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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED

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ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Radiation Protection Services diagnostic and therapy rulemaking amendments

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/21/2023 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

A public rulemaking hearing may be requested in writing by 10 or more people, or by a group with 10 or more members, within 21 days following the publication of the Notice of Proposed Rulemaking in the Oregon Bulletin or 28 days from the date the Notice was sent to people on the agency mailing list, whichever is later. If sufficient hearing requests are received, the notice of the date and time of the rulemaking hearing must be published in the Oregon Bulletin at least 14 days before the hearing.

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NEED FOR THE RULE(S)

The Oregon Health Authority, Public Health Division, Center for Health Protection, Radiation Protection Services (RPS), is proposing rulemaking to Oregon Administrative Rules (OAR).

The X-ray program is proposing rule amendments to clarify that the X-ray registrant must ensure direct supervision of a non-certified Medical Physicist is provided by a Medical Physicist who is certified in Therapeutic Radiological Physicist or Radiation Oncology. Currently in rule, the term supervision is used and is vague regarding the type of supervision is required. Direct supervision requires the Certified Radiological Practitioner to be physically in the medical facility. Amended rules will allow the dental registrant to utilize a rectangular rather than a circular intraoral image receptor which lowers the X-ray radiation dose to the patient and improve the image quality. Amended rules will now define a Naturopathic doctor as a person who practices the healing arts which will make the practitioner eligible for fluoroscopic operations.

The Radioactive Materials program is proposing rulemaking to remove the statement "not to exceed \$3,000 in a year" within the reciprocal recognition fee rule to align with in-state fees. Currently ORS 453.757 directs annual radioactive material licensing fees to not exceed \$5,000 per year. Amended rules are being proposed to better define a radiation area by inserting language that means radiation areas expose persons to radioactive materials within a specific area. Rules pertaining to notification of a medical event are being amended by removing a rule reference number since the referenced rule does not provide the criteria to define a medical event and corrects grammar within that rule.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Oregon Revised Statutes ORS 453.605 – 453.807: https://www.oregonlegislature.gov/bills_laws/ors/ors453.html

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

Proposed rulemaking is to ensure that all Oregonians, citizens, and communities are afforded with compatible state and federal laws designed to protect all persons from radiation exposure that does not have a direct benefit. In addition, proposed rules will allow for equity to all Oregon and out of state businesses applying for a radioactive material license.

FISCAL AND ECONOMIC IMPACT:

There is no anticipated fiscal or economic impact as a result of the proposed amendments to OARs within divisions 100, 103, 106, 116, 120, and 123.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) There is no anticipated cost of compliance impact to the Oregon Health Authority, other state agencies, units of local government or the public as a result of the proposed rule amendments.

(2)(a) RPS does not possess the data to determine how many small businesses providing X-ray and radioactive materials services within the academia, research and development, industrial and medical industries will be subject to these rules. Small businesses will not be negatively impacted by these proposed amended rules.

(b) Licensees and registrants will not experience increased administrative activities with the proposed rule amendments.

(c) No additional supplies, labor or administrative oversight will be required for compliance with these proposed rules.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were not involved in the development of these rules.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

333-100-0005, 333-103-0030, 333-106-0325, 333-116-1000, 333-120-0015, 333-123-0015

AMEND: 333-100-0005

RULE SUMMARY: OAR 333-100-0005 is amended by adding language to recognize that Naturopathic Doctors practice the healing arts.

CHANGES TO RULE:

333-100-0005
Definitions ¶

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

- (1) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.¶
- (2) "Accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV. For purposes of this definition, "particle accelerator" is an equivalent term.¶
- (3) "Accelerator-produced material" means any material made radioactive by a particle accelerator.¶
- (4) "Act" means Oregon Revised Statutes 453.605 through 453.807.¶
- (5) "Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq), defined as one disintegration per second, and the curie (Ci), defined as 3.7×10^{10} disintegrations per second.¶
- (6) "Adult" means an individual 18 or more years of age.¶
- (7) "Agreement State" means any state with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689). States not entering an agreement under the Act are considered a non-agreement state.¶
- (8) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.¶
- (9) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive material, composed wholly or partly of licensed material, exist in concentrations:¶
 - (a) In excess of the derived air concentrations (DACs) specified in Appendix B, Table I, column 3, to 10 CFR Part 20.1001 to 20.2401; or¶
 - (b) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.¶
- (10) "ALARA" (acronym for "As Low As Reasonably Achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.¶
- (11) "Alert" means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.¶
- (12) "Annual" means occurring every year or within a consecutive twelve month cycle.¶
- (13) "Annual Limit on Intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the Reference Man that could result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Appendix B, Table I, Columns 1 and 2, to 10 CFR Part 20.1001 to 20.2401.¶
- (14) "As Low As Reasonably Achievable" see "ALARA."¶
- (15) "Authority" means the Oregon Health Authority.¶
- (16) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include sources of radiation from radioactive or special nuclear materials regulated by the Authority.¶
- (17) "Becquerel" (Bq) means one disintegration per second.¶
- (18) "Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations, of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, "radiobioassay" is an equivalent term.¶
- (19) "Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.¶
- (20) "Byproduct material" means¶
 - (a) Any radioactive material, except special nuclear material, yielded in, or made radioactive by, exposure to the

