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SUBJECT: Oregon Regulations

DATE: July 3, 2002
(via Diskette)

DIVISION 100

GENERAL REQUIREMENTS

Scope

333-100-0001 Except as otherwise specifically provided, these rules apply to all persons who acquire receive, possess, use, transfer, own, or dispose of any source of radiation; provided, however, that nothing in these rules shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission.

NOTE: Attention is directed to the fact that state regulation of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the state and the U.S. Nuclear Regulatory Commission and to **10 CFR Part 150** of the Commission's regulations.

[**Publications:** The publication(s) referred to or incorporated by reference in this rule are available for review at *the* **Oregon Health Services**, Radiation Protection Services office *of the Health Division*.]

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-

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Definitions

333-100-0005 As used in these rules, these terms have the definitions set forth below. Additional definitions used only in a certain Division will 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 to 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) "Agency" means *the* Radiation Protection Services of *the* Oregon *State* Health *Division* Services.

(8) "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).

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

(10) "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 (DAC's) specified in appendix B, Table I, 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.

(11) "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.

~~(12)~~ "Annual Limit on Intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B to 10 CFR Part 20.1001 to 20.2401.

~~(13)~~ "As Low As ~~is~~ Reasonably Achievable" see **"ALARA"** ~~means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the licensed or registered 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 or registered sources of radiation in the public interest.~~

~~(14)~~ "Annual": Occurring every year or within a consecutive twelve month cycle.

~~(15)~~ "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. "Background radiation" does not include sources of radiation from radioactive materials regulated by the Agency.

~~(16)~~ "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).

~~(17)~~ "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 ~~regulations~~ **rules**, "radiobioassay" is an equivalent term.

~~(18)~~ "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, ~~intercavitary~~ **intracavitary**, or interstitial application.

~~(19)~~ "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 ~~these~~ such solution extraction operations do not constitute " byproduct material " within this definition.

~~(19)20~~ "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall 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 shall change the method observed ~~by them~~ for determining calendar quarters ~~for purposes of these rules~~ except at the beginning of a calendar year.

~~(20)21~~ "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.

~~(21)22~~ "CFR" means Code of Federal Regulations.

~~(22)23~~ "Chelating agent" means amine polycarboxylic acids, hydroxy-carboxylic acids, gluconic acid, and polycarboxylic acids.

~~(23)24~~ "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of these rules, "lung class" or "inhalation class" are equivalent terms.

~~(24)25~~ "Clinical laboratory" means a laboratory licensed [under] pursuant to ORS 438.110 to 438.140.

~~(25)26~~ "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.

~~(26)27~~ "Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

~~(27)28~~ "Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \sum W_T H_{T,50}$).

~~(28)29~~ "Contamination" (Radioactive) ~~means:~~ ~~(a) D~~ 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. ~~(b)~~ Contamination may be divided into two types: Fixed and removable. ~~(A)~~ Removable contamination may be ~~feasibly~~ 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. ~~(B)~~ 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.

~~(29)30~~ "Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material [which] that decays at the rate of ~~3.7E+10~~ $\times 10^{10}$ disintegrations or transformations per second (dps or tps).

~~(30)31~~ "Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

~~(31)32~~ "Decommission" means to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of license.

(~~f32~~33) "Deep dose equivalent" (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

(~~f33~~34) "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.

(~~f34~~35) "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.

(~~f35~~36) "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).

(~~f36~~37) "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.

(~~f37~~38) "Dose equivalent" H_T means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem (see "Rem"). (See OAR 333-100-0070(2) for SI equivalent sievert.)

(~~f38~~39) "Dose limits" means the permissible upper bounds of radiation doses established in accordance with these ~~fregulations~~ rules. For purposes of these ~~fregulations~~ rules, "limits" is an equivalent term.

(~~f39~~40) "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. [$(H_{E,50} = \sum w_T H_{T,50})$.]

(~~f40~~41) "Effective dose equivalent (H_E)" means the sum of the products of the dose equivalent to ~~each~~ the organ or tissue (H_T) and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum w_T H_T$).

(~~f41~~42) "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.

(~~f42~~43) "Embryo/fetus" means the developing human organism from conception until the time of birth.

(~~f43~~44) "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.

(~~f44~~45) "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.

(~~f45~~46) "Explosive material" means any chemical compound, mixture, or device that [which] produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

(~~f46~~47) "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) ~~Exposure also means~~ being exposed to ionizing radiation or to radioactive material.

~~NOTE: When not underlined as above (or indicated as 'exposure' (X)), the term 'exposure' has a more general meaning in these rules.~~

~~(47)48~~ "Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

~~(48)49~~ "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

~~(49)50~~ "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

~~(50)51~~ "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).

~~(51)52~~ "Fixed gauge" means a measuring or controlling device that is intended to be mounted at a specific location, stationary, and not moved, that is, not portable.

~~(52)53~~ "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.

~~(53)54~~ "General license" means a license **granted by rule, in contrast to an issued license,** ~~effective under these rules~~ to acquire, own, possess, use, or transfer radioactive material or a device that contains radioactive material.

~~(54)55~~ "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.

~~(55)56~~ "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))

~~(56)57~~ "Hazardous waste" means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

~~(57)58~~ "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 agency, 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.**

~~(58)59~~ "High radiation area" means ~~any~~ area, accessible to individuals, in which ~~there exists~~ radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or from any surface that the radiation penetrates.

~~(59)60~~ "Human use" means the internal or external administration of radiation or radioactive material to human beings.

~~(60)61~~ "Individual" means any human being.

~~(61)62~~ "Individual monitoring" means:

(a) The assessment of dose equivalent by the use of devices designed to be worn by a 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.

~~(62)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.

~~(63)64~~ "Inhalation class" (see "Class").

~~(64)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 Agency.

~~(65)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.

~~(66)67~~ "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

~~(67)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.

~~(68)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.

~~(69)70~~ "License" means a license issued by the Agency in accordance with ~~*Divisions 100 through 120 of this chapter*~~ **rules adopted by the Agency .**

~~(70)71~~ "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license **granted or issued** by the Agency. **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.**

~~(71)72~~ "Licensee" means any person who is licensed by the Agency in accordance with these rules and the Act.

~~(72)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.

~~(73)74~~ "Limits" (dose limits) means the permissible upper bounds of radiation doses.

~~(74)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.

~~(75)76~~ "Lung class" (see "Class").

~~(76)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 section ~~*71.4 of 10 CFR Part 71*~~ **Division 118 of this Chapter.**

~~{(77) "Manufacturing and Distribution" license means specific authorization to possess and use specifically licensed radioactive materials to manufacture (fabricate, produce) another article containing radioactive materials, for sale, transfer, or distribution (shipping, disbursement) to another specific or general license, or for sale or distribution to persons exempt from these rules for naturally occurring or accelerator-produced radioactive materials (NARM) only.}~~

~~(78) "Member of the public" means an individual *in an unrestricted area. However, an individual is not a member of the public during any period in which the individual receives an occupational dose*, 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 ~~regulations~~ 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 ~~which~~ that is found in nature as a radioactive material (i.e., not technologically produced).

(84) "Natural thorium" means thorium-232 in equilibrium with all decay products.

(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.

~~{(84/86) "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.~~

~~{(85/87) "Normal form" radioactive material" means *any* radioactive material *which* that has not been demonstrated to *does not* qualify as "special form radioactive material". See "Special form".~~

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

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

~~{(86/90) "Occupational dose" means the dose received by an individual [in a restricted area or] in the course of employment in which the individual's assigned duties **for a licensee or registrant** involve exposure to sources of radiation, whether **or not the sources of radiation are** in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received[:] from background radiation, or as a patient from medical practices, or from voluntary participation in medical research programs, or as a member of the public.~~

~~{(87/91) "Package" means packaging together with its radioactive contents as presented for transport.~~

~~{(88/92) "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.~~

~~{(89/93) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this ~~is~~State, any other ~~is~~State or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing[:], *but shall not include federal government agencies*.~~

(f90f94) "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".

(f91f95) "Pharmacist" means ~~any~~ individual licensed by ~~this~~ a state ~~to compound and dispense drugs, prescriptions, and poisons~~ or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy. (See also Authorized Nuclear Pharmacist).

(f92f96) "Physician" means an individual licensed by the Oregon State Board of Medical Examiners to **dispense drugs in the practice of medicine**.

(f93f97) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

NOTE: Although there is an annual occupational radiation dose limit, additional dose is permitted provided the situation is planned in advance and a justification is provided that the extra dose is necessary. There is a limit to planned special exposures (PSEs) of 1 times the annual limit in any year and 5 times the annual limit in a lifetime. This translates to:

	<i>Standard Annual Limit</i>	<i>Maximum Annual PSE</i>	<i>Maximum Lifetime PSE</i>
<i>Whole Body</i>	5	5	25
<i>Skin/Extremity/Organ</i>	50	50	250
<i>Lens of the Eye</i>	15	15	75

	Standard Annual Limit	Maximum Annual PSE	Maximum Lifetime PSE
Whole Body	5	5	25
Skin, Extremity, Organ	50	50	250
Lens of the Eye	15	15	75

(f94f98) "Portable gauge" means a measuring or controlling device that is intended to be portable, that 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).**

(f95f99) "Public dose" means the dose received by a member of the public ~~from~~ by exposure to sources of radiation **from licensed or registered operations. Public dose** *[either within a licensee's or registrant's controlled area or in unrestricted areas. It]* does not include occupational dose, or dose received from background radiation, or dose received as a patient from medical practices, or dose from voluntary participation in medical research programs.

(f96f100) "Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below 130 °F (54.4 °C). A pyrophoric solid is 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.

~~(f97)101~~ "Qualified expert" means an individual, **approved by the Agency**, who has demonstrated, pursuant to these rules, that he/she possesses the knowledge, skills, and training to **measure ionizing radiation, to evaluate safety techniques, to evaluate radiation parameters, to evaluate safety techniques, and to advise regarding radiation protection needs. The individual shall: (1) 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 (2) Hold a master's or doctor's degree in physics, biophysics, radiological physics, health physics, or medical physics and have completed 1 year of documented, full time training in the appropriate field and also 1 year of documented, full time work experience under the supervision of a qualified expert in the appropriate field. To meet this requirement, the individual shall have performed the tasks required of a qualified expert during the year of work experience; or (3) Receive approval from the Department for specific activities.**

~~(f98)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. ~~fAs used in this Division, the quality factors for converting absorbed dose to dose equivalent are shown in Table 1004(b).1.f~~

~~(f99)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.

~~(f100)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.

~~(f101)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 Agency 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 Agency has determined to present a biological hazard to the occupational or public health and safety.

~~(f102)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 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

~~(f103)107~~ "Radiation machine" means any device capable of producing radiation except those which produce radiation only from radioactive material.

~~(f104)108~~ "Radiation safety officer" means **(a) an individual [one]** who has the knowledge, ~~fand~~ responsibility, **and authority** to apply appropriate radiation protection rules; **(b) the representative of licensee management, authorized by the Agency, and listed on the specific license as the radiation safety officer, who is responsible for the licensee's radiation safety program.**

~~(f105)109~~ "Radioactive material" means any solid, liquid, or gas ~~fwhich~~ that emits radiation spontaneously. **Radioactive material, as used in these rules, includes (a) byproduct material, as defined in OAR 333-100-0005(19)(a), naturally occurring radioactive material, and accelerator**

produced material; and (b) source material and byproduct material, as defined in OAR 333-100-0005(19)(b).

(110) "Radioactive waste" means radioactive material that is unwanted or is unusable, as defined in Division 50 of OAR 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 Agency and is legally obligated to register with the Agency 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 shall furnish information to the Agency in accordance with the rules adopted by the Agency.

~~(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}~~ **2.58** $\times 10^{-4}$ 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 ~~permanently bonded or fixed~~ **encased** in a capsule ~~for matrix~~ designed to prevent leakage or escape ~~release and dispersal~~ of the radioactive material ~~funder the most severe conditions which are likely to be encountered in normal use and handling~~.

(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.

(~~119~~125) "Shallow dose equivalent" (H_s), 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 1 square centimeter.

(~~120~~126) "SI" means the abbreviation for the International System of Units.

(~~121~~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).

(~~122~~128) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

(~~123~~129) "Source material" means ~~uranium or thorium, or any combination thereof, in any physical or chemical form, or~~ material, in any physical or chemical form, including ores ~~which~~ 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.

(~~124~~130) "Source material milling" means any activity that results in the production of byproduct material, as defined by the definition in ~~subsection~~ OAR 333-100-005(~~119~~)~~(b)~~ ~~of this rule~~, "~~bb~~Byproduct material".

(~~125~~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.

(~~126~~132) "Special form radioactive material" means radioactive material ~~which~~ 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 (~~0.197~~ 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, ~~may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.~~ 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.

(~~127~~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 shall not exceed one (1). For example, the following quantities in combination would not exceed the limitation and are within the formula: *

$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

(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, shall mean 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 agency.

~~(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 ~~to~~ **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 and the committed dose equivalent to the organ receiving the highest dose as described in **OAR 333-120-650(1)(d)** ~~of these rules~~.

~~(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).

~~(138)~~**146** "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

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

~~(139)~~**147** "Unrestricted area" means an ~~any~~ area, access to which is *[not]* **neither limited nor** controlled by the licensee or registrant. ~~For purposes of [protection of individuals from exposure to radiation and radioactive material, and any area used for residential quarters]~~ **these rules,**

"uncontrolled area" is an equivalent term.

(148) "Uranium - depleted, enriched" (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.

~~(140)~~**149** "Validation certificate" means the official document issued upon payment to the Agency of the appropriate fee listed in Division 103 of these rules. The license or registration is subject and void without the annual validation certificate.

~~(141)~~**150** "Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation or from any surface that the radiation penetrates. (At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.)

(151) "Waste" means radioactive waste.

~~(143)~~**152** "Week" means 7 consecutive days starting on Sunday.

~~(144)~~**153** "Weighting factor" w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS	
Organ or Tissue	W_T
Gonads	0.25
Breast	0.15
Red Bone Marrow	0.12
Lung	0.12
Thyroid	0.03
Bone Surfaces	0.03
Remainder	0.30 ^a
Whole Body	1.00 ^b

^a 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

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

~~(145)~~154 "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

~~(146)~~155 "Worker" means an individual engaged in work under a license or registration issued by the Agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

~~(147)~~156 "Working level" (WL) means any combination of short-lived radon progeny in 1 liter of air that will result in the ultimate emission of ~~1.3E+5~~ 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.

~~(148)~~157 "Working level month" (WLM) means an exposure to 1 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.)

~~(149)~~158 "Year" means the period of time beginning in January used to determine compliance with the provisions of these ~~regulations~~ 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.

~~**Publications:** The publication(s) referred to or incorporated by reference in this rule are available from the office of the Health Division.~~

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & ef. 1-8-91; HD 15-1994, f. & ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95

Additional Definitions

333-100-0010 Other definitions used only in a certain Division of these rules will be found in that Division.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 10-1987, f. & ef. 7-28-87; HD 1-1991, f. & cert. ef. 1-8-91

Interpretations

333-100-0015 Except as specifically authorized by the Agency in writing, no interpretation of the meaning of these rules by any officer or employee of the Agency, other than a written interpretation, will be recognized to be binding upon the Agency.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Prohibited Uses

333-100-0020 (1) Hand-held fluoroscopic screens unless they have been listed in the Registry of Sealed Source and Devices or accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health.

(2) Shoe-fitting fluoroscopic devices shall not be used.

(3) Sources of radiation shall not be used to expose any individual solely for training or demonstration purposes.

(4) Sources of radiation shall not be used for the purpose of screening or inspecting individuals for concealed weapons, hazardous materials, stolen property, illegal goods or contraband.

(5) No person shall intentionally apply or allow to be applied, either directly or indirectly, ionizing radiation to human beings except by, or under the supervision of, persons licensed by the State of Oregon to practice the healing arts and who are authorized to use radiation on humans. Notwithstanding this restriction, the Agency recognizes practitioners of the healing arts to be as outlined in ORS 676.110, that is:

(a) Podiatrists, Chiropractors, Dentists, Naturopath, Osteopaths, Physicians, and Veterinarians.

(b) Nurse Practitioners and Physician Assistants may prescribe x-ray when doing so within the bounds of their independent rules.

(c) No person will be allowed to use x-ray producing equipment without first meeting the requirements of 333-106-0045(7) or 333-106-0055.

(6) No person shall intentionally or unintentionally expose another individual to radiation other than ionizing radiation in such a way as to adversely affect the health or safety of that individual.

Notwithstanding this restriction, the use of radiation other than ionizing radiation by persons licensed by the State of Oregon to practice the healing arts and who are authorized to use radiation will be allowed.

(7) Dental units which are 50 kVp and below are prohibited from being sold, leased, transferred or

lent.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.775

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 15-1994, f. & cert. ef. 5-6-94

Exemptions

333-100-0025 (1) General Provision. The Agency may, upon application or upon its own initiative, grant such exemptions or exceptions from the requirements of these rules as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

(2) U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors. Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this state is exempt from these rules to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

(a) Prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(b) Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

(c) Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and,

(d) Any other prime contractor or subcontractor of the U.S. Department of Energy of the U.S. Nuclear Regulatory Commission when the state and the U.S. Nuclear Regulatory Commission jointly determine:

(A) That the exemption of the prime contractor or subcontractor is authorized by law; and,

(B) That, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94

Additional Requirements

333-100-0030 The Agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in these rules as it deems appropriate or necessary to minimize danger to public health and safety or property.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Violations

333-100-0035 An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any rule or order issued thereunder. Any person who willfully violates any provision of the Act or any rule or order issued thereunder may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by ORS 453.990.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 431.990, 453.715

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Impounding

333-100-0040 Sources of radiation shall be subject to impounding pursuant to section 453.705 of the Act.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.705

Hist.: HD 4-1985, f. & cert. ef. 3-20-85

Communications

333-100-0045 All communications and reports concerning these rules, and applications filed thereunder, should be addressed to the Radiation Protection Services, Oregon State Health Division, 800 NE Oregon #21, Portland, OR 97232.

Stat. Auth.: ORS Ch. 453

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 15-1994, f. & cert. ef. 5-6-94

Severability

333-100-0050 Should any section, subsection, paragraph, sentence, clause or phrase of these rules be declared unconstitutional or invalid for any reason, the remainder of these rules shall not be affected thereby.

Stat. Auth.: ORS Ch. 453

Stats. Implemented: ORS 453.735

Hist.: HD 4-1985, f. & ef. 3-20-85

Records

333-100-0055 Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these rules.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.695

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Maintenance of records

333-100-0057 Each record required by this Division shall be legible throughout the retention period specified by each 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 of 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.

Inspections

333-100-0060 (1) Each licensee and registrant shall afford to the Agency at all reasonable times opportunity to inspect sources of radiation **and radioactive material** and the premises and facilities wherein such sources of radiation **and radioactive material** are used or stored.

(2) Each licensee and registrant shall make available to the Agency for inspection, upon reasonable notice, records maintained pursuant to ~~these~~ the rules in this Chapter.

(3) Within the available resources of the Agency, X-Ray Machine Registrants shall be inspected at the following frequency based upon the class of X-Ray machine(s) registered:

Hospitals	Every year
Radiologists	Every year
Chiropractors	Every two years
Osteopaths	Every two years
Medical	Every two years
Podiatry	Every three years
Dental	Every three years
Veterinary	Every three years
Academic	Every three years
Industrial	Every three years

Notwithstanding the above, the Agency may inspect more frequently as deemed necessary to protect public health and safety.

NOTE: Nothing in this section affects the fee schedule in ORS 453.670 for X-Ray machine registrants.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.685, 453.761

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & ef. 1-8-91; HD 16-1994, f. & ef. 6-27-94; HD 1-1995, f. & cert. ef. 4-26-95

Tests

333-100-0065 Each licensee and registrant shall perform ~~upon instructions from the Agency~~, or ~~shall~~ permit the Agency to perform, such ~~reasonable~~ tests as the Agency deems appropriate or necessary for the administration of the rules in this Division and Divisions 101, 105, 106, 108, 109, 112, 113, 115, 116, 117, 119, and 121 of this Chapter including, but not limited to, tests of:

- (1) Sources of radiation **and radioactive material**;
- (2) Facilities wherein sources of radiation **and radioactive material** are used or stored;
- (3) Radiation detection and monitoring instruments; and,
- (4) Other equipment and devices used in connection with **the** utilization or storage of licensed or registered sources of radiation **and radioactive material**.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.685, 453.752

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Units of Exposure and Dose

333-100-0070 The Metric Conversion Act of 1975 (PL 94-168) urged the increasing awareness and use of the International System of Units (SI). The generally accepted regulatory values in the narrative portions of this document are followed by the SI equivalents in parentheses. Where appropriate, schedules and appendices are provided with notes concerning conversion factors. The inclusion of the SI equivalent is for informational purposes only.

(1) The unit of exposure is the coulomb per kilogram (C/kg). One roentgen is equal to ~~2.58~~ $\times 10^{-4}$ coulomb per kilogram of air.

(2) The units of radiation dose are:

(a) Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad);

(b) Rad is 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 Gy);

(c) Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

(d) Sievert is the 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 Sv = 100 rem).

(e) As used in these regulations, the quality factors for converting absorbed dose to dose equivalent are shown in 10 CFR 20 part 20.1004 Table 1004 (b).1.

(3) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rem per hour or sieverts per hour, as provided in paragraph (b) of this section, 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of the regulations in this part, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee may use the fluence rate per unit dose equivalent or the appropriate Q value from 10 CFR 20 part 20.1004 Table 1004(b).2 (at the end of this division) to convert a measured tissue dose in gray or rad to dose equivalent in sievert rem.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 1-1991, f. & ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94

Deliberate Misconduct

333-100-0080 (1) Any licensee or any employee of a licensee; and any contractor (including a supplier or consultant), subcontractor, or any employee of a contractor or subcontractor, of any licensee, who knowingly provides to any licensee, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's activities subject to this part; may not:

(a) Engage in deliberate misconduct that causes or, but for detection, would have caused, a licensee to be in violation of any rule, regulation, or order, or any term, condition, or limitation of any license, issued by the Agency, or

(b) Deliberately submit to the Agency, a licensee, or a licensee's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Agency.

(2) A person who violates paragraph (1)(a) or (1)(b) of this rule may be subject to enforcement action in accordance with OAR 333-100-0035.

(c) For purposes of paragraph (1)(a) of this rule, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee to be in violation of any rule, regulation, or order, or any term, condition, or limitation, of any license issued by the Agency, or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order or policy of a licensee, contractor, or subcontractor.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD

DIVISION 101

**REGISTRATION OF RADIATION
MACHINES, GENERAL LICENSE RADIOACTIVE MATERIALS,
LICENSING OF RADIATION SERVICES,
AND ACCREDITATION OF HOSPITAL RADIOLOGY INSPECTORS**

Purpose and Scope

333-101-0001 (1) This Division provides for the registration of radiation machines, general license radioactive materials, and for the licensing of persons providing radiation machine, radioactive material, or tanning installation, consultation, servicing, and/or services, and hospital radiology inspectors performing hospital X-ray machine inspections, unless such activities are subject to other Divisions of these Rules.

(2) In addition to the requirements of this Division, all licensees, registrants, and accredited individuals are subject to the applicable provisions of other portions of these rules.

~~*(3) As used in this Division, "facility" means the location at which one or more devices or sources of radiation (X-ray, radioactive materials, or non-ionizing radiation) are installed and/or located within one building, vehicle, or under one roof, and are under the same administrative control.*~~

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & ef. 1-8-91; HD 15-1994, f. & ef. 5-6-94; HD 1-1995, f. & ef. 4-26-95; HD 1-1996, f. & cert. ef. 7-1-96

Definitions

333-101-0003 (1) "Facility" means the location, building, vehicle, or complex under one administrative control, at which one or more devices or sources of radiation (X-ray, radioactive materials, or non-ionizing radiation) are installed.

(2) "Health Physics Consultant" means a person, business, facility, or institution providing health physics knowledge and skills for a fee. A health physics consultant may not use or possess radioactive material without specific license authorization pursuant to OAR 333-102-200.

(3) "Storage" means a condition in which a device or source is not being used for an extended period of time, and has been made inoperable.

(4) "Vendor" means a person, business, facility, or institution providing a product or service for a fee. Radiation vendors include machine salespersons, repair and technical personnel, or marketing representatives who sell, demonstrate, or market x-ray machines or tanning beds and provide advice, consultation, service, or technical information to registrants.

Application for Registration of Radiation Machines

333-101-0005 No X-ray machine shall be operated on or after July 1, 1996 unless the machine has a valid X-ray machine registration. Each person having a radiation machine shall:

(1) Apply, in writing, for registration of such machines with the Agency prior to the operation of a radiation machine. All operable radiation machines must be registered and the appropriate fee, which is listed in Division 103 of these rules, must be paid. Hospitals wishing to register any radiation machine shall meet the additional requirements of OAR 333-101-0200. To avoid radiation machine registration and fees,

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the X-ray tube must be removed or the machine must be disassembled. Application for registration shall be completed on forms furnished by the Agency and shall contain the following information or such other information as may be required:

- (a) Name of the owner or person having administrative control and responsibility for use. "Person" is defined in OAR 333-100-0005 to include "organization";
- (b) Address and telephone number where the machine is located and used except that a central headquarters address may be given for a mobile machine used at various temporary field locations;
- (c) A description of the type, model and control panel serial number of the radiation machine (state I.D. number if issued) and its rated capacity in peak kilovolts and maximum milliamperes;
- (d) A description of the use (dental, medical, industrial, veterinary, research, etc.) of the machine;
- (e) Date of application and signature of registrant;
- (f) The individual and the signature of the individual designated under OAR 333-101-0005(3);
- (g) If the facility is mobile, the geographic areas within the state to be covered;
- (h) Name of the radiation machine supplier, installer and service agent.

(2) The registrant shall notify the Agency within 30 days of any change which increases the radiation output or rating of the radiation machine or of any other change which renders the information required in section (1) of this rule no longer accurate.

(3) When required by the Agency, the registrant shall designate an individual who will be responsible for radiation protection for the machine. Such individual shall:

- (a) Be qualified by training and experience concerning all hazards and precautions involved in operating the machine for which he or she is responsible;
- (b) Recommend a detailed program of radiation safety for effective compliance with the applicable requirements of these rules;
- (c) Give instructions concerning hazards and safety practices to individuals who may be occupationally exposed to radiation from the machine; and
- (d) Make surveys and carry out other procedures as required by these rules.

(4) When, in the opinion of the Agency, the individual designated to be responsible for radiation safety does not have qualifications sufficient to insure safe use of the machine for which he or she is responsible, the Agency may order the registrant to designate another individual who meets the requirements of this Division.

