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OREGON ADMINISTRATIVE RULES
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 100

CONTROL OF RADIATION IN OREGON

General Requirements

333-100-0005

Definitions

The following definitions apply to OAR chapter 333 divisions 100, 102, 103, 106, 111, 116, 118, 119, 120, 121, 122, 123, and 124. Additional definitions used only in a certain division can be found in that division.

- (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) "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 MeV. For purposes of this definition, "particle accelerator" is an equivalent term.
- (3) "Accelerator-produced material" means any material made radioactive by a particle accelerator.
- (4) "Act" means Oregon Revised Statutes 453.605 through 453.807.
- (5) "Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq), defined as one disintegration per second, and the curie (Ci), defined as 3.7×10^{10} disintegrations per second.
- (6) "Adult" means an individual 18 or more years of age.
- (7) "Agreement State" means any state with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689). States not entering an agreement under the Act are considered a non-agreement state.
- (8) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.
- (9) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive material, composed wholly or partly of licensed material, exist in concentrations:
 - (a) In excess of the derived air concentrations (DACs) specified in Appendix B, Table I, column 3, to 10 CFR Part 20.1001 to 20.2401; or

(b) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

(10) "ALARA" (acronym for "As Low As Reasonably Achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part 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 utilization of nuclear energy and licensed materials in the public interest.

(11) "Alert" means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

(12) "Annual" means occurring every year or within a consecutive twelve month cycle.

(13) "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 could 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 Appendix B, Table I, Columns 1 and 2, to 10 CFR Part 20.1001 to 20.2401.

(14) "As Low As Reasonably Achievable" see "ALARA."

(15) "Authority" means the Oregon Health Authority.

(16) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including 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 sources of radiation from radioactive or special nuclear materials regulated by the Authority.

(17) "Becquerel" (Bq) means ~~the International System of Units (SI) unit of activity. One becquerel is equal to one~~ disintegration ~~or transformation~~ per second. ~~(dps or tps).~~

(18) "Bioassay" 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. For purposes of these rules, "radiobioassay" is an equivalent term.

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

(20) "Byproduct material" means:

(a) Any radioactive material, except special nuclear material, yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or utilizing special nuclear material; ~~and~~

(b) The tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction process. Underground ore bodies depleted by such solution extraction operations do not constitute "byproduct material" within this definition;

(c) 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; or

(d) Any material that:

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(C) Any discrete source of naturally occurring radioactive material, other than source material, that:

(i) The Nuclear Regulatory 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 state and federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

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

(21) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year must begin in January and subsequent calendar quarters must be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant may change the method observed for determining calendar quarters except at the beginning of a calendar year.

(22) "Calibration" means the determination of:

(a) The response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

(b) The strength of a source of radiation relative to a standard.

(23) "CFR" means Code of Federal Regulations.

(24) "Chelating agent" means amine polycarboxylic acids, hydroxy-carboxylic acids, gluconic acid, and polycarboxylic acids.

(25) "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. For purposes of these rules, "lung class" or "inhalation class" are equivalent terms. Materials are classified as D, W, or Y, which applies to a range of clearance half-times:

- (a) For Class D, Days, of less than 10 days;
- (b) For Class W, Weeks, from 10 to 100 days; and
- (c) For Class Y, Years, of greater than 100 days.

(26) "Clinical laboratory" means a laboratory licensed pursuant to ORS 438.110 through 438.140.

(27) "Collective dose" means 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.

(28) "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.

(29) "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 each of these organs or tissues ($HE, 50 = \sum WT, HT, 50$).

(30) "Contamination" (Radioactive) means deposition or presence of radioactive material in any place where it is not desired, and particularly in any place where its presence can be harmful. The harm may be in compromising the validity of an experiment or a procedure, or in being a source of danger to persons. Contamination may be divided into two types: Fixed and removable. Removable contamination may be transferred easily from one object to another by light rubbing or by the use of weak solvents such as water or alcohol. Removable contamination is evaluated and recorded in units of microcuries or dpm. Fixed contamination is not easily transferred from one object to another and requires mechanical or strong chemicals to remove it from its current location. Fixed contamination is evaluated and recorded in units of mR/hr.

(31) "~~Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material that decays at the rate of 3.7×10^{10} disintegrations or transformations per second (dps or tps).~~ means that amount of radioactive materials which disintegrates at the rate of 37 billion atoms per second.

(32) "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.

(33) "Decommission" means to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits:

- (a) Release of the property for unrestricted use and termination of license; or
- (b) Release of the property under restricted conditions and termination of the license.

(34) "Deep dose equivalent" (Hd) which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

(35) "Depleted uranium" means source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

(36) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by 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 rules, 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 Appendix B to 10 CFR Part 20.1001 to 20.2401.

(37) "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 may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

(38) "Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these rules, "radiation dose" is an equivalent term.

(39) "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 sievert (Sv) and rem (see "Rem"). (See OAR 333-100-0070(2) for SI equivalent sievert.)

(40) "Dose limits" means the permissible upper bounds of radiation doses established in accordance with these rules. For purposes of these rules, "limits" is an equivalent term.

(41) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.

(42) "Effective dose equivalent" (HE) means 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 ($HE = \sum WT HT$).

(43) "Electronic product" means any manufactured product or device or component part of such a product or device that is capable of generating or emitting electromagnetic or sonic radiation such as, but not limited to, X-rays, ultrasonic waves, microwaves, laser light or ultraviolet light.

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

(45) "Entrance or access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

(46) "Exclusive use" (also referred to in other regulations as "sole use" or "full load") means the sole use of a conveyance by a single consignor and for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee.

(47) "Explosive material" means any chemical compound, mixture, or device that produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

(48) "Exposure" means:

(a) The quotient of dQ by dm where " dQ " is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass " dm " are completely stopped in air. The SI unit of exposure is the coulomb per kilogram.

(b) Being exposed to ionizing radiation or to radioactive material.

(49) "Exposure rate" means the exposure per unit of time, such as roentgen per minute (R/min) and milliroentgen per hour (mR/hr).

(50) "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

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

(52) "Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm²).

(53) "Fixed gauge" means a measuring or controlling device that is intended to be mounted at a specific location, stationary, not to be moved, and is not portable.

(54) "Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

(55) "General license" means a license granted by rule, in contrast to an issued license, to acquire, own, possess, use, or transfer radioactive material or a device that contains radioactive material.

(56) "Generally applicable environmental radiation standards" means standards issued by the U.S. 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.

(57) "Gray" (Gy) means the International System of Units (SI), unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram (100 rad). (See OAR 333-100-0070(2))

(58) "Hazardous waste" means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

(59) "Healing arts" means:

(a) The professional disciplines authorized by the laws of this state to use X-rays or radioactive material in the diagnosis or treatment of human or animal disease. For the purposes of this division they are Medical Doctors, Osteopaths, Dentists, Veterinarians, Chiropractors, and Podiatrists; or

(b) Any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury or unhealthy or abnormal physical or mental condition.

(60) "Human use" means the internal or external administration of radiation or radioactive material to human beings.

(61) "Individual" means any human being.

(62) "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, that is, DAC-hours; or

(c) The assessment of dose equivalent by the use of survey data.

(63) "Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

(64) "Inhalation class" (see "Class").

(65) "Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Authority.

(66) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

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

(68) "Ionizing radiation" means any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, in its passage through matter. It includes any or all of the following: Alpha particles, beta particles, electrons, positrons, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, fission fragments and other atomic and subatomic particles; but not sound or radio waves, or visible, infrared, or ultraviolet light.

(69) "Laser" means any device which, when coupled with an appropriate laser energy source, can produce or amplify electromagnetic radiation by the process of controlled stimulated emission.

(70) "License" means a license issued by the Authority in accordance with rules adopted by the Authority.

(71) "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license granted or issued by the Authority. For the purpose of meeting the definition of a Licensing State by the Conference of Radiation Control Program Directors, Inc. (CRCPD), Naturally Occurring and Accelerator Produced Radioactive Material (NARM) refers only to discrete sources of NARM. Diffuse sources of NARM are excluded from consideration by the CRCPD for Licensing State designation purposes.

(72) "Licensee" means any person who is licensed by the Authority in accordance with these rules and the Act.

(73) "Licensing state" means any state with rules or regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and having an effective program for, the regulatory control of NARM.

(74) "Limits" (dose limits) means the permissible upper bounds of radiation doses.

(75) "Lost or missing licensed or registered source of radiation" means licensed or registered source(s) of radiation whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

(76) "Lung class" (see "Class").

(77) "Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in division 118 of this chapter.

(78) "Member of the public" means an individual, except when that individual is receiving an occupational dose.

(79) "Minor" means an individual less than 18 years of age.

(80) "Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

(81) "NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.

(82) "Natural radioactivity" means radioactivity of naturally occurring nuclides.

(83) "Naturally-occurring radioactive material" (NORM) means any nuclide that is found in nature as a radioactive material (~~i.e.,~~ and not technologically produced).

(84) "Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

(85) "Natural uranium" means a mixture of the uranium isotopes 234, 235 and 238 (approximately 0.7 weight percent uranium- 235 and the remainder by weight essentially uranium-238), found in nature, that is neither enriched nor depleted in the isotope uranium 235.

(86) "Nonstochastic effect" means a health effect that varies with the dose and a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, "deterministic effect" is an equivalent term.

(87) "Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as "special form radioactive material". See "Special form."

(88) "NRC" is the acronym for Nuclear Regulatory Commission.

(89) "Nuclear Regulatory Commission" ("NRC" or "Commission") means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

(90) "Package" means the packaging together with its radioactive contents as presented for transport.

(91) "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 one MeV.

(92) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing.

(93) "Personnel monitoring equipment" means devices such as film badges, pocket dosimeters, and thermoluminescent dosimeters designed to be worn or carried by an individual for the purpose of estimating the dose received by the individual. See "Individual monitoring devices."

(94) "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.

(95) "Physician" means an individual licensed by the Oregon Medical Board to dispense drugs in the practice of medicine.

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

(97) "Portable gauge" means a measuring or controlling device that is intended to be portable and is not fixed to a specific location. All portable gauges require a specific license (there is no general license granted for portable generally licensed devices in the State of Oregon).

(98) "Program" means the Radiation Protection Services section of the Public Health Division of the Oregon Health Authority.

(99) "Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below 130OF (54.4OC).

(100) "Pyrophoric solid" means any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

(101) "Qualified expert" means an individual, approved by the Authority, who has demonstrated, pursuant to these rules, that he/she possesses the knowledge, skills, and training to measure ionizing radiation, to evaluate radiation parameters, to evaluate safety techniques, and to advise regarding radiation protection needs. The individual must:

(a) Be certified in the appropriate field by the American Board of Radiology, the American Board of Health Physics, the American Board of Medical Physics or the American Board of Nuclear Medicine Science; or

(b) Hold a master's or doctor's degree in physics, biophysics, radiological physics, health physics, or medical physics and have completed one year of documented, full time training in the appropriate field and also one year of documented, full time work experience under the supervision of a qualified expert in the appropriate field. To meet this requirement, the individual must have performed the tasks required of a qualified expert during the year of work experience; or

(c) Receive approval from the Authority for specific activities.

(102) "Quality factor" (Q) means the modifying factor (listed in Tables 1004(b).1 and 1004(b).2 of 10 CFR Part 20.1004 provided at the end of this division) that is used to derive dose equivalent from absorbed dose.

(103) "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.

(104) "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray). See OAR 333-100-0070(2) for SI equivalent gray.

(105) "Radiation" means:

(a) Ionizing radiation including gamma rays, X-rays, alpha and beta particles, protons, neutrons, and other atomic or nuclear particles or rays;

(b) Any electromagnetic radiation which can be generated during the operations of electronic products and which the Authority has determined to present a biological hazard to the occupational or public health and safety but does not include electromagnetic radiation which can be generated during the operation of an electronic product licensed by the Federal Communications Commission;

(c) Any sonic, ultrasonic or infrasonic waves which are emitted from an electronic product as a result of the operation of an electronic circuit in such product and which the Authority has determined to present a biological hazard to the occupational or public health and safety.

(106) "Radiation area" means any 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 source of radiation or from any surface that the radiation penetrates.

(107) "Radiation machine" means any device capable of producing radiation except those which produce radiation only from radioactive material.

(108) "Radiation safety officer" means:

(a) An individual who has the knowledge, responsibility, and authority to apply appropriate radiation protection rules; or

(b) The representative of licensee management, authorized by the Authority, and listed on the specific license as the radiation safety officer, who is responsible for the licensee's radiation safety program.

- (109) "Radioactive material" means any solid, liquid, or gas that emits radiation spontaneously.
- (a) Radioactive material, as used in these rules, includes: byproduct material, naturally occurring radioactive material, accelerator produced material, and source material, as defined in this rule.
- (b) Radioactive material, as used in these rules, does not include special nuclear material.
- (110) "Radioactive waste" means radioactive material that is unwanted or is unusable, as defined in division 50 of chapter 345. No radioactive material may be disposed of in Oregon except as provided in division 50 of chapter 345.
- (111) "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.
- (112) "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 workers 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."
- (113) "Registrant" means any person who is registered with the Authority and is legally obligated to register with the Authority pursuant to these rules and the Act.
- (114) "Registration" means the identification of any material or device emitting radiation, and the owner of such material or device must furnish information to the Authority in accordance with the rules adopted by the Authority.
- (115) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189 and Parts 390-397.
- (116) "Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).
- (117) "Research and development" means:
- (a) Theoretical analysis, exploration, or experimentation; or
- (b) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.
- (118) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.
- (119) "Restricted area" means an area to which access is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A 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.

- (120) "Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} Coulombs/kilogram of air (see "Exposure" and division 120).
- (121) "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.
- (122) "Screening" means the use of a systematic approach to obtain cursory examinations of a person or group of persons without regard to specific clinical indications.
- (123) "Sealed source" means radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.
- (124) "Sealed Source and Device Registry" means the national registry that contains all the registration certificates, generated by both the U.S. Nuclear Regulatory Commission and Agreement States, that summarize the radiation safety information for sealed sources and devices and describe the licensing and use conditions approved for the product.
- (125) "Shallow dose equivalent" (Hs), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of one square centimeter.
- (126) "SI" means the abbreviation for the International System of Units.
- (127) "Sievert" means the International System of Units (SI), unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor ($1 \text{ Sv} = 100 \text{ rem}$). (See OAR 333-100-0070(2)).
- (128) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.
- (129) "Source material" means:
- (a) Uranium or thorium or any combination of uranium and thorium in any physical or chemical form; or
 - (b) Ores that contain by weight one-twentieth of one percent (0.05 percent) or more of uranium, thorium, or any combination thereof. Source material does not include special nuclear material.
- (130) "Source material milling" means any activity that result in the production of byproduct material, as defined by this rule.
- (131) "Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation. Source of radiation, pursuant to this rule, includes, but is not limited to, radiation facilities, radiation producing machines, radiation producing devices, radioactive material sealed and unsealed form (normal form and special form), and radioactive material uses.
- (132) "Special form radioactive material" means radioactive material that satisfies the following conditions:
- (a) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

- (b) The piece or capsule has at least one dimension not less than five millimeters (0.2 inch); and
- (c) It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, and a special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on March 31, 1996, and constructed prior to April 1, 1998, may continue to be used. Any other special form encapsulation either designed or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.

(133) "Special nuclear material" means:

(a) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

(b) Any material artificially enriched by any of the foregoing but does not include source material.

(134) "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination must not exceed one.

For example, the following quantities in combination does not exceed the limitation and are within the formula: $175 \text{ (grams U-235)/350} + 50 \text{ (grams U-233)/200} + 50 \text{ (grams Pu)/200} = 1$.

(135) "Specific activity of a radionuclide" means the radioactivity of the radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

(136) "Stochastic effect" means health effects that occur 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.

(137) "Supervision" as used in these rules, means the responsibility for, and control of, the application, quality, radiation safety and technical aspects of all sources of radiation possessed, used and stored through authorization granted by the Authority.

(138) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

(139) "Termination" means:

(a) The end of employment with the licensee or registrant or, in the case of individuals not employed by the licensee or registrant, the end of work assignment in the licensee's or registrant's restricted area in a given calendar quarter, without expectation or specific scheduling of re-entry into the licensee's or registrant's restricted area during the remainder of that calendar quarter; or

(b) The closure of a registered or licensed facility and conclusion of licensed or registered activities, pursuant to a registration or specific license.

(140) "Test" means the process of verifying compliance with an applicable rule.

(141) "These rules," mean all parts of the Oregon Administrative Rules promulgated under ORS 453.605 through 453.807.

(142) "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.

(143) "Total organ dose equivalent" (TODE) means the sum of the deep dose equivalent (DDE) and the committed dose equivalent (CDE) to the organ receiving the highest dose as described in OAR 333-120-0650(1)(d).

(144) "Transport index" means the dimensionless number (rounded up to the first decimal place) placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number expressing the maximum radiation level in millirem per hour at one meter from the external surface of the package.

(145) "U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237 42 U.S.C. 5814, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

(146) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

NOTE: "Ore" refers to fuel cycle materials pursuant to 10 CFR Part 150.

(147) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these rules, "uncontrolled area" is an equivalent term.

(148) "Uranium — depleted, enriched" means:

(a) "Depleted uranium" means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(b) "Enriched uranium" means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

(149) "Validation certificate" means the official document issued upon payment to the Authority of the appropriate fee listed in division 103 of this chapter. The license or registration is subject and void without the annual validation certificate.

(150) "Waste" means radioactive waste.

(151) "Week" means seven consecutive days starting on Sunday.

(152) "Weighting factor" (WT) for an organ or tissue (T) means:

(a) 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:

(A) Gonads 0.25;

(B) Breast 0.15;

(C) Red Bone Marrow 0.12;

(D) Lung 0.12;

(E) Thyroid 0.03;

(F) Bone Surfaces 0.03;

(G) Remainder 0.30 (see note below);

(H) Whole Body 1.00.