- radiation incident to the process of producing or utilizing special nuclear material;¶
- (b) The tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction process. Underground ore bodies depleted by such solution extraction operations do not constitute "byproduct material" within this definition;¶
- (c) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or¶
- (d) Any material that:¶
- (A) Has been made radioactive by use of a particle accelerator; and¶
- (B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and¶
- (C) Any discrete source of naturally occurring radioactive material, other than source material, that:¶
- (i) The Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate state and federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and¶
- (ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.¶
- (21) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year must begin in January and subsequent calendar quarters must be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant may change the method observed for determining calendar quarters except at the beginning of a calendar year.¶
- (22) "Calibration" means the determination of:¶
- (a) The response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or¶
- (b) The strength of a source of radiation relative to a standard.¶
- (23) "CFR" means Code of Federal Regulations.¶
- (24) "Chelating agent" means amine polycarboxylic acids, hydroxy-carboxylic acids, gluconic acid, and polycarboxylic acids.¶
- (25) "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. For purposes of these rules, "lung class" or "inhalation class" are equivalent terms. Materials are classified as D, W, or Y, which applies to a range of clearance half-times:¶
- (a) For Class D, Days, of less than 10 days;¶
- (b) For Class W, Weeks, from 10 to 100 days; and¶
- (c) For Class Y, Years, of greater than 100 days.¶
- (26) "Clinical laboratory" means a laboratory licensed pursuant to ORS 438.110 through 438.140.¶
- (27) "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.¶
- (28) "Committed dose equivalent" (HT, 50) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.¶
- (29) "Committed effective dose equivalent" (HE, 50) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues (HE, 50 = WT,HT,50).¶
- (30) "Contamination" (Radioactive) means deposition or presence of radioactive material in any place where it is not desired, and particularly in any place where its presence can be harmful. The harm may be in compromising the validity of an experiment or a procedure, or in being a source of danger to persons. Contamination may be divided into two types: Fixed and removable. Removable contamination may be transferred easily from one object to another by light rubbing or by the use of weak solvents such as water or alcohol. Removable contamination is evaluated and recorded in units of microcuries or dpm. Fixed contamination is not easily transferred from one object to another and requires mechanical or strong chemicals to remove it from its current location. Fixed contamination is evaluated and recorded in units of mR/hr.¶
- (31) "Curie" means that amount of radioactive materials which disintegrates at the rate of 37 billion atoms per second.¶
- (32) "Declared pregnant woman" means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.¶
- (33) "Decommission" means to remove (as a facility) safely from service and reduce residual radioactivity to a level

that permits:¶

(a) Release of the property for unrestricted use and termination of license; or¶

(b) Release of the property under restricted conditions and termination of the license.¶

(34) "Deep dose equivalent" (Hd) which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm²).¶

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

(36) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by Reference Man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these rules, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B to 10 CFR Part 20.1001 to 20.2401.¶

(37) "Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).¶

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

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

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

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

(42) "Effective dose equivalent" (HE) means the sum of the products of the dose equivalent to the organ or tissue (HT) and the weighting factor (WT) applicable to each of the body organs or tissues that are irradiated (HE = WT HT).¶

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

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

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

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

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

(48) "Exposure" means:¶

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

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

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

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

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

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

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

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

(55) "General license" means a license granted by rule, in contrast to an issued license, to acquire, own, possess,

use, or transfer radioactive material or a device that contains radioactive material.¶

(56) "Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.¶

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

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

(59) "Healing arts" means:¶

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

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

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

(61) "Individual" means any human being.¶

(62) "Individual monitoring" means:¶

(a) The assessment of dose equivalent by the use of devices designed to be worn by an individual;¶

