333-102-0203

#### Definitions

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

- (9) "Commencement of construction" means taking any action defined as "construction" or any other activity at the site of a facility subject to the regulations in this division that has a reasonable nexus to radiological health and safety, any clearing of land, excavation or other substantial action related to a proposed activity for specific licensing that can adversely affect the natural environment of a site.
- (10) "Construction" means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the regulations in this part that are related to radiological safety or security. The term "construction" does not include:
- (a) Changes for temporary use of the land for public recreational purposes;
- (b) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;
- (c) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;
- (d) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this part:
- (e) Excavation;
- (f) Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;
- (g) Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);
- (h) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or
- (i) Taking any other action that has no reasonable nexus to radiological health and safety

#### 333-102-0305

## Specific Terms and Conditions of License

- Each license issued pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120, 121 and 124 of this chapter are subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations and orders of the Authority.
- (2) No license issued or granted pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter nor any right may be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Authority, after securing full information, shall find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.
- (3) An application for transfer of license must include:
- (a) The identity, technical and financial qualification of the proposed transferce; and
- (b) Financial assurance for decommissioning as required by OAR 333-102-0200(6)

333-106-0005

## Definitions

As used in this division, the following definitions apply:

- (34) "Direct supervision" means that the person who directs the X-ray or fluoroscopic equipment operator(s) shall be present in the room while the individual operates the equipment.
- (4243) "General supervision" means that the person who directs the X-ray or thuoroscopic equipment operator(s), must be immediately available by telephone, pager, or other mode of communication, to provide direction if needed or requested.
- (501) "Indirect supervision" means that the person who directs the X-ray or fluoroscopic equipment operator(s) be readily available on facility premises when the X-ray or fluoroscopic equipment is operated.
- (8023) "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 shall:

- (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 general supervision of a qualified expert in the appropriate field. To meet this requirement, the individual shall have performed the tasks required of a qualified expert during the year of work experience; or
- (c) Receive approval from the Authority for specific activities.
- (10810) "Supervision" means the supervising individual routinely reviews and monitors the work being performed. There are three categories of supervision:
- (a) "General Supervision" means that the supervisor is not required to be on-site, but must be available for direct communication, either in person, by telephone, or other electronic means.
- (b) "Direct Supervision" means that the supervisor is physically present in the building and immediately available to furnish assistance as needed.
- (c) "Personal Supervision" means that the supervisor is physically present in the room during the performance of the procedure at all times.

333-106-0025

#### Protection of Patients and Personnel

(1) (1) Except for patients who cannot be moved out of the unprotected area, only the staff and ancillary personnel required for the medical procedure or training shall be in the unprotected area during the radiographic exposure.

### Other than the patient being examined:

- (42) Other than the patient being examined, Aall individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter (mm) lead equivalent.
- (23) Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent.
- (34) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 mm lead equivalent or shall be

so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & cf. 3-20-85; HD 1-1991, f. & cert. cf. 1-8-91; PII 12-2006, f. &

cert, ef. 6-16-06

333-106-0040

Patient Holding and Restraint

- (1) When a patient or film must be provided with auxiliary support during a radiation exposure:
- (4a) Mechanical holding devices shall be provided and used when the technique permits. The safety rules, required by OAR 333-106-0020 of these rules, shall list individual projections where holding devices cannot be used.
- (2b) Written safety procedures, as required by OAR 333-106-0020 of these rules, shall indicate the requirements for selecting a holder and the procedure the holder shall follow.
- $(3\underline{c})$  The human holder shall be protected, as required by OAR 333-106-0025(1) and (2) of these rules.
- (42) No individual shall be used routinely to hold film or patients.
- (53) Occupationally exposed personnel are prohibited from holding human patients during radiographic examination.
- (64) The Authority may require a separate record to be maintained which would include the name of the human holder, date of the examination, number of exposures and technique factor used for the exposure(s).
- (75) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest exposed to the useful beam shall be protected by not less than 0.5 mm lead equivalent material.
- (86) Holding of patients shall be permitted only when it is otherwise impossible to obtain the necessary radiograph.
- (97) Individuals stressing joints shall be exempt from section (35) of this rule.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: IID 4-1985, f. & cf. 3-20-85; HD 1-1991, f. & ccrt. cf. 1-8-91; PH 12-2006, f. & ccrt. cf. 6-16-06; PH 14-2008, f. & ccrt. cf. 9-15-08

### 333-106-0045

## Use of Best Procedures and Equipment

- (1) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. <del>This is</del> interpreted to include, but is not limited to:
- (42) This is interpreted to include, but is not limited to, : The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.
- (23) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality, see Tables 1, 2 and 3. The referenced tables are available on the Program's website: www.healthoregon.org/rps.
- (34) Portable or mobile X-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary X-ray installation due to the medical status of the patient or the inability of the patient to be left alone during the imaging procedure except as permitted under section (4) of this rule.
- (45) Hand-held dental units may be used at facilities or programs as defined in ORS 680.205(1) and (2).
- (56) X-ray systems subject to OAR 333-106-0301(1) shall not be utilized in procedures where the source to patient distance is less than 30 centimeters (cm).
  - (67) Cardboard cassettes without screens shall not be used (dental intraoral excluded).
  - (78) The number of radiographs taken for any radiographic examination should be the minimum number needed to adequately diagnose the clinical condition.
- (89) Use of techniques designed to compensate for anatomical thickness variations after the primary beam has exited the patient is specifically prohibited. This includes "split screen" imaging techniques whereby multiple speed intensifying screens are placed in the same cassette, or any techniques which rely on attenuation of secondary (remnant) radiation for compensatory purposes. Lead lined grids, which are designed to reduce scattered radiation are excluded from this provision.
- (910) Filter slot covers shall be provided for the X-ray operator's protection.
- (4011) Facilities shall determine or cause to be measured the typical patient exposure for their most common radiographic examinations. The exposures shall be recorded as

milliroentgens measured in free air at the point of skin entrance for an average patient. These exposure amounts must then be compared to existing guidelines and rules, and if they exceed such guidelines or rules, action must be taken to reduce the exposure while at the same time maintaining or improving diagnostic image quality. In addition, typical patient exposure values shall be posted in the radiographic examination rooms so that they are readily available to administrators, X-ray operators, patients and practitioners.

