Qualitative fit test (QLFT)" means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

(69~~64~~) "Quantitative fit test (QNFT)" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

(70~~65~~) "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.

(71~~66~~) "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.

(72~~67~~) "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 one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

(73~~68~~) "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."

(74~~69~~) "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 and previous burials at the site.

(75~~70~~) "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.

(76~~71~~) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

(77~~72~~) "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.

(78~~73~~) "Self-contained breathing apparatus" (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

(79~~74~~) "Shallow-dose equivalent" (HS), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm2) averaged over an area of one square centimeter.

(80~~75~~) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

(81~~76~~) "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.

(82~~77~~) "Supplied-air respirator" (SAR) or airline respirator means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

(83~~78~~) "Survey" means an evaluation 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.

(84~~79~~) "Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

(85~~80~~) "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).

(86~~81~~) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee.

(87~~82~~) "User seal check" means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

(88~~83~~) "Very 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 an absorbed dose in excess of five gray (500 rad) in one hour at one meter from a source of radiation or from any surface that the radiation penetrates. 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.

(89) "Waste" means those low-level radioactive wastes containing source, special nuclear or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel or byproduct material as defined sections (2), (3), and (4) of the definition of (14) Byproduct material of this rule

(90~~84~~) "Weighting factor" (WT) for an organ or tissue means the proportion of the risk of 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 WT are:

Organ Dose Weighting Factors

Organ or Tissue -- WT

Gonads -- 0.25

Breast -- 0.15

Red bone marrow -- 0.12

Lung -- 0.12

Thyroid -- 0.03

Bone surfaces -- 0.03

Remainder -- 0.30 (see (a) below)

Whole Body -- 1.00 (see (b) below)

(a) 0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye that receives 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, WT = 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.

(91~~85~~) "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

(92~~86~~) "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 one liter of air that will result in the ultimate emission of 1.3x105 MeV of potential alpha particle energy.

(93~~87~~) "Working level month" (WLM) means an exposure to one working level for 170 hours (2,000 working hours per year/12 months per year equals approximately 170 hours per month).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10

For Part 20.2001

333-120-0500

General Requirements

(1) A licensee must 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, ~~and~~ 333-120-0540 and 333-120-0545.

(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 Statutes.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

For Parts 20.2008

333-120-0545

Disposal of Certain Byproduct Material

(1) Licensed material as defined in sections (3) and (4) of the definition of byproduct material outlined in OAR 333-120-0015(14) may be disposed of in accordance with 10 CFR Part 61 even though it is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility or transferred for ultimate disposal at a facility licensed under 10 CFR Part 61 must meet the requirements of 333-120-0550.

(2) A licensee may dispose of byproduct material as defined in sections (3) and (4) of the definition of byproduct material outlined in OAR 333-120-0015(14) at a disposal facility authorized in accordance with any Federal or State solid or hazardous waste laws including the Solid Waste Disposal Act as authorized under the Energy Policy Act of 2005.

For Parts 20.2006

333-120-0550

Transfer for Disposal and Manifests

(1) The requirements of this rule and 10 CFR Part 20 Appendix G 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 G 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 G** 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, must comply with the requirements specified in 10 CFR Part 20 section III of **Appendix G** to 20.1001 to 20.2401.

(5) Any licensee shipping byproduct material defined in sections (3) and (4) of the definition of Byproduct material outlined in OAR 333-120-0015(14) intended for ultimate disposal at a land disposal facility licensed under 10 CFR Part 61 must document the information required on the Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee.

[ED. NOTE: Appendices referenced are available from the agency.]

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

For Parts 30.3

333-102-0001

Purpose and Scope

(1) This division prescribes rules applicable to all persons in the State of Oregon governing licensing of radioactive material, and for exemptions from licensing requirements. No person may receive, produce, possess, use, transfer, own or acquire byproduct material~~radioactive material~~ except as authorized in a specific or general license pursuant to this division or divisions 105, 113, 115, 116, 117, or 121 of this chapter.

(2) In addition to the requirements of division 102, all licensees are subject to applicable requirements in divisions 100, 103, 111, 118, and 120 of this chapter. The requirements of this division are in addition to, and not in substitution for, other requirements of this chapter. In any conflict between the requirements in this division and a specific requirement in another division of the rules in this chapter, the specific requirement governs.

(3) This division establishes general licenses for the possession and use of source material and depleted uranium, for radioactive material contained in certain items, and for ownership of radioactive material.

(4) This division gives notice to all persons who knowingly provide to any licensee, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's activities subject to this division, that they may be individually subject to Department actions pursuant to OAR 333-100-0035 or 333-100-0040.

(5) This division prescribes requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing radioactive material for sale or distribution to persons granted a general license by this division or to persons authorized by the US Nuclear Regulatory Commission to distribute to persons exempted from licensing requirements, and it prescribes certain rules governing holders of these licenses. In addition, this division prescribes requirements for the issuance of specific licenses to persons who introduce radioactive material into a product or material owned by or in the possession of the licensee or another and rules governing holders of such licenses.

Further, this division describes procedures and prescribes requirements for the issuance of certificates of registration (governing radiation safety information about a product) to manufacturers or initial transferors of sealed source or devices containing sealed sources, which are to be used by persons specifically licensed under this division or equivalent regulations of an Agreement State or the US Nuclear Regulatory Commission.