(b) The assessment of committed effective dose equivalent by bioassay (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours; or¶

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(76) "Lung class" (see "Class").¶

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

- (78) "Member of the public" means an individual, except when that individual is receiving an occupational dose.¶
- (79) "Minor" means an individual less than 18 years of age.¶
- (80) "Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.¶
- (81) "NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.¶
- (82) "Natural radioactivity" means radioactivity of naturally occurring nuclides.¶
- (83) "Naturally-occurring radioactive material" (NORM) means any nuclide that is found in nature as a radioactive material (and not technologically produced).¶
- (84) "Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).¶
- (85) "Natural uranium" means a mixture of the uranium isotopes 234, 235 and 238 (approximately 0.7 weight percent uranium-235 and the remainder by weight essentially uranium-238), found in nature, that is neither enriched nor depleted in the isotope uranium 235.¶
- (86) "Nonstochastic effect" means a health effect that varies with the dose and a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, "deterministic effect" is an equivalent term.¶
- (87) "Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as "special form radioactive material". See "Special form."¶
- (88) "NRC" is the acronym for Nuclear Regulatory Commission.¶
- (89) "Nuclear Regulatory Commission" ("NRC" or "Commission") means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.¶
- (90) "Package" means the packaging together with its radioactive contents as presented for transport.¶
- (91) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one MeV.¶
- (92) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing.¶
- (93) "Personnel monitoring equipment" means devices such as film badges, pocket dosimeters, and thermoluminescent dosimeters designed to be worn or carried by an individual for the purpose of estimating the dose received by the individual. See "Individual monitoring devices."¶
- (94) "Pharmacist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.¶
- (95) "Physician" means an individual licensed by the Oregon Medical Board to dispense drugs in the practice of medicine.¶
- (96) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.¶
- (97) "Portable gauge" means a measuring or controlling device that is intended to be portable and is not fixed to a specific location. All portable gauges require a specific license (there is no general license granted for portable generally licensed devices in the State of Oregon).¶
- (98) "Program" means the Radiation Protection Services section of the Public Health Division of the Oregon Health Authority.¶
- (99) "Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below 130°F (54.4°C).¶
- (100) "Pyrophoric solid" means any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.¶
- (101) "Qualified expert" means an individual, approved by the Authority, who has demonstrated, pursuant to these rules, that he/she possesses the knowledge, skills, and training to measure ionizing radiation, to evaluate radiation parameters, to evaluate safety techniques, and to advise regarding radiation protection needs. The individual must:¶
- (a) Be certified in the appropriate field by the American Board of Radiology, the American Board of Health Physics, the American Board of Medical Physics or the American Board of Nuclear Medicine Science; or¶
- (b) Hold a master's or doctor's degree in physics, biophysics, radiological physics, health physics, or medical physics and have completed one year of documented, full time training in the appropriate field and also one year

of documented, full time work experience under the supervision of a qualified expert in the appropriate field. To meet this requirement, the individual must have performed the tasks required of a qualified expert during the year of work experience; or¶

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

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

(103) "Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.¶

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

(105) "Radiation" means:¶

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

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

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

(106) "Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.¶

(107) "Radiation machine tube" means a device for generating X-rays by accelerating electrons to high energies and causing them to strike a metal target from which the X-rays are emitted.¶

(108) "Radiation safety officer" means:¶

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

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

(109) "Radioactive material" means any solid, liquid, or gas that emits radiation spontaneously.¶

(a) Radioactive material, as used in these rules, includes: byproduct material, naturally occurring radioactive material, accelerator produced material, and source material, as defined in this rule.¶

(b) Radioactive material, as used in these rules, does not include special nuclear material.¶

(110) "Radioactive waste" means radioactive material that is unwanted or is unusable, as defined in division 50 of chapter 345. No radioactive material may be disposed of in Oregon except as provided in division 50 of chapter 345.¶

(111) "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.¶

(112) "Reference Man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the Reference Man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."¶

(113) "Registrant" means any person who is registered with the Authority and is legally obligated to register with the Authority pursuant to these rules and the Act.¶

(114) "Registration" means the identification of any material or device emitting radiation, and the owner of such material or device must furnish information to the Authority in accordance with the rules adopted by the Authority.¶

(115) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189 and Parts 390-397.¶

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

(117) "Research and development" means:¶

(a) Theoretical analysis, exploration, or experimentation; or¶

(b) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.¶

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

(119) "Restricted area" means an area to which access is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.¶