NOTE: Assignment of 0.30 for the remaining organs results from a weighting factor of 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

(b) For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $WT = 1.0$, has been specified. The use of other weighting factors for external exposure may be approved on a case-by-case basis until such time as specific guidance is issued.

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

(154) "Worker" means an individual engaged in work under a license or registration issued by the Authority and controlled by a licensee or registrant, but does not include the licensee or registrant.

(155) "Working level" (WL) means any combination of short-lived radon progeny in one liter of air that will result in the ultimate emission of 1.3×10^5 MeV of potential alpha particle energy. The short-lived radon-222 progeny are: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220 the progeny are: polonium-216, lead-212, bismuth-212, and polonium-212.

(156) "Working level month" (WLM) means an exposure to one working level for 170 hours (2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.)

(157) "Year" means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

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

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

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

DIVISION 102

LICENSING OF RADIOACTIVE MATERIAL

Exemptions

333-102-0005

Unimportant Quantities of Source Material

- (1) Any person is exempt from this division to the extent that such person receives, possesses, uses, owns or transfers source material in any chemical mixture, compound, solution or alloy in which the source material is by weight less than 1/20 of one percent (0.05 percent) of the mixture, compound, solution or alloy.
- (2) Any person is exempt from this division to the extent that such person receives, possesses, uses or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person must not refine or process such ore.
- (3) Any person is exempt from this division to the extent that such person receives, possesses, uses or transfers:
 - (a) Any quantities of thorium contained in:
 - (A) Incandescent gas mantles;
 - (B) Vacuum tubes;
 - (C) Welding rods;
 - (D) Electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium;
 - (E) Germicidal lamps, sun lamps and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium;
 - (F) Rare earth metals and compounds, mixtures and products containing not more than 0.25 percent by weight thorium, uranium or any combination of these; or
 - (G) Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium.

(b) Source material contained in the following products:

(A) Glazed ceramic tableware manufactured before August 27, 2013, provided that the glaze contains not more than 20 percent by weight source material;

(B) Piezoelectric ceramic containing not more than two percent by weight source material;

(C) Glassware containing more than two percent by weight source material or, for glassware manufactured before August 27, 2013, not more than ten percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass or ceramic used in construction; or

(D) Glass enamel or glass enamel frit containing not more than ten percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983.

(c) Photographic film, negatives and prints containing uranium or thorium;

(d) Any finished product or part fabricated of, or containing tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed four percent by weight and that this exemption must not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such product or part;

(e) Uranium contained in counterweights installed in aircraft, rockets, projectiles and missiles or stored or handled in connection with installation or removal of such counterweights, provided that:

~~(A) The counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 CFR Part 40;~~

~~(AB)~~ Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM";

NOTE: The requirements specified in paragraphs (3)(e)(~~AB~~) and (3)(e)(~~BC~~) of this rule need not be met by counterweights manufactured prior to December 31, 1969 provided, that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and are impressed with the legend required by ~~paragraph 10 CFR 40.13(e)(5)(ii) (3)(e)(B) of this rule~~ in effect on June 30, 1969, ~~which read CAUTION—RADIOACTIVE MATERIAL—URANIUM.~~

~~(BC)~~ Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED"; and

~~(CD)~~ This exemption must not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.

(f) Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

(A) The shipping container is conspicuously and legibly impressed with the legend "CAUTION - - RADIOACTIVE SHIELDING -- URANIUM"; and

(B) The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of 1/8 inch (3.2 mm).

(g) Thorium or uranium contained in finished optical lenses and mirrors, provided that each lens does not contain more than ~~1030~~ percent by weight of thorium or uranium or, for lenses manufactured before August 27, 2013, 30 percent by weight of thorium; and that this exemption must not be deemed to authorize either:

(A) The shaping, grinding or polishing of such lens or mirrors or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror; or

(B) The receipt, possession, use or transfer of uranium or thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

~~(h) Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 185 Bq (0.005 microCi) of uranium; or~~

(hi) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

(A) The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and

(B) The thorium content in the nickel-thoria alloy does not exceed four percent by weight.

(4) The exemptions in section (3) of this rule do not authorize the manufacture of any of the products described.

(5) No person may initially transfer for sale or distribution a product containing source material to persons exempt under this rule, U.S. Nuclear Regulatory Commission or equivalent regulations of an Agreement State, unless authorized by a license issued under OAR 333-102-0300 and 333-102-0305 to initially transfer such products for sale or distribution.

(a) Persons initially distributing source material in products covered by the exemptions in this rule before August 27, 2013, without specific authorization may continue such distribution for one year beyond this date. Initial distribution may also be continued until the Authority takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than one year beyond this date.

(c) Persons authorized to manufacture, process, or produce these materials or products containing source material by an Agreement State, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued under OAR 333-102-0300 and 333-102-0305 for distribution only and are exempt from the requirements of divisions 111 and 120 of this chapter, and OAR 333-102-0200(2) and (3).

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

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Exemptions — Byproduct Radioactive Material Other than Source Material

Exempt Items

333-102-0015

Certain Items Containing By Product Material~~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.

(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 paragraph (1)(e)(A) of this rule.

~~(d)~~ 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.

(f) Static elimination devices that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device.

(g) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 millicuries(18.5 MBq) of polonium-210 per device or of a total of not more than 50 millicuries (1.85 GBq) of hydrogen-3 (tritium) per device.

(h) Such devices authorized before October 23, 2012 for use under the general license then provided in 10 CFR Part 31.3 and equivalent regulations of Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Nuclear Regulatory Commission.

(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

333-102-0025

Gas and Aerosol Detectors Containing ~~Radioactive Material~~ Byproduct Material

(1) Except for persons who manufacture, process, produce or initially transfer for sale or distribution gas and aerosol detectors containing ~~byproduct 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 byproduct material in gas and aerosol detectors designed to protect ~~health, safety, or property life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been and~~ manufactured, ~~processed, produced, or initially imported or~~ transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Parts 32.26 of; or a Licensing State pursuant to OAR 333-102-0260, which authorizes the initial 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 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) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct materials, or to initially transfer such products for use under section (1) of this rule shall apply for a license under OAR 333-102-0260 and for a certificate of registration in accordance with 10 CFR Part 32.210. 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

333-102-0030

Self-Luminous Products Containing ~~Radioactive Material~~ Tritium, Krypton-85, or Promethium-147

~~(1) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, and except as provided in section (3) of this rule, any person is exempt from the requirements for a license set forth in divisions 105, 113, 115, 116, 117, 120, 121 and 124 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to OAR 333-102-0245, which authorizes the initial transfer of the product for use under this section.~~

~~(1) Except for persons who manufacture, process, produce or initially transfer for sale or distribution self-luminous products 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, 121 and 124 of this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in self-luminous products designed to protect life or property from fires and airborne hazards provided that the products containing radioactive material must have been manufactured, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to section 32.26 of~~

~~10 CFR Part 32; or a Licensing State pursuant to OAR 333-102-0265, which authorizes the transfer of the 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) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under section (1) of this rule, shall apply for a license under OAR 333-102-0245 and for a certificate of registration in accordance with 10 CFR Part 32.210. 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 333-102-0265.~~

~~(3) The exemption in section (1) of this rule does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments. 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 333-102-0265.~~

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

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

333-102-0033

Certain Industrial Devices

~~(1) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material 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 an ionized atmosphere, any person is exempt from the requirements for a license set forth in 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 byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under this division, which authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.~~

(2) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under section (1) of this rule shall apply for a license under this division and for a certificate of registration in accordance with 10 CFR Part 32.210.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 – 453.807

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 333-102-0015+05(12)(g) 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 material. .

(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 Authority 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

Licenses

333-102-0075

Types of Licenses

Licenses for radioactive materials are of two types: General and specific.

(1) General licenses provided in this division are granted as being effective without the filing of applications with the Agency Authority or the issuance of licensing documents to particular persons, except Depleted Uranium subject to OAR ~~333-102-0103~~333-102-0106, Measuring, Gauging, and Controlling devices subject to OAR 333-102-0115, and In Vitro Clinical or Laboratory Testing subject to OAR 333-102-0130.

(2) Specific licenses require the submission of an application to the Authority Agency and the issuance of a specific licensing document by the Authority Agency. The licensee is subject to all applicable portions of these rules as well as any limitations specified in the licensing document. Specific licenses are issued to named persons upon applications filed pursuant to OAR 333-102-0200 and divisions 105, 113, 115, 116, 117, and 121 of this chapter.

(3) General licenses granted by OAR 333-102-0101, ~~333-102-0103~~333-102-0106, 333-102-0115, and 333-102-0130 require the submission of an application to the Authority Agency for registration pursuant to 333-101-0007, payment of a fee in accordance with 333-103-0015, and the issuance of a registration (licensing document or general license acknowledgment) by the Agency Authority.

(4) General licenses are subject to 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 103, 111, 118, and 120 of this chapter unless indicated otherwise in the language of the general license.

NOTE: Attention is directed particularly to the provisions of the regulations in division 120 of this chapter that relate to the labeling of containers and notification of incidents.

(5) Any record required by this division must be legible throughout the retention period specified by each Authority Agency rule. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as letters, stamps, initials, and signatures. The licensee must maintain adequate safeguards against tampering with and loss of records.

General Licenses

333-102-0101

General Licenses — Small Quantities of Source Material

(1) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to use and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operations purposes in the following forms and quantities: not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive or possess more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.

(a) No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms such as gaseous, liquid, or powder, at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year. Persons possessing source material in excess of these limits as of August 27, 2013, may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for one year beyond this date, or until the Commission takes final action on a pending application submitted on or before August 27, 2014, for a specific license for such material; and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until December 31, 2014, or until the Commission takes final action on a pending application submitted on or before August 27, 2014, for a specific license for such material; and

(b) No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this section may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this section unless it is accounted for under the limits of subsection (1)(a) of this rule; or

(c) No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this section; or

(d) No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this section may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

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

(a) Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Authority in a specific license.

(b) Shall not abandon such source material. Source material may be disposed of as follows:

(A) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of this paragraph is exempt from the requirements to obtain a license under this rule to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under this chapter; or

(B) In accordance with OAR 333-120-0500, Waste Disposal – General Requirements.

(c) Is subject to the provisions in OAR 333-100-0080, 333-102-0001, 333-102-0005, 333-102-0075, 333-102-0101, 333-102-0305, 333-102-0330, 333-102-0350, and 333-102-0353.

(d) Shall not export such source materials except in accordance with 10 CFR Part 110.

(3) Any person who receives, possesses, uses, or transfers source material in accordance with section (1) of this rule shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Authority about such contamination and may consult with the Authority as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in 10 CFR Parts 20.1402.

(4) Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in section (1) of this rule is exempt from the provisions of division 111 and 120 of this chapter and 10 CFR Part 21 to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of CFR 10 Parts 20.1402 and 20.2001 to the extent necessary to meet the provisions of subsection (2)(b) and section (3) of this rule. However, this exemption does not apply to any person who also holds a specific license issued under this division.

(5) No person may initially transfer or distribute source material to persons generally licensed under subsection (1)(a) or section (2) of this rule, or equivalent regulations of an Agreement State, unless authorized by a specific license issued in accordance with OAR 333-102-0102 or equivalent provisions of an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by section (1) of this rule before August 27, 2013 without specific authorization may continue for one year beyond this date. Distribution may also be continued until the Commission takes final action on a pending application for license or license amendment to specifically authorize distribution submitted on or before August 27, 2014.

~~(1) Persons who receive, possess, use, or transfer source material pursuant to the general license granted by section (1) of this rule are prohibited from administering source material, or the~~

~~radiation therefrom, either externally or internally to human beings except as may be authorized by the Authority in a specific license.~~

~~(2) Persons who receive, possess, use or transfer source material pursuant to the general license granted by section (1) of this rule are exempt from the provisions of divisions 111 and 120 of this chapter to the extent that such receipt, possession, use or transfer is within the terms of such general license; provided, however, that this exemption must not be deemed to apply to any such person who also is in possession of source material under a specific license issued pursuant to this division.~~

~~(63)~~ A general license is hereby granted authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use or transfer source material.

~~(74)~~ Persons who receive, acquire, possess or use source material pursuant to the general license granted by section (1) of this rule must develop and maintain procedures to establish physical control over the source material and prevent transfer of such source material to persons not authorized to receive the source material.

~~(85)~~ A person who receives, acquires, possesses or uses source material pursuant to the general license granted by section (1) of this rule:

(a) Must not introduce such source material, in any form, into a chemical, physical, or metallurgical treatment or process;

(b) Must not abandon such source material; and

(c) Must transfer or dispose of such source material only by transfer in accordance with the provisions of OAR 333-102-0330 or 333-120-0500.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

333-102-0102

Requirements for License to Initially Transfer Source Material for Use Under the Small Quantities of Source Materials General License

An application for a specific license to initially transfer source material for use under OAR 333-102-0101, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State shall be approved if:

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

(2) The applicant submits adequate information on, and the Commission approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 – 453.807

333-102-0104

Conditions of Licenses to Initially Transfer Source Material for Use Under the ‘Small Quantities of Source Material’ General License: Quality Control, Labeling, Safety Instructions, and Records and Reports

(1) Each person licensed under OAR 333-102-0102 shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words "radioactive material".

(2) Each person licensed under OAR 333-102-0102 shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

(3) Each person licensed under OAR 333-102-0102 shall provide the information specified in this rule to each person to whom source material is transferred for use under OAR 333-102-0101, equivalent provisions in Agreement State or the U.S. Nuclear Regulatory Commission’s regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

(a) A copy of OAR 333-102-0101 and OAR 333-102-0330, or relevant equivalent regulations of the Agreement State or the U.S. Nuclear Regulatory Commission; and

(b) Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

(4) Each person licensed under OAR 333-102-0102 shall report transfers as follows:

(a) File a report with the Authority. The report shall include the following information:

(A) The name, address, and license number of the person who transferred the source material;

(B) For each general licensee under OAR 333-102-0102:

(i) Equivalent Agreement State provisions or the Nuclear Regulatory Commission regulations to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter;

(ii) The name and address of the general licensee to whom source material is distributed;

(iii) A responsible agent, by name and position, and phone number, of the general licensee to whom the material was sent; and

(iv) The type, physical form, and quantity of source material transferred.

(C) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

(b) File a report with each responsible Agreement State or U.S. Nuclear Regulatory Commission agency that identifies all persons, operating under provisions equivalent to OAR 333-102-0102, to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the Agreement State being reported to:

(A) The name, address, and license number of the person who transferred the source material; and

(B) The name and address of the general licensee to whom source material was distributed; a responsible agent, by name or position and phone number of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred.

(C) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the Agreement State or U.S. Nuclear Regulatory Commission's jurisdiction.

(c) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under OAR 333-102-0101 or equivalent Agreement State or U.S. Nuclear Regulatory Commission's provisions during the current period, a report shall be submitted to the Authority indicating so. If no transfers have been made to general licensees in a particular Agreement State or U.S. Nuclear Regulatory Commission's jurisdiction during the reporting period, this information shall be reported to the responsible Agreement State agency upon request of the agency

(5) Each person licensed under OAR 333-102-0102 shall maintain all information that supports the reports required by this rule concerning each transfer to a general licensee for a period of one year after the event is included in a report to the Authority, Agreement State agency, or the U.S. Nuclear Regulatory Commission.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: : ORS 453.605 - 453.807

Exempt Items

333-102-010~~6~~3

General Licenses -- Depleted Uranium in Industrial Products and Devices

(1) A general license is hereby granted to receive, acquire, possess, use or transfer, in accordance with the provisions of sections (2), (3), (4) and (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in section (1) of this rule applies only to industrial products or devices that have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to OAR 333-102-0235 or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State that authorizes manufacture of the products or devices for distribution to persons granted a general license by the U.S. Nuclear Regulatory Commission or an Agreement State.

(3) Persons who receive, acquire, possess or use depleted uranium pursuant to the general license established by section (1) of this rule must apply for registration of the general license pursuant to OAR 333-101-0007, and submit the required fee pursuant to 333-103-0015. Applicants will receive a validation certificate from the Authority. Application for registration must be submitted within 30 days after the first receipt or acquisition of such depleted uranium.

(a) The general licensee must provide the following information in accordance with the registration application required by OAR 333-101-0007 and such other information as may be required by that form:

(A) Name and address of the general licensee;

(B) A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in section (1) of this rule and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(C) Name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in subsection (3)(b) of this rule.

(b) The general licensee possessing or using depleted uranium under the general license established by section (1) of this rule must report any changes in information in writing to the Authority within 30 days after the effective date of such change.

(4) A person who receives, acquires, possesses or uses depleted uranium pursuant to the general license established by section (1) of this rule:

(a) Must not introduce such depleted uranium, in any form, into a chemical, physical or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(b) Must not abandon such depleted uranium;

(c) Must transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of OAR 333-102-0330. In the case where the transferee receives the depleted uranium pursuant to the general license granted by section (1) of this rule, the transferor must furnish the transferee a copy of this rule and a copy of the general license registration application required by 333-101-0007. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to section (1) of this rule, the transferor must furnish the transferee a copy of this rule and a copy of the general license registration application required by 333-101-0007 accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this rule;

(d) Must report in writing to the Authority, within 30 days of any transfer, the name and address of the person receiving the depleted uranium pursuant to such transfer; and

(e) Must not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using or transferring depleted uranium pursuant to the general license established by section (1) of this rule is exempt from the requirements of divisions 111 and 120 of this chapter with respect to the depleted uranium covered by that general license.