(5) Each registrant shall prohibit any person from furnishing radiation machine servicing or services as described in OAR 333-101-0020(4) to his radiation machine facility until such person provides evidence that he has been licensed with the Agency as a provider of services in accordance with OAR 333-101-0020.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.655, 453.752, 453.754

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & ef. 1-8-91; HD 15-1994, f. & ef. 5-6-94; HD 1-1996, f. & cert. ef. 7-1-96

Application for General License Registration for Radioactive Materials Gauges, In Vitro Testing, Source Material, Reference and Calibration Sources, and Reciprocal Recognition of Specific Radioactive Materials License

333-101-0007 Except for specific licensees granted a general license under OAR 333-102-0340 for reciprocal use of specific license radioactive material, each person, pursuant to OAR 333-102-0103, 333-102-0115(1), 333-102-0125, or 333-102-0130, having general license radioactive material shall:

(1) Apply for registration of such materials with the Agency within thirty (30) days of possession of such device, in vitro radioactive material used for testing, or source material. Application for registration shall be completed on forms furnished by the Agency and shall include the name of the general license supplier, installer, and service agent.

(2) The general license registrant shall notify the Agency within thirty (30) days of any change in information required in section (1) of this rule.

(3) Each general license registrant shall prohibit any person from furnishing servicing or services to any general license device until such person provides evidence that the servicing agent has been registered with the Agency as a provider of services in accordance with OAR 333-101-0020.

(4) Each general license granted pursuant to OAR 333-102-0340 shall provide the specific information required pursuant to that rule.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.655, 453.665

Hist.: HD 1-1995, f. & cert. ef. 4-26-95

Exemptions

333-101-0010 (1) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this Division, providing dose equivalent rate averaged over an area of 10 square centimeters does not exceed ~~*f0.5 millirem (5 μSv)*~~ **5 μSv (0.5 millirem)** per hour at five centimeters from any accessible surface of such equipment. The production, testing or factory servicing of such equipment shall not be exempt.

(2) Radiation machines while in transit or inoperable are exempt from the requirements of this Division. For the purposes of registration and fees, the Agency considers an X-ray unit to be inoperable only if the machine's X-ray tube (insert) has been removed or the machine disassembled. With the X-ray tube in place, and the machine assembled, the unit is considered to be operable. If a machine is "in storage," it must be registered and charged a registration fee. However, an "inoperable" machine need not be registered or assessed a fee.

(3) Domestic television receivers are exempt from the requirements of this Division.

(4) Electron microscopes are exempt from the requirements of this Division, provided that the dose equivalent rate, averaged over an area of 10 square centimeters, does not exceed ~~*f0.5 millirem (5 μSv)*~~ **5 μSv (0.5 millirem)** per hour at five centimeters from any accessible surface of the equipment.

NOTE: Electron microscope: A type of microscope which uses electrons to produce magnified images and may therefore produce ionizing radiation incidental to its use.

(5) Electron beam welding machines and electron beam furnaces are exempt from the requirements of this Division, provided that the dose equivalent rate, averaged over an area of 10 square centimeters, does not exceed ~~*f0.5 millirem (5 μSv)*~~ **5 μSv (0.5 millirem)** per hour at five centimeters from any accessible surface of the equipment.

(6) Persons licensed under OAR 333-102-0200 or equivalent specific licenses rules under an Agreement State or the U.S. Nuclear Regulatory Commission are exempt from this requirement.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & ef. 1-8-91; HD 15-1994, f. & ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95

Transfer or Disposal of Radiation Producing Machines or Equipment

333-101-0015 Whenever radiation producing machines or equipment, including general license devices containing radioactive material, are transferred or disposed of, the Agency shall be notified in

writing by the registrant within 30 days of the date of such transfer or disposal, and include the name and address of the person to whom it was transferred or its final disposition.

NOTE: General License radioactive materials can only be transferred pursuant to requirements in OAR 333-102.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Application for License of Sales, Services, Consultation, and Servicing For Radiation Machines

333-101-0020 (1) Each person who is engaged in the business of selling, leasing, transferring, lending, installing or offering to install radiation machines or tanning beds, or is engaged in the business of furnishing or offering to furnish radiation machine, radioactive material (unless such activities are authorized under a specific license), or tanning servicing or services in this state, shall apply for license of such services with the Agency within 30 days following the effective date of this rule or thereafter prior to furnishing or offering to furnish any such services.

(2) Application for a license shall be completed on forms furnished by the Agency and shall contain the following information or such other information as may be required:

(a) Name, address and telephone number of the following:

(A) The individual or the company to be licensed;

(B) The owner(s) of the company.

(b) The services which are to be provided;

(c) The area of the state and other states to be covered;

(d) A list of the individuals qualified to provide these services;

(e) The date of application and signature of the individual responsible for the company, beneath a statement of the items specified in OAR 333-101-0020(3).

(3) Each person applying for license under this Division shall specify:

(a) That they have read and understand the requirements of these rules;

(b) The services for which they are applying for license;

(c) The training and experience that qualify them or their technical staff to discharge the services for which they are applying for license;

(A) Training for radiation machine vendors shall include, but shall not be limited to, a minimum of 20 formal hours in radiation use and safety.

(B) Subjects to be covered shall include but not be limited to:

(i) Nature of X-rays;

(ii) Radiation units;

(iii) Biological effects of X-ray radiation;

(iv) Principals of radiation protection;

(v) Radiation survey instruments;

(vi) Personnel monitoring equipment; and

(vii) Applicable radiation regulations.

(d) The type of measurement instruments to be used, frequency of calibration, source of calibration; and

(e) The type of personnel dosimeters supplied, frequency of reading and replacement or exchange schedule;

(4) All radiation machine vendors shall have measurement instruments that will assure compliance with all X-ray machine, or tanning bed installation requirements according to all applicable federal standards, as well as instruments to properly check items such as collimation, HVL, kVp, mA, time, and

radiation output, or assure these tests are made by a qualified expert, and that the information is included in the installation report.

(5) For the purpose of OAR 333-101-0020, services may include but shall not be limited to:

- (a) Installation and/or servicing of radiation machines and associated radiation machine components;
- (b) Calibration of radiation machines or radiation measurement instruments or devices;
- (c) Radiation protection or health physics consultations or surveys; and
- (d) Personnel dosimetry services (not otherwise licensed under these rules).

(6) No individual shall perform services that are not specifically stated for that individual on the notice of licensure (certificate of validation or acknowledgment of validation) issued by the Agency.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.655

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & ef. 1-8-91; HD 15-1994, f. & ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95

Application for License of Sales, Consulting Services, and Servicing for Radioactive Materials Devices under General License

333-101-0023 (1) Each person who is engaged in the business of selling, installing, surveying, consulting, training, or servicing radioactive material in general license measuring, gauging, or controlling devices, or selling In Vitro testing kits, or source material, or is engaged in the business of furnishing or offering to furnish radioactive material consulting services in this state, shall apply for license of such services with the Agency within 30 days following the effective date of this rule or thereafter prior to furnishing or offering to furnish any such services.

(2) Application for a license shall be completed on forms furnished by the Agency.

(3) Each person applying for license under this Division shall specify:

- (a) That they have read and understand the requirements of these rules;
- (b) The services for which they are applying for license;

(c) The training and experience that qualify them or their technical staff to discharge the services for which they are applying for license;

(4) All vendors shall have measurement instruments that will assure compliance with all applicable standards, as well as instruments to properly check items such as collimation, time, and radiation output, or assure these tests are made by a qualified expert, and that the information is included in the installation report.

(5) For the purpose of OAR 333-101-0020, services may include but shall not be limited to:

- (a) Installation and/or servicing of radiation machines and associated radiation machine components;
- (b) Calibration of general license radioactive material used for measuring, gauging, or controlling;
- (c) Radiation protection or health physics consultations or surveys; and
- (d) Personnel dosimetry services (not otherwise licensed under these rules).

(6) No individual shall perform services that are not specifically stated for that individual on the license application (certificate of validation or acknowledgment of validation) issued by the Agency.

(7) Persons licensed under OAR 333-102-0200 (specific radioactive materials license) are exempt from the requirements of this rule at the location where that license was issued.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.655, 453.665

Hist.: HD 1-1995, f. & cert. ef. 4-26-95

Out-of-State Radiation Machines

333-101-0025 (1) Whenever any radiation machine is to be brought into the state, for any temporary use, the person proposing to bring such machine into the state shall give written notice to the Agency (at least two working days) before such machine is to be used in the state. The notice shall include:

- (a) The type of radiation machine;
- (b) The nature, duration and scope of use;
- (c) The exact location(s) where the radiation machine is to be used; and
- (d) The States in which this machine is registered.

(2) If for a specific case, the two working-day period would impose an undue hardship on the person, upon application to the Agency, permission to proceed sooner may be granted.

(3) The person referred to in OAR 333-101-0025(1) shall:

- (a) Comply with all applicable rules of the Agency;
- (b) Supply the Agency with such other information as the Agency may reasonably request; and
- (c) Not operate within the state on a temporary basis in excess of 180 calendar days per year.

(4) Notwithstanding OAR 333-101-0025(1), (2), and (3), registered general licenses for out-of-state radioactive material under specific license may be brought into the state for use at temporary job sites only under the provisions of OAR 333-102-0340.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.655, 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Additional Requirements

333-101-0030 [HD 4-1985, f. & ef. 3-20-85; Repealed by HD 1-1991, f. & ef. 1-8-91]

Issuance of Notice of Registration for X-ray Machines

333-101-0035 (1) Upon a determination that an applicant meets the requirements of the rules, the Agency shall issue a registration and/or a validation certificate.

(2) The Agency may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of radiation machines as it deems appropriate or necessary.

(3) Prior to issuance of an X-ray machine registration to a hospital, the X-ray machine will be approved by an X-ray machine inspector employed by the Agency, or inspected by an accredited radiology inspector.

(4) Prior to issuance of an X-ray machine registration to a facility other than a hospital, the X-ray machine shall be approved by an X-ray machine inspector employed by the Agency.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.655, 453.752

Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1996, f. & cert. ef. 7-1-96

Expiration of Notice of Registration

333-101-0040 (1) Except as provided by OAR 333-101-0045(2) each notice of registration shall expire at the end of the specified day in the month and year stated therein.

(2) An X-ray machine registration shall terminate if the X-ray machine is relocated for use in a physical surrounding other than the physical surrounding it occupied when originally registered.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.761

Hist.: HD 1-1991, f. & ef. 1-8-91; HD 1-1996, f. & cert. ef. 7-1-96

Renewal of Notice of Registration

333-101-0045 (1) Application for renewal of registration shall be filed in accordance with OAR 333-101-0005 or 333-101-0020.

(2) In any case in which a registrant has filed an application in proper form for renewal, not less than 30 days prior to the expiration of his existing notice of registration, such existing notice of registration shall not expire until the application status has been determined by the Agency.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.754

Hist.: HD 1-1991, f. & ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94

Report of Changes

333-101-0050 The registrant shall notify the Agency in writing before making any change which would render the information contained in the application for registration and/or the notice of registration no longer accurate.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.754

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

Approval Not Implied

333-101-0055 (1) No person, in any advertisement, shall refer to the fact that their facility is registered with the Agency pursuant to the provisions of OAR 333-101-0005 or 333-101-0020 and no person shall state or imply that any activity under such registration has been approved by the Agency.

(2) No person shall refer to any rule, or state or imply rules in any advertisement without citing the exact wording of the rule in its entirety.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625

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

Assembler and/or Transfer Obligation

333-101-0060 (1) Any person who sells, leases, transfers, lends, disposes, assembles or installs radiation machines in this state shall notify the Agency within 15 days of:

- (a) The name and address of persons who have received these machines;
- (b) The manufacturer, model and serial number of each radiation machine transferred; and
- (c) The date of transfer of each radiation machine.

(2) No person shall make, sell, lease, transfer, lend, assemble or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and used shall meet the requirements of these rules.

(3) In the case of diagnostic X-ray systems which contain certified components, a copy of the assembler's report prepared in compliance with requirements of the federal diagnostic X-ray standard (21

CFR 1020.30(d)) shall be submitted to the Agency within 15 days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.655

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

X-ray Machine Registration Fee Proration

333-101-0070 (1) Notwithstanding the registration requirements of Division 103 of these rules, the Agency shall, at the written request of the X-ray machine owner, adjust the registration expiration date of any X-ray machine to coincide with the registration expiration date of other X-ray machines currently registered to the machine owner.

(2) When requested in writing the Agency shall prorate the registration fee according to the following:

(a) If a machine is registered for 19 to 24 months in a biennium, the registration fee shall be 100 percent;

(b) If a machine is registered for 13 to 18 months in a biennium the registration fee shall be 75 percent;

(c) If a machine is registered for 7 to 12 months in a biennium the registration fee shall be 50 percent;

(d) If a machine is registered for 1 day to 6 months in a biennium the registration fee shall be 25 percent.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.761

Hist.: NEW

X-ray Machine Registration Denial

333-101-0080 (1) The Agency may deny the registration or may grant a provisional registration permitting temporary operation pending compliance with Agency standards for any of the following:

(a) The X-ray machine does not comply with one or more standards adopted by rule by the Agency;

(b) The equipment associated with the operation of the X-ray machine does not comply with one or more standards adopted by rule by the Agency;

(c) The physical surroundings associated with the operation of the X-ray machine does not comply with one or more standards adopted by rule by the Agency.

(2) The Agency may deny, condition, suspend or revoke a X-ray machine registration if the Agency believes that the X-ray machine or the physical surroundings or the equipment used in conjunction with the operation of the X-ray machine presents a danger to the health or safety of the operator or the public.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.761

Hist.: NEW

Investigation and Civil Penalty

333-101-0090 (1) If after an investigation by an Agency-employed X-ray machine inspector, the Agency has reason to believe that an act prohibited by Division 101 of these rules has been committed, the Agency may impose a civil penalty not to exceed \$5,000. The Agency reserves the right to pursue other remedies against alleged violators and may take any other disciplinary action at its discretion that it finds proper.

(2) In establishing the amount of the penalty for each violation, the Agency shall consider, but not be limited to, the following factors:

(a) The gravity and magnitude of the violation.

(b) The person's, as defined in OAR 333-100-0005(89), previous record of complying or failing to comply with Division 101 of these rules.

(c) The person/company's history in taking all feasible steps or in following all procedures necessary or appropriate to correct the violation; and

(d) Such other considerations as the Agency may consider appropriate.

(3) Civil penalties shall be imposed in the manner provided by ORS 183.090.

Stat. Auth.: ORS Ch. 453.685 - 453.807

Stats. Implemented: ORS 453.771

Hist.: NEW

Hospital X-ray Machine Registration

333-101-0200 (1) Prior to issuance of an X-ray machine registration to a hospital, the X-ray machine shall be approved by an X-ray machine inspector employed by the Agency or inspected by an Agency-accredited hospital radiology inspector, and;

(2) If inspection is performed by an accredited hospital radiology inspector, the test results must be reviewed and approved by the Agency, and;

(3) All standards adopted by rule of the Agency are met, and;

(4) A properly completed registration application has been submitted by the X-ray machine owner, and;

(5) All required fees have been paid.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.752

Hist.: NEW

Hospital Radiology Inspector

333-101-0210 An accredited hospital radiology inspector is an individual who has a combination of education and experience as indicated in OAR 333-101-0220. This individual must have been tested on knowledge of Agency radiation rules governing the X-ray machine inspection program, including but not limited to, safety requirements and inspection procedures. Those individuals with current accreditation are then allowed at a participating hospital's request, to complete the annual Agency radiation inspection.

Stat. Auth.: 453.605 - 453.807

Stats. Implemented: ORS 453.780

Hist.: NEW

Hospital Radiology Inspector Qualifications

333-101-0220 (1) All applicants for licensure as hospital radiology inspectors shall possess at a minimum one of the following combinations of education and experience:

(a) One year of experience using X-ray machines and associated auxiliary equipment, and at least one of the following;

(A) Certification by the American Board of Radiology or the American Board of Health Physics;

(B) A doctoral degree in a physical or biological science; or

(C) A doctor of medicine degree or a degree recognized by the Agency as an equally qualified health professional degree.

(b) Two years of experience using X-ray machines and associated auxiliary equipment, and a master's degree in a physical or biological science.

(c) Four years of experience using X-ray machines and associated auxiliary equipment, and a bachelor's degree in a physical or biological science.

(d) Six years of experience using X-ray machines and associated auxiliary equipment, and an associate's degree in a physical or biological science.

(2) Experience of an applicant includes, but is not limited to, measuring ionizing radiation, evaluating radiation safety and documenting radiation protection needs in a diagnostic radiology setting.

(3) In addition to meeting the education and experience requirements of this section, applicants shall be tested on knowledge of Agency rules governing the X-ray machine inspection program, including but not limited to, safety requirements and inspection procedures.

(4) Applicants shall also complete such additional written or practical testing as the Agency may require.

(5) An accreditation shall not be issued or renewed to an applicant unless the applicant has paid all required fees.

Stat. Auth.: 453.605 - 453.807

Stats. Implemented: ORS 453.780

Hist.: NEW

Hospital Radiology Inspector Testing

333-101-0230 (1) The Agency shall offer quarterly examinations for licensure. A schedule of examination dates and times will be available upon request. The Agency reserves the right to alter or adjust examination dates, times and locations as it deems necessary and will notify applicants whenever possible.

(2) Testing will be done by the Agency or the Agency's representative and upon passing the test, the Agency will issue a radiology inspector accreditation.

(3) Applicants shall qualify for examination upon compliance with all applicable provisions of OAR 333-101-0020. Applicants shall not be allowed to sit for the examination if documentation is incomplete or incorrect.

(4) Documentation shall be submitted to the Agency office within seven days of the examination date. No accreditation will be issued without proper documentation.

(5) Applicants providing documentation to the Agency shall submit the official transcript in a sealed envelope, issued from the school or training organization. The school shall attest to the documents authenticity and accuracy.

(6) Applicants taking the examination must present photographic identification, such as a driver's license, before sitting for the examination.

(7) Each applicant shall complete a written examination to test the applicant's knowledge in the following subjects:

(a) Licensure and registration requirements and applicable radiation rules including:

(A) Registrant's administrative responsibilities,

(B) Registrant's X-ray machine operator responsibilities,

(C) Registrant's X-ray machine responsibilities,

(D) Registrant's responsibilities regarding film, film processing, and all quality control related to the hospital radiology department,

(E) Hospital radiology inspector responsibilities;

(b) Agency inspection procedures and practice application;

(c) The basic principles of radiation safety;

- (d) Inspection equipment and tools.
- (8) The applicant must pass the examination by a score of at least 75 percent.
- (9) All examinations shall be prescheduled.

Stat. Auth.: 453.605 - 453.807

Stats. Implemented: ORS 453.780

Hist.: NEW

Hospital Radiology Inspector Accreditation

333-101-0240 (1) Accreditation as a radiology inspector shall be valid for two years and shall expire in the second year on the last day of the month of issuance unless renewed.

(2) An accreditation may be renewed if the radiology inspector has complied with the continuing education requirements specified in OAR 333-101-0260 and has paid the renewal fee.

(3) An accreditation for the current period shall be provided by the Agency.

Stat. Auth.: 453.605 - 453.807

Stats. Implemented: ORS 453.785

Hist.: NEW

Hospital Radiology Inspector Accreditation Revocation

333-101-0250 The Agency may condition, suspend, revoke or refuse to renew accreditation of a radiology inspector for the following reasons:

(1) Knowingly falsifying information included on the inspection report form supplied by the Agency.

(2) Substantially failing to comply with Agency procedures.

(3) Failing to meet Agency accuracy requirements.

Stat. Auth.: 453.605 - 453.807

Stats. Implemented: ORS 453.790

Hist.: NEW

Hospital Radiology Inspector Continuing Education

333-101-0260 (1) Each radiology inspector requesting an accreditation renewal shall complete 10 clock hours of continuing education every two years from the date of accreditation to qualify for renewal of accreditation.

(2) Accreditation will not be renewed without receipt of the required continuing education report, by the Agency.

(3) Accredited hospital radiology inspectors failing to obtain 10 clock hours of continuing education every two years, must reapply, complete 5 hours of continuing education for the current year, and successfully pass a written examination.

(4) Continuing education includes attendance or participation at a radiology instructional program presented, organized or under the auspices of any organization or association. For example, lectures, post-secondary school, or post-graduate courses, scientific sessions at conventions, or correspondence courses.

(5) Subject matter shall be related to the law and rules regulating hospital radiology inspectors, and the regulatory concept pertaining to radiation machines and their use in the State of Oregon.

(6) Documentation shall include the name of the sponsoring institution/association or organization, title of presentation, description of content, name of instructor or presenter, date, clock hours, and a statement of attendance or completion provided by the sponsor.

(7) Submission to the Agency of proof of participation in continuing education is the responsibility of the hospital radiology inspector. Such proof shall be held by the hospital accredited radiology inspector until submitted to the Agency biennially at the time of renewal.

(8) Hours obtained in excess of the 10 required for each two-year period shall not be carried forward as credit for the subsequent two-year continuing education requirement.

Stat. Auth.: 453.605 - 453.807

Stats. Implemented: ORS 453.785 & 795

Hist.: NEW

Hospital Responsibilities Re: X-ray Machines

333-101-0270 Each hospital that is utilizing the services of an accredited radiology inspector shall comply with the following and any other applicable sections of these rules:

(1) Contact the Agency, in writing, for information and authorization which shall allow the hospital to use the services of an accredited radiology inspector.

(a) Contact must be made three months prior to the facility's one year inspection due date or before May 1 of each renewal year by the registrant.

(b) Contact with the Agency must be remade and a new authorization given by the Agency for every renewal period.

(2) Continually have available the services of an accredited radiology inspector or notify the Agency if they have terminated the services of the accredited radiology inspector.

(3) Records of safety inspections shall be kept for two years after completion of the last inspection.

(4) Have procedures in place and followed which comply with all applicable parts of Divisions 100, 101, 106, 109, 111, and 120 of these rules.

(5) Have an inspection and safety program in place which complies with all applicable parts of Divisions 100, 101, 106, 109, 111 and 120 of these rules.

(6) Make records, X-ray machines, and related equipment available for inspection by the Agency during normal working hours.

Stat. Auth.: 453.605 - 453.807

Stats. Implemented: ORS 453.775

Hist.: NEW

Agency Responsibilities Regarding the Radiology Inspection

333-101-0280 The Agency responsibilities shall include the following as well as other applicable sections of these rules:

(1) Do annual audits of hospital programs to monitor accredited radiology inspector results and to monitor changes in the performance of registered X-ray machines during the registration period.

(2) Evaluate registrant test results provided by the accredited radiology inspectors.

(3) Grant or deny X-ray machine registrations, accreditation of hospital radiology inspectors and issue documents of registration and accreditation.

(4) Deny, condition, suspend, or revoke an X-ray machine registration or radiology inspector accreditation.

(5) Grant a provisional registration permitting temporary operation pending compliance with Agency standards.

(6) Investigate any alleged prohibited act and resolve complaints against accredited radiology inspectors and their employers.

(7) Impose civil penalties.

- (8) Develop programs to evaluate hazards associated with the use of X-ray machines.
- (9) Develop testing, training and continued education standards for accreditation of radiology inspectors.
- (10) Promulgate standards and make regulations relating to the registration of X-ray machines, accreditation of radiology inspectors, X-ray machine operation, physical surroundings and equipment related to the operation of the X-ray machines, operator training, and approved X-ray machine operating practices.
- (11) Test applicants for radiology inspector accreditation.
- (12) Collect and disseminate information relating to X-ray machine users.
- (13) Provide technical assistance and safety information to X-ray machine users.

Stat. Auth.: 453.605 - 453.807

Stats. Implemented: ORS 453.795

Hist.: NEW

Accredited Hospital Radiology Inspector Responsibilities

333-101-0290 The accredited radiology inspector's responsibilities shall include the following and compliance with any other applicable sections of these rules:

- (1) Be currently accredited by the Agency as an accredited hospital radiology inspector.
- (2) Each accredited hospital radiology inspector conducting a registration inspection on a hospital X-ray machine shall collect information and do tests in the manner required by the Agency.
- (3) Each accredited hospital radiology inspector shall make calculations in the manner prescribed by the Agency and shall enter the results and such other information as the Agency may require, on a form provided by the Agency.
- (4) Each accredited hospital radiology inspector shall make all inspection records and results available for audit or investigation by Agency inspectors.
- (5) Accredited hospital radiology inspectors shall not misrepresent in any way, a device identifying an X-ray machine registration.
- (6) Accredited hospital radiology inspectors shall not alter, obscure, deface, or remove a device identifying registration of an X-ray machine.
- (7) Accredited hospital radiology inspectors shall possess equipment appropriate and capable of doing the testing, monitoring, etc., required by applicable Agency standards.
- (8) Assure all X-ray output and scatter radiation monitoring equipment have been calibrated within the past 12 months with X-rays in the same energy range as the diagnostic equipment being evaluated. Such calibration must be traceable to the National Institute of Standards and Technology (NIST).

Stat. Auth.: 453.605 - 453.807

Stats. Implemented: ORS 453.766, 453.775, 453.780

Hist.:

DIVISION 102

LICENSING OF RADIOACTIVE MATERIAL

Purpose and Scope

333-102-0001 (1) This Division prescribes rules applicable to all persons in the State of Oregon governing licensing of radioactive material, and for exemptions from licensing requirements. ~~[and Divisions 105, 110, 113, 115, 116, 117, and 118 of these rules, provide for the licensing of radioactive material.]~~ No person shall receive, produce, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license ~~issued~~ pursuant to this Division or Divisions 105, ~~110,~~ 113, 115, 116, ~~for~~ 117, or 121 of ~~these rules~~ this Chapter ~~;~~ ~~or as otherwise provided in these Divisions~~].

(2) In addition to the requirements of Division 102, all ~~[radioactive material]~~ licensees are subject to ~~applicable~~ ~~the~~ requirements ~~off~~ in Divisions 100, 103, 111, 118, and 120 of ~~these rules~~ this Chapter. The requirements of this Division are in addition to, and not in substitution for, other requirements of this Chapter. In any conflict between the requirements in this Division and a specific requirement in another Division of the rules in this chapter, the specific requirement governs. ~~[In addition:~~

~~—(a) Licensees engaged in industrial radiographic operations are subject to the requirements of Division 105 of these rules; and~~

~~—(b) Licensees engaged in the healing arts are subject to the requirements of Division 116 of these rules; and~~

~~—(c) Licensees engaged in wireline and subsurface tracer studies are subject to the requirements of Division 113 of these rules; and~~

~~—(d) Licensees engaged in the use of Natural Occurring Radioactive Materials (NORM) are subject to the requirements of Division 117 of these rules; and~~

~~—(e) Licensees engaged in [generation of radioactive tailings stored in ponds are subject to the requirements of Division 110 of these rules; and~~

~~—(f) Licensees engaged in the use of X-ray and Hybrid industrial Gauges are subject to the requirements of Division 115 of these rules.]~~

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

(4) This Division gives notice to all persons who knowingly provide to any licensee, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's activities subject to this Division, that they may be individually subject to Agency actions pursuant to OAR 333-100-035 or 333-100-040.