(120) "Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} Coulombs/kilogram of air (see "Exposure" and division 120).¶

(121) "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.¶

(122) "Screening" means the use of a systematic approach to obtain cursory examinations of a person or group of persons without regard to specific clinical indications.¶

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

(124) "Sealed Source and Device Registry" means the national registry that contains all the registration certificates, generated by both the U.S. Nuclear Regulatory Commission and Agreement States, that summarize the radiation safety information for sealed sources and devices and describe the licensing and use conditions approved for the product.¶

(125) "Shallow dose equivalent" (Hs), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of one square centimeter.¶

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

(127) "Sievert" means the International System of Units (SI), unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor ($1 \text{ Sv} = 100 \text{ rem}$). (See OAR 333-100-0070(2)).¶

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

(129) "Source material" means:¶

(a) Uranium or thorium or any combination of uranium and thorium in any physical or chemical form; or¶

(b) Ores that contain by weight one-twentieth of one percent (0.05 percent) or more of uranium, thorium, or any combination thereof. Source material does not include special nuclear material.¶

(130) "Source material milling" means any activity that result in the production of byproduct material, as defined by this rule.¶

(131) "Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation. Source of radiation, pursuant to this rule, includes, but is not limited to, radiation facilities, radiation producing machines, radiation producing devices, radioactive material sealed and unsealed form (normal form and special form), and radioactive material uses.¶

(132) "Special form radioactive material" means radioactive material that satisfies the following conditions:¶

(a) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;¶

(b) The piece or capsule has at least one dimension not less than five millimeters (0.2 inch); and¶

(c) It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, and a special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on March 31, 1996, and constructed prior to April 1, 1998, may continue to be used. Any other special form encapsulation either designed or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.¶

(133) "Special nuclear material" means:¶

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

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

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

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

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

(136) "Stochastic effect" means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

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

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

(139) "Termination" means:

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

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

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

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

(142) "Total effective dose equivalent" (TEDE) means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

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

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

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

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

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

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

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

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

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

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

(150) "Waste" means radioactive waste.

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

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

(a) The proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk

of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of WT are:¶¶

(A) Gonads 0.25;¶¶

(B) Breast 0.15;¶¶

(C) Red Bone Marrow 0.12;¶¶

(D) Lung 0.12;¶¶

(E) Thyroid 0.03;¶¶

(F) Bone Surfaces 0.03;¶¶

(G) Remainder 0.30 (see note below);¶¶

(H) Whole Body 1.00.¶¶

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

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

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

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

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

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

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

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-103-0030

RULE SUMMARY: OAR 333-103-0030, reciprocal recognition fee is being amended to remove the statement "not to exceed \$3,000 in a year" due to the directive within ORS 453.757(2) relating to the licensing fee cap to not exceed \$5,000 a year for various radioactive material licensing fees.

CHANGES TO RULE:

333-103-0030

Reciprocal Recognition Fee ¶

(1) Any radiation machine or radioactive material source brought into the state for use under reciprocity must pay a fee equal to 100 percent of the appropriate license or registration validation fee, listed in OAR 333-103-0005 or 333-103-0010, ~~not to exceed \$3,000 in a year.~~ ¶

(2) Reciprocal fees shall be due and payable prior to entry into the state. ¶

(3) An acknowledgment of fee payment, such as a certificate of validation, shall be provided by the Oregon Health Authority. The acknowledgment of fee payment must be retained by the licensee or registrant and attached to the license or registration. ¶

(4) Reciprocal fees shall not be transferred or refunded. ¶

(5) Reciprocal fees shall expire 12 months from the issue date. ¶

(6) Any use of radioactive material in Oregon pursuant to OAR 333-102-0340 exceeding 180 consecutive days may be required to apply for an Oregon specific radioactive materials license pursuant to OAR 333-102-0190.

Statutory/Other Authority: ORS 453.757

Statutes/Other Implemented: ORS 453.757

AMEND: 333-106-0325

RULE SUMMARY: OAR 333-106-0325 is being amended by allowing the use of rectangular cones for oral dental X-ray beam limitation when the minimum source-to-skin distance is less than 18 centimeters. By amending this rule, dental registrants will be able to improve the quality of diagnostic radiographs while reducing radiation exposure to the patient.