(6) The Department may engage the services of qualified persons in order to assist the Department in meeting the requirements of this chapter, including, but not limited to, evaluating information that may be required under OAR 333-102-0200(6).

(7) Information provided to the Department by an applicant for a license or by a licensee or information required by statute or by the Department's rules, orders, or license conditions to be maintained by the applicant or the licensee must be complete and accurate in all material respects.

(8) Each applicant or licensee must notify the Department of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety. An applicant or licensee violates this rule only if the applicant or licensee fails to notify the Department of information that the applicant or licensee has identified as having a significant implication for public health and safety. Notification must be provided to the Department within two working days of identifying the information. This requirement is not applicable to information that already is required to be provided to the Department by other reporting or updating requirements.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.625 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

Exempt Items

For Parts 30.4

333-102-0015

Certain Items Containing Radioactive Material

(1) Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from these rules to the extent that he or she receives, possesses, uses, transfers, owns or acquires the following products:

NOTE: Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are

exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(a) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

(A) 25 millicuries (925 MBq) of tritium per timepiece;

(B) Five millicuries (185 MBq) of tritium per hand;

(C) 15 millicuries (555 MBq) of tritium per dial (when used, bezels must be considered as part of the dial);

(D) 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece;

(E) 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand;

(F) 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial (when used, bezels must be considered as part of the dial);

(G) 0.15 microcurie (5.55 kBq) of radium per timepiece;

(H) 0.03 microcurie (1.11 kBq) of radium per hand;

(I) 0.09 microcurie (3.33 kBq) of radium per dial (when used, bezels must be considered as part of the dial);

(J) The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(i) For wrist watches, 0.1 millirad (one Gy) per hour at 10 centimeters from any surface;

(ii) For pocket watches, 0.1 millirad (one Gy) per hour at one centimeter from any surface; and

(iii) For any other timepiece, 0.2 millirad (two Gy) per hour at 10 centimeters from any surface.

(K) One microcurie (37 kBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007. ~~timepieces acquired prior to June 1, 1977.~~

(b) Precision balances containing not more than one millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part manufactured before December 17, 2007;

(c) Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas manufactured before December 17, 2007;

(d) Electron tubes: Provided, that each tube does not contain more than one of the following specified quantities of radioactive material:

(A) 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube;

(B) One microcurie (37 kBq) of cobalt-60;

(C) Five microcuries (185 kBq) of nickel-63;

(D) 30 microcuries (1.11 MBq) of krypton-85;

(E) Five microcuries (185 kBq) of cesium-137; or

(F) 30 microcuries (1.11 MBq) of promethium-147.

(G) And provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed one millirad (10 Gy) per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber.

NOTE: For purposes of, subsection (1)(d) of this rule "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents.

(e) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:

(A) Each source contains no more than one exempt quantity set forth in 10 CFR Part 30.71 Schedule B; and

(B) Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in 10 CFR Part 30.71 Schedule B provided that the sum of such fractions must not exceed unity.

(C) For americium-241, 0.05 microcuries (1.85 kBq) is considered an exempt quantity under section (B~~8~~) of this rule.

(i) Ionization chamber smoke detectors containing not more than one microcurie (uCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(2) The exemptions contained in this rule must not authorize any of the following:

(a) The manufacture of any product listed;

(b) The application or removal of radioactive luminous material to or from meters and timepieces or hands and dials therefore;

(c) The installation into automobile locks of illuminators containing tritium or promethium-147 or the application of tritium to balances of precision or parts thereof;

(d) Human use, or the use in any device or article, except timepieces, which is intended to be placed on or in the human body;

(e) As applied to radioactive material exempted under section (1) of this rule, the production, packaging, repackaging or transfer of radioactive material for purposes of commercial distribution or the incorporation of radioactive material into products intended for commercial distribution.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10

For Parts 30.18

333-102-0035

Exempt Quantities

(1) Except as provided in sections (2), (3) and (5) of this rule, any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities, each of which does not exceed the applicable quantity set forth in 10 CFR Part 30.71 Schedule B.

(2) This rule does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution or the incorporation of radioactive material into products intended for commercial distribution.

(3) Any person who possesses radioactive material received or acquired under the general license formerly provided in OAR 333-102-0105(2) is exempt from the requirements for a license set forth in this rule to the extent that such person possesses, uses, transfers or owns such byproduct ~~radioactive~~ material. ~~Such exemption does not apply for radium-226~~.

(4) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in 10 CFR Part 30.71 Schedule B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this rule or equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to section 32.18 of 10 CFR Part 32 or by the Department pursuant to OAR 333-102-0255, which license states that the radioactive material may be transferred by the licensee to persons exempt under this rule or the equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State.

(5) No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by this exemption so that the aggregate quantity exceeds the limits set forth in 10 CFR Part 30.71, Schedule B, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this rule.

NOTE: Authority to transfer possession or control by the manufacturer, processor or producer or any equipment, device, commodity or other product containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

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

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-2985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10

For Parts 30.20

333-102-0025

Gas and Aerosol Detectors Containing Radioactive Material

(1) Except for persons who manufacture, process, produce or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from the requirements for a license and from the rules in this division and in divisions 105, 113, 115, 116, 117, 120, and 121 of this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Parts~~section~~ 32.26 of ~~10 CFR Part 32~~; or a Licensing State pursuant to OAR 333-102-0260, which authorizes the transfer of the product for use under this rule. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by a State under comparable provisions to OAR 333-102-0260 authorizing distribution ~~detectors~~ to persons who are exempt from regulatory requirements.