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

General Licenses -- Radioactive Material Other than Source Material

~~333-102-0105~~

~~Certain Devices and Equipment~~

~~A general license is hereby granted to transfer, receive, acquire, own, possess and use radioactive material incorporated in the following devices or equipment that have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to section 31.3 of 10 CFR Part 31. This general license is 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), and 333-100-0065 (Tests), 333-102-0010(2) (Exempt Concentrations), 333-102-0305(1) through 333-102-0305(7) (Terms and Conditions of Licenses), 333-102-0330 (Transfer of Material), 333-102-0335 (Modification, Revocation, and Termination of Licenses), and divisions 111, 118, and 120 of this chapter.~~

~~**NOTE:** Attention is directed particularly to the provisions of division 120 of this chapter that relate to the labeling of containers (OAR 333-120-0430 and 333-120-0440).~~

~~(1) Static Elimination Devices. Devices designed for use as static eliminators that contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 microcuries) of polonium 210 per device;~~

~~(2) Ion Generating Tubes. Devices designed for ionization of air that contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 microcuries) of polonium 210 per device or a total of not more than 1.85 GBq (50 millicuries) of hydrogen 3 (tritium) per device.~~

~~**NOTE:** Different general licenses are issued in this division, each of which has its own specific conditions and requirements.~~

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

~~Stat. Auth.: ORS 453.635, 453.665~~

~~Stats. Implemented: ORS 453.605 - 453.807~~

333-102-0190

Application for Specific Licenses:

(1) Applications for specific licenses must be filed on a form prescribed by the Authority. Information contained in previous applications, statements or reports filed with the Authority, 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 Authority 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 Authority to determine whether the application ~~shall~~ be granted or denied or whether a license ~~shall~~ 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 Authority.

(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 Authority 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 Authority 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 ~~byproduct~~ 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); or

(c) ~~For s~~ Sources or devices ~~containing naturally occurring or accelerator produced radioactive material~~ manufactured prior to ~~November 30, 2007~~ October 23, 2012 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 the device; and

(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.:

(i) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR Part 32.210(g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity; or

(ii) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

(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 ~~shall~~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 ~~shall~~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 ~~shall~~would reduce the dose received;

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

(F) Operating restrictions or procedures ~~shall~~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 if** an accident occurs, including identification of personnel responsible for promptly notifying offsite response organizations and the Authority; 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 Authority 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 Authority.

(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 can** 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 division 116 of this chapter or equivalent Agreement State requirements shall include:

- (i) 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.
- (ii) Evidence that the applicant is qualified to produce radiopharmaceutical drugs for medical use by meeting one of the criteria in 10 CFR 32.72(a)(2).
- (iii) 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 333-116-0910.
- (iv) Information identified in 10 CFR Part 32.72(a)(3) on the PET radiopharmaceutical to be non-commercially transferred to members of its consortium.
- (v) 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 73.23 as applicable.

(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 Authority. The licensee must provide any comments received within the 60 days to the Authority 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

333-102-0200

General Requirements for the Issuance of Specific Licenses

An application for a specific license, will be approved if:

- (1) The application is for a purpose authorized by the Act;
- (2) The applicant is qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property;
- (3) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property;
- (4) The applicant satisfies any applicable special requirements contained in divisions 102, 105, 113, 115, 116, 117, or 121 of this chapter; and
- (5) In the case of an application for a license to receive and possess radioactive material for the conduct of any activity which the Authority determines will significantly affect the quality of the environment, the Authority Manager or designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to Subpart A of Part 51 of 10 CFR, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion must be grounds for denial of a license to receive and possess byproduct material in such plant or facility. As used in this rule, the term "commencement of construction" means any clearing of land, excavation, or other substantial action that ~~would~~can adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values. Upon a determination that an application meets the requirements of the Act, and the rules of the Authority, the Authority will issue a specific license authorizing the possession and use of radioactive material (Radioactive Materials License").
- (6) Financial assurance and recordkeeping for decommissioning ~~must meet the~~ following the requirementsspecific requirements listed below:
 - (a) 10 CFR 30.35 and 30.36 for radioactive material that is not source or special nuclear material; or
 - (b) 10 CFR 40.36 for source material; or
 - (c) 10 CFR 70.25 for special nuclear material.

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

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

333-102-0203

Definitions

The following definitions apply for Radioactive Material Licenses issued pursuant to this division and divisions 105, 113, 115, 117, and 121 of this chapter:

NOTE: Unless otherwise specified in this rule, the licenses described in this rule are limited by conditions of the radioactive materials license issued pursuant to OAR 333-102-0200, and other applicable rules in this chapter.

- (1) "Analytical Leak Test" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(a), authorizing possession of environmental samples, sealed source leak-test, contamination wipe and samples for radioanalytical measurements. This license does not authorize collection of samples, or decommissioning or decontamination activities.
- (2) "Assets" means anything of material value or usefulness. In the context of a materials license, assets include all existing capital, effects, possessions, and belongings and all probable future economic benefits obtained or controlled by a particular entity.
- (3) "Basic License" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(b) authorizing the receipt, possession, use, transfer, and disposal of sources of radiation or radioactive materials incident to gauge service, teletherapy service, medical afterloader service, and other licensed service activities; pre-packaged waste pickup (not packaging), storage of materials prior to license termination, instrument quality control servicing or calibration (excluding activities authorized by 333-103-0010(2)(m)), or other minor activities not otherwise specified in these rules, such as authorization for "systems," as defined in these rules, pursuant to that definition.
- (4) "Beneficiating" means subjecting a product to any process that can increase or concentrate any component (including the radioactive materials) to benefit the product.
- (5) "Brachytherapy" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(c) authorizing the use of brachytherapy sources for in vivo application of radiation in accordance with 333-116-0420. Brachytherapy includes radioactive material sealed sources in seeds, needles, plaques, or other localized medical devices, but excludes remote afterloaders.
- (6) "Broad Scope A" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(d), authorizing activities in 333-102-0900(1)(a), under the authority of a Radiation Safety Committee.
- (7) "Broad Scope B" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(e) authorizing activities described in 333-102-0900(1)(b), under the authority of a Radiation Safety Officer.
- (8) "Broad Scope C" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(f) authorizing activities described in 333-102-0900(1)(c), under the authority of an authorized user.
- (9) "Commencement of construction" means taking any action defined as "construction" or any other activity at the site of a facility subject to the regulations in this division that has a reasonable nexus to radiological health and safety.

(10) "Construction" means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the regulations in this division that are related to radiological safety or security. The term "construction" does not include:

- (a) Changes for temporary use of the land for public recreational purposes;
- (b) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;
- (c) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;
- (d) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this division;
- (e) Excavation;
- (f) Erection of support buildings (for example, construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;
- (g) Building of service facilities (for example, paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);
- (h) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or
- (i) Taking any other action that has no reasonable nexus to radiological health and safety.

(11) "Current assets" means cash or other assets or resources commonly identified as those which are reasonably expected to be realized in cash or sold or consumed during the normal operating cycle of the business.

(12) "Decontamination and Decommissioning" means:

- (a) A facility specific license issued pursuant to OAR 333-103-0010(2)(w) authorizing activities that result in returning a site to its original pre-license condition prior to termination of licensed activities; and
- (b) Activities performed pursuant to OAR 333-102-0335 on any portion of a site prior to license termination.

(13) "Diagnosis" means examination, determination, identification, study, or analysis of a medical condition.

(14) "Distribution" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(g), authorizing transfer or distribution (sale) of general or specific license radioactive material to persons granted a general license or issued a specific license, or, in the case of NARM, to persons exempt from the rules in this chapter.

- (15) "Exempt Source" means radioactive material, exempt from the rules in this chapter.
- (16) "Facility" means location of licensed activities under the direct control of licensee management. If a "facility," as used in this division, includes multiple separate addresses, the Authority may determine how the scope of licensed activities, pursuant to OAR 333-102-0190, 333-102-0300, 333-102-0305, 333-102-0315, 333-102-0320, or 333-102-0325, is authorized.
- (17) "Fixed Gauge" means a source-specific license for measuring, gauging, or controlling devices pursuant to OAR 333-103-0010(2)(h). The fixed gauge license also includes X-ray & Hybrid Gauges pursuant to division 115 of this chapter, that contain either an X-ray source or a radioactive sealed source.
- (18) "General License" means a granted license, as opposed to an issued license, effective under these rules, to acquire, own, possess, use, or transfer radioactive material or a device that contains radioactive material.
- (19) "General License Depleted Uranium" means the general license granted subject to receipt of the registration application pursuant to OAR 333-101-0007, and fee, pursuant to 333-103-0015, for depleted uranium used for shielding or counter weights and issued pursuant to ~~333-102-0103~~333-102-0106.
- (20) "General License Device" means the general license for in vitro materials granted subject to receipt of the registration application pursuant to OAR 333-101-0007, and fee, pursuant to 333-103-0015, for measuring, gauging.
- (21) "General License In Vitro Laboratory" means the general license granted by OAR 333-102-0130, subject to receipt of the registration application pursuant to 333-101-0007, and fee, pursuant to 333-103-0015, for in vitro materials granted a general license by 333-102-0130.
- (22) "General License Source Material" means the general license granted for use and possession of source material pursuant to OAR 333-102-0101.
- (23) "General License for Certain Devices and Equipment" means the general license granted for use and possession of devices consisting of not more than 500 microcuries of polonium-210 or not more than 50 millicuries of tritium (H-3) per device, pursuant to 10 CFR 31.3.
- (24) "General License for Luminous Devices for Aircraft" means the general license granted for use and possession of devices containing not more than ten curies of tritium or not more than 300 millicuries of promethium-147.
- (25) "General License for Ownership of Radioactive Material and Limits of Possession" means the general license granted to own material that is not necessarily possessed; conversely, material that is possessed is, by grant of general license, not necessarily owned, pursuant to the general license in OAR 333-102-0120.
- (26) "General License for Calibration and Reference Sources" means the general license granted to possess not more than five microcuries (185 kBq) of americium-241, plutonium-238, plutonium-239, or radium-226, pursuant to the general license in OAR 333-102-0125.
- (27) "General License for Ice Detection Devices" means the general license granted to possess not more than 50 microcuries (1.85 MBq) of strontium-90, pursuant to the general license in OAR 333-102-0135.

- (28) "Generators and Kits" means "Imaging and Localization."
- (29) "Healing Arts Specific License" means a specific license authorizing activities in division 116 of this chapter.
- (30) "High Doserate Remote Afterloader" means a source-specific license issued pursuant to OAR 333-103-0010(2)(i) authorizing the use of sources in accordance with 333-116-0475, which may be either mobile or stationary, and which deliver a doserate in excess of two Gray (200 rad) per hour at the point or surface where the dose is prescribed. A device may be designated as being high, medium, or pulsed dose remote afterloader or mobile high, medium, or pulsed doserate remote afterloader.
- (31) "Hybrid Gauge" means a fixed gauging device that contains both a sealed source and an X-ray source, pursuant to division 115 of this chapter.
- (32) "In Vitro Laboratory" means a Healing Arts facility-specific license, under management of a physician or Healing Arts specialist, issued pursuant to OAR 333-103-0010(2)(k) authorizing the use of prepackaged radioactive materials in quantities greater than those authorized by the General License granted by 333-102-0130(2).
- (33) Imaging and Localization means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(j) authorizing the use of generators and kits for nuclear medicine imaging and localization in accordance with 333-116-0320 or positron emission tomography studies in accordance with 333-116-0800 through 333-116-0880.
- (34) "Industrial Radiography" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(l) authorizing activities in division 105 of this chapter.
- (35) "Instrument Calibration" means a source-specific radioactive materials license issued pursuant to OAR 333-103-0010(2)(m) for sources of radiation used to calibrate instruments.
- (36) "Investigational New Drug" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(n) authorizing the use of any investigational product or device approved by the US Food and Drug Administration (FDA) for human use research, diagnosis, or therapy, in accordance with the rules in this chapter.
- (37) "Irradiator-Other" means an irradiator with greater than 10,000 curies (370 TBq) licensed pursuant to OAR 333-103-0010(2)(w) and 333-103-0010(7), designed to produce extremely high dose rates as authorized by division 121 of this chapter.
- (38) "Irradiator Self-shielded or Other — Less than 10,000 Curies" means a source-specific license issued pursuant to OAR 333-103-0010(2)(o) authorizing self-shielded irradiators, including blood irradiators, panoramic irradiators, and converted teletherapy units, with less than 10,000 Ci (370 TBq) activity.
- (39) "Liabilities" means probable future sacrifices of economic benefits arising from present obligations to transfer assets or provide services to other entities in the future as a result of past transactions or events.
- (40) "Lot Tolerance Percent Defective" means, expressed in percent defective, the poorest quality in an individual inspection lot that can be accepted.

(41) "Low Doserate Remote Afterloader Device" means a Healing Arts source-specific license issued pursuant to OAR 333-103-0010(2)(b) authorizing devices 333-116-0475, which remotely deliver a doserate of less than two Gray (200 rad) per hour at the point or surface where the dose is prescribed.

(42) "Manufacturing or Compounding" means a facility-specific radioactive materials license issued pursuant to OAR 333-103-0010(2)(p) authorizing manufacture, fabrication, assembly, construction, combining, processing, concentrating, beneficiating, or processing items or products using or containing radioactive materials into a finished product containing radioactive material in accordance with applicable requirements in division 102 of this chapter.

(43) "Manufacturing or Compounding and Distribution" means activities performed as defined in sections (14) and (42) of this rule and require separate specific licenses for each activity.

(44) "Mobile Nuclear Medicine Service" means a facility-specific Healing Arts license issued pursuant to OAR 333-116-0120 authorizing the medical use of radioactive material at specified temporary locations.

(45) "Nationally Tracked Source" means a sealed source containing a quantity equal to or greater than Category 1 or 2 levels of any radioactive material listed in 10 CFR 20 Appendix E.

(46) "Naturally occurring radioactive material (NORM)" means radioactive material in the uranium or thorium decay series existing in nature in concentrations less than 0.05 percent source material.

(47) "Net working capital" means current assets minus current liabilities.

(48) "Net worth" means total assets minus total liabilities and is equivalent to owner's equity.

(49) "Neutron Howitzer" means a device that contains a sealed source containing Special Nuclear Material (see definition in OAR 333-100-0005) that generates neutrons that are used for analytical, teaching, or research purposes.

(50) "Neutron Production" denotes a process in which neutrons are produced, either by natural or artificial means.

(51) "NORM (no processing)" means a facility-specific license pursuant to OAR 333-103-0010(2)(r) authorizing possession, use, and transfer of NORM in accordance with division 117 of this chapter.

NOTE: NORM licenses authorize licensable quantities of radioactive material in the uranium or thorium decay series. Licensable quantities of NORM are derived from disposal limits in OAR chapter 345, division 50. Any material that contains NORM requires a specific license unless exempted in OAR chapter 345, division 50. Zircon sand is used as the NORM model for licensing purposes. Quantities of zircon sand in excess of 20,000 pounds in a year constitute a licensable quantity of NORM. NORM materials that are not zircon are based on the zircon model.

(52) "Nuclear Laundry" means a laundry facility designed specifically to clean or launder clothing contaminated with licensed radioactive materials. Nuclear Laundry facilities must have process and waste management control procedures to prevent reconcentrating of licensed materials in sewers, drains, premises, and the environment. Nuclear Laundry activities are

authorized pursuant to OAR 333-103-0010(2)(w), "Radioactive Material Not Otherwise Specified Facility," see 333-102-0203(61).

(53) "Nuclear Pharmacy" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(s) for activities authorized by 333-102-0285 and the Oregon Board of Pharmacy rules, to compound Radiopharmaceutical and distribute (sell or transfer) to persons specifically licensed to receive such compounds or products.

NOTE: Nuclear Pharmacies, pursuant to policy provisions of chapter 345 division 50 may collect syringes containing residual licensed material from spent patient doses, since the syringe is considered to be a transport device under the administrative control of the pharmacy rather than the licensed material transferred as the dose. Residual licensed material may be considered either to be exempt pursuant to Table 1 of division 50 or under the authority of a division license if the receding licensee stores syringes for decay. In either case, the division license specifies which disposal method is being used by the pharmacy and licensee to avoid compatibility conflicts with division 50 requirements.

(54) "Other Measuring Device" means a source-specific license issued pursuant to OAR 333-103-0010(2)(t), authorizing analytical instruments, gas chromatograph electron capture detectors, and other non-portable analytical instruments, including those devices that contain multiple sources but are configured and used as a "system," in accordance with the definition in this rule.

NOTE: General license gas chromatograph detectors that formerly were granted a general license by OAR 333-102-0115, but which required a registration fee pursuant 333-103-0015(2)(b), now are subject to the specific license in 333-103-0010(2)(t).

(55) "Pool-type Irradiator" means an irradiator with greater than 10,000 curies (370 TBq) in which water provides the radiation shielding, authorized in accordance with division 121 of this chapter.

(56) "Portable Gauge" means a source-specific license issued pursuant to OAR 333-103-0010(2)(u) for sources used in devices that can be transported and used at temporary job sites.

NOTE: Any device that meets the definition of "portable gauge" and is transported or used at temporary job sites within the state of Oregon, requires an application for and issuance of an Oregon specific license subject to OAR 333-103-0010(2)(u).

(57) "Positron Emission Tomography" (PET) means a licensed healing arts activity authorized by OAR 333-116-0800 and included in the facility specific license issued pursuant to 333-103-0010(2)(j). PET nuclides, which are NARM, are subject to all Oregon rules.

(58) "Possession or Storage of Industrial Wastes Containing Radioactive Material" means activities subject to division 110 of this chapter for the production or storage of wastes that are exempt from division 50 of chapter 345 facility siting requirements, and were generated under a current NRC, Agreement State, or Licensing State specific radioactive materials license.

(59) "Possession or Storage of Uranium Tailings" means activities incident to uranium processing or milling operations resulting in the production of tailings.

(60) "Principal Activities" means activities authorized by the license that are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no

licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

(61) "Processing" means chemically or physically changing a licensed material from one physical form to another form or specie (for example, breaking an ore down into its components resulting in "tailings"; milling a raw licensed material and combining to form another product or material. See "Beneficiating"; "Manufacturing or Compounding").

(62) "Radiation Source" means source of radiation (see definition of "Source of radiation" in OAR 333-100-0005).