CHANGES TO RULE:

333-106-0325

Additional Requirements for Radiographic Machines: Intraoral Dental Radiographic Systems ¶¶

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

- (1) Source-to-Skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance, to not less than 18cm.¶¶
- (2) Beam Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:¶¶
 - (a) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than seven centimeters; or¶¶
 - (b) If the minimum SSD is less than 18 centimeters, the X-ray field, at the minimum SSD, shall be containable in a circle or rectangular cone having a diameter of no more than six centimeters.¶¶
- (3) Radiation Exposure Control (Timers). Means shall be provided to control the radiation exposure through the adjustment of exposure time in seconds, milliseconds (ms) or, number of pulses, or current/milliamps (mA), or the product of current and exposure time (mAs) or adjustment of kVp. In addition:¶¶
 - (a) Exposure Initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and¶¶
 - (b) It shall not be possible to make an exposure when the timer is set to a "0" or "off" position if either position is provided;¶¶
 - (c) Exposure Indication. Means shall be provided for visual indication, observable at or from the operator's protected position, whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.¶¶
 - (d) Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure time (T) shall be greater than or equal to five times the minimum exposure time (Tmax) minus the minimum exposure time (Tmin) when four timer tests are performed: $(T) > 5 (T_{max} - T_{min})$.¶¶
 - (A) Means shall be provided to terminate the exposure at a preset, time interval, mAs, number of pulses, or radiation to the image receptor.¶¶
 - (B) An X-ray exposure control shall be incorporated into each system such that an exposure can be terminated by the operator at any time, except for exposures of 0.5 second or less.¶¶
 - (C) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "0".¶¶
- (4) Radiation Exposure Control Location and Operator Protection. Each X-ray control must be located in such a way as to meet the following requirements:¶¶
 - (a) The exposure switch shall be able to be operated in a protected area, as defined in OAR 333-106-0005(78), and the operator shall remain in that protected area during the entire exposure; and¶¶
 - (b) The operator's protected area shall provide visual indication of the patient during the X-ray procedure.¶¶
 - (c) Mobile and portable X-ray systems which are:¶¶
 - (A) Used for greater than one week in the same location, such as a room or suite, shall meet the requirements of subsections (4)(a) and (4)(b) of this rule.¶¶
 - (B) Used for less than one week at the same location, such as a room or suite, shall be provided with:¶¶
 - (i) Either a protective barrier of at least 6.5 feet (2 meters) high for operator protection; or¶¶
 - (ii) A means to allow the operator to be at least nine feet (2.7 meters) from the tube housing assembly while making exposures.¶¶
- (5) Exposure Reproducibility. The coefficient of variation shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to five times the maximum exposure (Emax) minus the minimum exposure (Emin): $E > 5 (E_{max} - E_{min})$ ¶¶

(6) Accuracy.¶

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

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

(7) Administrative Controls.¶

(a) Patient and film holding devices shall be used when the techniques permit;¶

(b) The tube housing and the PID shall not be hand held during an exposure;¶

(c) The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of section (2) of this rule or its updated version;¶

(d) All pediatric patients shall wear a 0.25 mm lead equivalent thyroid collar to protect the thyroid during intraoral X-ray exposures;¶

(e) Dental fluoroscopy without image intensification shall not be used; and¶

(f) Pointed cones shall not be utilized unless specific authorization has been granted by the Authority Oregon Health Authority (Authority).¶

(8) Hand-held X-ray systems.¶

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

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

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

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

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

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

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

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

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

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

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

(c) Operators must complete machine specific applications training as described in OAR 333-106-0055(9) before using a hand-held unit. Training on the safe use of the unit shall be documented and include at a minimum:¶

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

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

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

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

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

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

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

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

Statutory/Other Authority: ORS 453.605 - 453.807

Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-116-1000

RULE SUMMARY: OAR 333-116-1000 is being amended by removing rule reference OAR 333-116-0020 from the rule since the referenced rule does not provide the criteria to define a medical event. In addition, the amended rule corrects a minor grammar error.