NOTE: Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(2) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State must be considered exempt under section (1) of this rule, provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of OAR 333-102-0260.

(3) Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a Licensing State must be considered exempt under section (1) of this rule, provided that the device is labeled in accordance with the specific license authorizing distribution and provided further that they meet the requirements of OAR 333-102-0260.

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

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-

8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

For Parts 30.32

333-102-0190

Application for Specific Licenses

(1) Applications for specific licenses must be filed on a form prescribed by the Department. Information contained in previous applications, statements or reports filed with the Department, the US Nuclear Regulatory Commission, or an Agreement State or a Licensing State or the Atomic Energy Commission may be incorporated by reference, provided that the reference is clear and specific.

(2) The Department 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 Department to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(3) Each application must be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's or licensee's behalf.

(4) Each applicant for a specific license is required to have a permanent in-state office with a copy of all required records available for inspection by the Department.

(5) An application for a license filed pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter will be considered also as an application for licenses authorizing other activities for which licenses are required by the Act, provided that the application specifies the additional activities for which licenses are requested and complies with rules of the Department and the US Nuclear Regulatory Commission as to applications for such licenses.

(6) Each new application for a radioactive material license must be accompanied by the fee prescribed by OAR 333-103-0010. No fee will be required to accompany an application for renewal or amendment of a license, except as provided in OAR 333-103-0010.

(7) An application for a license to receive and possess radioactive material for the conduct of any activity that the Department has determined, pursuant to Subpart A of Part 51 of 10 CFR (Environmental Protection Regulations applicable to materials licensing), will significantly affect the quality of the environment, must be filed at least nine months prior to commencement of construction of the plant or facility in which the activity will be conducted and must be accompanied by any Environmental Report required pursuant to Subpart A of 10 CFR Part 51.

(8) An application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source must either:

(a) Identify the source or device by manufacturer and model number as registered with the US Nuclear Regulatory Commission under 10 CFR Part 32.210 or with an Agreement State; or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to 10 CFR Parts 32.210; or

(b) Contain the information identified in 10 CFR Part 32.210(c).

(c) Sources or devices containing naturally occurring or accelerator produced radioactive material manufactured prior to November 30, 2007 that are not registered with the Nuclear Regulatory Commission or an Agreement State which the applicant is unable to provide all categories of information specified in 10 CFR Part 32.210(c) the applicant must provide:

(A) All available information identified in 10 CFR Part 32.210(c) concerning the source and if applicable;

(B) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Information must include a description of the source or device, description of radiation safety features, intended use and associated operating experience and the results of a recent leak test.

(9) As provided by OAR 333-102-0200, certain applications for specific licenses filed under this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning as follows:

NOTE: If a renewal application was submitted on or before July 27, 1990, the decommissioning information may follow the renewal application but must be submitted prior to the license being issued.

(10)(a) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 10 CFR 30.72, "Schedule C -- Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must contain either:

(A) An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed one rem effective dose equivalent or five rems to the thyroid; or

(B) An emergency plan for responding to a release of radioactive material.

(b) One or more of the following factors may be used to support an evaluation submitted under paragraph (10)(a)(A) of this rule:

(A) The radioactive material is physically separated so that only a portion could be involved in an accident;

(B) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(C) The release fraction in the respirable size range would be lower than the release fraction shown in 10 CFR Part 30.72 (Schedule C -- Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release) due to the chemical or physical form of the material;

(D) The solubility of the radioactive material would reduce the dose received;

(E) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in 10 CFR Part 30.72;

(F) Operating restrictions or procedures would prevent a release fraction as large as that shown in 10 CFR Part 30.72; or

(G) Other factors appropriate for the specific facility.

(c) An emergency plan for responding to a release of radioactive material submitted under paragraph (10)(a)(B) of this rule must include the following information:

(A) Facility description. A brief description of the licensee's facility and area near the site.

(B) Types of accidents. An identification of each type of radio-active materials accident for which protective actions may be needed.

(C) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

(D) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

(E) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(F) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

(G) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the Department; also responsibilities for developing, maintaining, and updating the plan.

(H) Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee also must commit to notify the Department immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

NOTE: These reporting requirements do not supercede or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499 or other state or federal reporting requirements.

(I) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the Department.

(J) Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training must familiarize personnel with site-specific emergency procedures. Also, the training must thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(K) Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

(L) Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee must invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios must not be known to most exercise participants. The licensee must critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

(M) Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the byproduct material.

(N) An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radiopharmaceutical drugs for noncommercial transfer to licensees in its consortium authorized for medical use under 10 CFR Part 35 or OAR 333-102-0290 or equivalent Agreement State requirements shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under 10 CFR Part 30 or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(2) Evidence that the applicant is qualified to produce radiopharmaceutical drugs for medical use by meeting criteria in OAR 333-116-0850.

(3) Identification of individual(s) authorized to prepare the PET radiopharmaceutical drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in OAR 333-116-0880 and OAR 333-116-0910.

(4) Information identified in 10 CFR Part 32.72(a)(3) on the PET radiopharmaceutical to be non-commercially transferred to members of its consortium.