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

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information about a product) to manufacturers or initial transferors of sealed source or devices containing sealed sources, which are to be used by persons specifically licensed under this Division or equivalent regulations of an Agreement State or the US Nuclear Regulatory Commission.

(6) The Agency may engage the services of qualified persons in order to assist the Agency in meeting the requirements of this Chapter, including, but not limited to, evaluating information that may be required under OAR 333-102-200(6). Payment for such services may be subject to 333-103-010(7).

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

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

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94

Exemptions

Source Material

333-102-0005 (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 shall 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;

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(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, 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 not more than 10 percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass or ceramic used in construction;

(D) Glass enamel or glass enamel frit containing not more than 10 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 (4) percent by weight and that this exemption shall 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;

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

NOTE: The requirements specified in **OAR 333-102-005(3)(e)(B)** and **333-102-005(3)(e)(C)** ~~of this subsection~~ need not be met by counterweights manufactured prior to December 31, 1969, ~~if~~ provided, that such counterweights **were manufactured under a specific license issued by the Atomic Energy Commission and are impressed with the legend required by 10 CFR 40.13(c)(5)(ii) in effect on June 30, 1969, which read ~~f,~~ CAUTION - RADIOACTIVE MATERIAL - URANIUM~~f,~~ as previously required by the rules.**

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

~~[NOTE: The requirements specified in [paragraphs] OAR 333-102-005(3)(e)(B) and 333-102-005(3)(e)(C) of this subsection need not be met by counterweights manufactured prior to December 31, 1969, provided, that such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM", as previously required by the rules.]~~

(D) This exemption shall 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).

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(g) Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that this exemption shall not be deemed to authorize either:

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

(B) The receipt, possession, use or transfer of 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 0.005 microcurie of uranium; or

(i) 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~~ **OAR 333-102-0005(3)** ~~of this rule~~ do not authorize the manufacture of any of the products described.

[**Publications:** The publication(s) referred to or incorporated by reference in this rule are available for review at ~~the Radiation Protection Services office of the Health Division~~ **Oregon Health Services Radiation Protection Services.**]

Stat. Auth ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 10-1987, f. & ef. 7-28-87; HD 1-1991, f. & cert. ef. 1-8-91; HD-1-1995, f. & cert. ef. 4-26-95

Exemptions -- Radioactive Material Other Than Source Material**Exempt Concentrations**

333-102-0010 (1) Except as provided in ~~section~~ **OAR 333-102-0010(2)** [of this rule], any person is exempt from this Division to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in **10 CFR Part 30.70 Schedule A**.

(2) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under ~~section~~ **OAR 333-102-010(1)** ~~of 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 pursuant to OAR 333-102-0245 or the general license ~~provided in~~ **granted by OAR 333-102-0340**.

[**Publications:** The publication(s) referred to or incorporated by reference in this rule are available for review at ~~the Radiation Protection Services office of the Health Division~~ **Oregon Health Services Radiation Protection Services.**]

ED NOTE: **10 CFR Part 30.70 Schedule A** referred to or incorporated by reference in this rule is attached to this Division or available from ~~the Health Division~~ **DHS-Oregon Health Services, Radiation Protection Services.**

Stat. Auth ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD-1-1995, f. & cert. ef. 4-

26-95

Exempt Items

Certain Items Containing Radioactive Material

333-102-0015 (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 shall 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;

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.

(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 shall 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 shall 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 μ Gy) per hour at 10 centimeters from any surface;

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

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

(K) One microcurie (37 kBq) of radium-226 per timepiece in timepieces acquired prior to June 1, 1977.

(b) Lock illuminators containing not more than 15 millicuries (555 MBq) of tritium or not more than two millicuries (74 MBq) of promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium-147 will not exceed one millirad (10 μ Gy) per hour at one centimeter from any surface when measured through 50 milligrams per square centimeter of absorber;

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(c) 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;

(d) Automobile shift quadrants containing not more than 25 millicuries (925 MBq) of tritium;

(e) 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;

(f) Thermostat dials and pointers containing not more than 25 millicuries (925 MBq) of tritium per thermostat;

(g) Electron tubes~~;~~ **Provided, That each tube does not contain more than one of the following specified quantities of radioactive material:**

~~[(A) Provided, that each tube does not contain more than one of the following specified quantities of radioactive material:]~~

~~(i)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;~~

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

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

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

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

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

And provided further, That the radiation dose rate from each electron tube containing radioactive material will not exceed one millirad (10 μ Gy) per hour at one centimeter from any surface when measured through seven (7) milligrams per square centimeter of absorber.

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

NOTE: For purposes of ~~this subsection~~, **333-102-0015(1)(g)** "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.

(h) 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 shall not exceed unity.

(C) For americium-241, 0.05 microcuries (1.85 kBq) is considered an exempt quantity under ~~section~~ **333-102-0015(8)** ~~of this rule~~.

(i) Spark gap irradiators containing not more than one microcurie (37 kBq) of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least three gallons per hour (11.4 liters per hour).

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

(a) The manufacture of any product listed;

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

(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 **OAR 333-102-0015(2)(e)** ~~this subsection~~, 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.

ED NOTE: 10 CFR Part 30.71 Schedule B referred to or incorporated by reference in this rule is attached to this Division or available from the ~~Health Division~~ **Oregon Health Services, Radiation Protection Services.**

Stat. Auth ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD-1-1995, f. & cert. ef. 4-26-95

Resins Containing Scandium-46, Designed for Sand Consolidation in Oil Wells

333-102-0020 Any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer of such resins pursuant to licensing requirements equivalent to those in sections 32.16 and 32.17 of **10 CFR Part 32** of the regulations of the U.S. Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing scandium-46.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available for review at ~~the Radiation Protection Services office of the Health Division~~ **Oregon Health Services Radiation Protection Services.**]

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD-1-1995, f. & cert. ef. 4-26-95

Gas and Aerosol Detectors Containing Radioactive Material

333-102-0025 (1) Except for persons who manufacture, process or produce gas and aerosol detectors containing radioactive material, any person is exempt from **the requirements for a license and from the rules in this Division and in Divisions 105, 113, 115, 116, 117, 120, and 121 of this Chapter** ~~these rules~~ to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires

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and airborne hazards provided that detectors containing radioactive material shall have been manufactured, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to section 32.26 of 10 CFR Part 32; or a Licensing State pursuant to OAR 333-102-0260, 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) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State shall be considered exempt under ~~fsection~~ **OAR 333-102-0025(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 shall be considered exempt under ~~fsection~~ **OAR 333-102-0025(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: The publication(s) referred to or incorporated by reference in this rule are available for review at ~~fthe Radiation Protection Services office of the Health Division~~ **Oregon Health Services Radiation Protection Services.**]

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD-1-1995, f. & cert. ef. 4-26-95

Self-Luminous Products Containing Radioactive Material

333-102-0030 (1) Tritium, Krypton-85 or Promethium-147. Except for persons who manufacture, process or produce self-luminous products containing tritium, krypton-85 or promethium-147, any person is exempt from these rules 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, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in this rule does not apply to tritium, krypton-85 or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

(2) Radium-226. Any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium-226, which were acquired prior to July 1, 1977.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available for review at ~~fthe Radiation Protection Services office of the Health Division~~ **Oregon Health Services Radiation Protection Services.**]

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Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD-1-1995, f. & cert. ef. 4-26-95

Exempt Quantities

333-102-0035 (1) Except as provided in ~~sections~~ **OAR 333-102-0035(2)** and **333-102-0035(3)** ~~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 333-102-105(2) is exempt from the requirements for a license set forth in this part to the extent that such person possesses, uses, transfers or owns such radioactive material. Such exemption does not apply for radium-226.**

~~(3)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~~ **OAR 333-102-035** 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 Agency 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.

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: The publication(s) referred to or incorporated by reference in this rule are available for review at ~~the Radiation Protection Services office of the Health Division~~ **Oregon Health Services Radiation Protection Services.**]

ED NOTE: **10 CFR Part 30.71 Schedule B** referred to or incorporated by reference in this rule is attached to this Division or available from ~~the Health Division~~ **DHS-Oregon Health Services, Radiation Protection Services.**

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.635

Hist.: HD 4-2985, f. & ef. 3-20-85; HD 1-1991, f. & ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD-1-1995, f. & cert. ef. 4-26-95

In Vivo Testing in Humans for H. Pylori Using Carbon-14 Labeled Urea

OAR 333-102-0040 (1) Except as provided in **333-102-0040(3)** and **333-102-0040(4)**, any

person is exempt from the requirements for a specific license pursuant to this Division and Division 116 of this Chapter provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 microcurie) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

Note: "Nominal variation" as used in this context means $\pm 10\%$ of the reported per capsule dose.

(2) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Division 102 of this Chapter.

(3) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to 10 CFR 32.21.

(4) Nothing in this rule relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.635

Hist.: HD-1-1998, f. & cert. ef.

Licenses

Types of Licenses

333-102-0075 Licenses for radioactive materials are of two types: General and specific.

(1) ~~[General licenses provided in this Division are effective without the filing of applications with the Agency or the issuance of licensing documents to the particular persons, except for source material described in OAR 333-102-0101, depleted uranium described in OAR 333-102-0103, measuring and gauging described in OAR 333-102-0115 and in vitro testing procedures described in OAR 333-102-0130. The general licensee is subject to all other applicable portions of these rules and any limitations of the general license.]~~ General licenses provided in this Division are granted as being effective without the filing of applications with the Agency or the issuance of licensing documents to particular persons, except Depleted Uranium subject to OAR 333-102-103, Measuring, Gauging, and Controlling devices subject to 333-102-115, and *In Vitro* Clinical or Laboratory Testing subject to 333-102-130.

(2) ~~[Specific licenses require the submission of an application to the Agency and the issuance of a specific licensing document by the 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 333-102-200 and Divisions 105, 113, 115, 116, 117, and 121 of this Chapter.

(3) General licenses ~~[described in]~~ granted by ~~[OAR 333-102-0101,]~~ 333-102-0103, 333-102-0115, 333-102-117, and 333-102-0130 require the submission of an application to the Agency for registration pursuant to 333-101-0007, payment of a fee in accordance with 333-103-015, and the issuance of a registration (licensing document ~~f{}~~ or general license acknowledgment) by the Agency. ~~[The licenses are subject to the requirements of OAR 333-102-0101, 333-102-0103, 333-102-0115 or 333-102-0130 and OAR 333-100-0001, 333-100-0005, 333-100-0015, 333-100-0020, 333-100-0030, 333-100-0035, 333-100-0040, 333-100-0045, 333-100-0050, 333-100-0055, 333-100-0060, 333-100-~~

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~~0065, 333-100-0070, 333-103-0010 and 333-103-0015.]~~

(4) General licenses are subject to 333-100-0005 (Definitions), 333-100-025 (Exemptions), 333-100-030 (Additional Requirements), 333-100-055 (Records), 333-100-060(1) and 333-100-060(2) (Inspections), 333-100-065 (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 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 shall maintain adequate safeguards against tampering with and loss of records.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.655

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD-1-1995, f. & cert. ef. 4-26-95

General Licenses

General Licenses - Source Material

333-102-0101 ~~f(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 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.

~~f(2)~~1 Persons who receive, possess, use, or transfer source material pursuant to the general license ~~issued~~ **granted by** ~~in section~~ **OAR 333-102-0101(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 Agency in a specific license.

~~f(3)~~2 Persons who receive, possess, use or transfer source material pursuant to the general license ~~issued~~ **granted by** ~~in section~~ **OAR 333-102-101(1)** ~~of this rule~~ are exempt from the provisions of Divisions 111 and 120 of ~~these rules~~ **this Chapter** to the extent that such receipt, possession~~s~~, use or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who ~~is~~ also is in possession of source material under a specific license issued pursuant to this Division.

~~f(4)~~3 A general license is hereby ~~issued~~ **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.

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~~(f5)4~~ Persons who receive, acquire, possess or use source material pursuant to the general license ~~granted~~ ~~established~~ by ~~section~~ OAR 333-102-101(1) ~~of this rule, shall submit the required Agency form. Applicants will receive from the Agency a validated license with certification number assigned. The form shall be submitted within 30 days after the first receipt or acquisition of such source material. The general licensee~~ shall develop and maintain procedures ~~designed~~ to establish physical control over the source material ~~described in section (1) of this rule~~ and ~~designed to~~ prevent transfer of such source material to persons not authorized to receive the source material.

~~(f6)5~~ A person who receives, acquires, possesses or uses source material pursuant to the general license ~~established~~ **granted** by ~~section~~ OAR 333-102-101(1) ~~of this rule~~:

- (a) Shall not introduce such source material, in any form, into a chemical, physical, or metallurgical treatment or process; ~~and~~
- (b) Shall not abandon such source material; and
- (c) Shall 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 Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 10-1987, f. & ef. 7-28-87; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94

General Licenses - Depleted Uranium in Industrial Products and Devices

333-102-0103(1) A general license is hereby **granted** ~~issued~~ to receive, acquire, possess, use or transfer, in accordance with the provisions of OAR 333-102-0103(2), **333-102-0103(3)**, **333-102-0103(4)** and **333-102-0103(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~~ OAR **333-102-0103(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 ~~generally licensed~~ **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~~ **333-102-0103(1)** ~~of this rule~~ shall ~~submit the required Agency form~~ **apply for registration of the general license pursuant to OAR 333-101-0007, and submit the required fee pursuant to 333-103-015.** Applicants will receive a **validation certificate** from the Agency ~~for a validated license with certification number assigned~~. The ~~form~~ **application for registration** shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. ~~The general licensee shall develop and maintain procedures designed to establish physical control over the depleted uranium described in section 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.~~

(a) **The general licensee shall 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:**

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(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 OAR 333-102-0103(1) 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 333-102-0103(3)(b).

~~(f4)b~~ The general licensee possessing or using depleted uranium under the general license established by OAR 333-102-0103(1) shall report **any changes in information** in writing to the Agency ~~any changes in information furnished by the licensee on the required Agency form~~ **within 30 days after the effective date of such change.**

~~(f5)4~~ A person who receives, acquires, possesses or uses depleted uranium pursuant to the general license established by ~~section~~ **OAR 333-102-103(1)** ~~of this rule~~:

(a) Shall 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) Shall not abandon such depleted uranium;

(c) Shall 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 ~~established~~ **granted by section OAR 333-102-103(1)** ~~of this rule~~, the transferor shall furnish the transferee a copy of this rule and a copy of the **general license registration application required by 333-101-0007 Agency form**. 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~~ **333-102-103(1)** ~~of this rule~~, the transferor shall furnish the transferee a copy of this rule and a copy of **the general license registration application required by 333-101-0007 Agency Form W** 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) Within 30 days of any transfer, shall report in writing to the Agency the name and address of the person receiving the depleted uranium pursuant to such transfer; and

(e) Shall 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**.

~~(f6)5~~ Any person receiving, acquiring, possessing, using or transferring depleted uranium pursuant to the general license established by ~~section~~ **OAR 333-102-103(1)** ~~of this rule~~ is exempt from the requirements of Divisions 111 and 120 of ~~these rules~~ **this Chapter** with respect to the depleted uranium covered by that general license.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.635

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94

**General Licenses-
Radioactive Material Other Than
Source Material**

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333-102-0105 A general license is hereby ~~issued~~ **granted** to transfer, receive, acquire, own, possess and use radioactive material incorporated in the following devices or equipment ~~which~~ **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 **10 CFR Part 31.3** ~~of 10 CFR Part 31~~. This general license is subject to the provisions of OAR ~~333-100-0040~~ **333-100-005 (Definitions), 333-100-025 (Exemptions), 333-100-030 (Additional Requirements), 333-100-055 (Records), 333-100-060(1) and 333-100-060(2) (Inspections), and 333-100-065 (Tests) through 333-100-0065, 333-102-0010(2) (**Exempt Concentrations**), 333-102-0305(1) through 333-102-305(7) (**Terms and Conditions of Licenses**), 333-102-0330 (**Transfer of Material**), 333-102-0335 (**Modification, Revocation, and Termination of Licenses**), ~~333-118, 333-120-0430 or 333-120-0440~~ and Division 111, **118, and 120** of ~~these rules~~ **this Chapter.****

NOTE: Attention is directed particularly to the provisions of Division 120 of this Chapter that relate to the labeling of containers (OAR 333-120-430 and 333-120-440).

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

(2) Ion Generating Tubes. Devices designed for ionization of air ~~which~~ **that** contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device or a total of not more than 50 millicuries (1.85 GBq) 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:** The publication(s) referred to or incorporated by reference in this rule are available for review at ~~the Radiation Protection Services office of the Health Division~~ **Oregon Health Services Radiation Protection Services.**]

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD-1-1995, f. & cert. ef. 4-26-95

Luminous Safety Devices for Aircraft

333-102-0110 (1) A general license is hereby ~~issued~~ **granted** to own, receive, acquire, possess and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

(a) Each device contains not more than 10 curies (370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147; and

(b) Each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in ~~section~~ **10 CFR Part 32.53** ~~of 10 CFR Part 32~~.

(2) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in ~~section~~ **OAR 333-102-0110(1)** ~~of this rule~~ are exempt from the requirements of Divisions 111 and 120 of ~~these rules~~ **this Chapter** except that they shall comply with the provisions

of [OAR] 333-120-0700 and 333-120-0710.

(3) This general license does not authorize the manufacture, assembly or repair of luminous safety devices containing tritium or promethium-147.

(4) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

(5) This general license is subject to the provisions of OAR [~~333-100-0040 through 333-100-0055, 333-102-0305 through 333-102-0330 333-102-0335 and 333-102-0400~~] **333-100-005 (Definitions), 333-100-025 (Exemptions), 333-100-030 (Additional Requirements), 333-100-055 (Records), 333-100-060(1) and 333-100-060(2) (Inspections), and 333-100-065 (Tests), 333-102-0305(1) through 333-102-305(7) (Terms and Conditions of Licenses), 333-102-0330 (Transfer of Material), 333-102-0335 (Modification, Revocation, and Termination of Licenses), and Division 118 of this Chapter.**

[**Publications:** The publication(s) referred to or incorporated by reference in this rule are available for review at ~~the Radiation Protection Services office of the Health Division~~ **Oregon Health Services Radiation Protection Services.**]

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD-1-1995, f. & cert. ef. 4-26-95

Certain Measuring, Gauging or Controlling Devices

333-102-0115 (1) A general license is hereby ~~issued~~ **granted** to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of OAR [~~333-103-0015~~] **333-102-115(2) ~~and sections (1), (2)~~, 333-102-115(3), ~~and~~ 333-102-115(4) ~~of this rule~~, and 333-102-115(5), and 333-102-115(6)**, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

Note: Different general licenses are issued in this section, each of which has its own specific conditions and requirements.

(2) The general license in ~~section~~ **OAR 333-102-115(1) ~~of this rule~~** applies only to radioactive material contained in devices that have been manufactured **or initially transferred** and labeled in accordance with the specifications contained in a specific license issued by the Agency pursuant to OAR [~~333-102-0200~~] **333-102-235** or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission **pursuant to 10 CFR 32.51, or in accordance with the specifications contained in a specific license issued by an Agreement State~~f,~~ or a Licensing State~~f,~~ ~~which~~ that** authorizes distribution of **the** devices to persons **granted a general license ~~generally licensed~~ by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State or a Licensing State and which have been received from one of these specific licensees or through a transfer pursuant to 333-102-115(3)(i).**

NOTE: Regulations under the Federal Food, Drug and Cosmetic Act authorizing the use of

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radioactive control devices in food production require certain additional labeling thereon which is found in **21 CFR 179.21**.

(3) Any person who owns, receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license granted in ~~fsection~~ OAR 333-102-115(1) ~~f of this rule~~:

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

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

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

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

(c) Shall assure that other testing, installation servicing, ~~fand~~ or removal ~~fing~~ ~~al~~ ~~f from installation involving~~ of the radioactive materials, its shielding or containment, are performed:

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

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

(d) Shall maintain records showing compliance with the requirements of ~~f subsections~~ **OAR 333-102-115(3)(b) and 333-102-115(3)(c) ~~f of this rule~~**. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing ~~f:~~ testing, installation servicing, ~~fand~~ or removal ~~f from installation concerning~~ of the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by ~~f subsection~~ **333-102-115(3)(b) ~~f of this rule~~** shall be maintained for one year after the next required leak test is performed or until the sealed source is disposed of or transferred. Records of tests of the "on-off" mechanism and indicator required by ~~f subsection~~ **333-102-115(3)(b) ~~f of this rule~~** shall be maintained for one year after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is disposed of or transferred. Records ~~f which~~ that are required by ~~f subsection~~ **333-102-115(3)(c) ~~f of this rule~~** shall be maintained for inspection by the Agency or until the device is disposed of or transferred;

(e) Upon the occurrence of a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the "on-off" mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding [an applicable] a specific license from the Agency, [the U.S. Nuclear Regulatory Commission,] an Agreement State or a Licensing State, **or the US Nuclear Regulatory Commission pursuant to Parts 20 and 32 of Title 10 CFR** to repair such devices, or disposed of by transfer to a person authorized by [an applicable] a specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the ~~f Agency~~ **Manager of Radioactive Materials Licensing, Radiation Protection Services, 800 NE Oregon Street Suite 260, Portland, Oregon, 97232**, a report containing a brief description of the event and the remedial action taken; **and, in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and**

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environs are acceptable for unrestricted use;

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

(g) Except as provided in ~~subsection~~ 333-102-115(3)(h) ~~of this rule~~, shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, whose specific license authorizes the individual to receive the device and within 30 days after transfer of a device to a specific licensee, shall furnish to the Agency a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

(h) **Except as provided in OAR 333-102-115(3)(i), ~~§~~ shall transfer or dispose of the device containing radioactive material ~~to another general licensee~~ only ~~by~~ by transfer to persons authorized to receive the device by a specific license issued under Division 102 of this Chapter, Parts 30 and 32 of Title 10 CFR, a specific license issued under 10 CFR Part 30 that authorizes waste collection, or a specific license issued under equivalent regulations of an Agreement State or a Licensing State. Within 30 days after transfer of a device to a specific licensee shall furnish to the Manager of Radioactive Materials Licensing, Radiation Protection Services, 800 NE Oregon Street Suite 260, Portland, Oregon, 97232, a report containing identification of the device by manufacturer's name, model number, and serial number and the name, address, license number of the person receiving the device, and the date of the transfer. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device. Devices may be transferred to other specific licensees only with written Agency approval prior to transfer;**

~~f—(A) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this rule and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Agency the manufacturer's name, and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the Agency and the transferee; or
—(B) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee.]~~

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

(A) Where the device remains in use at a particular location. In such case, the transferor shall give the transferee a copy of this rule and any safety documents identified in the label of the device and within 30 days of the transfer, report to the Manager of Materials, 800 NE Oregon Street Suite 260, Portland, Oregon, 97232, the manufacturer's name and model number and serial number of the device transferred, the name and address of the transferee, and the name and phone number of the individual designated by the transferee in accordance with OAR 333-102-115(3)(l) to be responsible for ensuring compliance with the appropriate regulations and requirements; or

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

~~[comply with the provisions of OAR 333-120-0700 and 333-120-0710 of these rules for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of Divisions 111 and 120 of these rules;]~~

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

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~~(fj)k~~ Shall submit the required Agency **application for registration** form and receive from the Agency a validated registration certificate **for each device** acknowledging the general license and verifying that all provisions of these rules have been met. The **application** form shall be submitted within 30 days after the first receipt or acquisition of such device. The general licensee shall develop and maintain procedures designed to establish physical control over the device as described in OAR 333-102-0115 and designed to prevent transfer of such devices in any form, including metal scrap, to persons not authorized to receive the devices. **The general license registration shall be validated annually with the fee listed in OAR 333-103-015(2)(b). Information submitted pursuant to OAR 333-101-0007 shall be furnished to the Agency at least annually.**

(l) Shall appoint an individual to act for the general licensee as responsible for ensuring the day-to-day compliance with the appropriate regulations and requirements. This appointment does not relieve the general licensee of responsibility in this regard.

(m) Shall register devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, or 37 MBq (1 mCi) of americium-241 or any other transuranic in accordance with paragraphs OAR 333-102-115(3)(m)(A) and 333-102-115(3)(m)(B) and 333-101-0007.

(A) If in possession of a device(s) meeting the criteria of paragraph (3)(m), shall register these devices annually with the Agency and shall pay the fee required by OAR 333-103-015. This must be done by verifying, correcting, and/or adding to the information in a request for registration received from the Agency. The registration information must be submitted to the Agency within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, general licensees holding devices meeting the criteria of paragraph (3)(m) are subject to the bankruptcy notification requirement in 333-102-305(7).

(B) In registering devices, the general licensee shall furnish the following information and any other information as may be specifically requested by the Agency:

(i) Name and mailing address of the general licensee.

(ii) Information about each device: the manufacturer, model number, serial number, the radioisotope and activity (as indicated on the label).

(iii) Name and telephone number of the responsible person designated as a representative of the general licensee under OAR 333-102-115(3)(l).

(iv) Address at which the device(s) are used and/or stored.

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

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

(n) Shall report changes of address, within 30 days after the moving of a device, to the Manager of Materials, 800 NE Oregon Street Suite 260, Portland, Oregon 97232.

(o) Shall not hold devices that are not in use for longer than two years. If devices are not being used, the shutter must be locked in the closed position. The testing required by OAR 333-102-115(3)(b) need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use.

(4) The general license in ~~fsection~~ OAR 333-102-115(1) ~~of this rule~~ does not authorize the manufacture or import of devices containing radioactive material.