- (4112) Protective equipment including aprons, gloves and shields shall be checked annually for defects, such as holes, cracks and tears to assure reliability and integrity. A record of this test shall be made and maintained for inspection by the Authority. If such defect is found, equipment shall be replaced or removed from service until repaired. Fluoroscopy shall only be used for this purpose if a visual and manual check indicated a potential problem.
- (4213) Dental X-ray machines designed and manufactured to be used for dental purposes shall be restricted to dental use only.
- (4314) An X-ray quality control program shall be implemented when required by the Authority.
- (44<u>15</u>) All X-ray equipment must be capable of functioning at the manufacturer's intended specifications.
- (4516) All patients' radiographic images or copies shall be made available for review by any practitioner of the healing arts, currently licensed by the appropriate Oregon licensing board, upon request of the patient.
  - (16) Requirements for the operation of fluoroscopic X ray equipment. The operation of fluoroscopic equipment shall be restricted to the following categories of properly trained operators:
  - (a) Radiologists;
  - (b) Non Radiologist practitioners with proper training in the operation and use of fluoroscopic X ray equipment;
  - (c) R.T.s, must be ARRT registered and in good standing with the Oregon Board of Medical Imaging.;
- (d) R.P.A.s and R.R.A.s;
- (e) Technologists, who have successfully completed an educational program in radiologic technology from an approved school as defined in ORS 688.405, may temporarily operate fluoroscopic equipment for up to one year as outlined in OAR 337 010-0045 while waiting to take the ARRT registry examination.

- (A) The temporary period expires when the individual has passed the registry examination and is considered an R.T.; or
- (B) One year from the date when the technologist completed his/her training, provided; and
- (C) The technologist, while in the temporary status referred to in subsection (16)(e) of this rule, has a current temporary license issued by the Oregon Board of Medical Imaging..
- (1) The operation of fluoroscopic equipment by R.T.s, or R.P.A.s or R.R.A.s shall be performed under the supervision of a radiologist and is restricted to the healing arts exclusively for the purpose of localization and to assist physicians in obtaining images for diagnostic purposes.
- (g) Where direct or indirect supervision by a radiologist is impractical, a non-radiologist practitioner who has had proper training in the use and operation of fluoroscopic X-ray equipment is permitted to supervise an R.T. operating fluoroscopic equipment provided that the registrant arranges to have a radiologist or Medical or Health physicist to assist in;
- (A) Developing fluoroscopic and radiation safety policies and procedures;
- (B) Conducting an on-site practical evaluation of the Non-Radiologist practitioner's knowledge of radiation safety practices and ability to operate the fluoroscopic equipment; and
- (C) At least annually, review the registrant's fluoroscopy program. The review includes an evaluation of the fluoroscopic on times Quality Assurance reports, condition of fluoroscopic equipment and compliance with current rules. The registrant shall correct any deficiencies noted by the review.
- (h) The operation of fluoroscopic equipment by a R.T. is restricted to the healing arts exclusively for the purpose of localization and to assist physicians in obtaining images for diagnostic purposes.
- (i) Students currently enrolled in an approved school of Radiologic Technology as defined in ORS 688.405, may only operate fluoroscopic equipment under the direct supervision of a Radiologist or a R.T. while in the clinical phase of training.
- (j) Students currently enrolled in an Authority approved R.P.A. or R.A. training program, may only operate fluoroscopic equipment under the direct or in direct supervision of a Radiologist during their clinical phase of training.

(k) Overhead fluoroscopy is not to be used as a positioning tool for radiog examinations except for those fluoroscopic examinations specified in the written policies/procedures for fluoroscopy.	
(1) Proper training in the operation of fluoroscopic X-ray equipment shall-be limited to the following:	inelude but not
(A) Principles and operation of the fluoroscopic X-ray machine;	
(i) Generating X-rays;	
(ii) kVp and mA;	
(iii) Image intensification;	
(iv) High level control versus standard operating mode;	
(v) Magnification (multi-field);	
(vi) Automatic Brightness Control (ABC);	5%
(vii) Pulsed versus Continuous X ray Dose Rates;	
(viii) Image recording modes;	
(ix) Imaging Systems (TV and Digital);	Œ
(x) Contrast, noise and resolution;	
(B) Radiation units;	8
(i) Traditional units;	
(ii) SI units;	
(iii) Dose Area Product;	
(C) Typical fluoroscopic outputs;	
(i) Patient skin entrance dose;	
(ii) Standard Roentgen per minute (R/min) dose-rates;	
(iii) High level/Boost enable Roentgen per minute (R/min) dose rates;	

(D) Dose reduction techniques for fluoroscopy;

(i) The use of collimation;	
(ii) X-ray tube and Image intensifier placement;	
(iii) Patient size versus Technique selection;	
(iv) Use of grid;	
(v) Use of last image hold;	
(vi) Additional-beam-filtration;	
(vii) Alternate gantry angles;	
(viii) Use of spacer cone;	
(ix) Pulsed fluoroscopy;	
(E) Factors affecting personnel dose;	
(i) Patient-dose;	
(ii) Scatter radiation;	
(iii) Tube and Image intensifier placement;	
(iv) Time, distance and shielding;	
(F) Protective devices;	
(i) Lead aprons and gloves;	
(ii) Thyroid collars;	
(iii) Protective glasses;	
(iv) Leaded drapes;	
(v) Bucky slot cover;	
(vi) Proteetive shields/barriers;	
(G) Radiation exposure monitoring;	
(i) Personnel monitors;	