(k) Each applicant for a license for byproduct material shall protect Safeguards Information against unauthorized disclosure in accordance with the requirements in 10 CFR Parts 73.21, 73.22 and/or 73.23 as applicable.

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(d) The licensee must allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the Department. The licensee must provide any comments received within the 60 days to the Department with the emergency plan.

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

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10

For Parts 30.34

333-102-0305

Specific Terms and Conditions of License

(1) Each license issued pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120, ~~and~~ 121 and 124 of this chapter are subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations and orders of the Department.

(2) No license issued or granted pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter nor any right may 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 Department, after securing full information, shall find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.

(3) Each person licensed by the Department pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter must confine the use and possession of the radioactive material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter shall carry with it the right to receive, acquire, own, and possess radioactive material. Preparation for shipment and transport of radioactive material must be in accordance with the provisions of division 118 of this chapter.

(4) Each license issued pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter shall be deemed to contain the provisions set forth in section 183b.-d., inclusive, of the Atomic Energy Act of 1954, as amended, whether or not these provisions are expressly set forth in the license.

(5) The Department may incorporate, in any license issued pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter, at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material as it deems appropriate or necessary in order to:

(a) Promote the common defense and security;

(b) Protect health or to minimize danger to life or property;

(c) Protect restricted data; and

(d) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

(6) Licensees required to submit emergency plans by OAR 333-102-0190(9) must follow the emergency plan approved by the Department. The licensee may change the approved plan without Department approval only if the changes do not decrease the effectiveness of the plan. The licensee must furnish the change to the Department and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the Department.

(7) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators must test the generator eluates for molybdenum-99 breakthrough in accordance with OAR 333-116-0330. The licensee must record the results of each test and retain each record for three years after the record is made.

(8)(a) Each general licensee subject to the registration requirement in OAR 333-101-0007 and each specific licensee must notify the Department 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 by or against:

(A) The licensee;

(B) An entity (as that term is defined in 11 U.S.C. 101 (14)) controlling the licensee or listing the license or 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.

(b) This notification must indicate:

(A) The bankruptcy court in which the petition for bankruptcy was filed; and

(B) The date of the filing of the petition.

(9) Sealed sources or detector cells containing licensed material must not be opened or sources removed from source holders or detector cells by the licensee.

(10) No licensee may acquire licensed radioactive material in a sealed source or in a device that contains a sealed source unless the source or device has been registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

(11) Any sealed source fabricated by a licensee must be registered, inspected, and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source in accordance with requirements in 10 CFR 32.210.

(12) Each licensee must conduct a physical inventory at intervals not to exceed six months to account for all radioactive material received and possessed by licensee. Inventories must include the types and quantities of radioactive material, location of materials, date of receipt, and the date of the inventory; and for sealed sources, the inventory must include the types and quantities of sealed sources, sealed source manufacturer, model number, serial number, date of receipt, condition of sealed sources, and the date of the inventory. Records of the inventories required by section (12) of this rule must be kept until inspection by the Department.

(13) Each licensee must transport radioactive material or deliver radioactive material to a carrier for transport in accordance with the provisions of Parts 170 through 189 of Title 49, Code of Federal Regulations and in accordance with division 118 of this chapter, "Transportation of Radioactive Material."

(14) Each licensee possessing a device licensed pursuant to OAR 333-103-0010(2)(h) must perform an inspection of all devices at intervals not to exceed six months. Inspections must include condition of labeling and posting of each radiation device, and corrective actions taken if any; condition of shutter operation, if applicable, of each device, and corrective actions taken if any; and location of each device. Records of the inspections required by section (14) of this rule must be kept until inspection by the Department.

(15) No licensee may open or remove radioactive material from sealed sources or detector cells containing licensed radiation sources.

(16) No person may repair, modify, dismantle, or effect any change in licensed devices or radiation sources, nor modify nor alter labels affixed to licensed devices by the manufacturer

(17) Installation, initial radiation survey, relocation, removal from service, maintenance, and repair of fixed gauging devices containing radioactive sealed sources, and installation, replacement, and disposal of sealed sources must be performed only by persons specifically authorized by the Department, the U.S. Nuclear Regulatory Commission, or another Agreement state to perform such services. Records of all surveys must be maintained for inspection by the Radiation Protection Services section.

(18) If the licensee has previously determined that monitoring for internal exposure pursuant to OAR 333-120-0130, 333-120-0210, or 333-120-0320 is required, the data and results of this evaluation must be placed in the worker's exposure records and included the worker's Oregon Form Z report.

(19) Testing for leakage or contamination of sealed sources must be in accordance with requirements in OAR 333-120-0460. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source or detector cell received from another person must not be put into use until tested.

(20) Detector cells must be used only in conjunction with a properly operating temperature control mechanism that prevents foil temperatures from exceeding manufacturer's specifications. Exhaust from detector cells must be vented to keep exposures to personnel and the public as low as reasonably achievable pursuant to OAR 333-120-0180.

(21) Licensees who possess sealed sources used for testing at field sites must possess at such locations transport documents, a current copy of the specific radioactive materials license, specific license validation certificates, the current leak test certificate, and the licensee's operating and emergency procedures. Licensed materials stored in an unrestricted area must be secured from unauthorized removal from the place of storage in accordance with provisions of OAR 333-120-0250 and 333-120-0260.

(22) Any specific licensee is authorized to receive, possess, use, transfer, and import up to 999 kilograms of uranium contained as shielding for specific licensed radioactive material authorized by license.