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(5) The general license granted by OAR 333-102-115(1) authorizes no more than 500 millicuries (18.5 GBq) of cesium-137, strontium-90, radium-226, americium-241, polonium-210, or cobalt-60. Any device granted a general license by 333-102-115(1) containing more than 500 millicuries (18.5 GBq) of these nuclides shall be subject to the specific license pursuant to 333-103-010(2)(h). ~~The general license provided in section (1) of this rule is subject to the provisions of OAR 333-100-0040 through 333-100-0055, 333-102-0305, 333-102-0330, 333-102-0335, 333-103-0015 and 333-118-0050.~~

(6) The general licensee possessing or using devices ~~licensed under~~ granted by the general license established by section 333-102-115(1) of this rule is subject to the provisions of 333-100-005 (Definitions), 333-100-025 (Exemptions), 333-100-030 (Additional Requirements), 333-100-055 (Records), 333-100-060(1) and 333-100-060(2) (Inspections), and 333-100-065 (Tests), 333-102-0305(1) through 333-102-305(7) (Terms and Conditions of Licenses), 333-102-0330 (Transfer of Material), 333-102-0335 (Modification, Revocation, and Termination of Licenses), and Division 118 of this Chapter. ~~shall report in writing to the Agency any changes in information furnished by the licensee on the required Agency form. The report shall be submitted within 30 days after the effective date of such change.~~

NOTE: Persons possessing radioactive material in devices under a general license in OAR 333-102-115 or 10 CFR Part 31.5 of the NRC regulations, or equivalent regulations an Agreement State or a Licensing State, before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of § 31.5 in effect on January 14, 1975.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD-1-1995, f. & cert. ef. 4-26-95

General License to Install Devices Generally Licensed in 333-102-115

333-102-0117 (1) A person who holds a specific license issued by the Agency, the US Nuclear Regulatory Commission, or an Agreement State authorizing the holder to manufacture, install, or service a device described in OAR 333-102-115 within such Agreement State hereby is granted a general license to install and service such device in the state of Oregon: Provided, That:

(a) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the Agreement State.

(b) Such person assures that any labels required to be affixed to the device under regulations of the Agreement State which licensed manufacture of the device bear a statement that removal of the label is prohibited.

(2) Persons granted a general license by OAR 333-102-117 shall submit the required Agency application for registration form and receive from the Agency a validated registration certificate for each billable object acknowledging the general license and verifying that all provisions of these rules have been met. The application form shall be submitted within 30 days after the first receipt or acquisition of such device. The general licensee shall develop and maintain procedures designed to establish physical control over the devices as described in OAR 333-102-0115 and designed to prevent transfer of such devices in any form, including metal scrap, to persons not

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authorized to receive the devices. The general license registration shall be validated annually with the fee listed in OAR 333-103-015(8). Information submitted pursuant to OAR 333-101-0007 shall be furnished to the Agency at least annually.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD

Ownership of Radioactive Material

333-102-0120 A general license is hereby ~~issued~~ **granted** to own radioactive material without regard to quantity. Notwithstanding any other provisions of this Division, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Calibration and Reference Sources

333-102-0125 (1) A general license is hereby ~~issued~~ **granted** to those persons listed in ~~subsections~~ OAR **333-102-0125(1)(a)** and **333-102-0125(1)(b)** ~~of this section~~ to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of ~~sections~~ **333-102-0125(4)** and **333-102-0125(5)** ~~of this rule~~, americium-241, plutonium, and/or radium-226, in the form of calibration or reference sources:

(a) Any person who holds a specific license issued by the Agency ~~which~~ **that** authorizes ~~them to receive~~ **receipt**, possession, use, and transfer of radioactive material; and

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

(2) A general license is hereby ~~issued~~ **granted** to own, receive, possess, use and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of [sections] **333-102-0125(4)** and **333-102-0125(5)** ~~of this rule~~ to any person who holds a specific license issued by the Agency ~~which~~ **that** authorizes ~~them to receive~~ **receipt**, possession, use, and transfer of radioactive material.

(3) A general license is hereby ~~issued~~ **granted** to own, receive, possess, use and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of ~~sections~~ **333-102-0125(4)** and **333-102-0125(5)** ~~of this rule~~ to any person who holds a specific license issued by the Agency ~~which~~ **that** authorizes ~~them to receive~~ **receipt**, possession, use, and transfer radioactive material.

(4) The general licenses in ~~sections~~ OAR **333-102-0125(1)**, **333-102-0125(2)**, and **333-102-0125(3)** ~~of this rule~~ apply only to calibration or reference sources that have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to section 32.57 of **10 CFR Part 32** or section 70.39 of **10 CFR Part 70** or that have been manufactured in accordance with the ~~authorizations~~ **specifications** contained in a specific license issued to the manufacturer by the

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Agency, any Agreement State or Licensing State~~,~~ pursuant to licensing requirements equivalent to those contained in section 32.57 of 10 CFR Part 32, or section 70.39 of 10 CFR Part 70.

(5) The general licenses provided in ~~sections~~ OAR 333-102-0125(1), 333-102-0125(2) and 333-102-0125(3) ~~of this rule~~ are subject to the provisions of ~~OAR 333-100-0040 through 333-100-0055~~ 333-100-005 (Definitions), 333-100-025 (Exemptions), 333-100-030 (Additional Requirements), 333-100-055 (Records), 333-100-060(1) and 333-100-060(2) (Inspections, 333-100-065 (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 ~~these rules~~ this Chapter. In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:

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

(b) Shall not receive, possess, use or transfer such source unless the source or the storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement ~~which~~ that contains the information called for in one of the following statements, as appropriate:

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

CAUTION - RADIOACTIVE MATERIAL -THIS SOURCE CONTAINS (AMERICIUM-241) (PLUTONIUM~~-238~~) ~~(PLUTONIUM-239)~~ DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or importer

NOTE: Show only the name of the appropriate material.

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

CAUTION - RADIOACTIVE MATERIAL -THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or importer

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

(d) Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium[-238, plutonium-239], or radium-226 that might otherwise escape during storage; and

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

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

[Publications: The publication(s) referred to or incorporated by reference in this rule are available for review at ~~the Radiation Protection Services office of the Health Division~~ Oregon

Health Services Radiation Protection Services.]

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625

Hist.: HD 4-1085, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD-1-1995, f. & cert. ef. 4-26-95

General License for Use of Radioactive Material for Certain *In Vitro* Clinical or Laboratory Testing

333-102-0130 (1) A general license is hereby ~~issued~~ **granted** to any physician, veterinarian, clinical laboratory, or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with ~~the provisions of sections~~ **OAR 333-102-0130(2), 333-102-0130(3), 333-102-0130(4), 333-102-0130(5) and 333-102-0130(6)** ~~of this rule~~, the following radioactive materials in prepackaged units **for use in *in Vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:**

(a) Iodine-125~~[, iodine-131, selenium-75, cobalt-57 and carbon-14]~~ in units not exceeding 10 microcuries (370 kBq) each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals;

(b) **Iodine-131, in units not exceeding 10 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals;**

(c) **Carbon-14, in units not exceeding 10 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals;**

(d) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals;

~~(e)~~ Iron-59 in units not exceeding 20 microcuries (740 kBq) each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals;

(f) **Selenium-75, in units not exceeding 10 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals;**

~~(g)~~ Mock iodine-125 reference or calibration sources, in units not exceeding 0.05 microcuries of iodine-129 and 0.005 microcuries of americium-241 each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(2) ~~Persons who~~ **A person shall not** receive, acquire, possess, use or transfer radioactive material ~~pursuant to~~ **under** the general license ~~established~~ **granted** by section **OAR 333-102-130(1)** ~~of this rule~~ **unless that person:**

(a) **Has filed** ~~shall submit~~ the required Agency **application for registration** ~~form~~ **pursuant to OAR 333-101-0007 and submitted the registration fee pursuant to 333-103-015 and** ~~Applicants will~~ received from the Agency a validated license with certification number assigned **or.** ~~The physician, veterinarian, clinical laboratory or hospital shall furnish on the form the following~~

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~~information and such other information as may be required by that form:~~

~~—(a) Name and address of the physician, veterinarian, clinical laboratory or hospital;~~

~~—(b) The location of use; and~~

~~—(c) A statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in section (1) of this rule and that such test will be performed only by personnel competent in the use of such instruments and in the handling of radioactive material.]~~

(b) Has a license that authorizes the medical use of byproduct material that was issued under OAR 333-116 of this chapter.

(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by section **333-102-130(1)** of this rule shall comply with the following:

(a) The general licensee shall not possess at any one time, at any one location of storage or use a total amount of iodine-125, iodine-131, selenium-75, cobalt-57 and/or iron-59 in excess of 200 microcuries (7.4 MBq);

~~[(b) The general licensee shall not possess at any one time, at any one location of storage or use a total amount of carbon-14 exceeding 100 microcuries and/or hydrogen-3 (tritium) exceeding one millicurie;]~~

~~[(c)]~~ The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection;

~~[(d)]~~ The general licensee shall use the radioactive material only for the uses authorized by ~~section~~ **OAR 333-102-130(1)** ~~of this rule~~;

~~[(e)]~~ The general licensee shall dispose of the mock iodine-125 reference or calibration sources described in ~~subsection~~ **333-102-130(1)(d)g)** of this rule as required by OAR 333-120-0500 and ~~section~~ **OAR 333-102-130(6)** ~~of this rule~~;

~~[(f)]~~ The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Agency, the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(4) The general licensee shall not receive, acquire, possess or use radioactive material pursuant to ~~section~~ **OAR 333-102-130(1)** ~~of this rule~~:

(a) Except as prepackaged units that are labeled in accordance with the provisions of an applicable specific license issued by the U.S. Nuclear Regulatory Commission, any Agreement State or any Licensing State that authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, cobalt-57, iron-59 or mock iodine-125 for distribution to persons generally licensed under section (1) of this rule or its equivalent; and

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

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

for the exercise of regulatory authority.

Name of Manufacturer

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

Name of Manufacturer

(5) The registrant [~~physician, veterinarian, clinical laboratory or hospital~~] possessing or using radioactive material granted by ~~funder~~ the general license of section OAR 333-102-130(1) ~~f of this rule~~ shall report in writing to the Agency any changes in the information furnished on the required Agency form. The report shall be furnished within 30 days after the date of such change.

(6) Any person using radioactive material pursuant to the general license granted by ~~f of section~~ OAR 333-102-130(1) ~~f of this rule~~ is exempt from the requirements of Divisions 111 and 120 of this chapter with respect to radioactive material covered by that general license, except that such persons using mock iodine-125 described in ~~f subsection~~ OAR 333-102-130(1) ~~(f d) g~~ ~~f of this rule~~ shall comply with provisions of OAR 333-120-0500, ~~f 333-102-0305~~ 333-120-700 and 333-120-0710.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94

Ice Detection Devices

333-102-0135 (1) A general license is hereby issued to own, receive, acquire, possess, use and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Agency or an Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in section 32.61 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess, use or transfer strontium-90 contained in ice detection devices pursuant to the general license granted by ~~f in section~~ OAR 333-102-0135(1) ~~f of this rule~~:

(a) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the Agency, the U.S. Nuclear Regulatory Commission or any other Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of OAR 333-120-0500;

(b) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

(c) Are exempt from the requirements of Divisions 111 and 120 of ~~f these rules~~ this Chapter

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except that such persons shall comply with the provisions of OAR 333-120-0500, **333-102-700**, and **333-120-710**.

(3) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

(4) This general license is subject to the provisions of OAR ~~333-100-0040 through 333-100-0055~~ **333-100-005, Definitions; 333-100-025, Exemptions; 333-100-030, Additional Requirements; 333-100-055, Records; 333-100-060(1) and 333-100-060(2), Inspections; 333-100-065, 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 Division 118 of ~~these rules~~ this Chapter.**

[**Publications:** The publication(s) referred to or incorporated by reference in this rule are available for review at ~~the Radiation Protection Services office of the Health Division~~ **Oregon Health Services Radiation Protection Services.**]

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD-1-1995, f. & cert. ef. 4-26-95

Specific Licenses

Application for Specific Licenses.

333-102-190 (1) Applications for specific licenses shall be filed on a form prescribed by the Agency. Information contained in previous applications, statements or reports filed with the Agency, 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 Agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

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

(4) 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 Agency and the US Nuclear Regulatory Commission as to applications for such licenses.

(5) Each new application for a radioactive material license shall be accompanied by the fee prescribed by OAR 333-103-010. No fee will be required to accompany an application for renewal or amendment of a license, except as provided in 333-103-010.

(6) An application for a license to receive and possess radioactive material for the conduct of any activity that the Agency has determined, pursuant to Subpart A of Part 51 of 10 CFR (Environmental Protection Regulations applicable to materials licensing), will significantly affect

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the quality of the environment, shall be filed at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted and shall be accompanied by any Environmental Report required pursuant to Subpart A of 10 CFR Part 51.

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

(a) Identify the source or device by manufacturer and model number as registered with the US Nuclear Regulatory Commission under 10 CFR Part 32.210 or with an Agreement State; or

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

(8) As provided by OAR 333-102-200, 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.

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

(A) An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 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 OAR 333-102-190(9)(a)(A) of this section:

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

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

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

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

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

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

(G) Other factors appropriate for the specific facility.

(c) An emergency plan for responding to a release of radioactive material submitted under paragraph (9)(a)(B) of this section 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 radioactive materials accident for which protective actions may be needed.

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

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

timely manner.

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

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

(G) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the Agency; 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 shall commit to notify the Agency 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 Agency.

(J) Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall 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 shall 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 shall not be known to most exercise participants. The licensee shall 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.

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99-499, if applicable to the applicant's activities at the proposed place of use of the byproduct material.

(d) The licensee shall 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 Agency. The licensee shall provide any comments received within the 60 days to the Agency with the emergency plan.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.:

General Requirements for the Issuance of Specific Licenses

333-102-0200 An application for a specific license *{application for sources of radiation, as defined in OAR 333-100-0005(125)}*, will be approved if *{the Agency determines that}*:

(1) The application is for a purpose authorized by the Act;

(2) The applicant is qualified by *{reason of}* training and experience to use the material *{in question}* for the purpose requested in *{accordance with these rules in}* such *{a}* manner as to protect health and minimize danger to *{public health and safety}* life or property;

~~(2)3~~ (3) The applicant's proposed equipment~~,~~ and facilities ~~{and procedures}~~ are adequate to protect health and minimize danger to life *{public health and safety}* or property;

~~{3}~~ *{The issuance of the license will not be inimical (detrimental) to the health and safety of the public; and}*

(4) The applicant satisfies any applicable special requirements contained in Divisions 102, 105, 113, 115, 116, 117, or 121 of this Chapter; and ~~[OAR 333-102-0225, 333-102-0235, 333-102-0240, 333-102-245, 333-102-0250, 333-102-0255, 333-102-0260, 333-102-0265, 333-102-0270, 333-102-0275, 333-102-0285, 333-102-0287, 333-102-0290, or 333-102-0293];~~

(5) In the case of an application for a license to receive and possess radioactive material for the conduct of any activity which the Agency determines will significantly affect the quality of the environment, the Agency 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 shall 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 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.

(b) Upon a determination that an application meets the requirements of the Act, and the rules of the agency, the Agency will issue a specific license authorizing the possession and use of radioactive material (Radioactive Materials License"). ~~[Environmental Report or Commencement of Construction Notification. If the agency determines that an activity specified in an application for a~~

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~~license to receive, possess and use radioactive material may significantly affect the quality of the environment and after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, the Agency will issue the proposed license with appropriate conditions to protect environmental values. Commencement of construction prior to environmental evaluation may be grounds for denial of a licensee to receive and possess radioactive material. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary 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.]~~

~~[(6) Financial assurance and recordkeeping for decommissioning must meet the requirements of 10 CFR 30.35 and 10 CFR Part 30.36.]~~

~~[(7) An application for a specific license to use radioactive materials 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 U.S. Nuclear Regulatory Commission under 32.210 of 10 CFR Part 32 or with an Agreement State; or~~

~~— (b) Contain the information identified in 32.210(c) of 10 CFR Part 32.]~~

~~[(8) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 30.72 of 10 CFR Part 30, "Schedule C, Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must meet the requirements of 30.32(i) subparts (1) through (4) of 10 CFR Part 30.]~~

~~[**ED NOTE:** 10 CFR Part 30.71 Schedule B and 30.72, "Schedule C -- Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," referred to or incorporated by reference in this rule are attached to this Division or available from the Agency.]~~

Publications: The publication(s) referred to or incorporated by reference in this rule are available for review at ~~[the Radiation Protection Services office of the Health Division]~~ **Oregon Health Services Radiation Protection Services.]**

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.655, 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD-1-1995, f. & cert. ef. 4-26-95

Definitions

333-102-0203 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** ~~[333-102-0300, 333-102-0305, or other subdivisions or divisions of these]~~ **rules in this Chapter.**

(1) "Analytical Leak Test" means a facility-specific license issued pursuant to **OAR 333-103-010(2)(a)**, authorizing **possession of environmental samples, sealed source leak-test, contamination wipe, etc. samples for** ~~[service activities,]~~ **radioanalytical measurements** ~~[for contamination leak test services, and possession of contaminated environmental samples, analytical samples, or sealed source~~

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~~leak test samples, and as required by these rules or license conditions}. This license does not authorize collection of samples, or decommissioning or decontamination activities for license to possess any other sources of radiation licensed pursuant to these rules}.~~

(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 333-103-010(2)(b) ~~issued pursuant to OAR 333-102-0200 authorizing the}~~ 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 OAR 333-103-010(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) ~~"Beneficiated" (or} "Beneficiating" {})~~ means ~~{concentrating or}~~ **subjecting a product to any process that will increase or concentrate ~~increasing}~~ any component (including the radioactive materials) ~~in a product or material}~~ to benefit the product;**

(5) "Brachytherapy" means a Healing Arts facility-specific license **issued pursuant to OAR 333-103-010(2)(c) authorizing the use of brachytherapy sources for *in vivo* ~~intracavitary, interstitial, or in vivo}~~ application of radiation ~~therapy pursuant to OAR}~~ 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 ~~"High Dose-rate Brachytherapy"~~**.**

(6) "Broad Scope A" means a facility-specific license **issued pursuant to OAR 333-103-010(2)(d), authorizing activities ~~pursuant to}~~ in 333-102-0900(1)(a), under the authority of a Radiation Safety Committee. ~~{, for multiple sites, multiple sources of radiation, and multiple users. The Broad Scope A license must meet the administrative requirements in OAR 333-102-0900(2), which includes a Radiation Safety Committee, a full-time Radiation Safety Officer, a Radiation Safety Office with full-time staff, and a full-time radiation safety program that provides user authorizations, inspections, personnel training, administrative audits, and health physics expertise and support. The Broad Scope A license does not authorize application of radioactive material to the environment (tracer studies), application of radioactive material to humans (human research), or industrial radiography activities}~~**

(7) "Broad Scope B" means a facility-specific license **issued pursuant to OAR 333-103-010(2)(e) authorizing activities described in 333-102-0900(1)(b), under the authority of a Radiation Safety Officer. ~~{This specific license authorizes only those radioactive materials listed pursuant to 10 CFR Part 33.100 Schedule A Column I "Limits for Broad Licenses." Other sources of radiation must be licensed separately pursuant to these rules. This license authorizes only those radionuclides used at one site or location. Other sources of radiation must be separately licensed.}~~**

(8) "Broad Scope C" means a facility-specific license **issued pursuant to 333-103-010(2)(f) authorizing activities described in 333-102-0900(1)(c), under the authority of an authorized user. ~~{This specific license authorizes only those radioactive materials listed in 10 CFR Part 33.100 Schedule A, Column II "Limits for Broad Licenses". This license authorizes only those radionuclides used at one site or location. Other sources of radiation must be separately licensed}~~**

(9) "commencement of construction" means any clearing of land, excavation or other substantial action related to a proposed activity for specific licensing that would adversely affect the natural environment of a site.

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~~(9)10~~ "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.

~~(10)11~~ "Decontamination and Decommissioning" means **(a) a facility specific license issued pursuant to OAR 333-103-010(2)(w) authorizing activities that result in** returning a site to its original **prelicense** condition prior to termination of licensed activities; **(b) activities performed** pursuant to OAR 333-102-0335~~. Decommissioning and Decontamination activities may be performed~~ on **any portion** ~~parts~~ of a site prior to **license** termination.

~~(11)12~~ "Diagnosis" means examination, determination, identification, study, or analysis of a medical condition.

~~(12)13~~ "Distribution" means a facility-specific ~~radioactive materials~~ license issued pursuant to OAR 333-103-010(2)(g), authorizing transfer or distribution (sale) of **general or specific license** radioactive material ~~for profit, pursuant to these rules, of items or products manufactured, assembled, constructed, fabricated, processed, benefited, or compounded, using or containing, radioactive material,~~ to persons **granted a general license** ~~generally~~ or ~~specifically~~ issued a **specific license**, or, in the case of NARM, to persons exempt from the rules in this Chapter ~~licensed under these rules to receive such sources of radiation~~.

~~(13)14~~ "Exempt Source" means radioactive material, exempt from ~~these~~ the rules in this Chapter ~~pursuant to OAR 333-102-0005, 333-102-0010, 333-102-0015, 333-102-0020, 333-102-0025, 333-102-0030, 333-102-0035, or 333-117-0040~~.

(15) "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 Agency may determine how the scope of licensed activities, pursuant to OAR 333-102-295, 333-102-300, 333-102-305, 333-102-315, 333-102-320, or 333-102-325, is authorized.

~~(14)16~~ "Fixed Gauge" means a source-specific license for ~~sealed sources registered in the "Sealed Source and Device Registry" requiring a specific license, used for~~ measuring, gauging, or controlling devices ~~purposes in fixed or hybrid gauges~~ pursuant to OAR ~~333-102-0200~~ 333-103-010(2)(h). The fixed gauge license also includes X-Ray & Hybrid Gauges~~, licensed~~ pursuant to ~~requirements in OAR 333-115,~~ Division 115 of this Chapter, ~~which~~ that contain ~~use~~ both ~~registered~~ X-Ray sources and radioactive sealed sources~~, pursuant to OAR 333-102-0200~~.

(17) "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.

~~(15)18~~ "General License Depleted Uranium" means the general license granted subject to receipt of the registration application pursuant to 333-101-0007, and fee, pursuant to 333-103-015, for depleted uranium used for shielding or counter weights and issued pursuant to 333-102-0103 ~~registration for possession of depleted uranium for shielding or mass incidental to the radiation therefrom pursuant to OAR 333-102-0103 and 333-101-0007~~.

~~(16)19~~ "General License Device" means the general license granted subject to receipt of the registration application pursuant to 333-101-0007, and fee, pursuant to 333-103-015, for measuring, gauging, or controlling devices granted the general license by 333-102-0015 ~~registration for use and possession of measuring, gauging, and controlling devices, except for those that produce an ionized atmosphere or light, including devices such as fixed gauges, fixed x-ray fluorescence devices, gas chromatograph detectors, and backscatter devices, pursuant to OAR 333-102-0103 and 333-101-0007~~.

~~(17)20~~ "General License In Vitro Laboratory" means the general license granted by OAR

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333-102-130, subject to receipt of the registration application pursuant to OAR 333-101-0007, and fee, pursuant to 333-103-015, for *in vitro* materials granted a general license by 333-102-0130 ~~[general license registration for in vitro testing procedures pursuant to OAR 333-102-0130 and 333-101-0007].~~

~~(18)21~~ "General License Source Material" means the general license **granted** ~~[registration]~~ for use and possession of source material pursuant to OAR 333-102-0101 ~~[and 333-101-0007].~~

(22) "General License for "Certain Devices and "Equipment" means the general license granted for use and possession of devices consisting for 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.

(23) "General License for Luminous Devices for Aircraft" means the general license granted for use and possession of devices containing not more than 10 curies of tritium or not more than 300 millicuries of promethium-147.

(24) "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 333-102-120.

(25) "General License for Calibration and Reference sources" means the general license granted to possess not more than five (5) microcuries (185 kBq) of americium-241, plutonium-238, plutonium-239, or radium-226, pursuant to the general license in OAR 333-102-125.

(26) "General License for Ice Detection Devices" means the general license granted to possess not more than fifty (50) microcuries (1.85 MBq) of strontium-90, pursuant to the general license in OAR 333-102-135.

~~(19)27~~ "Generators and kits" means "Imaging and Localization."

~~(20)28~~ "Healing Arts Specific License~~s~~" means a specific license authorizing activities in Division 116 of this Chapter. ~~[include the following facility-specific licenses authorized pursuant to OAR 333-116 to use radioactive material in the Healing Arts, as defined in OAR 333-100-0005(57):~~

- ~~— (a) "Medical Diagnostic Mobile;~~
- ~~— (b) "Uptake [&] and Dilution";~~
- ~~— (c) "Imaging and Localization";~~
- ~~— (d) "Radiopharmaceutical Therapy";~~
- ~~— (e) "Sealed Sources for Diagnosis";~~
- ~~— (f) "Brachytherapy";~~
- ~~— (g) "Teletherapy";~~
- ~~— (h) "Use of Xenon Gas;~~
- ~~— (i) "High Doserate Brachytherapy;~~
- ~~— (j) "In Vitro Laboratory";~~
- ~~— (k) "Investigational New Drug" (IND).]~~

~~(21)29~~ "High Doserate ~~[Brachytherapy]~~ Remote Afterloader" means a source-specific license issued pursuant to OAR 333-103-010(2)(i) authorizing ~~[to]~~ the use of ~~[high dose rate brachytherapy]~~ sources in accordance with 333-116-475, which ~~[such as remote afterloading devices (as contrasted with high doserate from external beam sources);]~~ may be either mobile or stationary, and which deliver a doserate in excess of 2 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.

~~(22)30~~ "Hybrid Gauge" means a fixed gauging device that contains both a ~~[radioactive material]~~ sealed source~~s~~ and an x-ray source ~~[of radiation]~~, pursuant to ~~[OAR 333-115]~~ Division

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115 of this Chapter. ~~[A hybrid gauge is considered to contain a fixed gauging source, which is specifically licensed pursuant to OAR 333-102-0200 and 333-103-0010]~~

~~[(23) "Generators and kits" means a facility-specific Healing Arts license authorized pursuant to OAR 333-116-0320.]~~ ~~duplicate~~

~~[(24)31]~~ "In Vitro Laboratory" means a Healing Arts facility-specific license, under management of a physician or Healing Arts specialist, **issued pursuant to OAR 333-103-010(2)(k) [to conduct] authorizing [activities pursuant to these rules, using] the use of prepackaged radioactive materials** in quantities greater than those authorized ~~[pursuant to]~~ by the General License **granted by [it]** OAR 333-102-0130(2).