(ii) Placement of personnel monitors; (iii) Occupational and non-occupational dose limits; (H) Biological effects of X ray radiation; (i) X rays and particulate matter; (ii) Absorption variables (field size, dose rate, etc.); (iii) Scatter radiation; (iv) Cell sensitivity: (v) Acute effects; (vi) Latent effects; Applicable regulations; (i) Federal; and (ii) Oregon Rules for the Control of Radiation to include, but not limited to, divisions 101, 103, 106, 111 and 120. (17) Radiologists, R.A.s or R.P.A.s and R.T.s currently licensed in Oregon are considered to have met the training requirements in subsection (16)(1) of this rule. (18) Fluoroscopic equipment operators who qualified to operate fluoroscopic X-ray equipment prior to April 11, 2005, are considered as having met the training requirements in subsection (16)(1) of this rule. (19) All images formed by the use of fluoroscopy shall be viewed, directly or indirectly, and interpreted by a radiologist, cardiologist, non-radiologist practitioner or other qualified specialist. R.As and R.P.As may issue a preliminary report, however, the final report must be issued by their supervising radiologist. (20) Written procedures for fluoroscopic X ray equipment operators shall be available at the worksite and include: (a) A list of all individuals who are permitted to operate fluoroscopic X-ray equipment at the facility;

(b) A list of the fluoroscopic X-ray equipment that each operator is qualified to operate;

- (e) Written procedures regarding the set up and operation of each fluoroscopic X-ray machine registered to the facility;
- (d) Written radiation safety procedures pertaining to the use and operation of fluoroscopy; and
- (e) The name and title of the individual who is responsible for the direction of R.T.s who operate fluoroscopic equipment.
- (21) Facilities shall determine, or cause to be determined, the typical patient entrance exposure rate for their most common fluoroscopic examinations. The determination shall be made using an attenuation block as described in OAR 333-106-0005(7)using measurement protocol in compliance with OAR 333-106-0210 and expressed in Roentgens per minute (R/min.) or milliRoentgens per minute (mR/min.). In addition, these entrance exposure rates shall be posted in the room where fluoroscopic examinations are conducted so that they are readily available to administrators, X-ray operators, patients and practitioners.
- (22) Facilities that utilize fluoroscopy shall maintain a record of the cumulative fluoroscopic exposure time used for each examination. The record must indicate the patients name, the type of examination, the date of the examination, the fluoroscopists name, the fluoroscopic room in which the examination was done and the total cumulative fluoroscopic on time for each fluoroscopic examination and:
- (a) No later than May 1, 2006, establish cumulative fluoroscopic on time benchmarks for at least two (if applicable) of the most common types of fluoroscopic examinations performed at the facility's site in each of the following categories:
- (A) Routine procedures performed on adults;
- (B) Routine procedures performed on children;
- (C) Orthopedic procedures performed in surgery;
- (D) Urologic procedures performed in surgery;
- (E) Angiographic procedures performed;
- (F) Interventional cardiac studies.
- (b) Develop and perform periodic (not to exceed 12 month intervals) quality assurance studies to determine the status of each individual fluoroscopist's cumulative on time in relation to the fluoroscopic benchmarks established for individual fluoroscopic examinations:

(e) Take appropriate action, when the established benchmarks are consistently exceeded. The Radiation Safety Committee (RSC) must review the results of the cumulative fluoroscopic on time Quality Assurance Study and take corrective action regarding those individuals who have exceeded the benchmarks established by the facility for a particular procedure more than ten percent of the total times the individual performed the procedure during the study period. Documentation of the RSC review, as well as any corrective actions taken, must be available for Authority review. Corrective actions, at a minimum, include:

## (A) Notification of the individual; and

(B) Recommendation that the individual undergo additional coaching, training, etc. in the safe use of fluoroscopic equipment in order to assist them in reducing their cumulative fluoroscopic on-times.

[ED. NOTE: Tables referenced are not included in rule text. Click here for PDF copy of table(s).]

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & cf. 3-20-85; HD 1-1991, f. & cert. cf. 1-8-91; HD 15-1994, f. & cert. cf. 5-6-94; HD 24-1994, f. & cert. cf. 9-6-94; HD 1-1995, f. & cert. cf. 4-26-95; PII 3-2003, f. & cert. cf. 3-27-03; PH 31-2004(Tcmp), f. & cert. cf. 10-8-04 thru 4-5-05; PII 36-2004, f. & cert. cf. 12-1-04; PH 5-2005, f. & cert. cf. 4-11-05; PII 12-2006, f. & cert. cf. 6-16-06; PH 14-2008, f. & cert. cf. 9-15-08; PH 10-2011, f. 9-30-11, cert. cf. 10-1-11; PH 4-2013, f. & cert. cf. 1-29-13

#### 333-106-0055

## X-ray Operator Training

- (1) The registrant shall assure that individuals who will be operating the X-ray equipment by physically positioning patients or animals, determining exposure parameters, or applying radiation for diagnostic purposes shall have adequate training in radiation safety.
- (a) Radiation safety training records shall be maintained by the registrant for each individual who operates X-ray equipment. Records must be legible and meet the requirements in OAR 333-120-0690.
- (b) When requested by the Authority, radiation safety training records shall be made available.
- (2) Adequate training in radiation safety means X-ray operators have completed an Authority approved radiation use and safety course. a minimum of 40 hours of didactic instruction for diagnostic medical X-ray equipment operators, eight hours for Grenz ray

X-ray equipment operators and 20 hours for veterinary X-ray equipment operators from

(3) At a minimum, an Authority approved training course shall covering the following

- subjects: (a) Nature of X rays; (b) Interaction of X rays with matter; (c) Radiation units: (d) Principles of the X-ray machine; (e) Biological effects of X-ray; (f) Principles of radiation protection; (g) Low dose techniques; (h) Applicable federal and state radiation regulations including those portions of divisions 100, 101, 103, 106, 111 and 120 of chapter 333; (i) Darkroom and film processing; (i) Film critique; and
- (k) Animal restraint training (for veterinary technologists or assistants only).