(63) "Radioactive Material Not Otherwise Specified Facility" means a license issued pursuant to OAR 333-103-0010(2)(w) authorizing activities that includes, but are not limited to, complex licensable activities such as facility decontamination and decommissioning, nuclear laundry activities, uranium mill tailings storage, storage of industrial wastes containing radioactive materials, large irradiator management, and other complex activities not otherwise specified in these rules.

(64) "Radioactive Materials License" means the document, pursuant to OAR 333-102-0300, issued after an application, pursuant to 333-102-0190, has been accepted as adequate, that specifies radioactive materials, use authorizations, safety procedures, and use locations.

(65) "Radiopharmaceutical Therapy" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(v) authorizing the use of Radiopharmaceutical for therapy in accordance with 333-116-0360.

(66) "Remote Afterloader" means a medical device that moves a sealed source to an interstitial (in vivo) location without exposing the practitioner to the radiation dose. Remote afterloader sources may be manipulated using computer software and engineering techniques.

(67) "Research & Development" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(x) authorizing research and development activities, as defined in 333-100-0005, but does not authorize additional specific sources of radiation, which must be licensed separately pursuant to 333-103-0010 and 333-103-0015.

(68) "Responsible Representative" means

(a) The person designated as having responsibility for general license device or general license material;

(b) The person management has selected to certify general license inventory; and

(c) The individual responsible to the Authority and to management to ensure that all regulatory elements are adequate.

(69) "Sealed Source/Device Evaluation" means the review of a licensee's prototype source or device prior to registration by the Nuclear Regulatory Commission in the Sealed Source and Device Catalog.

NOTE: The Authority no longer has authority to review sources or devices. All source or device reviews must be forwarded to the NRC for review. Authority to conduct device or source evaluations was rescinded by the NRC in 1998.

(70) "Site Area Emergency" means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

(71) "Sealed Sources for Diagnosis" means a Healing Arts source-specific license issued pursuant to OAR 333-103-0010(2)(y) authorizing the use of sealed sources for diagnosis in accordance with 333-116-0400.

(72) "Special Nuclear Material" means:

(a) Plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the NRC, pursuant to the provisions of section 51 of the act, determines to be special nuclear material, but does not include source material; or

(b) Any material artificially enriched by any of the foregoing but does not include source material.

(73) "Specific License Radioactive Material" means radioactive material that requires authorization in a specific license document pursuant to OAR 333-102-0075(2) where materials must be annotated on the specific license, and validated with a specific license fee pursuant to 333-103-0010(2)(a) through 333-103-0010(2)(hh) (see "Radioactive Materials License").

(74) "System," as used in this division, means multiple separate (individual) sources of radiation (sealed radioactive sources), which together, rather than independently, achieve a desired functionality. Such "system" is subject to one specific license fee or general license registration fee, as the case may be.

(75) "Tangible Net Worth" means the tangible assets that remain after deducting liabilities; such assets may not include intangibles such as goodwill and rights to patents or royalties.

(76) "Teletherapy" means a Healing Arts source-specific license issued pursuant to OAR 333-103-0010(2)(cc) authorizing teletherapy procedures in accordance with OAR 333-116-0480. This license also includes other high dose rate external beam therapy devices such as the "gamma knife."

(77) "Temporary Job Site" means any location, where specific license material is used that is either:

(a) Not the specific location of the licensee if an in-state licensee; or

(b) Any location in the state if an out-of-state specific licensee pursuant to a specific radioactive materials license.

NOTE: Persons authorized for temporary jobsites in Oregon must have a specific license for such activities.

(78) "Therapy" means a process that is meant to be restorative, promotes healing, or is beneficial to a patient in a healing arts context.

(79) "Unique" means a specific license issued pursuant to OAR 333-103-0010(2)(dd) to agencies in the Oregon Health Authority.

(80) "Uptake and Dilution" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(ee) authorizing activities in 333-116-0300 for uptake, dilution, and excretion studies.

(81) "Use and Possession of Source Material " means a facility-specific radioactive materials license issued pursuant to OAR 333-103-0010(2)(z) to possess, use, process, or transfer source material, as defined in OAR 333-100-0005, in quantities greater than general license quantities or in concentrations greater than 0.05 percent source material.

NOTE: This definition was amended to avoid confusion between the definition of "source material" in division 100 of this chapter and the specific license (billable object) in division 103 of this chapter.

(82) "Use of Xenon Gas" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(ff) authorizing the use of Xe-133 for diagnosis pursuant to 333-116-0280.

(83) "Waste Packaging" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(gg), authorizing packaging, collection, storage, and transfer of radioactive waste. This specific license does not authorize storage of radioactive wastes, but does authorize temporary job sites.

(84) "Well Logging" means a license issued pursuant to OAR 333-103-0010(2)(hh) authorizing the possession, use, transfer, or disposal of sources of radiation used for well logging activities authorized by division 113 of this chapter.

NOTE: Unless specifically authorized in this rule or in a radioactive materials license that authorizes temporary job sites, specific licenses must be used only at one authorized site.

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

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

333-102-0235

Requirements for License to Manufacture, or Initially Transfer Radioactive Material Contained in Devices Granted a General License Under OAR 333-102-0115

(1) An application for a specific license to manufacture, or initially transfer devices containing radioactive material, excluding special nuclear material, to persons granted a general license by OAR 333-102-0115 or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State will be approved if:

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

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(A) The device can be safely operated by persons not having training in radiological protection;

(B) Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device; and it is unlikely that any person will receive in one year a dose in excess of ten percent of the annual limits specified in OAR 333-120-0100; and

(C) Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person ~~may~~ receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in 10 CFR Part 32.24:

(i) Whole body, head and trunk, active blood-forming organs, gonads, or lens of eye 150 mSv (15 rem);

(ii) Hands and forearms, feet and ankles, localized areas of skin averaged over areas no larger than one square centimeter two Sv (200 rem);

(iii) Other organs 500 mSv (50 rem).

(c) Each device bears a durable, legible, clearly visible label or labels approved by the Authority, which contain in a clearly identified and separate statement:

(A) Instructions and precautions necessary to assure safe installation, operation and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

(B) The requirements, or lack of requirement, for leak testing, or for testing of any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(C) The information called for in the following statement in the same or substantially similar form:

The receipt, possession, use and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label must be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION — RADIOACTIVE MATERIAL

(Name of manufacturer or initial transferor)

~~NOTE: Devices licensed under 10 CFR Part 32.51 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975. The model, serial number, and name of manufacturer, or initial transferor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.~~

(D) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material," the

radiation symbol described in OAR 333-120-0400, and the name of the manufacturer or initial distributor.

(E) Each device meeting the criteria of OAR 333-102-0115(9)(a), bears a permanent label, such as being (e.g., embossed, etched, stamped, or engraved.) ~~label~~-affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in OAR 333-120-0400.

(F) The device has been registered in the Sealed Source and Device Registry

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or both, the applicant must include in this application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices, and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Authority will consider information that includes, but is not limited to:

- (a) Primary containment (source capsule);
- (b) Protection of primary containment;
- (c) Method of sealing containment;
- (d) Containment construction materials;
- (e) Form of contained radioactive material;
- (f) Maximum temperature withstood during prototype tests;
- (g) Maximum pressure withstood during prototype tests;
- (h) Maximum quantity of contained radioactive material;
- (i) Radiotoxicity of contained radioactive material; and
- (j) Operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under OAR 333-102-0115, or under equivalent rules of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant must include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and the bases for these estimates. The submitted information must demonstrate that performance of this activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of ten percent of the annual limits specified in OAR 333-120-0100.

(4) Prior to transfer of a device to a person granted a general license by OAR 333-102-0115(1), the licensee must:

(a) Furnish a copy of the general license contained in OAR 333-102-0115 to each person to whom the licensee directly, or through an intermediate person, transfers radioactive material in a device for use pursuant to the general license contained in 333-102-0115;

(b) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State's rules equivalent to OAR 333-102-0115. Alternatively, a copy of the general license contained in 333-102-0115 must be furnished to each person to whom directly, or through an intermediate person, is transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the Agreement State or the Licensing State. If a copy of the general license in 333-102-0115 is furnished to such person, it must be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State under requirements substantially the same as those in 333-102-0115;

(c) Report to the Authority all transfers of such devices to persons for use under the general license in OAR 333-102-0115. Such report must identify each general licensee by name and address, an individual by name ~~and~~/or position who may constitute a point of contact between the Authority and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report must include identification of each intermediate person by name, address, contact and relationship to the intended user. If no transfers have been made to persons granted a general license by 333-102-0115 during the reporting period, the report must so indicate. The report must cover each calendar quarter and must be filed within 30 days after the end of each quarter;

(d) Furnish reports to other agencies

(A) Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in section 31.5 of 10 CFR Part 31. Reports must be submitted on the NRC form "Transfers of Industrial Devices Report" or on a clear and legible report containing all of the data required by the form. The required information includes:

(i) The identity of each general licensee by name and address;

(ii) The name and phone number of the person designated by the general licensee to be responsible for ensuring compliance with the appropriate regulations and requirements;

(iii) The date of transfer;

(iv) The type, model number, and serial number of the device transferred; and

(v) The quantity and type of byproduct material contained in the device.

(B) If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report must include the same information for each intermediate person, and clearly designate that person as an intermediate person.

(C) If the device transferred replaced another returned by the general licensee, report also the type, model number, and serial number of the one returned.

(D) If no transfers have been made to persons generally licensed under 10 CFR 31.5 or OAR 333-102-0115 during the reporting period, the report must so indicate.

(E) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(F) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(e) Report to the responsible Agreement or Licensing State Authority all transfers of such devices to persons for use under a general license in an Agreement State's regulations equivalent to OAR 333-102-0115. Such reports must identify all of the information in 333-102-0235(4)(d) of this rule, including each general licensee by name and address, an individual by name ~~and~~/or position who may constitute a point of contact between the Authority and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report must include identification of each intermediate person by name, address, contact and relationship to the intended user. The report must be submitted within 30 days after the end of each calendar quarter in which such device is transferred to the person granted a general license;

(f) If no transfers have been made to U.S. Nuclear Regulatory Commission's licensees during the reporting period, this information must be reported to the U.S. Nuclear Regulatory Commission;

(g) If no transfers have been made to persons granted a general license within a particular Agreement State during the reporting period, this information must be reported to the responsible Agreement State Agency upon request of the Authority;

(h) Keep records showing the name, address and the point of contact for each general licensee to whom directly, or through an intermediate person is transferred radioactive material in devices for use pursuant to the general license provided in OAR 333-102-0115 or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The records ~~must~~~~should~~ show the date of each transfer, the isotope and the quantity of radioactive material in each device transferred, the identity of any intermediate person and compliance with the reporting requirements of subsection (4)(h) of this rule. Records required by this rule must be maintained for a period of three years following the estimated useful life of the device or the date of final disposition, if known;

(i) Furnish a list of the services that only can be performed by a specific licensee, and information on acceptable disposal options, including estimated costs of disposal, to each person to whom he directly, or through an intermediate person, transfers radioactive material in a device for use under the general license granted in OAR 333-102-0115;

(j) Furnish the name, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained. If a copy of the general license in OAR 333-102-0115 is furnished to such person, it must be accompanied by a note explaining that use of the device is regulated by the Agreement State.

(k) Label each device transferred if more than one year after the effective date of this rule in accordance with the labeling requirements in 10 CFR Part 32.51(a)(3) through (5).

(l) If a notification of bankruptcy has been made under 10 CFR Part 30.34(h) or the license is to be terminated, provide, upon request, to the NRC and to any appropriate Agreement State, records of final disposition required under 10 CFR Part 32.52(c).

(5) License Conditions.

(a) If a device containing radioactive material is to be transferred for use under the general license contained in OAR 333-102-0115, each person that is licensed under this rule must provide the information specified in this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(A) A copy of the general license contained in OAR 333-102-0115; if 333-102-0115(4)(b) through (d) or 333-102-0115(8) do not apply to the particular device, those sections may be omitted;

(B) A copy of OAR 333-102-0115, 333-100-0055, 333-100-0057, 333-120-0700 and 333-120-0710;

(C) A list of the services that can only be performed by a specific licensee;

(D) Information on acceptable disposal options including estimated costs of disposal; and

(b) If radioactive material is to be transferred in a device for use under an equivalent general license of an Agreement State, each person that is licensed under this rule must provide the information specified in this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(A) A copy of the Agreement State's regulations equivalent to OAR 333-102-0115, 333-100-0055, 333-100-0057, 333-120-0700 and 333-120-0710 or a copy of 10 CFR Secs. 31.5, 31.2, 30.51, 20.2201, and 20.2202. If a copy of the Nuclear Regulatory Commission regulations is provided to a prospective general licensee in lieu of the Agreement State's regulations, it must be accompanied by a note explaining that use of the device is regulated by the Agreement State. If certain sections of the regulations do not apply to the particular device, those sections may be omitted;

(B) A list of the services that can only be performed by a specific licensee;

(C) Information on acceptable disposal options including estimated costs of disposal; and

(D) The name or title, address, and phone number of the contact at the Agreement State regulatory agency or the Nuclear Regulatory Commission from which additional information may be obtained.

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

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

333-102-0285

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

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

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

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

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

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

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

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

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

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

(d) The applicant satisfies the following labeling requirements:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(B) The Commission or Agreement State license; or

(C) Commission master materials licensee permit; or

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

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

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

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

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

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

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

NOTE: Although the Authority 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 Authority for use by persons licensed for medical use pursuant to OAR chapter 333, division 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

333-102-0290

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

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

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

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

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

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

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

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

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

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

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

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

(c) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, date of assay and a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source or device) to persons licensed to use radioactive material identified in OAR 333-116-0190, 333-116-0400, or 333-116-0420, as appropriate, and to persons who hold an equivalent license issued by an Agreement State or the US Nuclear Regulatory Commission. However, labels worded in accordance with requirements that were in place on March 30, 1987 may be used until March 30, 1989.

(d) The source or device has been registered in the Sealed Source and Device Registry.

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

(a) The applicant must include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

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

(A) Primary containment or source capsule;

(B) Protection of primary containment;

(C) Method of sealing containment;

(D) Containment construction materials;

(E) Form of contained radioactive material;

(F) Maximum temperature withstood during prototype tests;

(G) Maximum pressure withstood during prototype tests;

(H) Maximum quantity of contained radioactive material;

(I) Radiotoxicity of contained radioactive material; and

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

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

333-102-0293

Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications

(1) An application for a specific license to manufacture industrial products or devices containing depleted uranium for use pursuant to OAR ~~333-102-0103~~333-102-0106 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

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

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses and potential hazards of the industrial product or device to provide reasonable assurance that possession, use or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of ten percent of the limits specified in OAR 333-120-0100; and

(c) The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the Authority will approve an application for a specific license under this rule only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The Authority may deny any application for a specific license under this rule if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to section (1) of this rule must:

(a) Maintain the level of quality control required by the license in the manufacture of the industrial product or device; and in the installation of the depleted uranium into the product or device;

(b) Label or mark each unit to:

(A) Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium and the quantity of depleted uranium in each product or device; and

(B) State that the receipt, possession, use and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an Agreement State.

(c) Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering:
Depleted Uranium.

(A) Furnish a copy of the general license contained in OAR ~~333-102-0103~~333-102-0106 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in ~~333-102-0103~~333-102-0106; or

(B) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to OAR ~~333-102-0103~~333-102-0106 and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in ~~333-102-0103~~333-102-0106 to each person to whom depleted uranium in a product or device is transferred for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in ~~333-102-0103~~333-102-0106.

(d) Report to the Authority all transfers of industrial products or devices to persons for use under the general license in OAR ~~333-102-0103~~333-102-0106. Such report must identify each general licensee by name and address, an individual by name ~~and~~/or position who may constitute a point of contact between the Authority and the general licensee, the type and model number of device transferred and the quantity of depleted uranium contained in the product or device. The report must be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons granted a general license by OAR ~~333-102-0103~~333-102-0106 during the reporting period, the report must so indicate.

(e) Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in section 40.25 of 10 CFR Part 40.

(A) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to OAR 333-102-0115 for use under a general license in that state's regulations equivalent to ~~333-102-0103~~333-102-0106.

(B) Such report must identify each general licensee by name and address, an individual by name ~~and~~/or position who may constitute a point of contact between the Authority and the general licensee, the type and model number of the device transferred and the quantity of depleted uranium contained in the product or device. The report must be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person.

(C) If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information must be reported to the U.S. Nuclear Regulatory Commission.

(f) If no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information must be reported to the responsible Agreement State Agency upon the request of that Agency.

(g) Keep records showing the name, address and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in OAR 333-102-0101(4) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records must be maintained until inspection by the Authority and must show the date of each transfer, the quantity of depleted uranium in each product or device transferred and compliance with the report requirements of section (9) of this rule.

(h) Licensees required to submit emergency plans by OAR 333-102-0190(10) must follow the emergency plan approved by the Commission. The licensee may change the plan without Commission approval if the changes do not decrease the effectiveness of the plan. The licensee must furnish the change to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease the effectiveness of the approved emergency plan may not be implemented without application to and prior approval by the Authority.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

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, 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 Authority.

(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 Authority, 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) An application for transfer of license must include:

(a) The identity, technical and financial qualification of the proposed transferee; and

(b) Financial assurance for decommissioning as required by [10 CFR Part 30.35](#). ~~OAR 333-102-0200(6)~~

(4) Each person licensed by the Authority 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.

(5) 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.

(6) The Authority 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.

(7) Licensees required to submit emergency plans by OAR 333-102-0190(10) must follow the emergency plan approved by the Authority. The licensee may change the approved plan without Authority approval only if the changes do not decrease the effectiveness of the plan. The licensee must furnish the change to the Authority 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 Authority.

(8) 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 or strontium-82 and strontium-85, respectively, 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.

(9)(a) Each general licensee subject to the registration requirement in OAR 333-101-0007 and each specific licensee must notify the Authority 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(154)) controlling the licensee or listing the 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.