~~[(25)32]~~ Imaging and Localization means a Healing Arts facility-specific license **issued pursuant to OAR 333-103-010(2)(j) authorizing the use of generators and kits for nuclear medicine imaging and localization [pursuant to] in accordance with 333-116-0320 or positron emission tomography studies in accordance with 333-116-800 through 333-116-880.**

~~[(26)33]~~ "Industrial Radiography" means a facility-specific license issued pursuant to OAR 333-103-010(2)(l) ~~[333-102-0225 and 333-105]~~ authorizing **activities in Division 105 of this Chapter [the possession, use, transfer, or disposal of sources of radiation used for industrial radiography].**

~~[(27)34]~~ "Instrument Calibration" means a source-specific radioactive materials license issued pursuant to OAR 333-103-010(2)(m) ~~[333-102-0200]~~ for ~~[a]~~ sources of radiation used to calibrate instruments. ~~[This specific license does not authorize other radioactive sources such as those used in measuring, gauging, controlling, radiography, or healing arts, which must be authorized by separate specific license.]~~

~~[(28)35]~~ "Investigational New Drug" ~~[(IND)]~~ means a Healing Arts facility-specific license **issued pursuant to OAR 333-103-010(2)(n) authorizing the use of any [Investigational New Drug (IND)] investigational product or device approved by the US Food and Drug Administration (FDA) for human use research, diagnosis, or therapy, [pursuant to] in accordance with the [se] rules in this Chapter.**

(36) "Irradiator-Other" means an irradiator with greater than 10,000 curies (370 TBq) licensed pursuant to OAR 333-103-010(2)(w) and 333-103-010(7), designed to produce extremely high dose rates as authorized by Division 121 of this Chapter.

~~[(29)37]~~ "Irradiator Self-shielded or Other - Less than 10,000 Curies" means a source-specific license **issued pursuant to OAR 333-103-010(2)(o) authorizing [for use in a] self-shielded irradiators, including blood irradiators, panoramic irradiators, and converted teletherapy units, with less than 10,000 Ci (370 TBq) activity.**

~~[(30)38]~~ "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.

(39) "Lot Tolerance Percent Defective" means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

(40) "Low Doserate Remote Afterloader Device" means a Healing Arts source-specific license issued pursuant to OAR 333-103-010(2)(b) authorizing devices 333-116-475, which remotely deliver a doserate of less than 2 Gray (200 rad) per hour at the point or surface where the dose is prescribed.

~~[(31)41]~~ "Manufacturing ~~[or]~~ Compounding" means a facility-specific radioactive materials license issued pursuant to OAR 333-103-010(2)(p) authorizing ~~[manufacturing]~~ **manufacture, fabrication, [which means] assembly, construction, combining, processing, [or] concentrating, beneficiating, or processing items or products using or containing radioactive materials into a finished**

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product containing radioactive material in accordance with applicable requirements in Division 102 of this Chapter.

~~(32)42~~ "Manufacturing or Compounding and Distribution" (Manufacturing and Distribution) means "Manufacturing or Compounding" pursuant to OAR 333-102-203(31) and "Distribution", pursuant to OAR 333-102-203(12). ~~[production of a product and transfer for profit (distribution) to persons or specifically or generally licensed, or exempt from licensing requirements, pursuant to these rules.]~~ Manufacturing activities and ~~d~~istribution activities require separate specific licenses.

~~(33)43~~ "Mobile Nuclear Medicine Service" means a facility-specific Healing Arts license issued ~~[authorized]~~ pursuant to OAR 333-116-0120 authorizing ~~[to provide mobile nuclear medicine services]~~ the medical use of radioactive material at specified temporary locations.

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

~~(34)45~~ "Net working capital" means current assets minus current liabilities.

~~(35)46~~ "Net worth" means total assets minus total liabilities and is equivalent to owner's equity.

~~(36)47~~ "Neutron Howitzer" means a device that contains ~~[a shielded]~~ a sealed source containing Special Nuclear Material (see definition in OAR 333-100-0005(127), which ~~[source, designed and used to produce]~~ generates neutrons that are used for analytical, teaching, or research purposes.

~~(37)48~~ "Neutron Production" denotes a process in which neutrons are produced, either by natural or artificial means ~~[see "Special Nuclear Material (sealed) or "Neutron Howitzer."]~~.

~~(38)49~~

"NORM (no processing)" means a facility-specific license pursuant to OAR 333-103-010(2)(n) authorizing ~~[to]~~ possession, use, ~~[or]~~ and transfer ~~[non-exempt concentrations]~~ of ~~[naturally occurring radioactive material (] NORM[)]~~ in accordance with Division 117 of this Chapter. ~~[which the radioactive materials may have been beneficiated or artificially increased in concentration.]~~

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 Division 50 of Chapter 345 of the Oregon Administrative Rules (OAR). Except for Division 50 exemptions, any material that contains NORM requires a specific license. 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. ~~[The NORM license authorizes beneficiated NORM products. It does not authorize processing, which may result in tailings containing source material or decay products from source material. Each use site must be separately licensed. Other sources of radiation must be licensed pursuant to this Division and Division 103]~~

~~(39)50~~ "Nuclear Laundry" means a laundry facility designed specifically to clean or launder clothing contaminated with licensed radioactive materials ~~[decontamination by laundering of clothing or laundry items contaminated with radioactive material]~~. Nuclear Laundry facilities must have process and waste management control procedures to prevent reconcentrating of licensed materials in ~~[contamination off]~~ sewers, drains, premises, and the environment. Nuclear Laundry activities are authorized pursuant to OAR ~~[333-102-0203]~~ 333-103-010(2)(w), "Radioactive Material Not Otherwise Specified Facility"(see 333-102-203(xx)).

~~(40)51~~ "Nuclear Pharmacy" means a facility-specific license issued pursuant to OAR 333-103-010(2)(s) for activities authorized by 333-102-0285 and the Oregon Board of Pharmacy rules, to

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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 Division 50 of OAR 345 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 should specify which disposal method is being used by the pharmacy and licensee to avoid compatibility conflicts with Division 50 requirements.

~~(41)52~~ "Other Measuring Device" means a source-specific license issued pursuant to ~~for registered sealed sources used for measuring, gauging, or controlling purposes in fixed devices or source holders~~ OAR 333-103-010(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 333-102-203(xx).

NOTE: General license gas chromatograph detectors that formerly were granted a general license by OAR 333-102-115, but which required a registration fee pursuant 333-103-015(2)(b), now are subject to the specific license in 333-103-010(2)(t).

~~(42)53~~ "Pool-type irradiator" means an irradiator with greater than 10,000 curies (370 TBq) ~~MCGA-curie device with~~ in which ~~the radioactive sources shielded with~~ water provides the radiation shielding, ~~designed to produce extremely high dose rates for uses~~ authorized in accordance with Division 121 of this Chapter ~~pursuant to 10 CFR Part 36~~.

~~(43)54~~ "Portable Gauge" means a source-specific license issued pursuant to OAR ~~333-102-0200~~ 333-103-010(2)(u) for sources used in devices ~~measuring or gauging device containing radioactive sealed sources~~ that can ~~may~~ be transported and used at temporary job sites. ~~Any measuring, gauging, or controlling device used at temporary job sites is considered a portable gauge under these rules. Portable x-ray fluorescence devices such as Lead-in-Paint Analyzers are considered "Portable Gauges"~~.

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 333-103-010(2)(u).

(55) "Positron Emission Tomography" (PET) means a licensed healing arts activity authorized by 333-116-800 and included in the facility specific license issued pursuant to OAR 333-103-010(2)(j). PET nuclides, which are NARM, are subject to all Oregon rules.

~~(44)56~~ "Possession or storage of industrial wastes containing radioactive material" means activities ~~incident~~ subject to Division 110 of this Chapter for the production or storage of wastes that are exempt from Division 50 of OAR Chapter 345 facility siting requirements ~~pursuant to OAR 345-50~~, and were generated under a current NRC, Agreement State, or Licensing State specific radioactive materials license.

~~(45)57~~ "Possession or storage of uranium tailings" means activities incident to uranium processing or milling operations resulting in the production of tailings~~, pursuant to OAR 333-110~~.

(58) "Principal activities" means activities authorized by the license that [which] 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.

~~(46)59~~ "Processing" means chemically or physically changing a licensed material from one

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physical form to another form or specie (e.g., breaking an ore down into its components resulting in "tailings"; milling a raw licensed material and combining to form another product or material. See "Beneficiated"; "Manufacturing or ~~Compounding~~".

~~(47)60~~ "Radiation Source" means source of radiation (see definition of "Source of radiation" in OAR 333-100-0005).

~~(48)61~~ "Radioactive Material Not Otherwise Specified ~~(RAM/NOS) Facility~~" means a ~~radioactive material~~ license issued pursuant to OAR 333-103-010(2)(w) authorizing activities that includes, but ~~is~~ are not limited to, complex licensable activities such as facility decontamination and decommissioning, ~~sealed source and device evaluations,~~ 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.

~~(49)62~~ "Radioactive Materials License" means the document, pursuant to OAR 333-102-0300, issued ~~to an applicant~~ after an application, pursuant to OAR 333-102-0295, has been accepted as adequate, which ~~that~~ specifies radioactive materials, use authorizations, **safety procedures**, and use locations. ~~The radioactive materials license may specify both specific license radioactive sources and general license registered radioactive sources. Both types of sources are validated with a fee pursuant to OAR 333-103-0010 and 333-103-0015.~~

~~(50)63~~ "Radiopharmaceutical Therapy" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-010(2)(v) authorizing the use of Radiopharmaceutical for therapy ~~pursuant to~~ in accordance with OAR 333-116-0360.

(64) "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.

~~(51)65~~ "Research & Development" means a facility-specific license issued pursuant to OAR ~~333-102-0200~~ 333-103-010(2)(x) authorizing research and development activities, as defined in OAR 333-100-005(112), ~~this license authorizes procedures~~ but does not authorize **additional** specific sources of radiation, which must be licensed separately pursuant to OAR 333-103-0010 and 333-103-0015.

(66) "Responsible Representative" means the person designated as having responsibility for general license device or general license material; the person management has selected to certify general license inventory; and the individual responsible to the Agency and to management to ensure that all regulatory elements are adequate.

~~(52)67~~ "Sealed source/device evaluation" means the ~~Agency~~ review of a licensee's prototype source or device prior to **registration** ~~issuance~~ by the Nuclear Regulatory Commission ~~of a~~ in the Sealed Source and Device Catalog ~~registration number~~.

NOTE: The Agency 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.

(68) "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.

~~(53)69~~ "Sealed Sources for Diagnosis" means a Healing Arts source-specific license issued pursuant to OAR 333-103-010(2)(y) authorizing the use of sealed sources for diagnosis ~~pursuant to~~ in accordance with OAR 333-116-0400.

~~(55)70~~ "Special Nuclear Material (sealed)" means a source-specific license issued pursuant to OAR 333-103-010(2)(aa), authorizing the use, possession, or transfer of sealed sources (special form)

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containing special nuclear material, as defined in OAR 333-100-005(1), (2), and (7). (See "Neutron Howitzer"; "Neutron Production".)

~~(56)71~~ "Special Nuclear Material (unsealed)" means a facility-specific license **issued pursuant to OAR 333-103-010(2)(bb)**, authorizing the use, possession, or transfer of unsealed (normal form) special nuclear material, as defined in OAR 333-100-005(1), (2), and (7).

~~(57)72~~ "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 specifically annotated listed on a radioactive materials license the specific license, pursuant to OAR 333-102-0075(2), and validated with a specific license fee pursuant to 333-103-010(2)(a) through 333-103-010(2)(hh) (see "Radioactive Materials License").**

(73) "System", as used in this chapter, 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.**

~~(58)74~~ "Tangible net worth" means the tangible assets that remain after deducting liabilities; such assets would not include intangibles such as goodwill and rights to patents or royalties.

~~(59)75~~ "Teletherapy ~~(external beam)~~" means a Healing Arts source-specific license **issued pursuant to OAR 333-103-010(2)(cc) authorizing teletherapy procedures sources of radiation for external beam radiation from a radioactive source outside of the body pursuant to** in accordance with OAR 333-116-0480. This license also includes other high dose rate external beam therapy devices such as the "gamma knife."

~~(60)76~~ "Temporary job site" means any ~~auxiliary or remote~~ 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 licensee, where specific licensed radioactive material may be used, stored, or possessed** pursuant to a specific radioactive materials license.

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

~~(61)77~~ "Therapy" means a process that is meant to be restorative, promotes healing, or is beneficial to a patient in a healing arts context.

~~(62)78~~ "Unique" means a specific license issued **pursuant to OAR 333-103-010(2)(dd) to Agencies in the Oregon Health Division Services**~~which carries no license fee~~.

~~(63)79~~ "Uptake and Dilution" means a Healing Arts facility-specific license issued pursuant to **OAR 333-103-010(2)(ee) authorizing activities in OAR 333-116-0300 authorizing** for uptake, dilution, and excretion studies ~~pursuant to OAR 333-116-0300~~.

~~(54)80~~ "Use and Possession of Source Material " means a facility-specific radioactive materials license **issued pursuant to OAR 333-103-010(2)(z) to possess, use, process, or transfer source material, as defined in OAR 333-100-005(1), (2), and (3)(123), 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.

~~(64)81~~ Use of Xenon Gas means a Healing Arts facility-specific license **issued pursuant to OAR 333-103-010(2)(ff) authorizing the use of Xe-133 for diagnosis pursuant to OAR 333-116-0340 333-116-280;**

~~(65)82~~ "Waste Packaging ~~for Brokering~~" means a facility-specific license **issued pursuant to OAR 333-103-010(2)(gg), authorizing packaging, collection, storage, and transfer of radioactive waste**

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~~[pursuant to these rules]. This specific license does not authorize storage of radioactive wastes unless specifically authorized and does not authorize other specific sources of radiation, which must be separately licensed], but does authorize temporary job sites.~~

~~(f66f83) "Well Logging" means a source-specific license issued pursuant to OAR 333-103-010(2)(hh) authorizing the possession, use, transfer, or disposal of sources of radiation used for well logging activities [as] authorized in OAR 333-113} 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 shall [only] be used only at one authorized site.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94

Human Use of Radioactive Material in Institutions

333-102-0205

[HD 4-1985, f. & ef. 3-20-85; HD 10-1987, f. & ef. 7-28-87; Repealed by HD 1-1991, f. & ef. 1-8-91]

Human Use of Radioactive Material by Individual Physicians

333-102-0210

[HD 4-1985, f. & ef. 3-20-85; Repealed by HD 1-1991, f. & ef. 1-8-91]

Human Use of Sealed Sources

333-102-0215

[HD 4-1985, f. & ef. 3-20-85; Repealed by HD 1-1991, f. & ef. 1-8-91]

Research and Development in Institutions

333-102-0220

[HD 4-1985, f. & ef. 3-20-85; Repealed by HD 1-1991, f. & ef. 1-8-91]

~~[Special Requirements for~~

~~Issuance of~~

~~Certain Specific Licenses for~~

~~Radioactive Material]~~

[Use of Sealed sources in Industrial Radiography

~~333-102-0225 In addition to the requirements set forth in OAR 333-102-0200, a specific license for use of sealed sources in industrial radiography will be issued if:~~

~~(1) The applicant will have an adequate program for training radiographic personnel and submits to the Agency a schedule or description of such program which specifies the:~~

~~(a) Initial training;~~

~~(b) Periodic training;~~

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- ~~— (c) On-the-job training; and~~
- ~~— (d) Means to be used by the licensee to determine the radiographic personnel's knowledge and understanding of and ability to comply with Agency rules and licensing requirement and the operating and emergency procedures of the applicant.~~
- ~~— (2) The applicant has established and submits to the Agency satisfactory written operating and emergency procedures described in OAR 333-105-0205; and~~
- ~~— (3) The applicant has established and submits to the Agency a description of its internal inspection program adequate to ensure that these rules, license provisions and the applicant's operating and emergency procedures are followed by radiographic personnel. The internal inspection program shall include the performance of internal program audits and inspections at intervals not to exceed three months. Records of audits and inspections shall be kept for three years; and~~
- ~~— (4) The applicant has established and submits to the Agency a description of its inspection program adequate to ensure that its radiographers and radiographers' assistants follow the Agency rule requirements and the applicant's operating and emergency procedures. The inspection program must:~~
- ~~— (a) Include observation of the performance of each radiographer and radiographer's assistant during an actual radiographic operation at intervals not to exceed three months; and~~
- ~~— (b) Provide that, if a radiographer or a radiographer's assistant has not participated in a radiographic operation for more than three months since the last inspection, that individual's performance be observed and recorded the next time the individual participates in a radiographic operation; and~~
- ~~— (c) Include the retention of inspection records on the performance of radiographers or radiographers' assistants for three years.~~
- ~~— (5) The applicant submits to the Agency a description of the overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program; and~~
- ~~— (6) The applicant who desires to conduct his own leak tests has established adequate procedures to be followed in testing sealed sources for possible leakage and contamination and submits to the Agency a description of such procedures including:~~
- ~~— (a) Instrumentation to be used; and~~
- ~~— (b) Method of performing tests; and~~
- ~~— (c) Pertinent experience of the individual who will perform the test.~~
- ~~— (7) The applicant shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety.]~~

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94

Licensing the Manufacture and Distribution of Radioactive Material for Human Use Under a General License

333-102-0230

[HD 4-1985, f. & ef. 3-20-85; Repealed by HD 1-1991, f. & ef. 1-8-91]

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~~Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed~~
Requirements for license to manufacture, or initially transfer Radioactive Material contained in devices Granted a General License Under OAR 333-102-0115

333-102-0235 (1) An application for a specific license to manufacture, or ~~fdistribute~~ **initially transfer** devices containing radioactive material, excluding special nuclear material, to persons ~~fgenerally licensed~~ **granted a general license funder** 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 ~~fany period of one calendar quarter~~ **one (1) year** a dose in excess of 10 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 would 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 ffollowing organ doses:**

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

(ii) Hands and forearms; feet and ankles; **localized** areas of skin averaged over areas no larger than one (1) square centimeter
200 rem (**2 Sv**)

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

(c) Each device bears a durable, legible, clearly visible label or labels approved by the Agency, 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 [one of] the following statement[s, as appropriate,] in the same or substantially similar form:

[(i)] 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 f**State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

[NOTE: The model, serial number, and name of manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.]

CAUTION - RADIOACTIVE MATERIAL[_____]

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(Name of manufacturer or ~~distributor~~ initial transferor)

[(ii) **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 a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.**

CAUTION - RADIOACTIVE MATERIAL

Name of manufacturer or distributor]

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 ~~distributor~~ initial transferor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

(d) For devices in which there is a separable source housing that provides the primary shielding for the source, the source housing also must bear 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 333-120-400, and the name of the manufacturer or initial distributor.

(e) For devices that meet the criteria of OAR 333-102-115(3)(m)(A), a permanent (e.g., embossed, etched, stamped, or engraved) label must be 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 333-120-400.

(2) In the event ~~if~~ the applicant ~~may request~~ 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, ~~and~~ or for leakage of radioactive material or both, the applicant ~~The application~~ the applicant shall include in this application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices, ~~and~~ and by ~~design~~ design features ~~which~~ that have a ~~sufficient~~ significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator ~~must also be included~~. In determining the acceptable interval for the test for leakage of radioactive material, the Agency will consider information ~~which~~ 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 ~~if~~ the applicant ~~may~~ 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 analysed 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 shall include in the application

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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 ~~[perform certain services associated with the device. Such services may include installation of the device, collection of the sample to be analyzed by a specific licensee for leakage of radioactive material, servicing of the device, testing the on-off mechanism and indicator or removal of the device from installation. The applicant shall include in the application written instructions to be followed by the general licensee for all services to be performed, estimated calendar quarter doses associated with such activity or activities and bases for such estimates. The submitted information shall demonstrate that performance of such 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 calendar quarter]~~ dose in excess of 10 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 333-102-115(1), the licensee ~~[Each person licensed under this rule to distribute devices to persons generally licensed]~~ shall:

(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, ~~is]~~ transfers~~ed]~~ radioactive material in a device for use pursuant to the general license contained in OAR 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 OAR 333-102-0115 shall be furnished to each person to whom directly, or through an intermediate person, is transfers~~ed]~~ 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 OAR 333-102-0115 is furnished to such person, it shall 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 OAR 333-102-0115;

(c) Report to the Agency all transfers of such devices to persons for use under the general license in OAR 333-102-0115. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency 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 shall include identification of each intermediate person by name, address, contact and relationship to the intended user. If no transfers have been made to persons ~~[generally licensed]~~ **granted a general license ~~[under]~~ by OAR 333-102-0115** during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days after the end of each quarter;

(d) Furnish reports to other agencies

~~(d)]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;

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- (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; the type, model number, and serial number of the device transferred; and
- (iv) The quantity and type of byproduct material contained in the device.
- (v) 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.
- (vi) If the device transferred replaced another returned by the general licensee, report also the type, model number, and serial number of the one returned.
- (vii) If no transfers have been made to persons generally licensed under 10 CFR 31.5 or OAR 333-102-115 during the reporting period, the report must so indicate.
- (viii) 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.
- (ix) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.;
- ~~(f)~~B Report to the responsible Agreement or Licensing State agency 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 shall identify **all of the information in 333-102-0235(4)(d), including** each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency 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 shall include identification of each intermediate person by name, address, contact and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such device is transferred to the person ~~generally licensed~~ **granted a general license**;
- ~~(f)~~e If no transfers have been made to U.S. Nuclear Regulatory Commission's licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission;
- ~~(f)~~g If no transfers have been made to persons ~~generally licensed~~ **granted a general license** within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon request of the agency;
- ~~(h)~~g 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 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 **333-102-0235(4)(h)**~~this section~~. **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.;**
- (h) 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 333-102-115;
- (i) 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

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license in OAR 333-102-115 is furnished to such person, it shall be accompanied by a note explaining that use of the device is regulated by the Agreement State.

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

(k) If a notification of bankruptcy has been made under § 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 § 32.52(c).

[**Publications:** The publication(s) referred to or incorporated by reference in this rule are available for review at ~~[the Radiation Protection Services office of the Health Division]~~ Oregon Health Services Radiation Protection Services.]

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD-1-1995, f. & cert. ef. 4-26-95

~~***Use of Multiple Quantities or Types of Radioactive Material in Processing***~~

~~— **333-102-0240** In addition to the requirements set forth in OAR 333-102-0200, a specific license for multiple quantities or types of radioactive material for use in processing for distribution to other authorized persons will be issued only if:~~

~~— (1) The applicant's staff has substantial experience in the use of a variety of radioisotopes for processing and distribution;~~

~~— (2) The applicant has appointed a radiation safety officer who will advise and assist on radiation safety problems.]~~

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Special Requirements for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices Which Contain Radioactive Material

Introduction [Licensing the Introduction] of Radioactive Material [into Products] in Exempt Concentrations into Products or Materials, and Transfer of Ownership or Possession:

Requirements for license

333-102-0245 ~~[(1) In addition to the requirements set forth in OAR 333-102-0200, a]~~ An application for a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another **and the transfer of ownership or possession of the product or material containing the radioactive material:** ~~[to be transferred to persons exempt under OAR 333-102-0010(1)]~~ will be approved ~~[issued]~~ if the applicant:

~~[(a)1] [The applicant]~~ **Satisfies the general requirements specified in OAR 333-102-200;**

(2) Provides ~~[submits]~~ a description of the product or material into which the radioactive

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material will be introduced, intended use of the radioactive material, and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the ~~radioactive material~~ **radioisotopes** in the product or material at the time of transfer;

~~(b)3~~ ~~The applicant p~~ Provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in **10 CFR Part 30.70 Schedule A**, that reconcentrating of the radioactive material in concentrations exceeding those in **10 CFR Part 30.70 Schedule A** is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

~~[(2) Each person licensed under this rule shall file an annual report with the Agency which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to this rule during the reporting period, the report shall so indicate. The report shall cover the year ending June 30 and shall be filed within 30 days thereafter.]~~

ED NOTE: 10 CFR Part 30.70 Schedule A referred to or incorporated by reference in this rule is attached to this Division or available from the Health Division.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Records and Material Transfer Reports

333-102-0247 (1) Each person licensed under OAR 333-102-245 shall maintain records of transfer of material and file a[n annual] report with the Agency.

(2) The report shall identify the:

(a) Type and quantity of each product or material into which radioactive material has been introduced during the reporting period;

(b) Name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction;

(c) The type and quantity of radionuclide introduced into each such product or material; and

(d) The initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee.

(3) The licensee shall file the report within 30 days following:

(a) Five years after filing the preceding report; or

(b) Filing an application for renewal of the license under OAR 333-102-315; or

(c) Notifying the Agency under OAR 333-102-305(5) of the licensee's decision to permanently discontinue activities authorized under the license issued under OAR 333-102-245.

(4) The report must cover the period between the filing of the preceding report and the

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occurrence specified in paragraphs OAR 333-102-247(3)(a), 333-102-247(3)(b), or 333-102-247(3)(c). If no transfers of radioactive material have been made [pursuant to this rule] under 333-102-245 during the reporting period, the report shall so indicate.

[The report shall cover the year ending June 30 and shall be filed within 30 days thereafter.]

(5) The licensee shall maintain the record of a transfer for a period of one year after the event is included in a report to the Agency.

(6) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 10 CFR Part 30.14 or equivalent regulations of an Agreement State, except in accordance with a license issued pursuant to 10 CFR Part 32.11 or the general license provided in 10 CFR Part 150.20 (reciprocity).

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

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

333-102-0250 An application for a specific license to manufacture or distribute radioactive material for use under the general license specified in OAR 333-102-0130 or equivalent will be approved if:

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

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

(a) Carbon-14 in units not exceeding 10 microcuries (370 kBq) each;

(b) Cobalt-57 in units not exceeding 10 microcuries (370 kBq) each;

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

(d) Iodine-125 in units not exceeding 10 microcuries (370 kBq) each;

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

(f) Iodine-131 in units not exceeding 10 microcuries (370 kBq) each;

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

(h) Selenium-75 in units not exceeding 10 microcuries (370 kBq) each.

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

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

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

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

(a) **This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *in vitro* clinical or**

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laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer _____

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

Name of manufacturer

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

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94

Licensing the Distribution of Radioactive Material in Exempt Quantities

333-102-0255 (1) An application for a specific license to distribute NARM to persons exempted from these rules pursuant to OAR 333-102-0035 will be approved if:

(a) The radioactive material is not contained in any food, beverage, cosmetic, drug or other commodity designed for ingestion or inhalation by, or application to, a human being;

(b) The radioactive material is in the form of processed chemical elements, compounds or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product or device intended for commercial distribution; and

(c) The applicant submits copies of prototype labels and brochures and the Agency approves such labels and brochures.

(2) The license issued under this rule is subject to the following conditions:

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) No more than 10 exempt quantities shall be sold or transferred in any single transaction.