NOTE: Subsections (1)(g), (1)(i), (1)(j) and (1)(k) of this rule are not required for Grenz ray X-ray equipment operator training.

- (a) Nature of X-rays
- (A) Interaction of X-rays with matter
- (B) Radiation units
- (C) X-ray production
- (D) Biological effects of X-rays
- (E) Risks of radiation exposure
- (b) Principles of the X-ray machine

(A) External structures and operating console (B) Internal Structures (i) Anode (ii) Cathode (C) Operation of an X-ray machine (D) Tube warm up (E) Factors affecting X-ray emission (i) mA (ii) kVp (iii) Filtration (iv) Voltage waveform (c) Principles of radiation protection (A) Collimation (B) Types of personal protection equipment & who must wear it (C) ALARA (D) Time, distance, shielding (E) Operator safety (F) Personal Dosimetry (i) Types of Dosimetry (ii) Proper placement of dosimetry (iii) Situations that require dosimetry (G) Occupational and non-occupational dose limits

(d) Radiographic technique

(A) Factors affecting technique choice (i) Thickness of part (ii) Body composition (iii) Pathology (iv) Film verses CR and DR (B) How to develop an accurate chart (C) Low dose techniques (D) Pediatric techniques (does not apply to veterinary) (E) AEC Techniques (e) Darkroom (A) Safelights (B) Chemical storage (C) Film storage (D) Darkroom cleanliness (f) Image processing (A) Automatic film processing (B) Dip tank film processing (C) Computed radiography (CR) processing (D) Digital radiography (DR) processing (g) Image critique (A) Reading room conditions (B) Light box conditions

(C) Image identification

- (D) Artifacts
- (E) Exposure indicators for CR and DR
- (F) Technical parameter evaluation
- (G) Positioning evaluation
- (h) Veterinary X-ray Use (for veterinary courses only)
- (Λ) Types of animal restraints
- (B) Small animal vs. large animal
- (C) Film holders
- (D) Portable X-ray machine safety
- (i) Applicable federal and state radiation regulations including those portions of chapter 333, division 100, 101, 103, 106, 111, 120, and 124
- (24) Dental X-ray operators who meet the following requirements are considered to have met the requirements in section (1) of this rule:
- (a) Currently licensed by the Oregon Board of Dentistry as a Dentist or Dental Hygienist; or
- (b) Is a Dental Assistant who is certified by the Oregon Board of Dentistry in radiologic proficiency,; and
- (c) Successfully completed didactic and clinical radiography training covering the subject areas outlined in section (1) of this rule; and
- (d) Passed the Radiation Health and Safety (RHS) or the Certified Dental Assistant (CDA) examination administered by the Dental Assisting National Board, Inc. (DANB) and clinical radiography examination or other comparable requirements approved by the Oregon Board of Dentistry.
- (c) Dental radiology students in an approved Oregon Board of Dentistry dental radiology course are permitted to take dental radiographs on human patients during their clinical training, under the indirect general [CH1] supervision of a Dentist or Dental Hygienist currently licensed, or a dental assistant who has been certified in radiologic proficiency, by the Oregon Board of Dentistry. -provided that:
- (A) They are enrolled in an Oregon Board of Dentistry approved radiology course; or

- (B) A student studying under an Oregon Board of Dentistry approved radiology instructor; and
- (C) The student has written authorization, signed by their instructor, attesting that the student has successfully completed training in the subject areas in section (3) of this rule; and
- (D) Demonstrated to the instructor that they are ready to take dental radiographs on human patients through:
- (i) The use of mannequins under indirect supervision; or
- (ii) Taking dental radiographs of human patients while under the direct supervision of the instructor; and
- (iii) The written authorization is on the training program or Oregon Board of Dentistry approved instructor's letterhead, a copy of which is maintained at the site(s) of their clinical training and available for review by the Oregon Health Authority, Public Health Division inspection staff at the time of inspection.
- (E) A student is considered to be in "student status" until they have successfully completed the clinical phase of their training. "Student status" shall not exceed a period of 12 consecutive months:
- (F) The students identified in section (8) of this rule are prohibited from taking radiographs on human patients without proper authorization from a practitioner of the healing arts who is currently licensed in Oregon, as required in OAR 333-106-0035 of these rules.
- (3) Medical X-ray equipment operators not regulated by the Oregon Board of Medical Imaging. In addition to the above, medical X-ray equipment operators using diagnostic radiographic equipment on human patients, and who are not regulated by the Oregon Board of Medical Imaging must have 100 hours or more of instruction in radiologic technology including, but not limited to, anatomy physiology, patient positioning, exposure and technique. The instruction must be appropriate to the types of X-ray examinations that the individual will be performing; and
- (a) Have 200 hours or more of X-ray laboratory instruction and practice in the actual use of an energized X-ray unit, setting techniques and practicing positioning of the appropriate diagnostic radiographic procedures that they intend to administer; and
- (b) Must have completed the required radiation use and safety hours and a minimum of 50 hours in X-ray laboratory before X-raying a human patient.