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

(11) 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.

(12) 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.

(13) 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 this section must be kept until inspection by the Authority.

(14) 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."

(15) 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 this section must be kept until inspection by the Authority.

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

(17) 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

(18) 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 Authority, 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.

(19) 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.

(20) 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.

(21) 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.

(22) 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.

(23) 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.

(24) A licensee may store, pursuant to OAR 333-120-0500, radioactive waste for decay in storage before disposal in accordance with 333-116-0290.

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

(26) 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.

(27) 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.

(28) 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.

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

(30) Authorization under OAR 333-102-0190(10)(c)(N) to produce Positron Emission Tomography (PET) radiopharmaceutical 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 radiopharmaceutical drugs.

(31) Each licensee authorized under OAR 333-102-0190(10)(c)(N) to produce PET radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium shall:

(a) Satisfy the labeling requirements in OAR 333-102-0285(1)(d) for each PET radiopharmaceutical drug transport radiation shield and each syringe, vial, or other container used to hold a PET radiopharmaceutical drug intended for noncommercial distribution to members of its consortium.

(b) Possess and use instrumentation to measure the radioactivity of the PET radiopharmaceutical 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 333-102-0285(3).

(32) A licensee that is a pharmacy authorized under OAR 333-102-0190(10)(c)(N) to produce PET radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radiopharmaceutical drugs shall be:

(a) An authorized nuclear pharmacist who 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.

(33) A pharmacy, authorized under OAR 333-102-0190(10)(c)(N) to produce PET radiopharmaceutical 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 333-116-0910.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

333-102-0310

Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas

(1)(a) Except as provided in subsection (1)(b) of this rule, each specific license must expire at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under OAR 333-102-0315 before the expiration date stated in the existing license (or, for those licenses subject to subsection (1)(b) of this rule, before the deemed expiration date in that section). If an application for renewal has been filed before the expiration date stated in the existing license (or, for those licenses subject to subsection (2)(a) of this rule, before the deemed expiration date in that section), the existing license expires at the end of the day on which the Authority makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(b) Each specific license that has an expiration date after July 1, 1995, and is not one of the licenses described in subsection (1)(c) of this rule, shall be deemed to have an expiration date that is five years after the expiration date stated in the current license.

(c) The following specific licenses are not subject to, or otherwise affected by, the provisions of subsection (1)(b) of this rule:

(A) Specific licenses for which, on February 15, 1996, an evaluation or an emergency plan is required in accordance with OAR 333-102-0190(10);

(B) Specific licenses whose holders are subject to the financial assurance requirements specified in OAR 333-102-0200(6), and on February 15, 1996, the holders either:

(i) Have not submitted a decommissioning funding plan or certification of financial assurance for decommissioning; or

(ii) Have not received written notice that the decommissioning funding plan or certification of financial assurance for decommissioning is acceptable;

~~(C) Specific licenses whose holders are listed in the SDMP List published in NUREG 1444, Supplement 1 (November 1995);~~

~~(CD)~~ Specific licenses who need an environmental assessment or environmental impact statement pursuant to ~~Subpart A of Part 51 and~~ OAR 333-102-0200(5);

~~(DE)~~ Specific licenses whose holders have not had at least one Authority inspection of licensed activities before February 15, 1996;

~~(EF)~~ Specific licenses whose holders, as the result of the most recent Authority inspection of licensed activities conducted before February 15, 1996, have been:

(i) Cited for a serious health and safety noncompliance;

(ii) Subject to an Order issued by the Authority; or

(iii) Subject to a Confirmatory Action Letter issued by the Authority.

~~(FG)~~ Specific licenses with expiration dates before July 1, 1995, for which the holders have submitted applications for renewal under OAR 333-102-0315.

(2) Each specific license revoked by the Authority expires at the end of the day on the date of the Commission's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Authority Order.

(3) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material or source material until the Authority notifies the licensee in writing that the license is terminated. During this time, the licensee must:

(a) Limit actions involving material to those related to decommissioning; and

(b) Continue to control entry to restricted areas until they are suitable for release in accordance with Authority requirements.

(4) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in OAR 333-100-0045, each licensee must provide notification to the Authority in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Authority requirements, or submit within 12 months of notification a decommissioning plan, if required by subsection (7)(a) of this rule, and begin decommissioning upon approval of that plan if:

(a) The license has expired pursuant to sections (1) or (2) of this rule; or

(b) The licensee has decided to permanently cease principal activities, as defined in OAR 333-102-0203, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Authority requirements; or

(c) No principal activities under the license have been conducted for a period of 24 months; or

(d) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Authority requirements.

(5) Coincident with the notification required by section (4) of this rule, the licensee must maintain in effect all decommissioning financial assurances established by the licensee pursuant to OAR 333-102-0200(6) in conjunction with a license issuance or renewal or as required by this rule. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to paragraph (7)(d)(E) of this rule.

(a) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan must do so when this rule becomes effective November 24, 1995.

(b) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Authority.

(6) The Authority may grant a request to extend the time periods established in section (4) of this rule if the Authority determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to section (4) of this rule. The schedule for decommissioning set forth in section (4) of this rule may not commence until the Authority has made a determination on the request.

(7)(a) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Authority and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(A) Procedures ~~may~~would involve techniques not applied routinely during cleanup or maintenance operations;

(B) Workers ~~that may~~would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(C) Procedures could result in significantly greater airborne concentrations of radioactive material or source material than are present during operation; or

(D) Procedures could result in significantly greater releases of radioactive material or source material to the environment than those associated with operation.

(b) The Authority may approve an alternate schedule for submittal of a decommissioning plan required pursuant to section (4) of this rule if the Authority determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(c) Procedures such as those listed in subsection (7)(a) of this rule with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(d) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(A) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(B) A description of planned decommissioning activities;

(C) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(D) A description of the planned final radiation survey; and

(E) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(F) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan must include a justification for the delay based on the criteria in section (9) of this rule.

(e) The proposed decommissioning plan will be approved by the Authority if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(8)(a) Except as provided in section (9) of this rule, licensees must complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(b) Except as provided in section (9) of this rule, when decommissioning involves the entire site, the licensee must request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(9) The Authority may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Authority determines that the alternative is warranted by consideration of the following:

(a) Whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(b) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(c) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(d) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(e) Other site-specific factors which the Authority may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(10) As the final step in decommissioning, the licensee must:

(a) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and

(b) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E. The licensee must, as appropriate:

(A) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters — removable and fixed — for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(B) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(11) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Authority determines that:

(a) Radioactive material or source material has been properly disposed;

(b) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(c)(A) A radiation survey has been performed that demonstrates that the premises are suitable for release or establishes the level of residual activity in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E; or

(B) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

(i) Funds placed into an account separate from the licensee's assets and outside of the licensee's control before the start of decommissioning operations; or

(ii) A statement of intent containing a cost estimate for decommissioning or an amount based on the table in paragraph (d) of 10 CFR section 30.35(d), and indicating that funds for decommissioning will be obtained when necessary; or

(iii) An arrangement deemed acceptable by the governmental entity that is assuming custody and ownership of a site.

(C) Alternate criteria for license termination. The Authority will terminate a license using alternate criteria greater than the dose criterion of OAR 333-102-0310, if the licensee:

(i) Provides assurance that public health and safety shall continue to be protected and that it is unlikely that the total effective dose equivalent from all combined man-made sources other than medical sources shall be more than 100 millirem per year (1 millisievert per year) by submitting an analysis of possible sources of exposure;

(ii) Has employed restrictions on site use in minimizing exposures at the site;

(iii) Reduces doses to ALARA levels considering any detriments such as traffic accidents potentially expected to result from decontamination and waste disposal; and

(D) Has submitted a decommissioning or license termination plan to the Authority indicating the licensee's intent to decommission as specified in OAR 333-102-0310, and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the license termination or decommissioning plan how the advice of individuals and institutions in the community who could be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice in:

(i) Participation by representatives of a broad cross section of community interests who could be affected by the decommissioning;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement on the issues.

(E) The use of alternate criteria to terminate a license requires the approval of the Authority after consideration of any comments provided by the U. S. Environmental Protection Agency and any public comments submitted.

(F) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E.

(d) The licensee has kept records of receipt, transfer, and disposal of radioactive material or source material, pursuant to OAR 333-100-0055 that meet the following criteria:

(A) The licensee must retain each record of receipt of radioactive material or source material as long as the material is possessed and for three years following transfer or disposal of the material.

(B) The licensee who transferred the material must retain each record of transfer for three years after each transfer unless a specific requirement in another part of the rules in this chapter dictates otherwise.

(C) The licensee who disposed of the material must retain each record of disposal of byproduct material until the Authority terminates each license that authorizes disposal of the material.

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

DIVISION 103

FEES

333-103-0005

Biennial Fee for Radiation Machines

(1) For the purpose of this division, a radiation machine is defined under OAR 333-100-0005.

(2) Each radiation machine shall be validated biennially by a radiation machine fee in the following amounts:

(a) Hospital, radiologist, chiropractic, osteopathic or medical X-ray machine, ~~\$285~~\$228;

(b) Hospital X-ray machine when ~~X~~-ray machine inspection is performed by an accredited hospital radiology inspector rather than an Authority inspector, ~~\$145~~\$116;

(c) Industrial or podiatry X-ray machine, ~~\$190~~\$152;

(d) Dental, academic or veterinary X-ray machine, ~~\$140~~\$112.

(3) The radiation machine fee shall be due and payable for each radiation machine on or before October 1 of each biennium.

(4) A certificate of validation or acknowledgment of validation for the current biennium must be posted on or near the radiation machine by the registrant.

(5) In any case in which a registrant has submitted the proper fee prior to the expiration of a validation certificate, such existing validation certificate shall not expire until the issuance of a new validation certificate for the current biennium.

(6) Upon written request and approval by the Authority, fees for new licenses or additional machines may be prorated on a biennial quarterly basis for the current biennium.

Stat. Auth.: ORS 453.757, 453.761
Stats. Implemented: ORS 453.757, 453.761

DIVISION 105

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Equipment Control

333-105-0420

Performance Requirements for Industrial Radiography Equipment

Equipment used in industrial radiographic operations must meet the following minimum criteria:

(1) Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standard Institute, N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma

Radiography," (published as NBS Handbook 136, issued January 1981). This publication may be purchased from the American National Standards Institute, Inc., 25 West 43rd Street, New York, New York 10036, Telephone (212) 642-4900.;

(2) In addition to the requirements specified in section (1) of this rule, the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources.;

(a) The licensee must ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the:

(A) Chemical symbol and mass number of the radionuclide in the device;

(B) Activity and the date on which this activity was last measured;

(C) Model or product code and serial number of the sealed source;

(D) Name of the manufacturer of the sealed source; and

(E) Licensee's name, address, and telephone number.

(b) Radiographic exposure devices intended for use as Type B packages must meet the applicable transportation requirements of division 118 of these rules.

(c) Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless approved by the Authority or other approval body.

(3) In addition to the requirements specified in sections (1) and (2) of this rule, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers;

(a) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(b) The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

(c) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

(d) Each sealed source or source assembly must have attached to it or engraved on it, a durable, legible, visible label with the words:

"DANGER --RADIOACTIVE."

The label may not interfere with the safe operation of the exposure device or associated equipment.

(e) The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.

(f) Guide tubes must be used when moving the source out of the device.

(g) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during industrial radiography operations.

(h) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.

(i) Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(4) All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of this divisionsection; and

(5) As an exception to section (1) of this rule, equipment used in industrial radiographic operations need not comply with 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can reasonably exert on the lever or crankshaft of the drive mechanism.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

DIVISION 106

X-RAYS IN THE HEALING ARTS

General Requirements

333-106-0055

X-ray Operator Training

(1) The registrant shall assure that individuals who will be operating the X-ray equipment by physically positioning patients or animals, determining exposure parameters, or applying radiation for diagnostic purposes shall have adequate training in radiation safety.

(a) Radiation safety training records shall be maintained by the registrant for each individual who operates X-ray equipment. Records must be legible and meet the requirements in OAR 333-120-0690.

(b) When requested by the Authority, radiation safety training records shall be made available.

(2) Dental X-ray operators who meet the following requirements are considered to have met the requirements in section (1) of this rule:

(a) Currently licensed by the Oregon Board of Dentistry as a dentist or dental hygienist; or

(b) Is a dental assistant who is certified by the Oregon Board of Dentistry in radiologic proficiency.

(c) Dental radiology students in an approved Oregon Board of Dentistry dental radiology course are permitted to take dental radiographs on human patients during their clinical training, under the direct supervision of a dentist or dental hygienist currently licensed, or a dental assistant who has been certified in radiologic proficiency by the Oregon Board of Dentistry.

(3) Veterinary X-ray operators who meet the following requirements are considered to have met the requirements in section (1) of this rule:

(a) Currently licensed by the Oregon Veterinary Medical Examining Board as a veterinarian or a certified veterinary technician.

(b) Veterinary students enrolled in a radiology course approved by the Oregon Veterinary Medical Examining Board are permitted to take radiographs on animal patients during their clinical training under the direct supervision of a veterinarian or a certified veterinary technician who is currently licensed.

(4) Diagnostic medical X-ray operators who meet the following requirements are considered to have met the requirements of section (1) of this rule:

(a) Holds a current license from the Oregon Board of Medical Imaging; or

(b) Holds a current limited X-ray machine operator permit from the Oregon Board of Medical Imaging; or

(c) Is a student in a two-year approved school of Radiologic Technology as defined in ORS 688.405 while practicing Radiologic Technology under the direct supervision of a radiologist who is currently licensed with the Oregon Medical Board or a radiologic technologist who is currently registered with the American Registry of Radiologic Technologists and licensed with the Oregon Board of Medical Imaging; or

(d) Is a student in an Oregon Board of Medical Imaging approved limited permit program under a radiologic technologist who is currently registered with the American Registry of Radiologic Technologists and licensed by the Oregon Board of Medical Imaging.

(25) All other types of X-ray operators must have Adequate training in radiation safety means X-ray operators have completed an Authority approved radiation use and safety course.

(36) At a minimum, an Authority approved training course shall cover the following subjects:

(a) Nature of X-rays:

- (A) Interaction of X-rays with matter ;
- (B) Radiation units;
- (C) X-ray production;
- (D) Biological effects of X-rays; and
- (E) Risks of radiation exposure.
- (b) Principles of the X-ray machine:
 - (A) External structures and operating console;
 - (B) Internal structures:
 - (i) Anode; and
 - (ii) Cathode.
 - (C) Operation of an X-ray machine;
 - (D) Tube warm up;
 - (E) Factors affecting X-ray emission:
 - (i) mA;
 - (ii) kVp;
 - (iii) Filtration; and
 - (iv) Voltage waveform.
- (c) Principles of radiation protection:
 - (A) Collimation;
 - (B) Types of personal protection equipment and who must wear it;
 - (C) ALARA;
 - (D) Time, distance, shielding;
 - (E) Operator safety;
 - (F) Personal dosimetry:
 - (i) Types of dosimetry;
 - (ii) Proper placement of dosimetry; and
 - (iii) Situations that require dosimetry.
 - (G) Occupational and non-occupational dose limits.
- (d) Radiographic technique:
 - (A) Factors affecting technique choice:
 - (i) Thickness of part;
 - (ii) Body composition;

- (iii) Pathology; and
- (iv) Film versus computed radiography (CR) and digital radiography (DR).
 - (B) How to develop an accurate chart;
 - (C) Low dose techniques;
 - (D) Pediatric techniques (does not apply to veterinary); and
 - (E) AEC Techniques.
- (e) Darkroom:
 - (A) Safelights;
 - (B) Chemical storage;
 - (C) Film storage; and
 - (D) Darkroom cleanliness.
- (f) Image processing:
 - (A) Automatic film processing;
 - (B) Dip tank film processing;
 - (C) Computed radiography (CR) processing; and
 - (D) Digital radiography (DR) processing.
- (g) Image critique:
 - (A) Reading room conditions;
 - (B) Light box conditions;
 - (C) Image identification;
 - (D) Artifacts;
 - (E) Exposure indicators for CR and DR;
 - (F) Technical parameter evaluation; and
 - (G) Positioning evaluation.
- (h) Veterinary X-ray use (for veterinary courses only):
 - (A) Types of animal restraints;
 - (B) Small animal versus large animal;
 - (C) Film holders; and
 - (D) Portable X-ray machine safety.
- (i) Applicable federal and state radiation regulations including those portions of chapter 333, divisions 100, 101, 103, 106, 111, 120, and 124.

~~(4) Dental X-ray operators who meet the following requirements are considered to have met the requirements in section (1) of this rule:~~

~~(a) Currently licensed by the Oregon Board of Dentistry as a Dentist or Dental Hygienist; or~~

~~(b) Is a Dental Assistant who is certified by the Oregon Board of Dentistry in radiologic proficiency.~~

~~(c) Dental radiology students in an approved Oregon Board of Dentistry dental radiology course are permitted to take dental radiographs on human patients during their clinical training, under the direct supervision of a Dentist or Dental Hygienist currently licensed, or a Dental Assistant who has been certified in radiologic proficiency by the Oregon Board of Dentistry.~~

~~(5) Diagnostic medical X-ray operators who meet the following requirements are considered to have met the requirements of section (1) of this rule:~~

~~(a) Holds a current license from the Oregon Board of Medical Imaging; or~~

~~(b) Holds a current limited X-ray machine operator permit from the Oregon Board of Medical Imaging; or~~

~~(c) Is a student in a two-year approved school of Radiologic Technology as defined in ORS 688.405 while practicing Radiologic Technology under the direct supervision of a radiologist who is currently licensed with the Oregon Medical Board or a radiologic technologist who is currently registered with the American Registry of Radiologic Technologists and licensed with the Oregon Board of Medical Imaging; or~~

~~(d) Is a student in an Oregon Board of Medical Imaging approved limited permit program under a Radiologic Technologist who is currently registered with the American Registry of Radiologic Technologists and licensed by the Oregon Board of Medical Imaging.~~

(67) In addition to the training outlined in section (36) of this rule, medical X-ray equipment operators using diagnostic radiographic equipment on human patients, and who are not regulated by the Oregon Board of Medical Imaging, must have 100 hours or more of instruction in radiologic technology including, but not limited to:

(a) Anatomy physiology, patient positioning, exposure and technique; and

(b) Appropriate types of X-ray examinations that the individual will be performing; and in addition

(c) Receive 200 hours or more of X-ray laboratory instruction and practice in the actual use of an energized X-ray unit, setting techniques and practicing positioning of the appropriate diagnostic radiographic procedures that they intend to administer.