(23) A licensee may store, pursuant to OAR 333-120-0500, radioactive waste with a physical half-life of less than 65 days, for decay-in-storage, before disposal in ordinary trash, provided that:

(a) Waste to be disposed of by storage-for-decay must be held for decay a minimum of 10 half-lives;

(b) Prior to disposal in ordinary trash, decayed waste must be surveyed with an instrument that will properly record background radiation dose, to confirm that the radioactivity cannot be distinguished from background. All radiation labels must be removed or obliterated; and

(c) Notwithstanding OAR 333-102-0305(23)(a) iodine-125 waste in microcurie amounts may be held for a minimum of five half-lives. Such waste must be surveyed with an appropriate instrument prior to disposal to confirm that waste is indistinguishable from background.

(24) Licensed materials in an unrestricted area and not in storage must be tended under the constant surveillance and immediate control of the licensee.

(25) Except as otherwise specified in a radioactive materials license, the licensee must have available and follow the instructions contained in the manufacturer's instruction manual for the chromatography device.

(26) In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in OAR 333-120-0400(2), the licensee is hereby authorized to label detector cells and cell baths, containing licensed radioactive material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.

(27) If a radiography licensee plans to use, during normal industrial radiographic operations subject to division 105 of this chapter, two or more exposure devices at one jobsite, the licensee must require at least one Radiographer or Radiographer Instructor authorized user for each exposure device, and the total number of authorized personnel (radiographers and assistant radiographers) at the temporary jobsite must not be less than n+1 where n=the number of cameras.

(28) Security requirements for portable devices containing licensed radioactive materials. Each portable device containing licensed radioactive materials must be secured using a minimum of three independent physical controls that form tangible barriers to prevent unauthorized removal or use, whenever the portable device is not under the direct control and constant surveillance of the licensee.

(29) (1) Authorization under OAR 333-102-0190 to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(2) Each licensee authorized under OAR 333-102-0190 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(a) Satisfy the labeling requirements in OAR 333-116-0220 for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(b) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in OAR 333-116-0165.

(3) A licensee that is a pharmacy authorized under 333-102-0190 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(a) An authorized nuclear pharmacist that meets the requirements in OAR 333-116-0910, or

(b) An individual under the supervision of an authorized nuclear pharmacist as specified in OAR 333-116-0100..

(4) A pharmacy, authorized under OAR 333-102-0190 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of OAR 333-116-0910.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10

For Parts 31.5

333-102-0115

Certain Measuring, Gauging and Controlling Devices

(1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of OAR 333-103-0015 and sections (2), (3) and (4) of this rule, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2) The general license in section (1) of this rule applies only to radioactive material contained in devices that have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the Department pursuant to OAR 333-102-0200 or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, that authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.

(3) The devices must have been received from one of the specific licensees described in section (2) of this rule or through a transfer made in accordance with subsection (4)(i) of this rule.

NOTE: Regulations under the Federal Food, Drug and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.

(4) Any person who owns, receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license in section (1) of this rule:

(a) Must assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and must comply with all instructions and precautions provided by such labels;

(b) Must assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however:

(A) Devices containing only krypton need not be tested for leakage of radioactive material; and

(B) Devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta and/or gamma emitting material or 10 microcuries (0.37 MBq) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose.

(c) Must assure that tests required in subsection (4)(b) of this rule and other testing, installation servicing and removing from installation involving the radioactive materials, its shielding or containment, are performed:

(A) In accordance with the instructions provided by the labels; or

(B) By a person holding an applicable specific license from the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such activities.

(d) Must maintain records showing compliance with the requirements of subsections (4)(b) and (4)(c) of this rule. The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installation servicing and removal from installation concerning the radioactive material, its shielding or containment. The licensee must retain these records as follows:

(A) Records of tests for leakage of radioactive material required by subsection (4)(b) of this rule must be maintained as required in OAR 333-100-0057.

(B) Records of tests of the on-off mechanism and indicator required by subsection (4)(b) of this rule must be maintained as required in OAR 333-100-0057.

(C) Records which are required by subsection (4)(c) of this rule must be maintained as required in OAR 333-100-0057.

(e) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more of removable radioactive material, the licensee must immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific

license from the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to repair such devices. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Department. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be submitted to the Department within 30 days. Under these circumstances, the criteria set out in OAR 333-120-0190, as determined by the Department, on a case-by-case basis;

(f) Must not abandon the device containing radioactive material;

(g) Except as provided in subsection (4)(i) of this rule, must transfer or dispose of the device containing radioactive material only by export as provided by subsection (4)(l) of this rule, by transfer to another general licensee as authorized in subsection (4)(i) of this rule, or by transfer to a specific licensee of the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State whose specific license authorizes the individual to receive the device; and

(A) Must furnish to the Department, within 30 days after transfer of a device to a specific licensee or export, a report containing identification of the device by manufacturer's name, model number, serial number, the date of transfer, and the name, address and license number of the person receiving the device;

(B) The general licensee must obtain written Department approval before transferring the device to any other specific licensee not specifically identified in subsection (4)(g) of this rule.

(h) A holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if the holder:

(A) Verifies that the specific license authorized the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(B) Removes, alters, covers, or clearly and unambiguously augments the existing label so that the device is labeled in compliance with OAR 333-120-0430, however the manufacturer model and serial numbers must be retained;

(C) Obtains manufacturer’s or initial transferor’s information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

(D) Reports the transfer under OAR 333-102-0115(4)(g)(A).