- -(4) Radiation Use and Safety Instructor Qualifications. The training required in sections (1), (2) and (3) of this rule must be taught by an Authority approved instructor. Approval will be based upon the following criteria:
- (a) Medical-use and safety instructor: An individual who is currently licensed as a Radiologic-Technologist and approved as an education provider by the Oregon Board of Medical-Imaging.
- (b) A dental radiation use and safety instructor is an individual who has:
- (A) Passed the Radiation Health and Safety (RHS) or the Certified Dental Assistant (CDΛ) examination administered DANB; or
- (B) Has been evaluated and approved as a qualified Dental radiation use and safety instructor by the Oregon Board of Dentistry; and
- (C) Is currently licensed by the Oregon-Board of Dentistry as a dentist; or
- (D) Is-a-dental hygienist; or
- (E) Is a dental assistant certified in Radiologic proficiency and has a minimum of two years of experience in taking dental radiographs.
- (e) A veterinarian radiation use and safety instructor is an individual who is:
- (A) Currently credentialed with the Oregon Veterinary Medical Examining Board, or licensed as a Radiologic Technologist by the Oregon Board of Medical Imaging; and
- (B) Has completed training specific to veterinarian radiography, including training in animal restraint; and
- (C) Have a minimum of two years of experience in taking veterinary radiographs.
- (d)(A) On a case by case basis, if an evaluation by the Authority reveals the individual has alternative qualifications that are substantially equivalent to the qualifications listed in subsections (4)(a), (4)(b) or (4)(c) of this rule or is an individual who is qualified under OAR 333-101-0230 as a Hospital Radiology Inspector; or
- (B) The individual meets the requirements of a qualified expert as defined in OAR 333-100-0005(80).
- (5) In addition to the requirements in sections (2), (9), (10) and (13), of this rule dental X-ray-equipment-operator must also satisfy any requirements established by the Oregon Board-of-Dentistry.

- (6) The operator shall be able to demonstrate competency in the safe use of the X-ray equipment and associated X-ray procedures.
- (75) Any dDiagnostic medical X-ray operators who meet the following requirements are considered to have met the requirements of section (1) of this rule: is deemed to have adequate training to meet the requirements of section (1) of this rule if they meet any of the following:
- (a) Holds a current license from the Oregon Board of Medical Imaging; or
- (b) Holds a current limited X-ray machine operator permit from the Oregon Board of Medical Imaging; or
- (c) Is a student in a two-year approved school of Radiologic Technology as defined in ORS 688.405 while practicing Radiologic Technology under the general supervision of a radiologist who is currently licensed with the Oregon Medical Board or a radiologic technologist who is currently registered with the American Registry of Radiologic Technologists and licensed with the Oregon Board of Medical Imaging; or
- (d) Is a student in an Oregon Board of Medical Imaging approved limited permit program under a Radiologic Technologist who is currently registered with the American Registry of Radiologic Technologists and licensed by the Oregon Board of Medical Imaging.
- (6) In addition to the training outlined in section (3) of this rule, medical X-ray equipment operators using diagnostic radiographic equipment on human patients, and who are not regulated by the Oregon Board of Medical Imaging must have 100 hours or more of instruction in radiologic technology including, but not limited to, anatomy physiology, patient positioning, exposure and technique. The instruction must be appropriate to the types of X-ray examinations that the individual will be performing; and
- (a) Have 200 hours or more of X-ray laboratory instruction and practice in the actual use of an energized X-ray unit, setting techniques and practicing positioning of the appropriate diagnostic radiographic procedures that they intend to administer.
- (8) Dental radiology students in an approved Oregon Board of Dentistry dental radiology course are permitted to take dental radiographs on human patients during their clinical training, under the indirect supervision of a Dentist or Dental Hygienist currently licensed or a dental assistant who has been certified in radiologic proficiency, by the Oregon Board of Dentistry provided that:
- (a) They are enrolled in an Oregon Board of Dentistry approved radiology course; or
- (b) A student studying under an Oregon Board of Dentistry approved radiology instructor; and

- (c) The student has written authorization, signed by their instructor, attesting that the student has successfully completed training in the subject areas in section (1) of this rule; and
- (d) Demonstrated to the instructor that they are ready to take dental radiographs on human patients through:
- (A) The use of mannequins under indirect supervision; or
- (B) Taking dental radiographs of human patients while under the direct supervision of the instructor; and
- (C) The written authorization is on the training program or Oregon Board of Dentistry approved instructor's letterhead, a copy of which is maintained at the site(s) of their elinical training and available for review by the Oregon Health Authority, Public Health Division inspection staff at the time of inspection.
- (9) The students identified in section (8) of this rule are prohibited from taking radiographs on human patients without proper authorization from a practitioner of the healing arts who is currently licensed in Oregon, as required in OAR 333-106-0035 of these rules.
- (10) The students identified in section (8) of this rule are considered to be in "student status" until they have successfully completed the clinical phase of their training. "Student status" shall not exceed a period of 12 consecutive months.
- (7) All X-ray operators shall be able to demonstrate competency in the safe use of the X-ray equipment and associated X-ray procedures.
- (8) When required by the Authority, applications training must be provided to the operator before use of X-ray equipment on patients.
- (a) Records of this training must be maintained and madke available to the Authority for inspection.

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- (b) The training may be in any format such as hands-on training by a manufacturer's representative, video or DVD instruction, or a training manual.
- (11) Radiation use and safety training programs approved prior to the May 1, 2005 will continue to be considered as meeting the requirements of section (1) of this rule provided they cover those portions of the Oregon Rules for the Control of Radiation indicated in subsection (1)(h) of this rule.