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However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity;

(b) Each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to OAR 333-102-0035~~ff~~. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem (five μ Sv) per hour;

(c) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

(A) Identifies the radionuclide and the quantity of radioactivity; and

(B) Bears the words **Radioactive Material**.

(d) In addition to the labeling information required by ~~[subsection]~~ **OAR 333-102-0255(2)(c)** ~~[of this section]~~, the label affixed to the immediate container, or an accompanying brochure, shall:

(A) State that the contents are exempt from Licensing State requirements;

(B) Bear the words, **Radioactive Material--Not for Human Use--Introduction into Foods, Beverages, Cosmetics, Drugs or Medicinals or into Products Manufactured for Commercial Distribution is Prohibited--Exempt Quantities Should Not Be Combined**; and

(C) Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage and disposal of the radioactive material.

(3) Each person licensed under this rule shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under OAR 333-102-0035 or the equivalent rules of any Agreement State or Licensing State and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Agency. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to this rule during the reporting period, the report shall so indicate.

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.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors

333-102-0260 An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under OAR 333-102-0025 will be approved if the application satisfies requirements equivalent to those contained in section 32.26 of **10 CFR Part 32**. The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie (3.7 kBq).

[Publications: The publication(s) referred to or incorporated by reference in this rule are available for review at ~~[the Radiation Protection Services office of the Health Division]~~ **Oregon Health Services Radiation Protection Services.**]

Stat. Auth.: ORS Ch. 453.605 - 453.807

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Stats. Implemented: ORS 453.625, 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD-1-1995, f. & cert. ef. 4-26-95

Special Requirements for the Manufacture, Assembly or Repair of Luminous Safety Devices for Use in Aircraft

333-102-0265 An application for a specific license to manufacture, assemble or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons ~~generally licensed~~ **granted a general license** ~~under~~ by OAR 333-102-0110 will be approved if:

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

(2) The applicant satisfies the requirements of sections 32.53, 32.54, 32.55, 32.56, ~~and~~ 32.101, **and 32.110 of 10 CFR Part 32** or their equivalent.

[**Publications:** The publication(s) referred to or incorporated by reference in this rule are available for review at ~~the Radiation Protection Services office of the Health Division~~ **Oregon Health Services Radiation Protection Services.**]

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.655, 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD-1-1995, f. & cert. ef. 4-26-95

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

333-102-0270 An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons ~~generally licensed~~ **granted a general license** ~~under~~ by OAR 333-102-0125 will be approved if:

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

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

[**Publications:** The publication(s) referred to or incorporated by reference in this rule are available for review at ~~the Radiation Protection Services office of the Health Division~~ **Oregon Health Services Radiation Protection Services.**]

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD-1-1995, f. & cert. ef. 4-26-95

Licensing the Manufacture and Distribution of Ice Detection Devices

333-102-0275 An application for a specific license to manufacture and distribute ice detection devices to persons [generally licensed] granted a general license [under] by OAR 333-102-0135 will be approved if:

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- (1) The applicant satisfies the general requirements of OAR 333-102-0200;
 (2) The criteria of sections 32.61, 32.62, [and] 32.103, **and 32.110** [of 10 CFR Part 32] are met.

[**Publications:** The publication(s) referred to or incorporated by reference in this rule are available for review at ~~[the Radiation Protection Services office of the Health Division]~~ **Oregon Health Services Radiation Protection Services.**]

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD-1-1995, f. & cert. ef. 4-26-95

Licensing the Manufacture and Distribution of Radioactive Material for Human Use Under Group Licenses

333-102-0280

[HD 4-1985, f. & ef. 3-20-85; Repealed by HD 1-1991, f. & ef. 1-8-91]

Manufacture, Preparation, or Transfer for Commercial ~~[and]~~ Distribution of ~~[Radiopharmaceuticals]~~ Radioactive Drugs Containing Radioactive Material for Medical Use Under Division 116

333-102-0285 (1) An application for a specific license to manufacture, **prepare, or transfer for commercial distribution** ~~[and distribute radiopharmaceuticals]~~ **radioactive drugs** containing radioactive material for use by persons ~~[licensed]~~ **authorized** pursuant to Division 116 **of this Chapter will be approved if** ~~[for the uses listed in OAR 333-116-0145, OAR 333-116-0155 and OAR 333-116-0175 or by persons authorized under a group license, or equivalent, issued by the U.S. Nuclear Regulatory Commission or any other Agreement State will be approved if]:~~

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

~~[(2)b]~~ (b) The applicant submits evidence that:

— ~~[(a) T]~~ **the applicant is at least one of the following:**

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

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

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

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

~~[radiopharmaceutical containing radioactive material will be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), a biologic product license issued by the FDA or a Notice of Claimed Investigational Exemption for a New Drug (IND) that has been accepted by the FDA, or]~~

~~[(b) The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act.]~~

~~[(3)c]~~ (c) The applicant submits information on the radionuclide, chemical and physical form; ~~packaging including]~~ **the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use** ~~[package and shielding provided]~~

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~~by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by group]~~ licensees; and

~~(f4)d) The applicant satisfies the following labeling requirements: [affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity and date of assay and the label affixed to each package, or the leaflet or brochure that accompanies each package, contains a statement that the radiopharmaceutical is licensed by the Agency for distribution to persons licensed to use radioactive material listed in OAR 333-116-0145, 333-116-0155 and 333-116-0175 of these rules, as appropriate, or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State,]~~

~~(f5A)~~ A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL”; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.

(B) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL” and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label. ~~[The labels, leaflets or brochures required by this section are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.]~~

(2) A licensee described by paragraph OAR 333-102-285(1)(b)(C) or 333-102-285(1)(b)(D) of this rule:

(a) May prepare radioactive drugs for medical use, as defined in OAR 333-116-020(14), provided that the radioactive drug is prepared either by an authorized nuclear pharmacist, as specified in paragraph (2)(b) and (2)(c), or an individual under the supervision of an authorized nuclear pharmacist as specified in 10 CFR 35.25.

(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 333-116-020***,

(B) This individual meets the requirements specified in OAR 333-116-0910 and 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 paragraph 333-116-285(2)(c).

(c) The actions authorized in paragraphs 333-116-285(2)(a) and 333-116-285(2)(b) are permitted in spite of more restrictive language in license conditions.

(d) May designate a pharmacist (as defined in OAR 333-116-020(23)) as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an “authorized user” on a nuclear pharmacy license issued by the Agency pursuant to this Division.

(e) Shall provide to the Division a copy of each individual’s certification by the Board of Pharmaceutical Specialties, the Commission or Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to paragraphs OAR 333-102-285(2)(b)(A) and 333-102-285(2)(b)(C), the individual to work as an authorized nuclear

pharmacist.

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive 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 radioactive 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 section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

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

[**Publications:** The publication(s) referred to or incorporated by reference in this rule are available for review at ~~the Radiation Protection Services office of the Health Division~~ **Oregon Health Services Radiation Protection Services.**]

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD-1-1995, f. & cert. ef. 4-26-95

[Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceutical Containing Radioactive Material.

~~333-102-0287 An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of Radiopharmaceutical by persons licensed pursuant to OAR 333-116-0320 for the uses listed in Schedule A of 10 CFR Part 35.100 will be approved if:~~

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

~~(2) the applicant submits evidence that;~~

~~(a) The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or~~

~~(b) the manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act.~~

~~(3) the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive~~

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~~material contained in the generator or reagent kit,~~

~~— (4) the label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay, and~~

~~— (5) the label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:~~

~~— (a) Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and~~

~~— (b) a statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the Agency pursuant to OAR 333-116-0320 or equivalent rules of an Agreement State or the U.S. Nuclear Regulatory Commission.~~

~~— NOTE: Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of Radiopharmaceutical containing radioactive material as 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 reagent kits approved by the Agency for use by persons licensed pursuant to OAR 333-116-0320 or equivalent Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission regulations, may submit the pertinent information specified in other divisions of these rules or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The labels, leaflets, or brochures required by this rule are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.]~~

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.665

Hist.: HD-1-1995, f. & cert. ef. 4-26-95

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

333-102-0290 (1) An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Division 116 of this Chapter for use as a calibration or reference source or for the uses listed in OAR ~~{333-116-0195}~~ **333-116-400** and ~~{333-116-0205}~~ **333-116-420** 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;

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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[; p]Provided, that instructions ~~which~~ that are too lengthy for such a label may be summarized on the label and printed in detail on a brochure ~~which~~ 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)** ~~source or device is licensed by the Agency for distribution~~ to persons licensed to use **radioactive material identified in OAR 333-116-190, 333-116-400, or 333-116-420, as appropriate, and to persons who hold an equivalent license issued by an Agreement State or the US Nuclear Regulatory Commission** ~~[pursuant to Division 116 and OAR 333-116-0195 and 333-116-0205 of these rules, or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, provided, that such labeling for sources which do not require long-term storage may be on a leaflet or brochure which accompanies the source]~~.

(2)(a) 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 shall 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 Agency 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 Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

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

333-102-0293 (1) An application for a specific license to manufacture industrial products or devices containing depleted uranium for use pursuant to OAR 333-102-0103 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

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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 10 percent of the limits specified in OAR 333-120-0100 of these rules; 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 Agency 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 Agency 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~~ 333-102-0293(1) ~~of this rule~~ shall:

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

~~(b) Maintain the level of quality control required by the license]~~ in the installation of the depleted uranium into the product or device.

~~(5) b~~ Label or mark each unit to:

~~(a) 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) 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.

~~(6) 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) A~~ Furnish a copy of the general license contained in OAR 333-102-0103 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in OAR 333-102-0103; or

~~(b) 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 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 OAR 333-102-0103 to each person to whom he transfers depleted uranium in a product or device 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 OAR 333-102-0103.

~~(7) d~~ Report to the Agency all transfers of industrial products or devices to persons for use under the general license in OAR 333-102-0103. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency 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 shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally

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licensed person. If no transfers have been made to persons ~~generally licensed~~ **granted a general license ~~under~~** by OAR 333-102-0103 during the reporting period, the report shall so indicate.

~~(f8)e~~ ~~(a)~~ 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**.

~~(b)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 OAR 333-102-0103.

~~(c)B~~ Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency 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 shall 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.

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

~~(e)F~~ If no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon the request of that agency.

~~(9)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 shall be maintained until inspection by the Agency and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred and compliance with the report requirements of **333-102-0293(9)**~~this section~~.

(h) Licensees required to submit emergency plans by OAR 333-102-190(9) shall 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 shall 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 Agency.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605, 453.625, 453.665

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94

~~[Specific Licenses]~~

Filing Application for Specific Licenses

~~333-102-0295 (1) Application[s] for specific license[s] shall be filed on a form prescribed by the Agency.~~

~~(2) The Agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.~~

~~(3) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his or her behalf.~~

~~(4) An application for a license may include a request for a license authorizing one or more activities.~~

~~(5) In the application, the applicant may incorporate by reference information contained in previous applications, statements or reports filed with the Agency provided such references are clear and specific.~~

~~(6) Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.]~~

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Sealed Source or Device Evaluation

333-102-0297 No sealed source or device containing radioactive material shall be authorized on a specific license or general license until radiation safety information for that sealed source or device has been evaluated by the Agency, the U.S. Nuclear Regulatory Commission, another Agreement State, or a Licensing State.

(1) Any manufacturer or initial distributor of a sealed source or device containing a sealed source licensed by the Agency shall submit a request to the Agency for evaluation of radiation safety information about the sealed source or device containing a sealed source.

(2) The request for review shall contain sufficient information about the sealed source or device to include the radioactive material contained, its chemical and physical form, and amount; details of design and construction; 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; details of quality control and quality assurance procedures to ensure that production sources and devices meet the standards of the design and prototype tests; labeling; proposed uses; and procedures for leak testing.

(3) For a device containing radioactive material, the request also shall contain sufficient information about the device to include the radiation profile of a prototype device; method of installation; service and maintenance requirements; and operating and safety instructions.

(4) After review of the request the Agency may issue an evaluation documenting the information

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in OAR 333-102-0297(2) for sealed sources and OAR 333-102-0297(3) for devices containing radioactive material.

(5) The manufacturer/distributor submitting the request for evaluation of the safety information about the product shall manufacture and distribute the product in accordance with the statements and representations contained in the request, documentation required to support the request, and the provisions of the evaluation.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

Hist.: HD-1-1995, f. & cert. ef. 4-26-95

Issuance of Specific Licenses

333-102-0300 (1) Upon a determination that an application meets the requirements of the Act and these rules, the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(2) The Agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this Division as it deems appropriate or necessary in order to:

- (a) Minimize danger to public health and safety or property;
- (b) Require such reports and the keeping of such records and to provide for such inspections of activities under the license as may be appropriate or necessary; and
- (c) Prevent loss of theft of material subject to this Division.

(3) **Whenever the Agency denies an application for a new license or a license renewal, the Agency will notify the applicant in writing stating the grounds for denial. Upon denial, the applicant may request a hearing pursuant to OAR 333-102-345.**

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.655

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Specific Terms and Conditions of License

333-102-0305 (1) Each license issued pursuant to **the rules in this Division and Divisions 105, 113, 115, 116, 117, and 121 of this Chapter** ~~{OAR 333-105, 333-110, 333-113, 333-115, 333-116, and 333-117,}~~ shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations and orders of the Agency.

(2) No license issued or granted ~~funder~~ **pursuant to the rules in this Division and Divisions 105, 113, 115, 116, 117, and 121 of this Chapter** ~~{OAR 333-105, 333-110, 333-113, 333-115, 333-116, and 333-117, and}~~ nor **any right** ~~{to possess or utilize radioactive material granted by any}~~ **under a license** ~~{issued pursuant to this Division}~~ shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Agency shall, after securing full information, find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.

(3) Each person licensed by the Agency pursuant to the rules in this Division and **Divisions 105,**

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113, 115, 116, 117, and 121 of this Chapter [~~OAR 333-105, 333-110, 333-113, 333-115, 333-116, and 333-117,~~] shall confine the use and possession of the radioactive material ~~[licensed]~~ to the locations and purposes authorized in the license. Except as otherwise provided in the license, a ~~[specific radioactive materials]~~ license issued pursuant to the rules in this Division and Divisions 105, 113, 115, 116, 117, and 121 of this Chapter [~~OAR 333-105, 333-110, 333-113, 333-115, 333-116, and 333-117,~~] shall carry with it the right to receive, acquire, own, and possess radioactive material. Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of [~~OAR 333-118~~] Division 118 of this Chapter [~~of these rules.~~]

(4) [~~Any~~] Each license issued ~~[under this]~~ pursuant to the rules in this Division and Divisions 105, 113, 115, 116, 117, and 121 of this Chapter [~~OAR 333-105, 333-110, 333-113, 333-115, 333-116, and 333-117,~~] shall be deemed to contain the provisions set forth in section 183b.-d., inclusive, of the Act, whether or not these provisions are expressly set forth in the license. [~~include license conditions derived from the evaluations of the application and analyses performed by the Agency, including amendments and changes made before a license is issued. License conditions may include but are not limited to items in the following categories:~~

- ~~— (a) restrictions as to the total radioactive inventory of radioactive waste to be received;~~
- ~~— (b) Restrictions as to size, shape, and materials and methods of construction of radioactive waste packaging and maximum number of package units stored, at any one time;~~
- ~~— (c) Restrictions as to the physical and chemical form and radioisotopic content and concentration of radioactive waste;~~
- ~~— (d) Controls to be applied to restrict access to the site;~~
- ~~— (e) Controls to be applied to maintain and protect the health and safety of the public and site employees and the environment;~~
- ~~— (f) Administrative controls, which are the provisions relating to organization, management, and operating procedures, recordkeeping, review and audit, and reporting necessary to assure that activities at the facility are conducted in a safe manner and in conformity with Agency rules and license conditions; and~~
- ~~— (g) Maximum retention time for radioactive waste received at the facility.]~~

(5) The Agency may incorporate, in any license issued pursuant to the rules in this Division and Divisions 105, 113, 115, 116, 117, 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;
- (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. [~~Licensees required to submit emergency plans pursuant to OAR 333-102-0200(8) shall follow the requirements of 10 CFR 30.34(f).]~~

(6) Licensees required to submit emergency plans by OAR 333-102-200(10) shall follow the emergency plan approved by the Agency. The licensee may change the approved plan without Agency approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the Agency 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

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to and prior approval by the Agency.

(7) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall test the generator eluates for molybdenum-99 breakthrough in accordance with OAR 333-116-330. The licensee shall record the results of each test and retain each record for three years after the record is made. *[Each licensee shall notify the Agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.]*

~~(7)~~(a) Each general licensee subject to the registration requirement in OAR 333-101-0007 and each specific licensee shall notify the Agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

~~(a)~~A) The licensee;

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

~~(c)~~C) An affiliate (as that term is defined in 11 U.S.C. 101 (2)) of the licensee.

~~(8)~~b) ~~The~~ This notification **must** ~~specified in section(7) of this rule shall~~ indicate:

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

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

(9) Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee. ~~f, nor shall anyf~~

(10) No licensee **shall** 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.

~~(10)~~11) Any sealed source fabricated by a licensee shall 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.

~~(11)~~12) Each licensee shall conduct a physical inventory **at intervals not to exceed six months** to account for all ~~[sources of radiation containing]~~ radioactive material received and possessed by licensee ~~[at intervals not to exceed six months]~~. Inventories shall include the types and quantities of ~~licensed sources of~~ radioactive material, location of materials, date of receipt, and the date of the inventory; and **for sealed sources, the inventory shall 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 OAR 333-102-0305(12) shall be kept until inspection by the agency.**

~~(12)~~13) Each licensee shall 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~~f, and Title 10, Code of Federal Regulations, Part 71f~~ and in accordance with **Division 118 of this Chapter, "Transportation of Radioactive Material."**

~~(13)~~14) Each licensee possessing a device licensed pursuant to OAR 333-103-010(2)(h) ~~[a specific licensed measuring, gauging, or controlling source of radiation containing a radioactive material sealed source]~~ shall perform an inspection of all devices ~~[such sources of radiation]~~ at intervals not to exceed six months. Inspections shall 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 ~~inventories and~~ inspections required by OAR 333-102-0305~~(8)~~14) ~~and (9)~~ shall be ~~maintained~~ kept until inspection by the agency.

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

~~(16)~~ No person shall 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 ~~without specific license authorization~~.

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

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

~~(19)~~ Testing for Leakage or Contamination of Sealed Sources shall 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 shall not be put into use until tested.

~~(20)~~ Detector cells shall [only] be used only in conjunction with a properly operating temperature control mechanism ~~which~~ that prevents foil temperatures from exceeding manufacturer's specifications. Exhaust from detector cells ~~containing tritium foils~~ shall be vented ~~through a laboratory fume hood or other suitable means designed~~ to ~~reduce potential~~ keep exposures to personnel and the public as low as reasonably achievable pursuant to OAR 333-120-180 ~~to the lowest practicable level~~.

~~(21)~~ Licensees who possess ~~S~~ sealed sources used for testing at field sites shall 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 shall be secured from unauthorized removal from the place of storage in accordance with provisions of OAR 333-120-0250 and 333-120-0260.

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

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

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

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

(c) Notwithstanding ~~subsection~~ OAR 333-102-305(22)(a) ~~above~~, iodine-125 waste in microcurie amounts may be held for a minimum of five half-lives. Such waste must be surveyed with an appropriate instrument prior to disposal to confirm that waste ~~is~~ is indistinguishable from background.

~~(24)~~ Licensed materials in an unrestricted area and not in storage shall be tended under the

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constant surveillance and immediate control of the licensee.

~~(24)25~~ Except as otherwise specified in a radioactive materials license, the licensee shall have available and follow the instructions contained in the manufacturer's instruction manual for the chromatography device.

~~(25)26~~ In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in OAR 333-120-0400(2) of the Oregon Rules for the control of Radiation, the licensee is hereby authorized to label detector cells and cell baths, containing licensed radioactive material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.

(27) If a radiography licensee plans to use, during normal industrial radiographic operations subject to Division 105 of this Chapter, two or more exposure devices at one jobsite, the licensee shall 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 shall not be less than n+1 where n=the number of cameras.~~[Detector cells shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 180 degrees Centigrade.]~~

~~—[(27) Detector cells containing titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 225 degrees Centigrade.]~~

~~—[(28) Detector cells containing scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 325 degrees Centigrade. Exhaust from detector cells containing tritium foils shall be vented through a laboratory fume hood or other suitable means designed to reduce potential exposure to personnel to the lowest practicable level.]~~

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD-1-1995, f. & cert. ef. 4-26-95

Financial Assurance and Recordkeeping for Decommissioning.

333-102-306 (1) Each applicant for a specific license authorizing the possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding 1×10^5 times the applicable quantities set forth in Appendix B to 10 CFR Part 30 shall submit a decommissioning funding plan as described in OAR 333-102-306(5). The decommissioning funding plan also must be submitted when a combination of isotopes is involved if R divided by 1×10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix B to 10 CFR Part 30.

(2) Each applicant for a specific license authorizing possession and use of byproduct material of half-life greater than 120 days and in quantities specified in OAR 333-102-306(4) shall either:

(a) Submit a decommissioning funding plan as described in OAR 333-102-306(5); or

(b) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by OAR 333-102-306(4) using one of the methods described in 333-102-306(6). For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of

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licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of 333-102-306(6)(f) must be submitted to the Agency before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Agency, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of 333-102-306(6)(f).

(3)(a) Each holder of a specific license issued on or after July 27, 1990, which is of a type described in OAR 333-102-306(1) or 333-102-306(2), shall provide financial assurance for decommissioning in accordance with the criteria set forth in this rule.

(b) Each holder of a specific license issued before July 27, 1990, and of a type described in OAR 333-102-306(1) shall submit, on or before July 27, 1990, a decommissioning funding plan as described in 333-102-306(5) or a certification of financial assurance for decommissioning in an amount at least equal to \$750,000 in accordance with the criteria set forth in this rule. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal.

(c) Each holder of a specific license issued before July 27, 1990, and of a type described in OAR 333-102-306(2) shall submit a decommissioning funding plan as described, in 333-102-306(5), or a certification of financial assurance for decommissioning in accordance with the criteria set forth in this rule.

(d) Any licensee who has submitted an application before July 27, 1990, for renewal of license in accordance with OAR 333-102-315 shall provide financial assurance for decommissioning in accordance with paragraphs 333-102-306(1) and 333-102-306(2). This assurance must be submitted before the renewal license is issued.

(4) Required amounts of financial assurance for decommissioning by quantity of material:

(A) greater than 1 x 10⁴ but less than or equal to 1 x 10⁵ times the applicable quantities of Appendix B to 10 CFR Part 30 in unsealed form. (For a combination of isotopes, if R, as defined in OAR 333-102-306(1), divided by 1 x 10⁴ is greater than 1 but R divided by 1 x 10⁵ is less than or equal to 1.) \$750,000

(B) greater than 1 x 10³ but less than or equal to 1 x 10⁴ times the applicable quantities of Appendix B to 10 CFR Part 30 in unsealed form. (For a combination of isotopes, if R, as defined in 333-102-306(1), divided by 1 x 10³ is greater than 1 but R divided by 1 x 10⁴ is less than or equal to 1.) \$150,000

(C) greater than 1 x 10¹⁰ times the applicable quantities of appendix B to 10 CFR Part 30 in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in 333-102-306(1), divided by 1 x 10¹⁰ is greater than 1) \$75,000

(5) Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from OAR 333-102-306(6), including means for adjusting cost estimates and associated funding levels periodically over the life of the facility. The decommissioning funding plan also must contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of 333-102-306(f).

(6) Financial assurance for decommissioning must be provided by one or more of the following methods:

(a) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid

assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(b) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix A of 10 CFR Part 30. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this rule. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix C to 10 CFR Part 30. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(A) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Agency, the beneficiary, and the licensee, of its intention not to renew. The surety method or insurance also must provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Agency within 30 days after receipt of notification of cancellation.

(B) The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(C) The surety method or insurance must remain in effect until the Agency has terminated the license.

(c) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in OAR (333-102-306 (6)(b)).

(d) In the case of Federal, State, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in 333-102-306(4), and indicating that funds for decommissioning will be obtained when necessary.

(e) When a government entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such government entity.

(7) Each person licensed under this Division and Divisions 105, 113, 115, 116, 117, or 121 of this Chapter shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with OAR 333-102-206(2), licensees shall transfer all

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records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Agency considers important to decommissioning consists of--

(a) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(b) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(c) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years, of the following:

(A) All areas designated and formerly designated restricted areas as defined in OAR 333-100-005 (For requirements prior to January 1, 1994, see 10 CFR 20.3 as contained in the CFR edition revised as of January 1, 1993.);

(B) All areas outside of restricted areas that require documentation under OAR 333-102-306(7)(a).

(C) All areas outside of restricted areas where current and previous wastes have been buried as documented under OAR 333-120-670; and

(D) All areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required either to decontaminate the area to meet the criteria for decommissioning in Division 120 of this Chapter or apply for approval for disposal under OAR 333-120-500(3).

(d) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.665

Hist.: HD

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

333-102-0310 (1)(a)Except as provided in OAR ~~{333-102-0315(2)}~~ 333-102-310(1)(b), each specific license shall expire at the end of the ~~{specified}~~ day on the expiration date stated in the license unless the licensee has filed an application for renewal under 333-102-315 before the expiration date stated in the existing license (or, for those licenses subject to paragraph 333-102-

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310(1)(b), before the deemed expiration date in that paragraph) ~~fin the month and year stated therein].~~ If an application for renewal has been filed before the expiration date stated in the existing license (or, for those licenses subject to paragraph (a)(2) of this section, before the deemed expiration date in that paragraph), the existing license expires at the end of the day on which the Agency 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 paragraph OAR 333-102-310(1)(c), 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 paragraph OAR 333-102-310(1)(b):

(A) Specific licenses for which, on February 15, 1996, an evaluation or an emergency plan is required in accordance with OAR 333-102-190(9);

(B) Specific licenses whose holders are subject to the financial assurance requirements specified in OAR 333-102-306, 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);

(D) Specific licenses who need an environmental assessment or environmental impact statement pursuant to Subpart A of Part 51 and OAR 333-102-200(5);

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

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

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

(B) Subject to an Order issued by the Agency; or

(ii) Subject to a Confirmatory Action Letter issued by the Agency.

(G) Specific licenses with expiration dates before July 1, 1995, for which the holders have submitted applications for renewal under OAR 333-102-315.