(78) All X-ray operators shall be able to demonstrate competency in the safe use of the X-ray equipment and associated X-ray procedures.

(98) When required by the Authority, applications training must be provided to the operator before use of X-ray equipment on patients.

(a) Records of this training must be maintained and made available to the Authority for inspection.

(b) The training may be in any format such as hands-on training by a manufacturer's representative, video or DVD instruction, or a training manual.

(910) X-ray equipment operators who have received their radiation safety training outside of Oregon will be considered to have met the training requirements in section (45) of this rule, if the Authority's or applicable Oregon Licensing Board's evaluation of their training or training and experience, reveals that they substantially meet the intent of section (63) of this rule.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

333-106-0325

Intraoral Dental Radiographic Systems

In addition to the provisions of OAR 333-106-0010 through 333-106-0101, the requirements of this rule apply to X-ray equipment and facilities where intraoral dental radiography is conducted. Requirements for extraoral dental radiographic systems are covered in OAR 333-106-0301 through 333-106-0320. Intraoral dental radiographic systems must meet the following requirements:

(1) Source-to-Skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance, to not less than 18cm.

(2) Beam Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:

(a) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than seven centimeters; or

(b) If the minimum SSD is less than 18 centimeters, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than six centimeters.

(3) Radiation Exposure Control (Timers). Means shall be provided to control the radiation exposure through the adjustment of exposure time in seconds, milliseconds (ms) or, number of pulses, or current/milliamps (mA), or the product of current and exposure time (mAs) or adjustment of kVp. In addition:

(a) Exposure Initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

(b) It shall not be possible to make an exposure when the timer is set to a "0" or "off" position if either position is provided;

(c) Exposure Indication. Means shall be provided for visual indication, observable at or from the operator's protected position, whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(d) Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure time (T) shall be greater than or equal to five times the minimum exposure time (T_{max}) minus the minimum exposure time (T_{min}) when four timer tests are performed: $(T) > 5 (T_{max} - T_{min})$.

(A) Means shall be provided to terminate the exposure at a preset, time interval, mAs, number of pulses, or radiation to the image receptor.

(B) An X-ray exposure control shall be incorporated into each system such that an exposure can be terminated by the operator at any time, except for exposures of 0.5 second or less.

(C) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "0".

(4) Radiation Exposure Control Location and Operator Protection. Each X-ray control must be located in such a way as to meet the following requirements:

(a) The exposure switch shall be able to be operated in a protected area, as defined in OAR 333-106-0005(77), and the operator shall remain in that protected area during the entire exposure; and

(b) The operator's protected area shall provide visual indication of the patient during the X-ray procedure.

(c) Mobile and portable X-ray systems which are:

(A) Used for greater than one week in the same location, such as a room or suite, shall meet the requirements of subsections (4)(a) and (4)(b) of this rule.

(B) Used for less than one week at the same location, such as a room or suite, shall be provided with:

(i) Either a protective barrier of at least 6.5 feet (2 meters) high for operator protection; or

(ii) A means to allow the operator to be at least nine feet (2.7 meters) from the tube housing assembly while making exposures; or

(iii) A full length protective apron, of not less than 0.25 millimeter lead equivalent for operator protection, when using a hand-held dental intraoral X-ray machine.

(5) Exposure Reproducibility. The coefficient of variation shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to five times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}): $E > 5 (E_{max} - E_{min})$

(6) Accuracy.

(a) Deviation of technique factors from the indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer.

(b) kVp Limitations. Dental X-ray machines with a nominal fixed kVp of less than 55 kVp shall not be used to make diagnostic dental radiographs on humans.

(7) Administrative Controls.

- (a) Patient and film holding devices shall be used when the techniques permit;
- (b) The tube housing and the PID shall not be hand held during an exposure;
- (c) The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of section (2) of this rule or its updated version;

~~(d) All patients shall be provided with a leaded apron during any dental X-ray exposure;~~

~~(de)~~ Dental fluoroscopy without image intensification shall not be used; and

~~(ef)~~ Pointed cones shall not be utilized unless specific authorization has been granted by the Authority.

(8) Hand-held X-ray systems.

(a) Registrants must provide for security and safe storage while not in use. A report must be filed with the Authority within 72 hours if the hand-held unit is lost or stolen.

(b) The image receptor used with hand-held dental X-ray systems must either be:

(A) A speed class of intra-oral film designated as "E/F", "F" or faster; or

(B) A digitally acquired image (CR or DR).

(c) The hand-held X-ray system must be equipped with a permanently attached backscatter shield of 0.25 mm Pb equivalent.

(d) The backscatter shield must be designed to appropriately protect the operator during an exposure. The manufacturer of the hand-held unit must provide documentation to the Authority of the design specifications of the backscatter shield's protection to the operator prior to sale and distribution in the State of Oregon.

(e) The hand-held unit must be capable of a minimum of 60 kVp and 2.0 mA.

(f) Hand-held units not meeting the requirements of subsections (8)(c), (8)(d) and (8)(e) of this rule may not be sold, distributed or used in the State of Oregon.

(9) Hand-held dental X-ray administrative controls.

(a) The operator must wear a whole body protective apron and thyroid collar of 0.25 mm of lead equivalent when using the unit.

(b) Hand-held units must meet the requirement of OAR 333-106-0045~~(5)(3)~~.

(A) The hand-held unit shall not be used for patient examinations in hallways and waiting rooms.

(B) The unit can only be operated in an enclosed room when possible. All individuals except the X-ray operator and the patient must leave the room and stand behind a protective barrier or be at least six feet from the X-ray source if a protective barrier is not available during radiographic exposures.

(c) Operators must complete machine specific applications training as described in OAR 333-106-0055(8) before using a hand-held unit. Training on the safe use of the unit shall be documented and include at a minimum:

(A) Proper positioning of the unit to ensure an adequate protected position;

(B) Limitations on the use of position indicating devices that require longer distances to the patient's face;

(C) Diagrams such as drawings, illustrations, or schematics of protected position and location in relationship to the unit;

(D) Diagrams such as drawings, illustrations, or schematics of the effect of improper distance or removal of shielding device; and

(E) Diagrams such as drawings, illustrations, schematics of common examples of improper positioning of the unit and or location of the operator.

(d) An appropriate receptor holder must be used during the X-ray exposure.

(e) A PID must be used during the X-ray exposure.

(f) A hand-held unit shall be held without any motion during a patient examination. A tube stand may be utilized to immobilize the hand-held unit during a patient examination.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

DIVISION 116

USE OF RADIONUCLIDES IN THE HEALING ARTS

333-116-0680

Training for ~~Use of Unsealed Byproduct Material for Which a Written Directive is Required Therapeutic Use of Radiopharmaceuticals~~

Except as provided in OAR 333-116-0740, the licensee must require an authorized user of unsealed byproduct material for the uses authorized under 333-116-0360 to be a physician who:

(1)(a) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraph (2)(b)(F) and subsection (2)(c) of this rule. (Specialty boards whose certification processes have been recognized by the NRC or an Agreement State shall be posted on the NRC's webpage). To be recognized, a specialty board shall require all candidates for certification to:

(b) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in subsection (2)(a) through paragraph (2)(b)(E). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required; or

(2) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include:

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

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0740, and sections (1) and (2) of this rule, or NRC or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in section (2) of this rule, must have experience in administering dosages in the same dosage category or categories as given in OAR 333-116-0680(2)(b)(F) as the individual requesting authorized user status. The work experience must involve:

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

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

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

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

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

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

(i) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

(ii) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

NOTE: Experience with at least three cases in subparagraph (ii) also satisfies the requirement in subparagraph (i).

(iii) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; or

(iv) Parenteral administration of any other radionuclide; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in sections (1) and (2) and paragraph (2)(b)(F) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under OAR 333-116-0360. The written attestation must be signed by a preceptor authorized user who meets the requirements in 333-116-0740, 333-116-0680 or equivalent NRC or Agreement State requirements. The preceptor authorized user, who meets the requirements in section (2) of this rule, must have experience in administering dosages in the same dosage category or categories as given in 333-116-0680(2)(b)(F)(i), (ii), (iii), or (iv) as the individual requesting authorized user status.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

DIVISION 118

TRANSPORTATION OF RADIOACTIVE MATERIAL

General Regulatory Provisions

333-118-0040

Exemptions

(1) Common and contract carriers, freight forwarders, ~~and~~ warehouse workers, and the U.S. Postal Service are exempt from the regulations in this division and divisions 102, 105, 113, 116, 121 and 125, that are subject to the requirements of the U.S. Department of Transportation in 49 CFR 170 through 189 or the U.S. Postal Service in the U.S. Postal Service Manual Domestic Mail Manual, (DMM), section C 023.9.0 are exempt from the rules in chapter 333, divisions 102, 105, 113, 115, 116, 117, and 121 and the requirements for a license to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to OAR 333-118-0030 and other applicable requirements of these rules.

(2) Any licensee is exempt from the requirements of this division to the extent that the licensee delivers to a carrier for transport a package containing radioactive material having a specific activity not greater than (0.002 microcurie per gram 70 Becquerels per gram (Bq/g).

(3) Any physician licensed under division 116 or by an Agreement State or the Nuclear Regulatory Commission to dispense radiopharmaceuticals in the practice of medicine, is exempt from OAR 333-118-0050 with respect to transporting licensed material for use in the practice of medicine.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

333-118-0190

Advance Notification of Transport of Nuclear Waste

~~(1) Nuclear waste transports shall be transported as specified in 10 CFR Part 71.97.~~

~~(2) Each licensee shall provide advance notification to the Governor of the State of Oregon or designee of the shipment of licensed material through or across the boundary of the state before the transport or delivery to a carrier for transport of licensed material outside the confines of the licensee's plant or other place of storage.~~

~~(3) Each licensee shall provide advance notification to the Tribal official of participating Tribes referenced in section (4) of this rule, or the official's designee, of the shipment of licensed material, within or across the boundary of the Tribe's reservation, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.~~

~~(4) A list of the mailing addresses of the governors and governors' designees is available upon request from the Director, Office of State, Local, and Indian Tribe Programs, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.~~

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

DIVISION 120

STANDARDS FOR PROTECTION AGAINST RADIATION

Reports

333-120-0710

Notification of Incidents

(1) Immediate notification: Notwithstanding any other requirements for notification, each licensee, or registrant, must immediately report any event involving a device or licensed radioactive material possessed by the licensee, or registrant, which may have caused or threatens to cause any of the following conditions:

(a) An individual to receive:

(A) A total effective dose equivalent of 0.25 Sv (25 rem) or more; or

(B) A lens dose equivalent of 0.75 Sv (75 rem) or more; or

(C) A shallow-dose equivalent to the skin or extremities of 2.5 gray (250 rad) or more; or

(b) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational annual limit on intake (the provisions of this rule do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).

(2) Twenty-four hour notification: Each licensee or registrant must, within 24 hours of discovery of the event, report any event involving loss of control of a device or licensed material possessed by the licensee that may have caused, or threatens to cause, any of the following conditions:

(a) An individual to receive in a period of 24 hours:

(A) A total effective dose equivalent exceeding 0.05 Sv (5 rems); or

(B) A lens dose equivalent exceeding 0.15 Sv (15 rems); or

(C) A shallow-dose equivalent to the skin or extremities exceeding 0.5 Sv (50 rems); or

(b) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit on intake (the provisions of this rule do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).

(3) The licensee must prepare any report filed with the Authority pursuant to this rule so that names of individuals who have received exposure to radiation or radioactive material are stated in a separate and detachable part of the report.

(4) Reports made by licensees, or registrants, in response to the requirements of subsections (1)(a) and (b) of this rule must be made by telephone and either by telegram, electronic mail, or facsimile to the Authority.

(5) The provisions of this rule do not include doses that result from planned special exposures, that are within the limits for planned special exposures, and that are reported under OAR 333-120-0730.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

333-120-0800

~~Reports of Transactions Involving Nationally Tracked Sources~~

~~Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally traced source shall complete and submit a National Source Tracking Transaction Report as specified in sections (1) through (5) of this rule for each type of transaction.~~

~~(1) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction report. The report must include the following information:~~

~~(a) The name, address, and license number of the reporting licensee;~~

~~(b) The name of the individual preparing the report;~~

~~(c) The manufacturer, model, and serial number of the source;~~

~~(d) The radioactive material in the source;~~

~~(e) The initial source strength in becquerels (curies) at the time of manufacture; and~~

~~(f) The manufacture date of the source.~~

~~(2) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction report. The report must include the following information:~~

- ~~(a) The name, address, and license number of the reporting licensee;~~
- ~~(b) The name of the individual preparing the report;~~
- ~~(c) The name and license number of the recipient facility and the shipping address;~~
- ~~(d) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the sources;~~
- ~~(e) The radioactive material in the source;~~
- ~~(f) The initial or current source strength in becquerels (curies);~~
- ~~(g) The date for which the source strength is reported;~~
- ~~(h) The shipping date;~~
- ~~(i) The estimated time of arrival date; and~~
- ~~(j) For nationally tracked sources transferred as waste under a Uniform Low Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked sources.~~

~~(3) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:~~

- ~~(a) The name, address, and license number of the reporting licensee;~~
- ~~(b) The name of the individual preparing the report;~~
- ~~(c) The name, address, and license number of the person that provided the source;~~
- ~~(d) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;~~
- ~~(e) The radioactive material in the source;~~
- ~~(f) The initial or current source strength in becquerels (curies);~~
- ~~(g) The date for which the source strength is reported;~~
- ~~(h) The date of receipt; and~~
- ~~(i) For material received under a Uniform Low Level radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.~~

~~(4) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:~~

- ~~(a) The name, address, and license number of the reporting licensee;~~
- ~~(b) The name of the individual preparing the report;~~

~~(c) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;~~

~~(d) The radioactive material in the source;~~

~~(e) The initial or current source strength in becquerels (curies);~~

~~(f) The date for which the source strength is reported; and~~

~~(g) The disassemble date of the source.~~

~~(5) Each Licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:~~

~~(a) The name, address, and license number of the reporting licensee;~~

~~(b) The name of the individual preparing the report;~~

~~(c) The waste manifest number;~~

~~(d) The container identification with the nationally tracked source;~~

~~(e) The date of disposal; and~~

~~(f) The method of disposal.~~

~~(6) The reports discussed in sections (1) through (5) of this rule must be submitted by the close of the next business day after the transactions. The report must be submitted to the National Source Tracking System by using:~~

~~(a) The online National Source Tracking System;~~

~~(b) Electronically using a computer readable format;~~

~~(c) By facsimile;~~

~~(d) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or~~

~~(e) By telephone with follow up by facsimile or mail.~~

~~(7) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within five business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by sections (1) through (5) of this rule. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.~~

~~(8) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by~~

~~January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified by subsection (6)(a) through (6)(e) of this rule. The initial inventory report must include the following information:~~

~~(a) The name, address, and license number of the reporting licensee;~~

~~(b) The name of the individual preparing the report;~~

~~(c) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;~~

~~(d) The radioactive material in the sealed source;~~

~~(e) The initial or current source strength in becquerels (curies); and~~

~~(f) The date for which the source strength is reported.~~

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

DIVISION 125

MATERIALS SAFETY AND SECURITY

333-125-0001

Nationally Tracked Sources

(1) Purpose and Scope. This rule outlines the reporting requirements for any licensees that possess an aggregated category 1 or category 2 quantity of radioactive material listed in Appendix A to 10 CFR Part 37 to report to the National Source Tracking System (NSTS). The mission of the NSTS is to track category 1 and category 2 radioactive materials from manufacturing through their disposal, decay, or exportation.

(2) Reports of Transactions. Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in subsections (2)(a) through (2)(e) of this rule for each type of transaction.

(a) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction report. The report must include the following information:

(A) The name, address, and license number of the reporting licensee;

(B) The name of the individual preparing the report;

(C) The manufacturer, model, and serial number of the source;

- (D) The radioactive material in the source;
- (E) The initial source strength in becquerels (curies) at the time of manufacture; and
- (F) The manufacture date of the source.
- (b) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction report. The report must include the following information:
 - (A) The name, address, and license number of the reporting licensee;
 - (B) The name of the individual preparing the report;
 - (C) The name and license number of the recipient facility and the shipping address;
 - (D) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the sources;
 - (E) The radioactive material in the source;
 - (F) The initial or current source strength in becquerels (curies);
 - (G) The date for which the source strength is reported;
 - (H) The shipping date;
 - (I) The estimated time of arrival date; and
 - (J) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked sources.
- (c) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:
 - (A) The name, address, and license number of the reporting licensee;
 - (B) The name of the individual preparing the report;
 - (C) The name, address, and license number of the person that provided the source;
 - (D) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
 - (E) The radioactive material in the source;
 - (F) The initial or current source strength in becquerels (curies);
 - (G) The date for which the source strength is reported;
 - (H) The date of receipt; and
 - (I) For material received under a Uniform Low-Level radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.
- (d) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- (A) The name, address, and license number of the reporting licensee;
 - (B) The name of the individual preparing the report;
 - (C) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
 - (D) The radioactive material in the source;
 - (E) The initial or current source strength in becquerels (curies);
 - (F) The date for which the source strength is reported; and
 - (G) The disassemble date of the source.
- (e) Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:
- (A) The name, address, and license number of the reporting licensee;
 - (B) The name of the individual preparing the report;
 - (C) The waste manifest number;
 - (D) The container identification with the nationally tracked source;
 - (E) The date of disposal; and
 - (F) The method of disposal.
- (f) The reports discussed in subsections (2)(a) through (2)(e) of this rule must be submitted by the close of the next business day after the transactions. The report must be submitted to the National Source Tracking System by using:
- (A) The online National Source Tracking System;
 - (B) Electronically using a computer readable format;
 - (C) By facsimile;
 - (D) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or
 - (E) By telephone with follow up by facsimile or mail.
- (g) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within five business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by subsections (2)(a) through (2)(e) of this rule. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

(h) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified by paragraph (2)(f)(A) through (2)(f)(E) of this rule. The initial inventory report must include the following information:

(A) The name, address, and license number of the reporting licensee;

(B) The name of the individual preparing the report;

(C) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;

(D) The radioactive material in the sealed source;

(E) The initial or current source strength in becquerels (curies); and

(F) The date for which the source strength is reported.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material

333-125-0005

Purpose and Scope

(1) OAR 333-125-0005 through 333-125-0200 contains the physical protection program requirements for any licensees that possess an aggregated category 1 or category 2 quantity of radioactive material listed in Appendix A to 10 CFR Part 37. These requirements provide reasonable assurance of the security of category 1 or 2 quantities of radioactive material by protecting these materials from theft or diversion. Specific requirements for access to material, use of material, transfer of material, and transport of material are included. No provision of this division authorizes the possession of licensed material.