- (12) X-ray operator training approved prior to May 1, 2005 will continue to be considered as having met the requirements of sections (1), (2) or (3) of this rule as applicable.
- (139) Reciprocity. X-ray equipment operators who have received their radiation safety training outside of Oregon will be considered to have met the training requirements listed in sections (1) or (2) of this rule, if the Authority's or applicable Oregon Licensing Board's evaluation of their training or training and experience, reveals that they substantially meet the intent of sections (1) or (2)(3) of this rule.
- (14) When required by the Authority, applications training must be provided to the operator before use of X-ray equipment on patients.
- (a) Records of this training must be maintained by the registrant for inspection.
- (b) The training may be in any format such as hands-on training by a manufacturer's representative, video or DVD instruction, or a training manual.

Stat. Auth.: ORS 453,605 - 453,807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & cf. 3-20-85; IID 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 24-1994, f. & cert. cf. 9-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. cf. 9-15-08; PH 20-2010, f. & cert. ef. 9-1-10; PII 10-2011, f. 9-30-11, cert. ef. 10-1-11

## 333-106-0060

## Radiation Use and Safety Instructor Qualifications

- (1) The training required in OAR 333-106-0055(1) of this rule must be taught by an Authority approved instructor. Approval will be based upon the following criteria:
- (a) A medical use and safety instructor is an individual who is currently:
- (Λ) Licensed as a Radiologic Technologist and approved as an education provider by the Oregon Board of Medical Imaging; or
- (B) A dental radiation use and safety instructor is an individual who is currently licensed by the Oregon Board of Dentistry as a Dentist, a Hygicnist, or has been approved by the Oregon Board of Dentistry as a radiation use and safety instructor.

## Fluoroscopic X-ray Systems Requirements

333-106-0201

## Fluoroscopic X-ray Systems

All Fluoroscopic X-ray Systems Shall Meet the Following Requirements:

Limitations of Useful Beam

- (1) Primary Barrier:
- (a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID;
- (b) The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam.
- (2) Nonimage intensified types of fluoroscopes shall not be used.
- (3) Image-Intensified Fluoroscopy and Spot Filming:
- (a) For image-intensified fluoroscopic equipment, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID. In addition:
- (A) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square cm shall be provided with means for stepless adjustment of the X-ray field;
- (B) All equipment with a fixed SID and a visible area of 300 square cm or less shall be provided with either stepless adjustment of the X-ray field or with means to further limit the X-ray field size at the plane of the image receptor to 125 square cm or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5 cm by 5 cm or less;
- (C) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor; and
- (D) Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular X-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.
- (b) Spot-film devices which are certified components shall meet the following additional requirements:

- (Λ) Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;
- (B) It shall be possible to adjust the X-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 cm by 5 cm;
- (C) The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the SID; and
- (D) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.
- (c) If a means exists to override any of the automatic X-ray field size adjustments required in section (23) of this rule that means:
- (A) Shall be designed for use only in the event of system failure;
- (B) Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and
- (C) Shall be clearly and durably labeled as follows:

#### "FOR X-RAY FIELD LIMITATION SYSTEM FAILURE"

Stat. Auth.: ORS 453.605 - 453.807

Stats, Implemented: ORS 453,605 - 453,807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert, ef. 1-8-91; PH 12-2006, f. &

cert. cf. 6-16-06; PH 14-2008, f. & cert. cf. 9-15-08

#### 333-106-0205

### Activation of the Fluoroscopic Tube

(1) X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate

the X-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

- (2) Requirements for the operation of fluoroscopic X-ray equipment. The operation of fluoroscopic equipment shall be restricted to the following categories of properly trained operators:
- (a) Radiologists;
- (b) Non-Radiologist practitioners with proper training in the operation and use of fluoroscopic X-ray equipment;
- (c) R.T.s, must be ARRT registered and in good standing with the Oregon Board of Medical Imaging.;
- (d) R.P.A.s and R.R.A.s;
- (e) Technologists, who have successfully completed an educational program in radiologic technology from an approved school as defined in ORS 688.405, may temporarily operate fluoroscopic equipment for up to one year as outlined in OAR 337-010-0045 while waiting to take the ARRT registry examination.
- (Λ) The temporary period expires when the individual has passed the registry examination and is considered an R.T.; or
- (B) One year from the date when the technologist completed his/her training, provided; and
- (C) The technologist, while in the temporary status referred to in subsection (2)(e) of this rule, has a current temporary license issued by the Oregon Board of Medical Imaging..
- (f) The operation of fluoroscopic equipment by R.T.s, or R.P.A.s or R.R.A.s shall be performed under the personal supervision of a radiologist and is restricted to the healing arts exclusively for the purpose of localization and to assist physicians in obtaining images for diagnostic purposes.
- (g) Where direct or indirect personal supervision by a radiologist is impractical, a nonradiologist practitioner who has had proper training in the use and operation of fluoroscopic X-ray equipment is permitted to personally supervise an R.T. operating fluoroscopic equipment provided that the registrant arranges to have a radiologist or Medical or Health physicist to assist in;
- (Λ) Developing fluoroscopic and radiation safety policies and procedures;