(i) Must transfer the device to another general licensee only:

(A) Where the device remains in use at a particular location. In such case the transferor must give the transferee a copy of this rule and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Department the manufacturer's (or initial transferor's) name, model number, serial number of the device transferred, the date of transfer, the name and address of the transferee and the location of use, and the name, title and phone number of the individual who is a point of contact between the Department and the transferee. This individual must have the knowledge and authority to take actions to ensure compliance with the appropriate rules and requirements concerning the possession and use of these devices; or

(B) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee.

(j) Must comply with the provisions of OAR 333-120-0700 and 333-120-0710 for reporting radiation incidents, theft or loss of licensed material but shall be exempt from the other requirements of divisions 111 and 120 of this chapter;

(k) Must submit the required Department form and receive from the Department a validated registration certificate acknowledging the general license and verifying that all provisions of these rules have been met. The form must be submitted within 30 days after the first receipt or acquisition of such device. The general licensee must develop and maintain procedures designed to establish physical control over the device as described in this rule and designed to prevent transfer of such devices in any form, including metal scrap, to persons not authorized to receive the devices.

(l) Shall not export a device containing radioactive material except in accordance with 10 CFR Part 110.

(5) The general license in section (1) of this rule does not authorize the manufacture of devices containing radioactive material.

(6) The general license provided in section (1) of this rule is subject to the provisions of OAR 333-100-0040 through 333-100-0055, 333-102-0335, 333-103-0015 and 333-118-0050.

(7) The general licensee possessing or using devices licensed under the general license established by section (1) of this rule must report in writing to the Department any changes in information furnished by the licensee on the required Department form. The report must be submitted within 30 days after the effective date of such change.

(8) The licensee must appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, must ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

(9)(a) A device distributed or otherwise received as a generally licensed device must be registered with the Department. Each address for a location of use, as described under subsection (9)(b) of this rule, represents a separate general licensee and requires a separate registration and fee. Devices containing more than 37 MBq (1 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, any quantity of americium-241, 3.7 MBq (0.1 mCi) of radium 226 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label are required to have a specific license. ~~Each address for a location of use, as described under subsection (9)(b) of this rule, represents a separate general licensee and requires a separate registration and fee.~~

(b) In registering devices, the general licensee must furnish the following information and any other information specifically requested by the Department:

(A) Name and mailing address of the general licensee;

(B) Information about each device. The manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label);

(C) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under section (8) of this rule.

(D) Address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage.

(E) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.

(F) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(10) General licensees must report changes to their mailing address or the location of use (including a change in name of general licensee) to the Department within 30 days of the effective date of the change.

(11) Generally licensed devices that are not in use for longer than two years must be transferred to an authorized recipient or disposed of as radioactive waste. Shutters must be locked in the closed position on devices that are not being used or are in storage. The testing required by subsection (4)(b) of this rule need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use.

(12) Persons generally licensed by an Agreement State with respect to devices meeting the criteria in subsection (9)(a) of this rule are not subject to registration requirements if

the devices are used in areas subject to NRC jurisdiction for a period less than 180 days in any calendar year. The Nuclear Regulatory Commission does not require registration information from such licensees.

(13) The general license in section (1) of this rule does not authorize the manufacture or import of devices containing radioactive material.

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

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef.

For Parts 31.12

333-102-0032

Self Luminous Products Containing Radium-226

(1) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer in accordance with the provisions of sections (1), (2), and (3) of this rule, radium-226 contained in the following products manufactured prior to November 30, 2007.

(a) Antiquities originally intended for use by the general public. For the purposes of this subsection, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(b) Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

(c) Luminous items installed in air, marine, or land vehicles.

(d) All other luminous products provided that no more than 100 items are used or stored at the same location at any one time.

(e) Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of this paragraph, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the Nuclear Regulatory Commission.

(2) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in section (1) of this rule are exempt from the provisions of the rules in this division and in divisions 105, 113, 115, 116, 117, 120, 121 and 124 of this chapter, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this chapter.

(3) Any person who acquires, receives, possesses, uses or transfers byproduct material in accordance with the general license in section (1) of this rule:

(a) Shall notify the Department should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Department within 30 days.

(b) Shall not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to 10 CFR Part 20.2008 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the Nuclear Regulatory Commission.

(c) Shall not export products containing radium-226 except in accordance with 10 CFR Part 110.

(d) Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific licensee or equivalent regulations of an Agreement State, or as otherwise approved by the Department.

(e) Shall respond to written requests from the Department to provide information relating to the general licensee within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by a written authorization to the Department

(f) The general license in section (1) of this rule does not authorize the manufacture, assembly, disassembly, repair or import of products containing radium-226, except that timepieces may be disassembled and repaired.

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For Parts 32.57

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333-102-0125

Calibration and Reference Sources

(1) A general license is hereby granted to those persons listed in subsections (1)(a) and (1)(b) of this rule to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of sections (4) and (5) of this rule, americium-241, plutonium, ~~and/~~or radium-226, in the form of calibration or reference sources:

(a) Any person who holds a specific license issued by the Department that authorizes receipt, possession, use, and transfer of radioactive material; and

(b) Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission that authorizes receipt, possession, use, and transfer of special nuclear material.