(2) ~~[Each licensee shall notify the Agency, in writing, and request termination of the license when the licensee decides to terminate all activities involving radioactive material authorized under the license. This notification and request for termination of the license must include the reports and information specified in subsection (4)(a) and (b) of this rule and a plan for completion of decommissioning if required by 10 CFR 30.36.]~~ Each specific license revoked by the Agency 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 Agency Order.

(3) ~~[No less than 30 days before the expiration date specified in the license, the licensee shall either:]~~ Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Agency notifies the licensee in writing that the license is terminated. During this time, the licensee shall--

(a) ~~[Submit an application for license renewal under OAR 333-102-0315; or]~~ Limit actions involving radioactive material to those related to decommissioning; and

(b) ~~[Notify the Agency, in writing, if the licensee decides not to renew the license.]~~ Continue to control entry to restricted areas until they are suitable for release in accordance with Agency requirements.

(4) ~~[If a licensee does not submit an application for license renewal under OAR 333-102-0315, the licensee shall, on or before the expiration date specified in the license:]~~ Within 60 days of the occurrence of any of the following, consistent with the administrative directions in OAR 333-100-045, each licensee shall provide notification to the Agency 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 Agency requirements, or submit within 12 months of notification a decommissioning plan, if required by paragraph (7)(a), and begin decommissioning upon approval of that plan if--

(a) ~~[Terminate use of radioactive material;]~~ The license has expired pursuant to paragraph OAR 333-102-310(1) or 333-102-310(2); or

(b) ~~[Remove radioactive contamination to the extent practicable;]~~ The licensee has decided to permanently cease principal activities, as defined in OAR 333-102-203(46??), 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 Agency requirements; or

(c) ~~[Properly dispose of radioactive material;]~~ No principal activities under the license have been conducted for a period of 24 months; or

(d) ~~[Submit a completed copy of the required Agency form; and]~~ 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 Agency requirements.

~~[(e) Submit a radiation survey report to confirm the absence of radioactive material or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual radioactive contamination in some other manner. The licensee shall, as appropriate:~~

~~—(A) Report levels of radiation in units of microrad per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces and report levels of radioactivity, including alpha, in units of transformations per minute (or microcuries) per 100 square centimeters removable and fixed on surfaces, microcuries per milliliter in water, and picocuries per gram in contaminated solids such as soils or concrete; and~~

~~—(B) Specify the instrumentation used and certify that each instrument was properly calibrated and tested.]~~

(5) ~~[If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found. The Agency will notify the licensee, in writing, of the termination of the license.]~~ Coincident with the notification required by OAR 333-102-310(4), the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to OAR 333-102-306 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 OAR 333-102-310(7)(d)(E) .

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

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(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 Agency.

(6) ~~[If detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual radioactive material present as contamination until the Agency notifies the licensee in writing that the license is terminated. During this time, the licensee is subject to the provision of subsection (7) of this rule. In addition to the information submitted under subsection (4)(d) and (e) of this rule, the licensee shall submit a plan for decontamination, if required, as regards residual radioactive contamination remaining at the time the license expires.]~~ The Agency may grant a request to extend the time periods established in OAR 333-102-310(4) if the Agency 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 333-102-310(4). The schedule for decommissioning set forth in 333-102-310(4) may not commence until the Agency has made a determination on the request.

(7) ~~[Each licensee who possesses residual radioactive material under section (6) of this rule, following the expiration date specified in the license shall:]~~

(a) ~~[Limit actions involving radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and]~~ 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 Agency 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 would involve techniques not applied routinely during cleanup or maintenance operations;

(B) Workers 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 materials than are present during operation; or

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

(b) ~~[Continued to control entry to restricted areas until they are suitable for release for unrestricted use and the Agency notifies the licensee in writing that the license is terminated.]~~ The Agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to OAR 333-102-310(4) of this section if the Agency 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 paragraph (g)(1) of this section 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;

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(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 shall include a justification for the delay based on the criteria in OAR 333-102-310(9).

(e) The proposed decommissioning plan will be approved by the Agency 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 OAR 333-102-310(9), licensees shall 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 OAR 333-102-310(9), when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(9) The Agency 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 Agency 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 Agency 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 shall--

(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 shall, 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.

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

(a) Radioactive 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 in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E; or

(B) 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, pursuant to OAR 333-100-055 that meet the following criteria:

(A) The licensee shall retain each record of receipt of radioactive 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 shall 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 shall retain each record of disposal of byproduct material until the Agency terminates each license that authorizes disposal of the material.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.665

Hist.: HD

Application for Renewal of Licenses

333-102-0315 (1) Application[s] for renewal of a specific license[s] [shall] must be filed in accordance with OAR [333-102-0295] 333-102-190.

(2) In any case in which a licensee, not less than 30 days prior to expiration of the existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the Agency.

(3) Unless otherwise specified, specific licenses shall expire after five (5) years.

(4) The Agency shall require reapplication when the license expires.

(5) The Agency may grant, upon written request from a licensee, extension of the license expiration date up to five (5) years from the original expiration date. Notwithstanding any licensee request, the Agency is not required, and may deny, any license extension, based on review of licensed activities.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Amendment of Licenses at Request of Licensee

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333-102-0320 Applications for amendment of a license shall be filed in accordance with OAR 333-102-0295 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85

Agency Action on Applications to Renew and Amend

333-102-0325 In considering an application by a licensee to renew or amend the license, the Agency will apply the criteria set forth in OAR 333-102-0200 and 333-102-0225 through 333-102-0290 as applicable.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94

Specifically Licensed Items - Registration of Product Information

333-102-0327 (1) Any manufacturer or initial distributor of ~~or~~ a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to the Agency for evaluation of radiation safety information about its product and for its registration.

(2) The request for review must be made in duplicate and sent to the Manager, Radioactive Materials Program, Oregon Health Division Radiation Protection Services, Suite 705, 800 N.E. Oregon Street, Portland, Oregon 97232.

(3) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

(4) The Agency normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the Agency formulates reasonable standards and criteria with the help of the manufacturer or distributor. The Agency shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.

(5) After completion of the evaluation, the Agency, after review by the U.S. Nuclear Regulatory Commission, issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.

(6) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:

(a) The statements and representations, including quality control program, contained in the request; and

(b) The provisions of the registration certificate.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD-1-1995, f. & cert. ef. 4-26-95

Transfer of Material

333-102-0330 (1) No licensee shall transfer radioactive material except as authorized pursuant to this rule.

(2) Except as otherwise provided in the license and subject to the provisions of ~~sections~~ **333-102-0330**(3) and **333-102-0330**(4) ~~of this rule~~, any licensee may transfer radioactive material:

(a) To the Agency;

NOTE: A licensee may transfer radioactive material to the Agency only after receiving prior approval in writing from the Agency.

(b) To the U.S. Department of Energy;

(c) To any person exempt from the rules in this Division to the extent permitted under such exemption;

(d) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Agency, the U.S. Nuclear Regulatory Commission, any Agreement State or any Licensing State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Agency, an Agreement State or a Licensing State; or

(e) As otherwise authorized by the Agency in writing.

(3) Before transferring radioactive material to a specific licensee of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a general licensee who is required to register with the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form and quantity of radioactive material to be transferred.

(4) Any of the following methods for the verification required by ~~section~~ **333-102-0330**(3) ~~of this rule~~ are acceptable:

(a) The transferor may possess and read a current copy of the transferee's specific license or registration certificate;

(b) The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date;

(c) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date; provided, that the oral certification is confirmed in writing within 10 days;

(d) The transferor may obtain other information compiled by a reporting service from official records of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State regarding the identity of licensees and the scope and expiration dates of licenses and registration;

(e) When none of the methods of verification described in ~~subsections~~ **OAR 333-102-330**(4)(a)

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through 333-102-330(4)(d) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Agency, the U.S. Nuclear Regulatory Commission, the licensing agency of an Agreement State or a Licensing State that the transferee is licensed to receive the radioactive material.

(5) Shipment and transport of radioactive material shall be in accordance with the provisions of Division 118 of this Chapter.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.695

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Modification, Revocation and Termination of Licenses

333-102-0335 (1) The terms and conditions of ~~that~~ each license~~s~~ issued pursuant to the rules in this Division and Divisions 105, 113, 115, 116, 117, and 121 of this Chapter shall be subject to amendment, revision or modification or ~~the license may be suspended or revoked~~ by reason of amendments to the Act, or by reason of rules, regulations and orders issued in accordance with the terms of the Act by the Agency.

(2) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under section 182 ~~provisions~~ of the Act, or because of conditions revealed by such application or statement of fact or any report, record or inspection or other means ~~which~~ that would warrant the Agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act or of ~~the license or of~~ any rule, regulation or order of the US Nuclear Regulatory Commission or the Agency.

(3) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

(4) The Agency may terminate a specific license upon request submitted by the licensee to the Agency in writing.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Reciprocity**Reciprocal Recognition of Licenses**

333-102-0340 ~~{(1) Licenses of byproduct, source and special nuclear material in quantities not sufficient to form a critical mass:}~~

~~{a}~~(1) Subject to these rules, any person who holds a specific license from the U.S. Nuclear Regulatory Commission, ~~for~~ an Agreement State, or a licensing state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at

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which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of ~~[30 consecutive days or]~~ **180 days in any calendar year** ~~[consecutive twelve month period beginning with the issue date of the reciprocity validation certificate in OAR 333-103-0030 and ending twelve months after the issue date]~~, provided that:

~~(A)a~~ The licensing document does not limit the activity authorized by such document to specified installations or locations;

~~(B)b~~ The out-of-state licensee **has notified the Agency using the Agency Reciprocity Application form at least three days prior to engaging in such activity and has paid the applicable registration fee pursuant to OAR 333-103-0030** ~~[notifies the Agency in writing at least three days prior to engaging in such activity]~~. Such notification shall indicate the location, period and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. The Agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license [provided in] granted by subsection **OAR 333-102-0340(1)(a)** ~~[of this section]~~;

~~(C)c~~ The out-of-state licensee complies with all applicable rules of the Agency and with all the terms and conditions of the licensing document, except any such terms and conditions that [which] may be inconsistent with applicable rules of the Agency or laws of the State of Oregon;

~~(D)d~~ The out-of-state licensee supplies such other information as the Agency may request; and

~~(E)e~~ The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in ~~subsection~~ **OAR 333-102-0340(1)(a)** [of this section] except by transfer to a person:

~~(i)A~~ Specifically licensed by the Agency or by the U.S. Nuclear Regulatory Commission to receive such material; or

~~(ii)B~~ Exempt from the requirements for a license for such material under OAR 333-102-0010(2).

~~(b)2~~ Notwithstanding the provisions of ~~this section~~ **OAR 333-102-0340(1)**, any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission, **pursuant to 10 CFR 31.6 or equivalent regulations of** ~~for~~ an Agreement State, authorizing the holder of the license to manufacture, transfer, install or service a device described in OAR 333-102-0115(1) within **the State of Oregon** ~~[areas subject to the jurisdiction of the licensing body]~~ is hereby granted a general license to install, transfer, demonstrate or service such a device in this state provided that:

~~(A)a~~ Such person shall **register the general license pursuant to OAR 333-101-0007**;

(b) ~~F~~file a report with the Agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred and the quantity and type of radioactive material contained in the device;

~~(B)c~~ **Ensure that** ~~f~~the device has been manufactured, labeled, installed and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an Agreement State;

~~(C)d~~ ~~[Such person shall assure]~~ **Ensure** that any labels required to be affixed to the device under rules of the licensing authority ~~[which licensed manufacture of the device]~~ ~~bear a~~ **also include the statement** ~~[that]~~ **“Removal of this label is prohibited”**; and

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~~(D)e~~ The holder of the specific license shall furnish to each general licensee to whom ~~the transfers~~ such device **is transferred**, or on whose premises **such a device** is installed, ~~such device~~ a copy of the general license contained in OAR 333-102-0115 or in equivalent rules of the agency having jurisdiction over the manufacture and distribution of the device.

~~(c)3~~ The Agency may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an Agreement State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(4) The out-of-state licensee shall at all times during work at any work location within the state have available the pertinent licensing document, the applicable sections of the State of Oregon radiation regulations, a complete source inventory, pertinent U.S. Department of Transportation documentation, leak test records, instrument calibration records, personnel training records, and necessary documentation required by applicable special requirements of these regulations.

(5) While working in Oregon, the out-of-state licensee shall notify the Agency (in writing, indicating date and court) immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title II (bankruptcy) of the United States code by or against:

(a) The licensee;

(b) An entity (as that term is defined in II U.S.C 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(c) An affiliate (as that term is defined in II U.S.C. 101(2)) of the license.

(6) The out-of-state licensee shall notify the Agency within 1 hour after arrival at the actual work location within the state and notification within 1 hour after any change of work location within the state.

(7) If multiple work crews or persons work concurrently at more than one work location under a general license granted pursuant to OAR 333-102-340, each day worked at each location shall count toward the limit of 180 days in a calendar year.

(8) The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U. S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(9) Each general licensee granted authorization to conduct activities within the State of Oregon pursuant to OAR 333-102-340, based upon an acceptable licensing document, will receive acknowledgment from the Department. This acknowledgment shall be kept at the site of use.

(10) Each general licensee granted authorization to conduct activities within the state of Oregon pursuant to OAR 333-102-340 based upon an acceptable licensing document is subject to the reciprocity fee and may be inspected by the Agency. The fee for the general license granting reciprocity shall:

(a) Be charged as provided by Division 103 of this Chapter; and

(b) Shall not be charged more often than once during each calendar year.

(11) Each general licensee operating within the state under reciprocity in areas of exclusive federal jurisdiction shall comply with the applicable provisions of 10 CFR 150.20.

~~[(2) Licenses of Naturally Occurring and Accelerator-Produced Radioactive Material (NARM):~~

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~~(a) Subject to these rules, any person who holds a specific license from a Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in any consecutive twelve month period beginning with the issue date of the reciprocity validation certificate in OAR 333-102-0030(5) and ending June 30, provided that:~~

~~(A) The licensing document does not limit the activity authorized by such document to specified installations or locations;~~

~~(B) The out-of-state licensee notifies the Agency in writing at least three days prior to engaging in such activity. Such notification shall indicate the location, period and type of proposed possession and use within the state and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. The Agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in subsection (a) of this section;~~

~~(C) The out-of-state licensee complies with all applicable rules of the Agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the Agency;~~

~~(D) The out-of-state licensee supplies such other information as the Agency may request; and~~

~~(E) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in subsection (a) of this section except by transfer to a person:~~

~~(i) Specifically licensed by the Agency or by another Licensing State to receive such material; or~~

~~(ii) Exempt from the requirements for a license for such material under OAR 333-102-0010.~~

~~(b) Notwithstanding the provisions of subsection(a) of this section, any person who holds a specific license issued by a Licensing State authorizing the holder to manufacture, transfer, install or service a device described in OAR 333-102-0115(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service such a device in this state provided that:~~

~~(A) Such person shall file a report with the Agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred and the quantity and type of radioactive material contained in the device;~~

~~(B) The device has been manufactured, labeled, installed and serviced in accordance with applicable provisions of the specific license issued to such person by a Licensing State;~~

~~(C) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that **Removal of this label is prohibited**; and~~

~~(D) The holder of the specific license shall furnish to each general licensee to whom is transferred such a device or on whose premises is installed such a device a copy of the general license contained in OAR 333-102-0115 or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.~~

~~(c) The Agency may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by a Licensing State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.]~~

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.665

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD-1-1995, f. & cert. ef. 4-26-95

Special Procedures in Regulatory Review

333-102-0345 (1) The provisions of OAR 333-12-001 to 333-12-003 governing contested cases are applicable in any case where the Agency proposes to refuse to issue, renew, modify, amend, revise, revoke or suspend a general or specific license or to find noncompliance with or to refuse to grant exemption from a regulation of the Agency.

(2) In any case where the Agency proposes to grant, issue, renew, modify, amend or revise a general or specific license, or to find compliance or to grant exemption from a regulation of the Agency and the Health Division Administrator determines that such action would first merit public notice and opportunity for hearing the following procedures shall be applicable:

(a) Notice of the proposed action shall be published in the Secretary of State's bulletin or a newspaper of general circulation in the state, which notice shall provide that within 15 days of the day of publication of the notice, any person whose interest may be affected by the outcome of the proceeding, or who represents a public interest in the results of the proceeding may file a petition to be made a party and given an opportunity for hearing in the matter. The notice of proposed action shall set forth:

(A) The nature of the action proposed;

(B) The manner in which and the location at which inspection may be made of the Agency records pertaining to the proposed action; and

(C) A reference of the Agency's rules governing institution and conduct of hearings in radiation control proceedings.

(b) If no request for hearing is filed within the time prescribed in the notice, the proposed action shall be taken;

(c) If a hearing is requested, the person requesting to participate as a party shall file a petition requesting party status and opportunity for hearing, setting forth the same information required of a person requesting party status in a contested case under OAR 333-12-001 when the agency has given notice that it intends to hold a contested case hearing pursuant to OAR 137-03-005(6). The same procedures for determining party status under OAR 137-03-005 shall be followed upon receipt of the petition;

(d) If the agency allows party status, it shall in the same order set the time for a contested case hearing and provide notice of the order to the petitioner and all parties;

(e) A contested case shall proceed in accordance with the provisions of OAR 333-12-0001 to 333-12-0003 governing contested cases.

Stat. Auth.: ORS Ch. 183 & 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Reporting requirements.

333-102-0350 (1) **Immediate report.** Each licensee shall notify the Agency as soon as possible

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but not later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(2) Twenty-four hour report. Each licensee shall notify the Agency within 24 hours after the discovery of any of the following events involving licensed material:

(a) An unplanned contamination event that:

(A) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(B) Involves a quantity of material greater than five times the lowest annual limit on intake specified in appendix B of Secs. 20.1001-20.2401 of 10 CFR part 20 for the material; and

(C) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(b) An event in which equipment is disabled or fails to function as designed when:

(A) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(B) The equipment is required to be available and operable when it is disabled or fails to function; and

(C) No redundant equipment is available and operable to perform the required safety function.

(c) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(d) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(A) The quantity of material involved is greater than five times the lowest annual limit on intake specified in appendix B of Secs. 20.1001-20.2401 of 10 CFR part 20 for the material; and

(B) The damage affects the integrity of the licensed material or its container.

(3) Preparation and submission of reports. Reports made by licensees in response to the requirements of this rule must be made as follows:

(a) Licensees shall make reports required by paragraphs OAR 333-102-350(1) and 333-102-350(2) by telephone to the Agency. To the extent that the information is available at the time of notification, the information provided in these reports must include:

NOTE: The 24-hour telephone number for the Agency is 503-731-4014.

(A) The caller's name and call back telephone number;

(B) A description of the event, including date and time;

(C) The exact location of the event;

(D) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(E) Any personnel radiation exposure data available.

(b) Written report. Each licensee who makes a report required by paragraph OAR 333-102-350(1) or 333-102-350(2) shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be Faxed or sent to the Agency with Attention

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to Radioactive Materials Manager, 800 NE Oregon Street, Portland, OR 97232. The reports must include the following:

- (i) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
 - (ii) The exact location of the event;
 - (iii) The isotopes, quantities, and chemical and physical form of the licensed material involved;
 - (iv) Date and time of the event;
 - (v) Corrective actions taken or planned and the results of any evaluations or assessments;
- and
- (vi) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.
- (3) The provisions of this rule apply to licensees subject to the notification requirements in OAR 333-102-200(5).

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.665

Hist.: HD

Records

333-102-0355 (1) Each person who receives radioactive material pursuant to a license issued in accordance with the rules in this Division and Divisions 105, 113, 115, 116, 117, and 121 of this chapter shall keep records showing the receipt, transfer, and disposal of the radioactive material as follows:

- (a) The licensee shall retain each record of receipt of radioactive 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 shall retain each record of transfer for three years after each transfer unless a specific requirement in another Division of the rules in this Chapter dictates otherwise.
- (c) The licensee who disposed of the material shall retain each record of disposal of radioactive material until the Agency terminates each license that authorizes disposal of the material.

(2) The licensee shall retain each record that is required by the rules in this Division and Divisions 105, 113, 115, 116, 117, and 121 of this Chapter or by license condition for the period specified by the appropriate rule or license condition. If a retention period is not otherwise specified by rule or license condition, the record must be retained until the Agency terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(3)(a) Records that must be maintained pursuant to this Division and Divisions 105, 113, 115, 116, 117, and 121 of this Chapter may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Agency rules. The record also may 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, or 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.

(b) If there is a conflict between the Agency's rules in this Division and Divisions 105, 113, 115, 116, 117, and 121 of this Chapter, license condition, or other written Agency approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the rules in this Division and Divisions 105, 113, 115, 116, 117, and 121 of this Chapter for such records shall apply unless the Agency, pursuant to OAR 333-102-0003, has granted a specific exemption from the record retention requirements specified in the rules in this Division or Divisions 105, 113, 115, 116, 117, and 121 of this Chapter.

(4) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the Agency Office:

- (a) Records of disposals of licensed material made prior to January 28, 1981; and
- (b) Records required by OAR 333-120-620(2)(d).

NOTE: Prior to EFSC rules burial of small quantities of licensed materials in soil was permitted without specific Agency authorization.

(5) If licensed activities are transferred or assigned in accordance with OAR 333-102-305(2), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

- (a) Records of disposal of licensed material made under OAR 333-120-510 (including burials authorized before January 28, 1981, 333-120-520, 333-120-530, 333-120.540; and
- (b) Records required by 120-620(2)(d).

(6) Prior to license termination, each licensee shall forward the records required by OAR 333-102-306(7) to the Agency Office.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.665

Hist.: HD

**Right to cause the withholding or recall of byproduct material.
333-102-0360**

The Agency may cause the withholding or recall of byproduct material from any licensee who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the Agency, or who uses such materials in violation of law or regulation of the Agency, or in a manner other than as disclosed in the application therefor or approved by the Agency.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.665

Hist.: HD

Third Party Method.

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333-102-365 If the applicant consents, the Agency may enter into third party agreements for the applicant to engage and pay for the services of a third party contractor to prepare an environmental impact analysis required by OAR 333-102-295 and/or to furnish an opinion of independent experts, satisfactory to the Agency, in respect to the completeness and adequacy of any information or data furnished by the applicant and on any aspect of the applicant's project or effects thereof.

(1) When the license applicant pays for a third party agreement, the monies paid for the consultant shall not be considered as specific license fees, pursuant to OAR 333-103-010 of this Chapter.

(2) In proceeding under the third party agreement, the Agency shall carry out the following practices:

(a) Such contractor shall be chosen solely by the Agency.

(b) The Agency shall manage the contract.

(c) The consultant shall be selected based on the consultant's ability and relevant and applicable work experience and an absence of conflict of interest. Third party contractors shall be required to execute a disclosure statement showing that they have no financial or other conflicting interest in the outcome of the project.

(d) The Agency shall specify the information to be developed and supervise the gathering, analysis and presentation of the information. The Agency shall have sole authority for approval and modification of the statement, analysis, and conclusions included in third party's report.

(e) The Agency has the single right of refusal of the final application. and the Agency is not obligated to approve the application or issue a license.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.665

Hist.: HD

Transport

Transportation of Radioactive Material

333-102-0400

[HD 4-1985, f. & ef. 3-20-85; HD 10-1987, f. & ef. 7-28-87; Repealed by HD 1-1991, f. & ef. 1-8-91]

Exemptions

333-102-0405

[HD 4-1985, f. & ef. 3-20-85; Repealed by HD 1-1991, f. & ef. 1-8-91]

Intrastate Transport

333-102-0410

[HD 4-1985, f. & ef. 3-20-85; Repealed by HD 1-1991, f. & ef. 1-8-91]

Preparation of Radioactive Material for Transport

333-102-0415

[HD 4-1985, f. & ef. 3-20-85; Repealed by HD 1-1991, f. & ef. 1-8-91]

Special Requirements for Specific Licenses of Broad Scope

333-102-0900 This Division prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain rules governing holders of such licenses.

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 from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(1) The different types of broad scope licenses are set forth below:

(a) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range;

(b) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in **10 CFR Part 33.100 Schedule A** for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in **10 CFR Part 33.100 Schedule A Column I**. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in **10 CFR Part 33.100 Schedule A Column I**, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity;

(c) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in **10 CFR Part 33.100 Schedule A** for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in **10 CFR Part 33.100 Schedule A Column II**. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in **10 CFR Part 33.100 Schedule A Column II**, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(2) An application for a Type A specific license of broad scope will be approved if:

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

(b) The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(c) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting and management review that are necessary to assure safe operations, including:

(A) The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management and persons trained and experienced in the safe use of radioactive materials;

(B) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(C) The establishment of appropriate administrative procedures to assure:

(i) Control of procurement and use of radioactive material;

(ii) Completion of safety evaluations of proposed uses of radioactive material which take into

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consideration such matters as the adequacy of facilities and equipment, training and experience of the user and the operating or handling procedures; and

(iii) Review, approval and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with OAR 333-102-0900(2)(c)(C)(ii) prior to use of the radioactive material.

~~NOTE: Only licensees meeting the administrative requirements pursuant to OAR 333-102-0900(2) may authorize multiple sources of radiation and multiple sites of use on a single specific license.~~

(3) An application for a Type B specific license of broad scope will be approved if:

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

(b) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting and management review that are necessary to assure safe operations, including:

(A) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(B) The establishment of appropriate administrative procedures to assure:

(i) Control of procurement and use of radioactive material;

(ii) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user and the operating or handling procedures; and

(iii) Review, approval and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with OAR 333-102-0900(3)(b)(B)(ii) prior to use of the radioactive material.

(4) An application for a Type C specific license of broad scope will be approved if:

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

(b) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

(A) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

(B) At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used.

(c) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting and management review necessary to assure safe operations.

(5) An application filed pursuant to OAR 333-102-200 for a specific license other than one of broad scope will be considered by the Agency as an application for a specific license of broad scope under this rule if the requirements of the applicable sections of this rule are satisfied.

~~(5)6~~ Specific licenses of broad scope are subject to the following conditions:

(a) Unless specifically authorized, persons licensed pursuant to OAR 333-102-0900 shall not:

(A) Conduct tracer studies in the environment involving direct release of radioactive material;

(B) Receive, acquire, own, possess, use or transfer devices containing 100,000 Curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;

(C) Conduct activities for which a specific license, **except a license of broad scope**, issued by the Agency under **Divisions 102, 105, 113, 115, 116, 117, or 121 of this Chapter** ~~OAR 333-102-0225,~~

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~~333-102-0235, 333-102-0240, 333-102-0245, 333-102-0250, 333-102-0255, 333-102-0260, 333-102-0265, 333-102-0270, 333-102-0275, 333-102-0285, 333-102-0290, 333-102-0293, 333-105, 333-110, 333-113, 333-115, 333-116, or 333-117~~ is required; or

(D) Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug or other product designed for ingestion or inhalation by, or application to, a human being.