- (B) Conducting an on-site practical evaluation of the Non-Radiologist practitioner's knowledge of radiation safety practices and ability to operate the fluoroscopic equipment; and
- (C) At least annually, review the registrant's fluoroscopy program. The review includes an evaluation of the fluoroscopic on-times Quality Assurance reports, condition of fluoroscopic equipment and compliance with current rules. The registrant shall correct any deficiencies noted by the review.
- (h) The operation of fluoroscopic equipment by a R.T. is restricted to the healing arts exclusively for the purpose of localization and to assist physicians in obtaining images for diagnostic purposes.
- (i) Students currently enrolled in an approved school of Radiologic Technology as defined in ORS 688,405, may only operate fluoroscopic equipment under the direct personal supervision of a Radiologist or an R.T. while in the clinical phase of training.
- (j) Students currently enrolled in an Authority approved R.P.A. or R.A. training program, may only operate fluoroscopic equipment under the direct or in-direct personal supervision of a Radiologist during their clinical phase of training.
- (k) Overhead fluoroscopy is not to be used as a positioning tool for radiographic examinations except for those fluoroscopic examinations specified in the registrant's written policies/procedures for fluoroscopy.
- (1) Proper training in the operation of fluoroscopic X-ray equipment shall include but not be limited to the following:
- (A) Principles and operation of the fluoroscopic X-ray machine;
- (i) Generating X-rays;
- (ii) kVp and mA;
- (iii) Image intensification;
- (iv) High level control versus standard operating mode;
- (v) Magnification (multi-field);
- (vi) Automatic Brightness Control (ABC);
- (vii) Pulsed versus Continuous X-ray Dose Rates;
- (viii) Image recording modes;

(ix) Imaging Systems (TV and Digital);
(x) Contrast, noise and resolution;
(B) Radiation units;
(i) Traditional units;
(ii) SI units;
(iii) Dose Area Product;
(C) Typical fluoroscopic outputs;
(i) Patient skin entrance dose;
(ii) Standard Roentgen per minute (R/min) dosc rates;
(iii) High level/Boost enable Roentgen per minute (R/min) dose rates;
(D) Dose reduction techniques for fluoroscopy;
(i) The use of collimation;
(ii) X-ray tube and Image intensifier placement;
(iii) Patient size versus Technique selection;
(iv) Use of grid;
(v) Use of last image hold;
(vi) Additional beam filtration;
(vii) Alternate gantry angles;
(viii) Use of spacer cone;
(ix) Pulsed fluoroscopy;
(E) Factors affecting personnel dose;
(i) Patient dose;
(ii) Scatter radiation;

(iii) Tube and Image intensifier placement;

(iv) Time, distance and shielding;

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(ii) Oregon Rules for the Control of Radiation to include, but not limited to, divisions 101, 103, 106, 111 and 120.	
(i) Federal; and	
(I) Applicable regulations;	
(vi) Latent effects;	
(v) Acute effects;	
(iv) Cell sensitivity;	
(iii) Scatter radiation;	
(ii) Absorption variables (field size, dose rate, etc.);	
(i) X-rays and particulate matter;	
(H) Biological effects of X-ray radiation;	
(iii) Occupational and non-occupational dose limits;	
(ii) Placement of personnel monitors;	
(i) Personnel monitors;	
(G) Radiation exposure monitoring;	
(vi) Protective shields/barriers;	
(v) Bucky slot cover;	
(iv) Leaded drapes;	
(iii) Protective glasses;	
(ii) Thyroid collars;	
(i) Lead aprons and gloves;	
(F) Protective devices;	

- (3) Radiologists, R.A.s or R.P.A.s and R.T.s currently licensed in Oregon are considered to have met the training requirements in subsection (2)(1) of this rule.
- (4) Fluoroscopic equipment operators who qualified to operate fluoroscopic X-ray equipment prior to April 11, 2005, are considered as having met the training requirements in subsection (2)(1) of this rule.
- (5) All images formed by the use of fluoroscopy shall be viewed, directly or indirectly, and interpreted by a radiologist, cardiologist, non-radiologist practitioner or other qualified specialist. R.As and R.P.As may issue a preliminary report, however, the final report must be issued by their supervising radiologist.
- (6) Written procedures for fluoroscopic X-ray equipment operators shall be available at the worksite and include:
- (a) Λ list of all individuals who are permitted to operate fluoroscopic X-ray equipment at the facility;
- (b) A list of the fluoroscopic X-ray equipment that each operator is qualified to operate;
- (c) Written procedures regarding the set up and operation of each fluoroscopic X-ray machine registered to the facility;
- (d) Written radiation safety procedures pertaining to the use and operation of fluoroscopy; and
- (e) The name and title of the individual who is responsible for the direction of R.T.s who operate fluoroscopic equipment.
- (7) Facilities shall determine, or cause to be determined, the typical patient entrance exposure rate for their most common fluoroscopic examinations. The determination shall be made using an attenuation block as described in OAR 333-106-0005(7)using measurement protocol in compliance with OAR 333-106-0210 and expressed in Roentgens per minute (R/min.) or milliRoentgens per minute (mR/min.). In addition, these entrance exposure rates shall be posted in the room where fluoroscopic examinations are conducted so that they are readily available to administrators, X-ray operators, patients and practitioners.
- (8) Facilities that utilize fluoroscopy shall maintain a record of the cumulative fluoroscopic exposure time used for each examination. The record must indicate the patients name, the type of examination, the date of the examination, the fluoroscopists name, the fluoroscopic room in which the examination was done and the total cumulative fluoroscopic on time for each fluoroscopic examination and:

- (a) No later than May 1, 2006, establish cumulative fluoroscopic on-time benchmarks for at least two (if applicable) of the most common types of fluoroscopic examinations performed at the facility's site in each of the following categories:
- (Λ) Routine procedures performed on adults;
- (B) Routine procedures performed on children;
- (C) Orthopedic procedures performed in surgery;
- (D) Urologic procedures performed in surgery;
- (E) Angiographic procedures performed;
- (F) Interventional cardiac studies.
- (b) Develop and perform periodic (not to exceed 12 month intervals) quality assurance studies to determine the status of each individual fluoroscopist's cumulative on-time in relation to the fluoroscopic benchmarks established for individual fluoroscopic examinations;
- (c) Take appropriate action, when the established benchmarks are consistently exceeded. The Radiation Safety Committee (RSC) must review the results of the cumulative fluoroscopic on-time Quality Assurance Study and take corrective action regarding those individuals who have exceeded the benchmarks established by the facility for a particular procedure more than ten percent of the total times the individual performed the procedure during the study period. Documentation of the RSC review, as well as any corrective actions taken, must be available for Authority review. Corrective actions, at a minimum, include:
- (A) Notification of the individual; and
- (B) Recommendation that the individual undergo additional coaching, training, etc. in the safe use of fluoroscopic equipment in order to assist them in reducing their cumulative fluoroscopic on-times.