(2) A general license is hereby granted to own, receive, possess, use and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of sections (4) and (5) of this rule to any person who holds a specific license issued by the Department that authorizes receipt, possession, use, and transfer of radioactive material.

(3) A general license is hereby granted to own, receive, possess, use and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of sections (4) and (5) of this rule to any person who holds a specific license issued by the Department that authorizes receipt, possession, use, and transfer radioactive material.

(4) The general licenses in sections (1), (2), and (3) of this rule apply only to calibration or reference sources that have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to section 32.57 of 10 CFR Part 32 or section 70.39 of 10 CFR Part 70 or that have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Department, any Agreement State or Licensing State pursuant to licensing requirements equivalent to those contained in section 32.57 of 10 CFR Part 32, or section 70.39 of 10 CFR Part 70.

(5) The general licenses provided in sections (1), (2) and (3) of this rule are subject to the provisions of OAR 333-100-0005 (Definitions), 333-100-0025 (Exemptions), 333-100-0030 (Additional Requirements), 333-100-0055 (Records), 333-100-0060(1) and 333-100-0060(2) (Inspections), 333-100-0065 (Tests), 333-102-0305(1) through 333-102-0305(8) (Terms and Conditions of Licenses), 333-102-0330 (Transfers), 333-102-0335 (Modification, Revocation, and Termination of Licenses), and divisions 111, and 120 of this chapter. In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:

(a) Must not possess at any one time, at any one location of storage or use, more than five microcuries (185 kBq) each of americium-241, of plutonium-238, plutonium-239, or of radium-226 in such sources; and

(b) Each license issued under this rule shall affix to each source or source storage container a label containing sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement: ~~Must not receive, possess, use or transfer such source unless the source or the storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement that contains the information called for in one of the following statements, as appropriate:~~

(A) The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL -THIS SOURCE CONTAINS (AMERICIUM-241) (PLUTONIUM) or (RADIUM 226 DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE. _____ Name of manufacturer or importer

NOTE: Show only the name of the appropriate material.

~~(B) The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of any Licensing State. Do not remove this label.~~

~~CAUTION - RADIOACTIVE MATERIAL -THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE._____ Name of manufacturer or importer~~

(c) Must not transfer, abandon or dispose of such source except by transfer to a person authorized by a specific license from the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive the source;

(d) Must store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 that might otherwise escape during storage; and

(e) Must not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(6) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

(7) Each licensee licensed under the provisions of 10 CFR Part 32.57 shall perform a dry wipe test as outlined in 10 CFR Part 32.59.

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

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1085, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

For Parts 32.71

333-102-0250

Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under a General License

An application for a specific license to manufacture or distribute radioactive material for use under the general license specified in OAR 333-102-0130 or equivalent will be approved if:

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

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

(a) Carbon-14 in units not exceeding ten microcuries (370 kBq) each;

(b) Cobalt-57 in units not exceeding ten microcuries (370 kBq) each;

(c) Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each;

(d) Iodine-125 in units not exceeding ten microcuries (370 kBq) each;

(e) Mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each;

(f) Iodine-131 in units not exceeding ten microcuries (370 kBq) each;

(g) Iron-59 in units not exceeding 20 microcuries (740 kBq) each;

(h) Selenium-75 in units not exceeding ten microcuries (370 kBq) each.

(i) Cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) each

(3) Each prepackaged unit bears a durable, clearly visible label:

(a) Identifying the radioactive contents as to chemical form and radionuclide and indicating that the amount of radioactivity does not exceed ten microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57 or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; ~~and~~ ; or colbalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) and;

(b) Displaying the radiation caution symbol described in OAR 333-120-0400 and the words, CAUTION, RADIOACTIVE MATERIAL and Not for Internal or External Use in Humans or Animals.

(4) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(a) This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____

Name of manufacturer

(b) This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

_____

Name of manufacturer

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements in OAR 333-120-0500.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

For Parts 32.72

333-102-0285

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

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

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

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

(A) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;

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

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

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

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

(d) The applicant satisfies the following labeling requirements:

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

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

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

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

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

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

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

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

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

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

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

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

~~the individual is identified as of December 2, 1994, as an authorized user on a nuclear pharmacy license issued by the Department pursuant to this division.~~

(e) Shall provide to the Department:

(A) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in

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OAR 333-116-0740 with the written attestation signed by a preceptor as required by OAR 333-116-0680(2)(b); or

(B) The Commission or Agreement State license, or

(C) Commission master materials licensee permit, or

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

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

(F) A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs 333-116-0020 and (2)(C)of this rule, the individual to work as an authorized nuclear pharmacist.

~~Must provide to the Department a copy of each individual's certification by the Board of Pharmaceutical Specialties, the Commission or Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to paragraphs (2)(b)(A) and (C) of this rule, the individual to work as an authorized nuclear pharmacist.~~

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

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

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

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

NOTE: Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such

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

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

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10

For Parts 32.102

333-102-0270

Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Granted a General License by OAR 333-102-0125

An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons granted a general license by OAR 333-102-0125 will be approved if:

(1) The applicant satisfies the general requirement of OAR 333-102-0200; and

(2) The applicant satisfies the requirements of sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and section 70.39 of 10 CFR Part 70 or their equivalent.