(2) Background investigations, access control program and physical protection during use requirements apply to any person who possesses or uses at any site, an aggregated category 1 or category 2 quantity of radioactive material.

(3) Physical protection in transit applies to any person who under the rules in this division:

(a) Transports or delivers to a carrier for transport in a single shipment, a category 1 or category 2 quantity of radioactive material; or

(b) Imports or exports a category 1 or category 2 quantity of radioactive materials. The rules that establish the physical protection program apply to the domestic portion of the transport.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0010

Definitions

- (1) "Access control" means a system for allowing only approved individuals to have unescorted access to the security zone and for ensuring that all other individuals are subject to escorted access.
- (2) "Aggregated" means accessible by the breach of a single physical barrier that shall allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a category 2 quantity of radioactive material.
- (3) "Approved individual" means an individual whom the licensee has determined to be trustworthy and reliable for unescorted access in accordance with OAR 333-125-0020 through 333-125-0095 and who has completed the training required by OAR 333-125-0115.
- (4) "Background investigation" means the investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.
- (5) "Category 1 quantity" means a quantity of radioactive material meeting or exceeding the category 1 threshold in Table 1 of Appendix A, Part 37. This is determined by calculating the ratio of the total activity of each radionuclide to the category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity shall be considered a category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.
- (6) "Category 2 quantity" means a quantity of radioactive material meeting or exceeding the category 2 threshold but less than the category 1 threshold in Table 1 of Appendix A, Part 37. This is determined by calculating the ratio of the total activity of each radionuclide to the category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity shall be considered a category 2 quantity. Category 2 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.
- (7) "Diversion" means the unauthorized movement of radioactive material subject to the physical protection program to a location different from the material's authorized destination inside or outside of the site at which the material is used or stored.
- (8) "Escorted access" means accompaniment while in a security zone by an approved individual who maintains continuous direct visual surveillance at all times over an individual who is not approved for unescorted access.
- (9) "Fingerprint orders" means the orders issued by the U.S. Nuclear Regulatory Commission or the legally binding requirements issued by Agreement States that require fingerprints and criminal history records checks for individuals with unescorted access to category 1 and category 2 quantities of radioactive material or safeguards information-modified handling.
- (10) "Local law enforcement agency (LLEA)" means a public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests, and is

authorized and has the capability to provide an armed response in the jurisdiction where the licensed category 1 or category 2 quantity of radioactive material is used, stored, or transported.

(11) "Lost or missing licensed material" means licensed material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

(12) "Mobile device" means a piece of equipment containing licensed radioactive material that is either mounted on wheels or casters, or otherwise equipped for moving without a need for disassembly or dismounting; or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location.

(13) "Movement control center" means an operations center that is remote from transport activity and maintains position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting incidents to appropriate agencies and can request and coordinate appropriate aid.

(14) "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.

(15) "No-later-than arrival time" means the date and time that the shipping licensee and receiving licensee have established as the time to initiate an investigation if the shipment has not arrived at the receiving facility. The no-later-than arrival time may not be more than six hours after the estimated arrival time for shipments of category 2 quantities of radioactive material.

(16) "Reviewing official" means the individual who shall make the trustworthiness and reliability determination of an individual to determine whether the individual may have, or continue to have, unescorted access to the category 1 or category 2 quantities of radioactive materials that are possessed by the licensee.

(17) "Sabotage" means deliberate damage, with malevolent intent, to category 1 or 2 quantity of radioactive material, a device that contains a category 1 or 2 quantity of radioactive material, or the components of the security system.

(18) "Safe haven" means a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law enforcement authorities.

(19) "Security zone" means any temporary or permanent area determined and established by the licensee for the physical protection of category 1 or category 2 of radioactive material.

(20) "Telemetric position monitoring system" means a data transfer system that captures information by instrumentation and measuring devices about the location and status of a transport vehicle or package between the departure and destination locations.

(21) "Trustworthiness and reliability" means the characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to category 1 or category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

(22) "Unescorted access" means solitary access to an aggregated category 1 or category 2 quantity of radioactive material or the devices that contain the material.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0015

Specific Exemptions

(1) A licensee that possesses radioactive waste that contains category 1 or category 2 of radioactive material is exempt from the requirements of OAR 333-125-0020 through OAR 333-125-0190. Except that any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs) is not exempt from the requirements within this division.

(2) The licensee shall implement the following requirements to secure the radioactive waste:

(a) Use continuous physical barriers that allow access to the radioactive waste only through established access control points;

(b) Use a locked door or gate with monitored alarm at the access control point;

(c) Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred:

(A) Immediately notify LLEA and request an emergency response upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains category 1 or category 2 quantities of radioactive materials; and

(B) As soon as reasonably possible, the licensee shall contact:

(i) The Oregon Health Authority, Radiation Protection Services 24-hour response line at (971) 673-0490; or

(ii) The Oregon Emergency Response System at 1-800-452-0311.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

Background Investigations and Access Control Program

333-125-0020

Personnel Access Authorization Requirements for Category 1 and 2 Quantities

(1) Each licensee that possesses an aggregated quantity of radioactive materials at or above the category 2 threshold shall establish, implement, and maintain an access authorization program in accordance with OAR 333-125-0020 through 333-125-0095.

(2) An applicant for a new license and each licensee that shall become newly subject upon application for modification of its license shall implement the requirements of OAR 333-125-0020 through 333-125-0095, as appropriate, before taking possession of an aggregated category 1 or category 2 of radioactive material.

(3) Any licensee that has not previously implemented the Security Orders or has been subject to the provisions of OAR 333-125-0020 through 333-125-0095 shall implement the provisions of those rules before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

(4) General performance objective. The licensee's access authorization program must ensure that the individuals specified in section (5) of this rule are trustworthy and reliable.

(5) Applicability. Licensees shall subject the following individuals to an access authorization program:

(a) Any individual whose assigned duties require unescorted access to category 1 or category 2 quantities of radioactive material or to any device that contains the radioactive material; and

(b) Reviewing officials.

(6) Licensees need not subject the categories of individuals listed in OAR 333-125-0085 subsections (1)(a) through (m) to the investigation elements of the access authorization program.

(7) Licensees shall approve for unescorted access to category 1 or category 2 quantities of radioactive material only those individuals with job duties that require unescorted access to category 1 or category 2 quantities of radioactive material.

(8) Licensees may include individuals needing access to safeguards information-modified handling under 10 CFR Part 73 in the access authorization program under OAR 333-125-0020 through 333-125-0095.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0025

Access Authorization Program Requirements

(1) Granting unescorted access authorization. Licensees shall implement the following requirements under OAR 333-125-0020 through 333-125-0095 for granting initial or reinstated unescorted access authorization:

(a) Individuals who have been determined to be trustworthy and reliable, shall complete the security training required by OAR 333-125-0105 before being allowed unescorted access to category 1 or category 2 of radioactive material.

(b) Reviewing officials shall be the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 of radioactive material possessed by the licensee.

(c) Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. The fingerprints of the named reviewing official must be taken by a law enforcement agency, federal or state agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a state to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every 10 years in accordance with OAR 333-125-0065.

(2) Reviewing officials must be permitted to have unescorted access to category 1 or category 2 quantities of radioactive materials and access to the licensee's safeguards information or safeguards information-modified handling, if the licensee possesses safeguards information or safeguards information-modified handling.

(3) Reviewing officials cannot approve other individuals to act as reviewing officials.

(4) A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

(a) The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

(b) The individual is subject to a category listed in OAR 333-125-0085.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0030

Informed Consent

(1) Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. The consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals that meet the requirements of OAR 333-125-0065. A signed consent must be obtained prior to any reinvestigation.

(2) The subject individual may withdraw his or her consent at any time. Licensees shall inform the individual that:

(a) If an individual withdraws his or her consent, the licensee may not initiate any elements of the background investigation that were not in progress at the time the individual withdrew his or her consent; and

(b) The withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0035

Personal History Disclosure

Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information required by this division is sufficient cause for denial or termination of unescorted access.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0040

Determination Basis

(1) The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all of the information collected to meet the requirements within this division.

(2) The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all of the information collected to meet the requirements of this division and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on information obtained at any time during the background investigation.

(3) The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

(4) The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual had been granted unescorted access authorization.

(5) Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or has become ineligible to meet access authorization requirements, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.

(6) The licensee shall take prompt immediate measures to ensure that the individual is unable to have unescorted access to the material.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635

333-125-0045

Access Authorization Program Procedures

Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures must include provisions for the notification of individuals who are denied unescorted access. The procedures must include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization. The procedures must contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635

333-125-0050

Right to Correct and Complete Information

(1) Prior to any final adverse determination, licensees shall provide each individual subject to this division with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification must be maintained by the licensee for a period of one year from the date of the notification.

(2) If an individual reviewing their criminal history record believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures.

(3) **Challenge** procedures include direct application by the individual challenging the record to the law enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D-2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in 28 CFR 16.30 through 16.34. In the latter case, the Federal Bureau of Investigation (FBI) will forward the challenge to the agency that submitted the data, and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency. Licensees must provide at least 10 days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his or her review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635

333-125-0055

Records

(1) The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three years from the date the individual no longer requires unescorted access to category 1 or category 2 radioactive materials.

(2) The licensee shall retain a copy of the current access authorization program procedures as a record for three years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee shall retain the superseded materials for three years after the records have been amended.

(3) The licensee shall retain the list of persons approved for unescorted access authorization for three years after the list is superseded or replaced.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635

333-125-0060

Initial Investigation

(1) Before allowing an individual unescorted access to materials and devices containing category 1 or category 2 radioactive materials, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation must encompass at least the seven years preceding the date of the background investigation or since the individual's 18th birthday, whichever is shorter.

(2) The background investigation must include at a minimum:

(a) Fingerprinting and an FBI identification and criminal history records check in accordance with OAR 333-120-0075 through 333-125-0080;

(b) Verification of true identity. Licensees shall verify the true identity of the individual who is applying for unescorted access authorization to verify that the applicant is who he or she claims to be. A licensee shall review official identification documents such as driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth and compare the documents to personal information data provided by the individual to identify any discrepancy in the information.

(A) Licensees shall document the type, expiration, and identification number of the identification document, or maintain a photocopy of identifying documents on file in accordance with OAR 333-125-0090; and

(B) Licensees shall certify in writing that the identification was properly reviewed, and shall maintain the certification and all related documents for review upon inspection.

(c) Employment history verification. Licensees shall complete employment and military history verification. Licensees shall verify the individual's employment with each previous employer for the most recent seven years before the date of application.

(d) Verification of education. Licensees shall verify that the individual participated in the education process during the claimed period.

(e) Character and reputation determination. Licensees shall complete reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under this division must be limited to whether the individual has been and continues to be trustworthy and reliable.

(A) The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the individual **such as seeking** references not supplied by the individual; **and**

(B) If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide information or indicates an inability or unwillingness to provide information within a time frame deemed appropriate by the licensee but at the least after 10 business days of the request or if the licensee is unable to reach the entity, the **licensee** shall document the refusal, unwillingness or inability in the record of investigation; and attempt to obtain the information from an alternate source.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0065

Grandfathering

(1) Individuals who have been determined to be trustworthy and reliable for unescorted access to category 1 or category 2 quantities of radioactive material under the Fingerprint Orders may continue to have unescorted access to **category 1 and category 2 quantities of radioactive materials** without further investigation. **These individuals shall be subject to the reinvestigation requirement outlined in OAR 333-125-0070.**

(2) Individuals who have been determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or the security orders for access to safeguards information, safeguards information-modified handling, or risk-significant material, may have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation.

(3) The licensee shall document that the individual was determined to be trustworthy and reliable under the provisions of **10 CFR Parts 73** or a security order. Security order, in this context, refers to any order that was issued by the NRC that required fingerprints and an FBI criminal history records check for access to safeguards information, safeguards information-modified handling, or risk significant material such as special nuclear material or large quantities of uranium hexafluoride. **These individuals shall be subject to the reinvestigation requirement per OAR 333-125-0070.**

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635

333-125-0070

Reinvestigation

- (1) Licensees shall conduct a reinvestigation every 10 years for any individual with unescorted access to category 1 or category 2 quantities of radioactive material.
- (2) The reinvestigation shall consist of fingerprinting, FBI identification, and criminal history records check in accordance with OAR 333-125-0075 through 333-125-0080.
- (3) The reinvestigations must be completed within 10 years of the date on which these elements were last completed.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635

333-125-0075

Requirements for Criminal History Records Checks of Individuals Granted Unescorted Access

- (1) General Performance Objective and Requirements. Except for those individuals listed in OAR 333-125-0085 and those individuals grandfathered under OAR 333-125-0065, each licensee subject to the provision of this division shall fingerprint each individual who is to be permitted unescorted access to category 1 and category 2 quantities of radioactive material.
- (2) Licensees shall transmit all collected fingerprints to the NRC for transmission to the FBI. The licensee shall use the information received from the FBI as part of the required background investigation to determine whether to grant or deny unescorted access to category 1 or category 2 quantities of radioactive material for that individual.
- (3) The licensee shall notify each affected individual that their fingerprints will be used to secure a review of their criminal history record, and shall inform the individual of the procedures for revising the record or adding explanations to the record.
- (4) Fingerprinting is not required if a licensee is reinstating an individual's unescorted access if
 - (a) The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of the individual's unescorted access authorization; and
 - (b) The previous access was terminated under favorable conditions.
- (5) Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to category 1 or category 2 radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee, based upon a background investigation conducted under OAR 333-125-0020 through 333-125-0095 or the Nuclear Regulatory Commission's Fingerprint Orders or 10 CFR Part 73. An existing criminal history check file may be transferred to another

licensee who is conducting a criminal history check for an individual requesting unescorted access in accordance with OAR 333-125-0090(3).

(6) Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to category 1 or category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

(7) Prohibitions: Licensees may not base a final determination to deny an individual unescorted access authorization to category 1 or category 2 quantities of radioactive materials solely on the basis of information received from the FBI involving:

(a) An arrest more than one year old for which there is no information of the disposition of the case; or

(b) An arrest that resulted in dismissal of the charge or an acquittal.

(8) Licensees may not use information received from a criminal history records check obtained under this division in a manner that can infringe upon the rights of any individual under the First Amendment of the Constitution of the United States, nor shall licensees use the information in any way that can discriminate among individuals on the basis of race, religion, national origin, gender, or age.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0080

Procedures for Processing of Fingerprint Checks

(1) For the purpose of complying with OAR 333-125-0020 through 333-125-0095, licensees shall submit to the U.S. Nuclear Regulatory Commission, Director, Division of Facilities and Security, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop T-03B46M, Rockville, Maryland 20852, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 1-630-829-9565, or by electronic mail to FORMS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at <http://www.nrc.gov/site-help/e-submittals.html>.

(2) Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." For guidance on making electronic payments, contact the Security Branch, Division of Facilities and Security at 301-415-7513. Combined payment for multiple applications is acceptable. The Commission publishes the amount of the fingerprint check application fee on the NRC's public website. (To find the current fee amount, go to the Electronic Submittals page

at <http://www.nrc.gov/site-help/e-submittals.html> and see the link for the Criminal History Program under Electronic Submission Systems.)

(3) The Commission shall forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0085

Relief from Fingerprinting, Identification, and Criminal History Record Checks and Other Elements of Background Investigations for Designated Categories of Individuals Permitted Unescorted Access to Certain Radioactive Materials

(1) Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, and other elements of the background investigation are not required for the following individuals prior to granting unescorted access to category 1 or category 2 quantities of radioactive materials:

(a) An employee of the Commission or of the Executive Branch of the U.S. Government who has undergone fingerprinting for a prior U.S. Government criminal history records check;

(b) A member of Congress;

(c) An employee of a member of Congress or Congressional committee who has undergone fingerprinting for a prior U.S. Government criminal history records check;

(d) The Governor of a state or his or her designated state employee representative;

(e) Federal, state, or local law enforcement personnel;

(f) State Radiation Control Program Directors and State Homeland Security Advisors or their designated state employee representatives;

(g) Agreement State employees conducting security inspections on behalf of the NRC under an agreement executed under section 274.i. of the Atomic Energy Act;

(h) Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S. and IAEA Safeguards Agreement who have been certified by the NRC;

(i) Emergency response personnel who are responding to an emergency;

(j) Commercial vehicle drivers for road shipments of category 1 and 2 quantities of radioactive material;

(k) Package handlers at transportation facilities such as freight terminals and railroad yards;

(L) Any individual who has an active federal security clearance, provided that he or she makes available the appropriate documentation. Written confirmation from the agency or employer that granted the federal security clearance or reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material; and

(m) Any individual employed by a service provider licensee for which the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to category 1 or category 2 quantities of radioactive material. Written verification from the service provider must be provided to the licensee. The licensee shall retain the documentation for a period of three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

(2) Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, are not required for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the last five years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check provided that he or she makes available the appropriate documentation. Written confirmation from the agency or employer that reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material. These programs include, but are not limited to:

(a) National Agency Check;

(b) Transportation Worker Identification Credentials (TWIC) under 49 CFR Part 1572;

(c) Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR Part 555;

(d) Health and Human Services security risk assessments for possession and use of select agents and toxins under 42 CFR Part 73;

(e) Hazardous Material security threat assessment for hazardous material endorsement to commercial driver's license under 49 CFR Part 1572; and

(f) Customs and Border Protection's Free and Secure Trade (FAST) Program.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0090

Protection of Information

(1) Each licensee who obtains background information on an individual under OAR 333-125-0020 through 333-125-0095 shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

(2) The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his or her representative, or to those who have a need to have access to the information in performing assigned duties in the process of granting or denying unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling. No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.