CHANGES TO RULE:

333-116-1000

Report and Notification of a Medical Event ¶

(1) A licensee must report any medical event ~~as defined in OAR 333-116-0020~~, except for an event that results from patient intervention, in which:¶

(a) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in:¶

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

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;¶

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or¶

(iii) The fractionated dose delivered differs from the prescribed dose for a single fraction by 50 percent or more.¶

(B) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:¶

(i) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;¶

(ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;¶

(iii) An administration of a dose or dosage to the wrong individual or human research subject;¶

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or¶

(v) A leaking sealed source.¶

(C) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:¶

(i) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and¶

(ii) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.¶

(b) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:¶

(A) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;¶

(B) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or¶

(C) An administration of a source that includes any of the following: ¶

(i) The wrong radionuclide;¶

(ii) The wrong individual or human research subject;¶

(iii) Sealed source(s) implanted directly into a location discontinuous from the treatment site, as documented in the post-implantation portion of the written directive; or¶

(iv) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.¶

(2) The licensee must notify by telephone the Authority Oregon Health Authority (Authority) no later than the next calendar day after discovery of the medical event.¶

(3) The licensee must submit a written report to the Authority within 15 days after discovery of the medical event.¶

(a) The written report must include:¶

(A) The licensee's name;¶

(B) The name of the prescribing physician;¶

(C) A brief description of the event;¶

(D) Why the event occurred;¶

(E) The effect, if any, on the individual(s) who received the administration;¶

(F) What actions, if any, have been taken or are planned to prevent recurrence; and¶

(G) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.¶

(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.¶

(4) The licensee must provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that they will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee must notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this rule, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee must inform the individual, or appropriate responsible relative or guardian that a written description of the event can be obtained from the licensee upon request. The licensee must provide such a written description if requested.¶

(5) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.¶

(6) A licensee shall:¶

(a) Maintain a copy of the report described in section (3) of this rule and annotate as follows:¶

(A) Name of the individual who is the subject of the event; and¶

(B) Identification number, or if no other identification number is available, the Social Security number of the individual who is the subject of the event.¶

(b) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-120-0015

RULE SUMMARY: OAR 333-120-0015 is being amended to better define a radiation area by inserting language that means radiation areas expose persons from radioactive materials within a specific area.

CHANGES TO RULE:

333-120-0015

General Provisions: Definitions ¶¶

- (1) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.¶¶
- (2) "Activity" is the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the becquerel (Bq) and the Curie (Ci). The becquerel is equal to one disintegration per second (dps) and the Curie is equal to 3.7×10^{10} dps.¶¶
- (3) "Accelerator produced radioactive material" means any material made radioactive by a particle accelerator.¶¶
- (4) "Adult" means an individual 18 or more years of age.¶¶
- (5) "Airborne radioactive material" means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.¶¶
- (6) "Airborne radioactivity area" means a room, enclosure, or area in which the airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations:¶¶
 - (a) In excess of the derived air concentrations (DACs) specified in 10 CFR 20 Appendix B; or¶¶
 - (b) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours present in a week, and intake of 0.6 percent of the annual limit of intake (ALI) or 12 DAC hours.¶¶
- (7) "Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.¶¶
- (8) "ALARA" (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this division as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the use of licensed materials in the public interest.¶¶
- (9) "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 on page 1 of Tables 1, 2, and 3, Appendix B to 10 CFR Part 20.¶¶
- (10) "Assigned protection factor (APF)" means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.¶¶
- (11) "Atmosphere supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.¶¶
- (12) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive material, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include radiation from radioactive or special nuclear materials regulated by the Oregon Health Authority.¶¶
- (13) "Bioassay" (radiobioassay) means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.¶¶
- (14) "Byproduct material" means:¶¶
 - (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 using special nuclear material.¶¶
 - (b) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute

byproduct material" within this definition.¶

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

(d) Any discrete source of naturally occurring radioactive material, other than source materials, that:¶

(A) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency determines a threat to the public health and safety or the common defense, is similar to the threat posed by a discrete source of radium-226 material to the public health and safety or the common defense and security; and¶

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

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

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

(17) "Committed dose equivalent" (HT,50) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.¶

(18) "Committed effective dose equivalent" (HE,50) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues (HE,50) = The Sum of WTHT,50.¶

(19) "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.¶

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

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

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

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

(24) "Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:¶

(a) Release of the property for unrestricted use and termination of the license; or¶

(b) Release of the property under restricted conditions and termination of the license.¶

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

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

(27) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of 10 CFR 20 Appendix B.¶

(28) "Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).¶

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

(30) "Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life

renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).¶

(31) "Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.¶

(32) "Dose or radiation dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in this rule.¶

(33) "Dose equivalent" (HT) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).¶

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

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

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

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

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

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

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

(41) "Eye dose equivalent" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm²). (See "lens dose equivalent").¶

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

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

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

(45) "Generally applicable environmental radiation standards" means standards issued by the Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.¶

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

~~(47) "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of one mSv (0.1 rem) in one hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.¶~~