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

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

For Parts 35.20

333-116-0020

Definitions

As used in this division, the following definitions apply:

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

(2) "Area of use" means location(s) at the address of use set aside for the purpose of receiving, using or storing radioactive material.

(3) “Attestation” means required training, experience and appropriate board certification is validated using the Nuclear Regulatory Commission’s form 313A.

(4) "Authorized Medical Physicist" means an individual who:

(a) Meets the requirements in OAR 333-116-0730, or 333-116-0905 and 333-116-0760; or

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

(A) A specific medical use license issued by the Department or an Agreement State or the US Nuclear Regulatory Commission;

(B) A medical use permit issued by a Commission master material licensee;

(C) A permit issued by a Commission or Agreement State broad scope medical use licensee; or

(D) A permit issued by a Commission master material license broad scope medical use permittee.

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

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

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

(c) Is identified as an authorized nuclear pharmacist on a license issued by a Department, 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 Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to approve authorized nuclear pharmacists.

(6) "Authorized user" means a physician, dentist or podiatrist who:

(a) Meets the requirements listed in OAR 333-116-0660, 333-116-0670, 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0690, 333-116-0700, 333-116-0710, 333-116-0720, and 333-116-0740;

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

(7) "Black Box" means the radiopharmaceutical production purification system used in a PET facility.

(8) "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

(9) "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.

(10) "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.

(11) "Dental use" means the intentional external administration of the radiation from radioactive 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.

(12) "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.

(13) "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.

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

(15) "Human Research Subject" means a living person that an authorized user, conducting research, obtains data resulting from the intentional internal or external administration of radioactive material, or the radiation from radioactive material, to the individual. For the purpose of these rules, unless otherwise noted, the term patient applies to a human research subject.

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

(17) "Management" means the chief executive officer or that individual's designee.

(18) "Manual Brachytherapy", as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed on, or in close proximity, to the treatment site or inserted directly into the tissue volume.

(19) "Medical Event or Medical Error" means an event where a patient or human research subject:

(a) Receives a dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin;

(b) Receives a dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site); or

(c) An event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(20) "Medical institution" means an organization in which more than one medical discipline is practiced.

(21) "Medical use" means the intentional internal or external administration of radioactive material, or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

(22) "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.

(23) "Misadministration" means the administration of:

(a) A radiopharmaceutical dosage greater than 1.11 megabecquerels (30 uCi) of either sodium iodide I-125 or I-131:

(A) Involving the wrong individual 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 1.11 megabecquerels (30 uCi).

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

(A) Involving the wrong individual, 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 individual 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 individual, 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 individual, 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 1.11 megabecquerels (30 uCi) of either sodium iodide I-125 or I-131:

(A) Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; or

(B) When the dose to the individual exceeds 50 millisieverts (5 rem) effective dose equivalent or 500 millisieverts (50 rem) dose equivalent to any individual organ.

(24) "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

(25) "Nuclear Pharmacist" means an authorized nuclear pharmacist, as defined in OAR 333-116-0020, who has received additional training, pursuant to OAR 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.

(26) "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.

(27) "Patient Intervention" means actions taken by a patient or human research subject, whether intentional or unintentional, interrupt or terminate the administration of radioactive materials or radiation.

(28) "PET" means Positron Emission Tomography.

(29) "PET Isotope Nuclear Pharmacy" means a licensed facility that compounds radiopharmaceuticals using positron emitting isotopes for use at licensed medical facilities.

(30) "PET cyclotron facility" means a facility that manufactures short-lived radioisotopes for use in compounding radiopharmaceuticals at a PET Isotope Nuclear Pharmacy.

(31) "PET Medical Facility" means a clinical nuclear medicine facility that utilizes positron-emitting isotopes for diagnostic imaging.

(32) "Pharmacist" 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 pharmacy.

(33) "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.

(34) "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.

(35) "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.

(36) "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 medical diagnostic purposes.

(37) "Preceptor" means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer. The preceptor must have previously met all of the applicable requirements and be so named on a radioactive materials license issued by the Department, the Nuclear Regulatory Commission, an Agreement State or licensing state.

(38) "Prescribed dosage" means the specified activity or range of activity of a radiopharmaceutical or radioisotope 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.

(39) "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;

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

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

(40) "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.

(41) "Radiation Safety Officer" means an individual who:

(a) Meets the requirements in OAR 333-116-0640, 333-116-0650, 333-116-0740 and 333-116-0760; or

(b) Is identified as a Radiation Safety Officer on:

(A) A specific medical use license issued by the Nuclear Regulatory Commission or Agreement State; or

(B) A medical use permit issued by a Nuclear Regulatory Commission master material licensee.

(42) "Recordable Event" (See Medical Event and Misadministration).

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

(44) "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.

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

(46) "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

(47) "Teletherapy physicist" means the individual identified as the qualified teletherapy physicist on a Department license.

(48) "Therapeutic Dosage" means a dosage of unsealed byproduct material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

(49) "Therapeutic Dose" means a radiation dose delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment.

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

(51) "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 Department as a nuclear pharmacy.

(52) "Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

(53) "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 1.11 megabecquerels (30 uCi) 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 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10

For Parts 35.11

333-116-0030

License Required

(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, a specific license is not needed for an individual to:

(a) 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; or

(b) Prepare unsealed byproduct material for medical use in accordance with the rules in this division under the supervision of an authorized nuclear pharmacist or 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 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 4-2007, f. & cert. ef. 3-1-07