(3) The personal information obtained on an individual from a background investigation may be provided to another licensee:

(a) Upon the individual's written request to the licensee holding the data to disseminate the information contained in his or her file; and

(b) The recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.

(4) The licensee shall make background investigation records obtained under OAR 333-125-0020 through 333-125-0095 available for examination by an authorized representative of the NRC to determine compliance with the regulations and laws.

(5) The licensee shall retain all fingerprint and criminal history records (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred, on an individual for three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0095

Access Authorization Program Review

(1) Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements within OAR 333-125-0020 through 333-125-0095 and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements. Each licensee shall annually review the access program content and implementation.

(2) The results of the reviews, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the access authorization program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

(3) Review records must be maintained for three years.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

Physical Protection Requirements During Use

333-125-0100

Security Program

(1) Applicability: Each licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements outlined in this rule through OAR 333-125-0155.

(a) An applicant for a new license and each licensee that becomes newly subject to the requirements of OAR 333-125-0020 through 333-125-0095 upon application for modification of its license shall implement the requirements of OAR 333-125-0020 through 333-125-0095 as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

(b) Any licensee that has not previously implemented the Security Orders or been subject to the provisions OAR 333-125-0100 through -333-125-0155 shall provide written notification to the Authority at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

(2) General performance objective: Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive material.

(3) Program features: Each licensee's security program must include the program features, as appropriate, described in OAR 333-125-0105 through 333-125-0150.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0105

General Security Program Requirements

(1) Security plan. Each licensee identified in OAR 333-125-0100(1) shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by this division. The security plan must, at a minimum:

(a) Describe the measures and strategies used to implement the requirements of OAR 333-125-0100 through 333-125-0155; and

(b) Identify the security resources, equipment, and technology used to satisfy the requirements of this division.

(2) The security plan must be reviewed and approved by the individual with overall responsibility for the security program.

(3) A licensee shall revise its security plan as necessary to ensure the effective implementation of the Authority' requirements. The licensee shall ensure that:

(a) The revision has been reviewed and approved by the individual with overall responsibility for the security program; and

(b) The affected individuals are instructed on the revised plan before the changes are implemented.

(4) The licensee shall retain a copy of the current security plan as a record for three years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0110

Security Program Implementation Plan

(1) The licensee shall develop and maintain a written implementation plan that provides procedures on how the requirements of the security plan will be met.

(2) The implementation plan's procedures and revisions must be approved in writing by the individual with overall responsibility for the security program.

(3) The licensee shall retain a copy of the implementation plan's current procedures as a record for three years after the implementation plan is no longer needed. Superseded portions of the plan's procedures must be retained for three years after the record is superseded.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0115

Security Program Training

(1) Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training must include instruction in:

(a) The licensee's security program and procedures to secure category 1 or category 2 quantities of radioactive material, and in the purposes and functions of the security measures employed;

(b) The responsibility to report promptly to the licensee any condition that causes or may cause a violation of the Authority's requirements;

(c) The responsibility of the licensee to report promptly to the local law enforcement agency and licensee any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material; and

(d) The appropriate response to security alarms.

(2) In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of category 1 or category 2 quantities of radioactive material. The extent of the training must be commensurate with the individual's potential involvement in the security of category 1 or category 2 quantities of radioactive material.

(3) Refresher training must be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training must include:

(a) Review of the training requirements in section (1) of this rule and any changes made to the security program since the last training;

(b) Reports on any relevant security issues, problems, and lessons learned;

(c) Relevant results of NRC inspections; and

(d) Relevant results of the licensee's program review and testing and maintenance.

(4) The licensee shall maintain records of the initial and refresher training for three years from the date of the training. The training records must include dates of the training, topics covered, and a list of the licensee's personnel in attendance, and related information.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0120

Security Program, Protection of Information

(1) Except as provided in section (9) of this rule, licensees authorized to possess category 1 or category 2 quantities of radioactive material shall secure from public disclosure and limit access to their security and implementation plans, and the list of individuals that have been approved for unescorted access.

(2) Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of the security and implementation plans.

(3) Before granting an individual access to the security plan or implementation plans, the licensee shall:

(a) Evaluate an individual's need to know of the security or implementation plans; and

(b) If the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in OAR 333-125-0060(2)(b) through (2)(f).

(4) Licensees need not subject the following individuals to the background investigation elements for protection of information:

(a) The categories of individuals listed in OAR 333-125-0085(1)(a) through (m); or

(b) Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in OAR 333-125-0060(2)(b) through (2)(f) has been provided by the security service provider.

(5) The licensee shall document the basis for concluding that an individual is trustworthy and reliable and allowed access to the security and implementation plans.

(6) Licensees shall maintain a list of persons currently approved for access to the security and implementation plans. When a licensee determines that a person no longer needs access to the security and implementation plans, or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to obtain the security plan or implementation procedures.

(7) When not in use, the licensee shall store its security and implementation plans in a manner to prevent unauthorized access. Information stored in non-removable electronic form must be password protected.

(8) The licensee shall retain as a record for three years after the document is no longer needed:

(a) A copy of the information protection procedures; and

(b) The list of individuals approved for access to the security plan or implementing procedures.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0125

Local Law Enforcement Agency Coordination (LLEA)

(1) A licensee subject to OAR 333-125-0100 through 333-125-0155 shall coordinate, to the extent practicable, with a LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA must include:

(a) A description of the facilities and the category 1 and category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with OAR 333-125-0100 through 333-125-0155; and

(b) A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of material.

(2) The licensee shall notify the Authority and the NRC regional office at U.S. Nuclear Regulatory Commission, Region IV, Division of Nuclear Materials Safety, 1600 E. Lamar Blvd., Arlington, TX 76011-4511; where electronic mail is appropriate, it shall be addressed to RidsRgn4MailCenter.Resource@nrc.gov within three business days if:

(a) The LLEA has not responded to the request for coordination within 60 days of the coordination request; or

(b) The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

(3) The licensee shall document its efforts to coordinate with the LLEA. The documentation must be kept for three years.

(4) The licensee shall coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0130

Security Zones

(1) Licensees shall ensure that all aggregated category 1 and category 2 quantities of radioactive material are used or stored within licensee-established security zones. Security zones may be permanent or temporary.

(2) Temporary security zones must be established as necessary to meet the licensee's transitory or intermittent business activities, such as periods of maintenance, source delivery, and source replacement.

(3) Security zones must, at a minimum, allow unescorted access only to approved individuals through:

(a) Isolation of category 1 and category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the category 1 or category 2 quantities of radioactive material within a security zone; or

(b) Direct control of the security zone by approved individuals at all times; or

(c) A combination of continuous physical barriers and direct control.

(4) For category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.

(5) Individuals not approved for unescorted access to category 1 or category 2 quantities of radioactive material must be escorted by an approved individual when in a security zone.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0135

Monitoring, Detection, and Assessment

(1) Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones. Licensees shall provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary

power source, or provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.

(2) Monitoring and detection must be performed by:

(a) A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility; or

(b) Electronic devices for intrusion detection alarms that will alert nearby facility personnel; or

(c) A monitored video surveillance system; or

(d) Direct visual surveillance by approved individuals located within the security zone; or

(e) Direct visual surveillance by a licensee designated individual located outside the security zone.

(f) A licensee subject to OAR 333-125-0100 through 333-125-0155 shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability must provide:

(A) For category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability must be provided by:

(i) Electronic sensors linked to an alarm; or

(ii) Continuous monitored video surveillance; or

(iii) Direct visual surveillance.

(g) For category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

(3) Assessment. Licensees shall immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.

(4) Personnel communications and data transmission. For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessment systems, licensees shall:

(a) Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and

(b) Provide an alternative communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of communication or data transmission and processing. Alternative communications and data transmission systems may not be subject to the same failure modes as the primary systems.

(5) Response. Licensees shall immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of category 1

or category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0140

Maintenance and Testing

(1) Each licensee subject to OAR 333-125-0100 through 333-125-0155 shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of this division must be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no manufacturer's suggested frequency, the testing must be performed at least annually not to exceed 12 months.

(2) The licensee shall maintain records on the maintenance and testing activities for three years.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0145

Requirements for Mobile Devices

(1) Each licensee that possesses mobile devices containing category 1 or category 2 quantities of radioactive material must have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee.

(2) For devices in or on a vehicle or trailer, unless the health and safety requirements for a site prohibit the disabling of the vehicle, the licensee shall utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0150

Security Program Review

(1) Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of this division and that comprehensive actions are taken to correct any noncompliance that is identified. The review must include the radioactive material security

program content and implementation. Each licensee shall periodically (at least annually) review the security program content and implementation procedures.

(2) The results of the review, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the security program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

(3) The licensee shall maintain the review documentation for three years.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0155

Reporting of Events

(1) The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the Authority by telephone at (971) 673-0490. In no case shall the notification to the Authority be later than four hours after the discovery of any attempted or actual theft, sabotage, or diversion.

(2) The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than four hours after notifying the LLEA, the licensee shall notify the Authority by telephone at (971) 673-0490.

(3) The initial telephonic notification required by section (1) of this rule must be followed within a period of 30 days by a written report submitted to the Authority. The report must include sufficient information for Authority analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

Physical Protection in Transit

333-125-0165

Additional Requirements for Transfer of Category 1 and Category 2 Quantities of Radioactive Material

(1) A licensee transferring a category 1 or category 2 quantity of radioactive material to a licensee of the Commission or an Agreement State shall meet the license verification provisions listed in subsections (a) through (c) below instead of those listed in OAR 333-102-0330(4).

(a) Any licensee transferring category 1 quantities of radioactive material to a licensee of the Commission or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

(b) Any licensee transferring category 2 quantities of radioactive material to a licensee of the Commission or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

(c) In an emergency where the licensee cannot reach the license issuing authority and the license verification system is nonfunctional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred. The certification must include the license number, current revision number, issuing agency, expiration date, and for a category 1 shipment the authorized address. The licensee shall keep a copy of the certification. The certification must be confirmed by use of the NRC's license verification system or by contacting the license issuing authority by the end of the next business day.

(2) The transferor shall keep a copy of the verification documentation as a record for three years.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0170

Applicability of Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Transit

The shipping licensee shall be responsible for meeting the requirements of OAR 333-125-0165 through 333-125-0190 unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under OAR 333-125-0165 through 333-125-0190.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0175

Preplanning and Coordination of Shipment of Category 1 or Category 2 Quantities of Radioactive Material

(1) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall:

(a) Preplan and coordinate shipment arrival and departure times with the receiving licensee;

(b) Preplan and coordinate shipment information with the Governor or the Governor's designee of any state through which the shipment will pass to:

(A) Discuss the state's intention to provide law enforcement escorts; and

(B) Identify safe havens; and

(C) Document the preplanning and coordination activities.

(2) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

(3) Each licensee who receives a shipment of a category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

(4) Each licensee, who transports or plans to transport a shipment of a category 2 quantity of radioactive material, and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to section (2) of this rule, shall promptly notify the receiving licensee of the new no-later-than arrival time.

(5) The licensee shall retain a copy of the documentation for preplanning and coordination and any revision thereof, as a record for three years.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0180

Advance Notification of Shipment of Category 1 Quantities of Radioactive Material

(1) As specified in sections (1) and (2) of this rule, each licensee shall provide advance notification to the NRC and the Governor of a state, or the Governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the state, before the transport, or delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

(a) Procedures for submitting advance notification. The notification must be made to the NRC and to the office of each appropriate Governor or Governor's designee. The contact information, including telephone and mailing addresses, of Governors and Governors' designees, is available on the NRC's website at <http://nrc-stp.ornl.gov/special/designee.pdf>. A list of the contact information is also available upon request from the Director, Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management

Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Notifications to the NRC must be to the NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The notification to the NRC may be made by e-mail to RAMQC_SHIPMENTS@nrc.gov or by fax to 301-816-5151.

(b) A notification delivered by mail must be postmarked at least seven days before transport of the shipment commences at the shipping facility.

(c) A notification delivered by any means other than mail must reach NRC at least four days before the transport of the shipment commences and must reach the office of the Governor or the Governor's designee at least four days before transport of a shipment within or through the state.

(2) Information to be furnished in advance notification of shipment. Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

(a) The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;

(b) The license numbers of the shipper and receiver;

(c) A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

(d) The point of origin of the shipment and the estimated time and date that shipment will commence;

(e) The estimated time and date that the shipment is expected to enter each state along the route;

(f) The estimated time and date of arrival of the shipment at the destination; and

(g) A point of contact, with a telephone number, for current shipment information.

(3) Revision notice. The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the Governor of the state or the Governor's designee and to the NRC's Director of Nuclear Security, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(a) A licensee shall promptly notify the Governor of the state or the Governor's designee of any changes to the information provided in accordance with sections (2) and (3) of this rule. The licensee shall also immediately notify the NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 of any such changes.

(4) Cancellation notice. Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the Governor of each state or to the Governor's designee previously notified and to the NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The licensee shall send the cancellation notice before the shipment has commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

(5) Records. The licensee shall retain a copy of the advance notification, any revision and cancellation notices as a record for three years after the notification has been made.

(6) Protection of information. State officials, state employees, and other individuals, whether or not licensees of the U.S Nuclear Regulatory Commission or an Agreement State, who receive schedule information of the kind specified in section (2) of this rule shall protect that information against unauthorized disclosure.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0185

Requirements for Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Shipment

(1)(a) Shipments by road. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(A) Ensure that movement control centers are established that maintain position information from a remote location. These control centers must monitor shipments 24 hours a day, seven days a week, and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies.

(B) Ensure that redundant communications are established that allow the transport to contact the escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication.

(C) Ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center must provide positive confirmation of the location, status, and control over the shipment. The movement control center must be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

(D) Provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver.

(E) Develop written normal and contingency procedures to address:

(i) Notifications to the communication center and law enforcement agencies;

(ii) Communication protocols. Communication protocols must include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost;

(iii) Loss of communications; and

(iv) Responses to an actual or attempted theft or diversion of a shipment.

(b) Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

(c) Each licensee that transports category 2 quantities of radioactive material shall maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

(d) Each licensee who delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(A) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it may arrive at the next point of control.

(B) Use carriers that maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(C) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

(2)(a) Shipments by rail. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(A) Ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

(B) Ensure that periodic reports to the communications center are made at preset intervals.

(b) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(A) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it may arrive at the next point of control.

(B) Use carriers that maintain constant control or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(C) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

(3) Investigations:

(a) Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall immediately conduct an investigation upon the discovery that a category 1 shipment is lost or missing.

(b) Each licensee who makes arrangements for the shipment of category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0190

Reporting of Events

(1) The shipping licensee shall notify the appropriate LLEA, and the NRC's Operations Center by telephone at (301) 816-5100 within one hour of its determination that a shipment of category 1 quantities of radioactive material is lost or missing. The appropriate LLEA is the law enforcement agency in the area of the shipment's last confirmed location. During the investigation required by OAR 333-125-0185(3), the shipping licensee shall provide agreed upon updates to the NRC's Operations Center on the status of the investigation.

(2) The shipping licensee shall notify the NRC's Operations Center by telephone at (301) 816-5100, within four hours of its determination that a shipment of category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secured, the licensee shall immediately notify the NRC's Operations Center.

(3) The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the NRC's Operations Center by telephone at (301) 816-5100 upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment of category 1 radioactive material.

(4) The shipping licensee shall notify the NRC's Operations Center by telephone at (301) 816-5100 as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment of a category 2 quantity of radioactive material.

(5) The shipping licensee shall notify the NRC's Operations Center by telephone at (301) 816-5100 and the LLEA as soon as possible upon recovery of any lost or missing category 1 quantities of radioactive material.

(6) The shipping licensee shall notify the NRC's Operations Center by telephone at (301) 816-5100 as soon as possible upon recovery of any lost or missing category 2 quantities of radioactive material.

(7) The initial telephonic notification required by sections (1) through (4) of this rule must be followed within a period of 30 days by a written report submitted to the Authority. A written report is not required for notifications on suspicious activities required by sections (3) and (4) of this rule. The report must set forth the following information:

(a) A description of the licensed material involved, including kind, quantity, and chemical and physical form;

(b) A description of the circumstances under which the loss or theft occurred;

(c) A statement of disposition, or probable disposition, of the licensed material involved;

(d) Actions that have been taken, or will be taken, to recover the material; and

(e) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

(8) Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0195

Form of Records

Each record required by this rule must be legible throughout the retention period. The record may be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

333-125-0200

Record Retention

Licensees shall maintain the records that are required by the regulations in this division for the period specified by the appropriate regulation. If a retention period is not otherwise specified,

these records must be retained until the Authority terminates the facility's license. All records related to this division may be destroyed upon the Authority terminating the facility's license.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635