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

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

~~(50) "Individual monitoring" means:¶~~

~~(a) The assessment of dose equivalent by the use of devices designed to be worn by an individual;¶~~

~~(b) The assessment of committed effective dose equivalent by bioassay (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e. such as DAC-hours; or¶~~

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

~~(51) "Individual monitoring devices" (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.¶~~

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

~~(53) "Lens dose equivalent (LDE)" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm²).¶~~

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

(554) "Member of the public" means any individual except when that individual is receiving an occupational dose.¶

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

(576) "Monitoring (radiation monitoring, radiation protection monitoring)" means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.¶

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

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

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

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

(6059) "Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these regulations, "deterministic effect" is an equivalent term.¶

(610) "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material for medical purposes and released under OAR 333-116-0260, from voluntary participation in medical research programs, or as a member of the public.¶

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

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

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

(654) "Powered air purifying respirator" (PAPR) means an air purifying respirator that uses a blower to force the ambient air through air purifying elements to the inlet covering.¶

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

(676) "Public dose" means the dose received by a member of the public from exposure to radiation or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material for medical purposes and released under OAR 333-116-0260, or from voluntary participation in medical research programs.¶

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

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

(7069) "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.¶

(710) "Radiation" (ionizing radiation) means alpha particles, beta particles, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Radiation, as used in this part, does not include non-ionizing radiation, such as radio- or microwaves, or visible, infrared, or ultraviolet light.¶

(721) "Radiation areas" means an area, where accessible to individuals, in which individuals may be exposed to radioactive materials. Radiation areas include the following categories:¶

(a) "Radiation area" means an area accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.¶

(73b) "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of one mSv (0.1

rem) in one hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.¶

(c) "Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of five gray (500 rad) in one hour at one meter from a source of radiation or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.¶

(72) "Reference man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health employees to standardize results of experiments and to relate biological insult to a common base. A description of the reference man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."¶

(743) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site.¶

(754) "Restricted area" means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.¶

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

(776) "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.¶

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

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

(8079) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.¶

(810) "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these regulations, "probabilistic effect" is an equivalent term.¶

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

(832) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.¶

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

(854) "Total Effective Dose Equivalent" (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).¶

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

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

(88) "Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of five gray (500 rad) in one hour at one meter from a source of radiation or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.¶

(897) "Waste" means those low-level radioactive wastes containing source, special nuclear or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel or byproduct material as defined in subsections (14)(b), (14)(c), and (14)(d) of this rule.¶

(9088) "Weighting factor" (WT) for an organ or tissue means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of WT are:¶

Organ Dose Weighting Factors¶

Organ or Tissue - WT¶

Gonads - 0.25¶

Breast - 0.15¶

Red bone marrow - 0.12¶

Lung - 0.12¶

Thyroid - 0.03¶

Bone surfaces - 0.03¶

Remainder - 0.30 (see (a) below)¶

Whole Body - 1.00 (see (b) below)¶

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

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

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

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

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

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-123-0015

RULE SUMMARY: OAR 333-123-0015 is being amended to clarify that the X-ray registrant must ensure direct supervision of a non-certified Medical Physicist by a Medical Physicist who is certified in Therapeutic Radiological Physicist or Radiation Oncology.

CHANGES TO RULE:

333-123-0015

Training and Qualification Requirements for Individuals in the External Beam Radiation Therapy Area ¶

(1) Radiation Therapy Physician. The registrant for any therapeutic radiation machine subject to OAR 333-123-0030 must require that the Radiation Therapy Physician be:¶

(a) Licensed by an appropriate Oregon medical licensing board; and¶

(b) Certified in:¶

(A) Radiology, Therapeutic Radiology or Radiation Oncology by the American Board of Radiology; or¶

(B) Radiation Oncology by the American Osteopathic Board of Radiology; or¶

(C) Radiology, with specialization in Radiotherapy, as a British Fellow of the Faculty of Radiology or Fellow of the Royal College of Radiology; or¶

(D) Therapeutic Radiology by the Canadian Royal College of Physicians and Surgeons; or¶

(c) Actively pursuing board certification in therapeutic radiology, and completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years full-time supervised clinical experience.¶

(A) To satisfy the requirement for instruction, the classroom and laboratory training must include:¶

(i) Radiation physics and instrumentation; and¶

(ii) Radiation protection; and¶

(iii) Mathematics pertaining to the use and measurement of ionization radiation; and¶

(iv) Radiation biology.¶

(B) To satisfy the requirement for supervised work experience, training must be under the supervision of a Radiation Therapy Physician qualified pursuant to subsections (1)(a) or (b) of this rule and must include:¶