(b) Each Type A specific license of broad scope issued under this Division shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee;

(c) Each Type B specific license of broad scope issued under this division shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer;

(d) Each Type C specific license of broad scope issued under this division shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of OAR 333-102-0900(4).

ED NOTE: 10 CFR Part 33.100 Schedule A referred to or incorporated by reference in this rule is attached to this Division or available from the Health Division.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 13-1988, f. 6-7-88, cert. ef. 7-1-88; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD-1-1995, f. & cert. ef. 4-26-95

Specific Terms and Conditions for Broad Licenses

333-102-0910 (1) No licensee shall use radioactive material in or on human beings or in field applications where radioactive material is released except as specifically authorized by license.

(2) Experimental animals administered radioactive materials or their products shall not be used for human consumption.

(3) Licensees shall conduct a physical inventory every six months to account for all radioactive material received and possessed under the license. The records of the inventories shall be maintained until inspection by the Radiation Protection Agency, and shall include the quantities and kinds of radioactive material, location of sealed sources and the date of the inventory.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD-1-1995, f. & cert. ef. 4-26-95

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10 CFR PART 30.70 SCHEDULE A

EXEMPT CONCENTRATIONS (See notes at the end of this Schedule)

Element (atomic number)	Isotope	Column I *	Column II
		Gas Concentration (μCi/ml)	Liquid and Solid Concentration (μCi/ml) **
Antimony (51)	Sb-122		3x10 ⁻⁴
	Sb-124		2x10 ⁻⁴
	Sb-125		1x10 ⁻³
Argon (18)	Ar-37	1x10 ⁻³	
	Ar-41	4x10 ⁻⁷	
Arsenic (33)	As-73		5x10 ⁻³
	As-74		5x10 ⁻⁴
	As-76		2x10 ⁻⁴
	As-77		8x10 ⁻⁴
Barium (56)	Ba-131		2x10 ⁻³
	Ba-140		3x10 ⁻⁴
Beryllium (4)	Be-7		2x10 ⁻²
Bismuth (83)	Bi-206		4x10 ⁻⁴
Bromine (35)	Br-82	4x10 ⁻⁷	3x10 ⁻³
Cadmium (48)	Cd-109		2x10 ⁻³
	Cd-115m		3x10 ⁻⁴
	Cd-115		3x10 ⁻⁴
Calcium (20)	Ca-45		9x10 ⁻⁵
	Ca-47		5x10 ⁻⁴
Carbon (6)	C-14	1x10 ⁻⁶	8x10 ⁻³
Cerium (58)	Ce-141		9x10 ⁻⁴
	Ce-143		4x10 ⁻⁴
	Ce-144		1x10 ⁻⁴
Cesium (55)	Cs-131		2x10 ⁻²
	Cs-134m		6x10 ⁻²
	Cs-134		9x10 ⁻⁵
Chlorine (17)	Cl-38	9x10 ⁻⁷	4x10 ⁻³
Chromium (24)	Cr-51		2x10 ⁻²
Cobalt (27)	Co-57		5x10 ⁻³
	Co-58		1x10 ⁻³
	Co-60		5x10 ⁻⁴
Copper (29)	Cu-64		3x10 ⁻³
Dysprosium (66)	Dy-165		4x10 ⁻³
	Dy-166		4x10 ⁻⁴
Erbium (68)	Er-169		9x10 ⁻⁴

	Er-171		1×10^{-3}
Europium (63)	Eu-152(9.2 h)		6×10^{-4}
	Eu-155		2×10^{-3}
Fluorine (9)	F-18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd-153		2×10^{-3}
	Gd-159		8×10^{-4}
Gallium (31)	Ga-72		4×10^{-4}
Germanium (32)	Ge-71		2×10^{-2}

Element (atomic number)	Isotope	Column I *	Column II
		Gas Concentration (μCi/ml)	Liquid and Solid Concentration (μCi/ml) **
Gold (79)	Au-196		2x10 ⁻³
	Au-198		5x10 ⁻⁴
	Au-199		2x10 ⁻³
Hafnium (72)	Hf-181		7x10 ⁻⁴
Hydrogen (1)	H-3	5x10 ⁻⁶	3x10 ⁻²
Indium (49)	In-113m		1x10 ⁻²
	In-114m		2x10 ⁻⁴
Iodine (53)	I-126	3x10 ⁻⁹	2x10 ⁻⁵
	I-131	3x10 ⁻⁹	2x10 ⁻⁵
	I-132	8x10 ⁻⁸	6x10 ⁻⁴
	I-133	1x10 ⁻⁸	7x10 ⁻⁵
	I-134	2x10 ⁻⁷	1x10 ⁻³
Iridium (77)	Ir-190		2x10 ⁻³
	Ir-192		4x10 ⁻⁴
	Ir-194		3x10 ⁻⁴
Iron (26)	Fe-55		8x10 ⁻³
	Fe-59		6x10 ⁻⁴
Krypton (36)	Kr-85m	1x10 ⁻⁶	
	Kr-85	3x10 ⁻⁶	
Lanthanum (57)	La-140		2x10 ⁻⁴
Lead (82)	Pb-203		4x10 ⁻³
Lutetium (71)	Lu-177		1x10 ⁻³
Manganese (25)	Mn-52		3x10 ⁻⁴
	Mn-54		1x10 ⁻³
	Mn-56		1x10 ⁻³
Mercury (80)	Hg-197m		2x10 ⁻³
	Hg-197		3x10 ⁻³
Mercury (80)	Hg-203		2x10 ⁻⁴
Molybdenum (42)	Mo-99		2x10 ⁻³
Neodymium (60)	Nd-147		6x10 ⁻⁴
	Nd-149		3x10 ⁻³
Nickel (28)	Ni-65		1x10 ⁻³
Niobium (Columbium) (41)	Nb-95		1x10 ⁻³
	Nb-97		9x10 ⁻³
Osmium (76)	Os-185		7x10 ⁻⁴
	Os-191m		3x10 ⁻²
	Os-191		2x10 ⁻³
	Os-193		6x10 ⁻⁴

Palladium (46)	Pd-103	3×10^{-3}
	Pd-109	9×10^{-4}
Phosphorus (15)	P-32	2×10^{-4}
Platinum (78)	Pt-191	1×10^{-3}
	Pt-193m	1×10^{-2}
	Pt-197m	1×10^{-2}
	Pt-197	1×10^{-3}
Potassium (19)	K-42	3×10^{-3}

Element (atomic number)	Isotope	Column I *	Column II
		Gas Concentration ($\mu\text{Ci/ml}$)	Liquid and Solid Concentration ($\mu\text{Ci/ml}$) **
Praseodymium (59)	Pr-142		3×10^{-4}
	Pr-143		5×10^{-4}
Promethium (61)	Pm-147		2×10^{-3}
	Pm-149		4×10^{-4}
Rhenium (75)	Re-183		6×10^{-3}
	Re-186		9×10^{-4}
	Re-188		6×10^{-4}
Rhodium (45)	Rh-103m		1×10^{-1}
	Rh-105		1×10^{-3}
Rubidium (37)	Rb-86		7×10^{-4}
Ruthenium (44)	Ru-97		4×10^{-3}
	Ru-103		8×10^{-4}
	Ru-105		1×10^{-3}
	Ru-106		1×10^{-4}
Samarium (62)	Sm-153		8×10^{-4}
Scandium (21)	Sc-46		4×10^{-4}
	Sc-47		9×10^{-4}
Scandium (21)	Sc-48		3×10^{-4}
Selenium (34)	Se-75		3×10^{-3}
Silicon (14)	Si-31		9×10^{-3}
Silver (47)	Ag-105		1×10^{-3}
	Ag-110m		3×10^{-4}
	Ag-111		4×10^{-4}
Sodium (11)	Na-24		2×10^{-3}
Strontium (38)	Sr-85		1×10^{-3}
	Sr-89		1×10^{-4}
Strontium (38)	Sr-91		7×10^{-4}
	Sr-92		
Sulfur (16)	S-35	7×10^{-4}	
		9×10^{-8}	
Tantalum (73)	Ta-182		4×10^{-4}
Technetium (43)	Tc-96m		1×10^{-1}
	Tc-96		1×10^{-3}
Tellurium (52)	Te-125m		2×10^{-3}
	Te-127m		6×10^{-4}
	Te-127		3×10^{-3}
	Te-129m		3×10^{-4}
	Te-131m		6×10^{-4}
	Te-132		3×10^{-4}

Terbium (65)	Tb-160	4×10^{-4}
Thallium (81)	Tl-200	4×10^{-3}
	Tl-201	3×10^{-3}
	Tl-202	1×10^{-3}
	Tl-204	1×10^{-3}
Thulium (69)	Tm-170	5×10^{-4}
	Tm-171	5×10^{-3}
Tin (50)	Sn-113	9×10^{-4}
	Sn-125	2×10^{-4}

Element (atomic number)	Isotope	Column I *	Column II
		Gas Concentration ($\mu\text{Ci/ml}$)	Liquid and Solid Concentration ($\mu\text{Ci/ml}$) **
Tungsten (Wolfram) (74)	W-181		4×10^{-3}
	W-187		7×10^{-4}
Vanadium (23)	V-48		3×10^{-4}
Xenon (54)	Xe-131m	4×10^{-6}	
	Xe-133	3×10^{-6}	
	Xe-135	1×10^{-6}	
Ytterbium (70)	Xb-175		1×10^{-3}
Yttrium (39)	Y-90		2×10^{-4}
	Y-91m		3×10^{-2}
	Y-91		3×10^{-4}
	Y-92		6×10^{-4}
Yttrium (39)	Y-93		3×10^{-4}
Zinc (30)	Zn-65		1×10^{-3}
	Zn-69m		7×10^{-4}
	Zn-69		2×10^{-2}
Zirconium (40)	Zr-95		6×10^{-4}
	Zr-97		2×10^{-4}
Beta- and/or gamma-emitting radioactive material not listed above with half-life of less than 3 years	1×10^{-10}	1×10^{-6}	

* Values in Column I are given only for those materials normally used as gases.

** $\mu\text{Ci/gm}$ for solids.

NOTE 1: Many radioisotopes transform into isotopes which are also radioactive. In expressing the concentrations in Schedule A, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of OAR 333-102-0010 where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Schedule A for the specific isotope when not in combination. The sum of such ratios may not exceed "1".

Example: $\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt Concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt Concentration of Isotope B}} \leq 1$

Exempt Concentration of Isotope B

NOTE 3: To convert $\mu\text{Ci/ml}$ to SI units of megabecquerels per liter multiply the above values by 37.

Example:

Zirconium (4) Zr-97 ($2 \times 10^{-4} \mu\text{Ci/ml}$ multiplied by 37 is equivalent to $74 \times 10^{-4} \text{MBq/l}$)

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EXEMPT QUANTITIES

Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100

Europium-152 (Eu 152) 9.2h	100
Europium-152 (Eu 152) 13 yr	1
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10

Radioactive Material	Microcuries
Germanium-68 (Ge 68)	10
Germanium-71 (Ge 71)	100
Gold-195 (Au 195)	10
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I-123)	100
Iodine-125 (I-125)	1
Iodine-126 (I-126)	1
Iodine-129 (I-129)	0.1
Iodine-131 (I-131)	1
Iodine-132 (I-132)	10
Iodine-133 (I-133)	1
Iodine-134 (I-134)	10
Iodine-135 (I-135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100

Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100

Radioactive Material	Microcuries
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100
Promethium-147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10

Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10

Radioactive Material	Microcuries
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha-emitting radioactive material	0.1

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Limits for Broad Licenses

Radioactive Material	Col. I curies	Col. II curies
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1.
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1.
Cesium-134m	100	1.
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1.
Chromium-51	100	1.
Cobalt-57	10	0.1
Cobalt-58m	100	1.
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1.
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2 h)	10	0.1

Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1.
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1.

Radioactive Material	Col. I curies	Col. II curies
Gold-198		0.1
Gold-199		0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1.
Indium-113m	100	1.
Indium-114m	1	0.01
Indium-115m	100	1.
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1.
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1.
Osmium-185	1	0.01
Osmium-191m	100	1.
Osmium-191	10	0.1

Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1.
Platinum-193	10	0.1
Platinum-197m	100	1.
Platinum-197	10	0.1

Radioactive Material	Col. I curies	Col. II curies
Polonium-210		0.01
Potassium-42		1
Praseodymium-142		10
Praseodymium-143		10
Promethium-147		1
Promethium-149		10
Radium-226		0.01
Rhenium-186		10
Rhenium-188		10
Rhodium-103m		1,000
Rhodium-105		10
Rubidium-86		1
Rubidium-87		1
Ruthenium-97		100
Ruthenium-103		1
Ruthenium-105		10
Ruthenium-106		0.1
Samarium-151		1
Samarium-153		10
Scandium-46		1
Scandium-47		10
Scandium-48		1
Selenium-75		1
Silicon-31		10
Silver-105		1
Silver-110m		0.1
Silver-111		10
Sodium-22		0.1
Sodium-24		1
Strontium-85m		1,000
Strontium-85		1
Strontium-89		1
Strontium-90		0.01
Strontium-91		10
Strontium-92		10
Sulphur-35		10
Tantalum-182		1
Technetium-96		10
Technetium-97m		10
Technetium-97		10
Technetium-99m		100
Technetium-99		1
Tellurium-125m		1

Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1

Radioactive Material	Col. I curies	Col. II curies
Thallium-202		10
Thallium-204		1
Thulium-170		1
Thulium-171		1
Tin-113		1
Tin-125		1
Tungsten-181		1
Tungsten-185		1
Tungsten-187		10
Vanadium-48		1
Xenon-131m		1,000
Xenon-133		100
Xenon-135		100
Ytterbium-175		10
Yttrium-91		1
Yttrium-92		10
Yttrium-93		1
Zinc-65		1
Zinc-69m		10
Zinc-69		100
Zirconium-93		1
Zirconium-95		1
Zirconium-97		1
Any radioactive material other than source material, special nuclear material, or alpha-emitting radioactive material not listed above.		0.1
		0.001

NOTE 1: To convert curies (Ci) to SI units of gigabecquerels (GBq), multiply the above values by 37.

Example:

Zirconium-97 (Col. II) (0.01 Ci multiplied by 37 is equivalent to 0.37 GBq).

Sec. 30.72 Schedule C--Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release.

Radioactive material \\\	Release fraction	Quantity (curies)
Actinium-228.....	0.001	4,000
Americium-241.....	.001	2
Americium-242.....	.001	2
Americium-243.....	.001	2
Antimony-124.....	.01	4,000
Antimony-126.....	.01	6,000
Barium-133.....	.01	10,000
Barium-140.....	.01	30,000
Bismuth-207.....	.01	5,000
Bismuth-210.....	.01	600
Cadmium-109.....	.01	1,000
Cadmium-113.....	.01	80
Calcium-45.....	.01	20,000
Californium-252.....	.001	9 (20 mg)
Carbon-14 (non-carbon dioxide).....	.01	50,000
Cerium-141.....	.01	10,000
Cerium-144.....	.01	300
Cesium-134.....	.01	2,000
Cesium-137.....	.01	3,000
Chlorine-36.....	.5	100
Chromium-51.....	.01	300,000
Cobalt-60.....	.001	5,000
Copper-64.....	.01	200,000
Curium-242.....	.001	60
Curium-243.....	.001	3
Curium-244.....	.001	4
Curium-245.....	.001	2
Europium-152.....	.01	500
Europium-154.....	.01	400
Europium-155.....	.01	3,000
Germanium-68.....	.01	2,000
Gadolinium-153.....	.01	5,000
Gold-198.....	.01	30,000
Hafnium-172.....	.01	400
Hafnium-181.....	.01	7,000
Holmium-166m.....	.01	100
Hydrogen-3.....	.5	20,000
Iodine-125.....	.5	10
Iodine-131.....	.5	10
Indium-114m.....	.01	1,000
Iridium-192.....	.001	40,000
Iron-55.....	.01	40,000
Iron-59.....	.01	7,000
Krypton-85.....	1.0	6,000,000
Lead-210.....	.01	8
Manganese-56.....	.01	60,000
Mercury-203.....	.01	10,000
Molybdenum-99.....	.01	30,000
Neptunium-237.....	.001	2
Nickel-63.....	.01	20,000

Niobium-94.....	.01	300	
Phosphorus-32.....	.5	100	
Phosphorus-33.....	.5	1,000	
Polonium-210.....	.01	10	
Potassium-42.....	.01	9,000	
Promethium-145.....	.01	4,000	
Promethium-147.....	.01	4,000	
Ruthenium-106.....	.01	200	
Samarium-151.....	.01	4,000	
Scandium-46.....	.01	3,000	
Selenium-75.....	.01	10,000	
Silver-110m.....	.01	1,000	
Sodium-22.....	.01	9,000	
Sodium-24.....	.01	10,000	
Strontium-89.....	.01	3,000	
Strontium-90.....	.01	90	
Sulfur-35.....	.5	900	
Technitium-99.....	.01	10,000	
Technitium-99m.....	.01	400,000	
Tellurium-127m.....	.01	5,000	
Tellurium-129m.....	.01	5,000	
Terbium-160.....	.01	4,000	
Thulium-170.....	.01	4,000	
Tin-113.....	.01	10,000	
Tin-123.....	.01	3,000	
Tin-126.....	.01	1,000	
Titanium-44.....	.01	100	
Vanadium-48.....	.01	7,000	
Xenon-133.....	1.0	900,000	
Yttrium-91.....	.01	2,000	
Zinc-65.....	.01	5,000	
Zirconium-93.....	.01	400	
Zirconium-95.....	.01	5,000	
Any other beta-gamma emitter.....	.01	10,000	
Mixed fission products.....	.01	1,000	
Mixed corrosion products.....	.01	10,000	
Contaminated equipment beta-gamma.....	.001	10,000	
Irradiated material, any form other than solid noncombustible.....			.01 1,000
Irradiated material, solid noncombustible.....	.001	10,000	
Mixed radioactive waste, beta-gamma.....	.01	1,000	
Packaged mixed waste, beta-gamma \4\.....	.001	10,000	
Any other alpha emitter.....	.001	2	
Contaminated equipment, alpha.....	.0001	20	
Packaged waste, alpha \4\.....	.0001	20	
Combinations of radioactive materials listed above\1\			

\1\ For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Schedule C exceeds one.

\2\ Waste packaged in Type B containers does not require an emergency plan.

[54 FR 14061, Apr. 7, 1989, as amended at 61 FR 9902, Mar. 12, 1996]

Appendix A to Part 30--Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

II. Financial Test

A. To pass the financial test, the parent company must meet the criteria of either paragraph A.1 or A.2 of this section:

1. The parent company must have:

(i) Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and

(ii) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used); and

(iii) Tangible net worth of at least \$10 million; and

(iv) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).

2. The parent company must have:

(i) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, A, or Baa as issued by Moody's; and

(ii) Tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a certification is used); and

(iii) Tangible net worth of at least \$10 million; and

(iv) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if certification is used).

B. The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform NRC within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

C. 1. After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

2. If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the Commission of intent to establish alternate financial assurance as specified in the Commission's regulations. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Parent Company Guarantee

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Commission. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Commission, as evidenced by the return receipts.

B. If the licensee fails to provide alternate financial assurance as specified in the Commission's regulations within 90 days after receipt by the licensee and Commission of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

C. The parent company guarantee and financial test provisions must remain in effect until the Commission has terminated the license.

D. If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Commission. An

acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.
[53 FR 24046, June 27, 1988]

Appendix B to Part 30--Quantities\1 of Licensed Material Requiring Labeling

<u>Material</u>	<u>Microcuries</u>
Americium-241.....	.01
Antimony-122.....	100
Antimony-124.....	10
Antimony-125.....	10
Arsenic-73.....	100
Arsenic-74.....	10
Arsenic-76.....	10
Arsenic-77.....	100
Barium-131.....	10
Barium-133.....	10
Barium-140.....	10
Bismuth-210.....	1
Bromine-82.....	10
Cadmium-109.....	10
Cadmium-115m.....	10
Cadmium-115.....	100
Calcium-45.....	10
Calcium-47.....	10
Carbon-14.....	100
Cerium-141.....	100
Cerium-143.....	100
Cerium-144.....	1
Cesium-131.....	1,000
Cesium-134m.....	100
Cesium-134.....	1
Cesium-135.....	10
Cesium-136.....	10
Cesium-137.....	10
Chlorine-36.....	10
Chlorine-38.....	10
Chromium-51.....	1,000
Cobalt-58m.....	10
Cobalt-58.....	10
Cobalt-60.....	1
Copper-64.....	100
Dysprosium-165.....	10
Dysprosium-166.....	100
Erbium-169.....	100
Erbium-171.....	100
Europium-152 9.2 h.....	100
Europium-152 13 yr.....	1
Europium-154.....	1
Europium-155.....	10
Fluorine-18.....	1,000
Gadolinium-153.....	10
Gadolinium-159.....	100
Gallium-72.....	10
Germanium-71.....	100
Gold-198.....	100
Gold-199.....	100
Hafnium-181.....	10
Holmium-166.....	100
Hydrogen-3.....	1,000
Indium-113m.....	100

Indium-114m.....	10
Indium-115m.....	100
Indium-115.....	10
Iodine-125.....	1
Iodine-126.....	1
Iodine-129.....	0.1
Iodine-131.....	1
Iodine-132.....	10
Iodine-133.....	1
Iodine-134.....	10
Iodine-135.....	10
Iridium-192.....	10
Iridium-194.....	100
Iron-55.....	100
Iron-59.....	10
Krypton-85.....	100
Krypton-87.....	10
Lanthanum-140.....	10
Lutetium-177.....	100
Manganese-52.....	10
Manganese-54.....	10
Manganese-56.....	10
Mercury-197m.....	100
Mercury-197.....	100
Mercury-203.....	10
Molybdenum-99.....	100
Neodymium-147.....	100
Neodymium-149.....	100
Nickel-59.....	100
Nickel-63.....	10
Nickel-65.....	100
Niobium-93m.....	10
Niobium-95.....	10
Niobium-97.....	10
Osmium-185.....	10
Osmium-191m.....	100
Osmium-191.....	100
Osmium-193.....	100
Palladium-103.....	100
Palladium-109.....	100
Phosphorus-32.....	10
Platinum-191.....	100
Platinum-193m.....	100
Platinum-193.....	100
Platinum-197m.....	100

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Platinum-197.....	100
Plutonium-239.....	.01
Polonium-210.....	0.1
Potassium-42.....	10
Praseodymium-142.....	100
Praseodymium-143.....	100
Promethium-147.....	10
Promethium-149.....	10
Radium-226.....	.01

Rhenium-186.....	100
Rhenium-188.....	100
Rhodium-103m.....	100
Rhodium-105.....	100
Rubidium-86.....	10
Rubidium-87.....	10
Ruthenium-97.....	100
Ruthenium-103.....	10
Ruthenium-105.....	10
Ruthenium-106.....	1
Samarium-151.....	10
Samarium-153.....	100
Scandium-46.....	10
Scandium-47.....	100
Scandium-48.....	10
Selenium-75.....	10
Silicon-31.....	100
Silver-105.....	10
Silver-110m.....	1
Silver-111.....	100
Sodium-24.....	10
Strontium-85.....	10
Strontium-89.....	1
Strontium-90.....	0.1
Strontium-91.....	10
Strontium-92.....	10
Sulphur-35.....	100
Tantalum-182.....	10
Technetium-96.....	10
Technetium-97m.....	100
Technetium-97.....	100
Technetium-99m.....	100
Technetium-99.....	10
Tellurium-125m.....	10
Tellurium-127m.....	10
Tellurium-127.....	100
Tellurium-129m.....	10
Tellurium-129.....	100
Tellurium-131m.....	10
Tellurium-132.....	10
Terbium-160.....	10
Thallium-200.....	100
Thallium-201.....	100
Thallium-202.....	100
Thallium-204.....	10
Thorium (natural) <SUP>1.....	100
Thulium-170.....	10
Thulium-171.....	10
Tin-113.....	10
Tin-125.....	10
Tungsten-181.....	10
Tungsten-185.....	10
Tungsten-187.....	100
Uranium (natural) <SUP>2.....	100
Uranium-233.....	.01
Uranium-234--Uranium-235.....	.01
Vanadium-48.....	10

Xenon-131m.....	1,000	
Xenon-133.....	100	
Xenon-135.....	100	
Ytterbium-175.....	100	
Yttrium-90.....	10	
Yttrium-91.....	10	
Yttrium-92.....	100	
Yttrium-93.....	100	
Zinc-65.....	10	
Zinc-69m.....	100	
Zinc-69.....	1,000	
Zirconium-93.....	10	
Zirconium-95.....	10	
Zirconium-97.....	10	
Any alpha emitting radionuclide not listed above or		mixtures of alpha emitters of unknown composition.....
.01		
Any radionuclide other than alpha emitting radionuclides,		
not listed above or mixtures of beta emitters of unknown composition.....		1

/1 Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.

/2 Based on alpha disintegration rate of U-238, U-234, and U-235.

Note: For purposes of Sec. 20.303, where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" (i.e., "unity").

[35 FR 6425, Apr. 22, 1970, as amended at 36 FR 16898, Aug. 26, 1971; 38 FR 29314, Oct. 24, 1973; 39 FR 23991, June 28, 1974; 45 FR 71763, Oct. 30, 1980. Redesignated at 56 FR 23391, May 21, 1991, and further redesignated at 58 FR 67659, Dec. 22, 1993]

Appendix C to Part 30--Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. To pass the financial test, a company must meet all of the following criteria:

(1) Tangible net worth at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(3) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.

B. To pass the financial test, a company must meet all of the following additional requirements:

(1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

(2) The company's independent certified public accountant must have compared the data used by the company in the

financial test which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform NRC within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send immediate notice to the Commission of its intent to establish alternate financial assurance as specified in the Commission's regulations within 120 days of such notice.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Commission. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Commission, as evidenced by the return receipt.

B. The licensee shall provide alternative financial assurance as specified in the Commission's regulations within 90 days following receipt by the Commission of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Commission has terminated the license or until another financial assurance method acceptable to the Commission has been put in effect by the licensee.

D. The licensee will promptly forward to the Commission and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the Commission within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of Section II.A. of this Appendix.

F. The applicant or licensee must provide to the Commission a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Commission, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

[58 FR 68730, Dec. 29, 1993; 59 FR 1618, Jan. 12, 1994]

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