(i) Review of the full calibration measurements and periodic quality assurance checks; and¶

(ii) Evaluation of prepared treatment plans and calculation of treatment times and patient treatment settings; and¶

(iii) Using administrative controls to prevent medical treatment events; and¶

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and¶

(v) Checking and using radiation survey meters.¶

(C) To satisfy the requirement for a period of supervised clinical experience, training must include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of a Qualified Radiation Therapy Physician. The supervised clinical experience must include:¶

(i) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications; and¶

(ii) Selecting proper dose and how it is to be administered; and¶

(iii) Calculating the external beam radiation therapy doses and collaborating with the Qualified Radiation Therapy Physician in the review of patients' progress and consideration of the need to modify originally prescribed doses and treatment plans as warranted by patients' reaction to radiation; and¶

(iv) Post-administration follow-up and review of case histories.¶

(d) To demonstrate compliance with subsections (1)(a) through (c) of this rule, the individual must obtain written documentation that he or she has satisfactorily completed these requirements and have achieved a level of competency sufficient to function independently as a qualified radiation therapy physician. The documentation must be from the entities or individual(s) specified in this rule.¶

(e) Notwithstanding the requirements of subsections (1)(a) and (b) of this rule, the registrant for any therapeutic radiation machine subject to OAR 333-123-0025 may also submit the training of the prospective Radiation Therapy Physician for ~~Authority~~ Oregon Health Authority (Authority) review on a case-by-case basis.¶

(f) A physician must not act as a Radiation Therapy Physician for any therapeutic radiation machine until said physician's training has been reviewed and approved by the appropriate state licensing body.¶

(g) A registrant may permit any physician to act as a visiting Radiation Therapy Physician under the term of the

registrant's Certificate of Registration for up to 60 days per calendar year under the following conditions:¶
(A) The visiting Radiation Therapy Physician has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee (where applicable); and¶
(B) The visiting Radiation Therapy Physician meets the requirements established in section (1) of this rule; and¶
(C) The registrant maintains copies of all records specified in subsection (1)(i) of this rule for five years from the date of the last visit.¶

(2) Medical Physicist Qualifications. The registrant for any therapeutic radiation machine subject to OAR 333-123-0025 must require that the Medical Physicist(s), who are providing consultative services to them be licensed with the Authority, under the provisions of OAR 333-101-0020, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units (The licensing requirement is only applicable to those physicists who provide medical physics consultation to facilities other than those of the registrant of which they are an employee).¶

(a) All Medical Physicists practicing in therapeutic radiological physics must be certified in Therapeutic Radiological Physics or Radiation Oncology by the:¶

(A) American Board of Radiology; or¶

(B) American Board of Medical Physics; or¶

(C) Canadian College of Physicists in Medicine.¶

(b) To demonstrate compliance, the individual must obtain written documentation that he or she is Board certified. The documentation must be from the credentialing body.¶

(c) Medical Physicists who, prior to January 1, 2007, have been actively working in the area of therapeutic radiation in the state of Oregon or licensed with the Authority to provide therapeutic radiation medical physics services in Oregon, are exempt from the certification requirement in subsection (2)(b) of this rule.¶

(d) Medical Physicists who, on or after January 1, 2007, wish to work in the area of therapeutic radiation or to be licensed with the Authority to provide therapeutic radiation services, must meet the certification requirements in subsection (2)(b) of this rule.¶

(e) Medical Physicists who do not meet the requirements of subsection (2)(b) of this rule must work under ~~the~~ direct supervision as defined in OAR 333-106-0005 of a Qualified Medical Physicist.¶

(3) Therapeutic Radiation Machine Operator's Qualifications. Individuals who will be operating a therapeutic radiation machine for medical use must be registered with the American Registry of Radiologic Technologists (ARRT) as a radiation therapist with the credential RT(T)(ARRT). Individuals who do not meet this criterion must submit evidence that they have satisfactorily completed a radiation therapy technologist training program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology.¶

(a) Individuals who have been operating a therapeutic radiation machine prior to January 1, 2007 shall be exempt from the requirement in section (3) of this rule.¶

(b) The names and training records of all personnel currently operating a therapeutic radiation machine must be kept on file at the facility. Training records of former operators must be retained for a period of at least two years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

Statutory/Other Authority: ORS 453.605 - 453.807

Statutes/Other Implemented: ORS 453.605 - 453.807