Stat. Auth.: ORS 453.605 - 453.807 Stats. Implemented: 453.605 - 453.807 Hist.: HD 4-1985, f. & ef. 3-20-85

333-106-0210

Fluoroscopic Entrance Exposure Rates

333-106-0215

## Fluoroscopic Barrier Transmitted Radiation Rate Limits

333-106-0220

## Fluoroscopic Indication of Potential and Current

333-106-0225

## Fluoroscopic Source-to-Skin Distance

- (1) The source-to-skin distance shall not be less than:
- (1a) Thirty-eight38 centimeters cm on stationary fluoroscopes manufactured on or after Λugust 1, 1974;
- (2b) 35.5 cm on stationary fluoroscopes manufactured prior to August 1, 1974;
- (3c) 30 cm on all mobile fluoroscopes; and
- (4d) 20 cm for image intensified fluoroscopes used for specific surgical application. The written safety procedures must provide precautionary measures to be adhered to during the use of this device.

Stat. Auth.: ORS 453,605 - 453,807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & cf. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. &

ccrt. cf. 6-16-06

333-106-0240

## Fluoroscopic Control of Scattered Radiation

333-106-0245

### Fluoroscopic Radiation Therapy Simulation Systems

- (1) Radiation therapy simulation systems shall be exempt from all the requirements of OAR 333-106-0201 through 333-106-0245 of these rules provided that:
- (a+2) Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing X-rays; and
  - (23b) Systems which do not meet the requirements of OAR 333-106-0230 of these rules are provided with a means of indicating the cumulative time that an individual patient has

been exposed to X-rays. Procedures shall require in such cases that the timer be reset between examinations.

333-106-0325

Intraoral Dental Radiographic Systems

Intraoral Dental Radiographic Systems

Veterinary X-ray Systems

333-106-0601

Veterinary Medicine Radiographic Installations Additional Requirements

## Mammography Requirements

333-106-0700

Mammography X-Ray Systems Definitions

333-106-0735

**Breast Density Notification** 

- (1) As used in this rule:
- (a) "Breast Density" refers to the relative amount of different tissues present in the breast. A dense breast has less fat than glandular and connective tissue. Mammogram films of breasts with higher density are harder to read and interpret than those of less dense breasts. (Source: National Cancer Institute).
- (b) "Facility" has the meaning given that term in 42 U.S.C. 263b and includes but is not limited to a hospital, outpatient department, clinic, radiology practice, or mobile unit, an office of a physician, or other facility that conducts breast cancer screening or diagnosis through mammography activities. "Facility" does not include a facility of the Department of Veterans Affairs.
- (c) "Mammography activities" means the operation of equipment to produce a mammogram, the processing of the film, the initial interpretation of the mammogram and the viewing conditions for that interpretation.
- (2) In all cases where a mammogram shows a patient <u>having</u> has extreme breast density <u>or heterogeneous breast density tissue</u>, the facility shall incorporate the following notification within the lay summary mammography report provided to the patient. When a mammogram shows a patient has heterogeneous breast density, the decision of whether

or not to incorporate the patient notification is left to the interpreting radiologist's discretion:

#### DENSE BREAST TISSUE NOTIFICATION

Your mammogram shows that your breast tissue is dense. For most women, breast density decreases with age, but in some women, there is little change. Dense breast tissue is common and is not abnormal. However, dense breast tissue can make it harder to evaluate the results of your find cancer on a mammogram and may also be associated with an increased risk of breast cancer. This information about the results of your mammogram is given provided to you by Oregon State Law-to raise your awareness and to promote discussion with your health care provider, about your own risk-for breast eaneer. Together, you can decide if you may benefit from further screening, if additional breast imaging tests such as a breast ultrasound, Magnetic Resonance Imaging (MRI) or Breast-Specific-Gamma-Imaging (BSGI) would be beneficial based on your risk factors and physical examinations. A report of your results was sent to your health care provider.

(3) The Dense Breast Tissue Notification statement and guidelines shall be included in the facility's policy on how they communicate mammography results to the patient and their health care providers.

Stat. Auth.: ORS 413.042 & 2013 OL Ch. 411

Stats, Implemented: 2013 OL Ch. 411

Hist.: PII 14-2013, f. 12-26-13, cert. ef. 1-1-14

333-106-0750

### Mammography Personnel Qualifications

- (1) Operator qualifications. In order to use any mammography X-ray machine the operator of the mammography X-ray unit must have the following qualifications:
- (a) Have a current license issued by the Oregon Board of Medical Imaging; and
- (b) Have prior to the effective date of these rules qualified as a radiologic technologist under the MQSA interim rules or completed 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not be limited to;
- (A) Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging patients with breast implants;
- (B) The performance of 25 examinations under the direct personal supervision of an individual qualified under this section; and

- (C) At least eight hours of training in each mammography modality to be used by the technologist in performing mammography exams; and
- (D) Be currently registered and in good standing with the American Registry of Radiologic Technologist (ΛRRT); and
- (E) Be certified in mammography by the ARRT or the equivalent; or
- (F) Provide documented evidence that an ARRT mammography certification test is scheduled. Technologists meeting the requirements of subsection (1)(a) and paragraphs (1)(b)( $\Lambda$ ), (B), (C), and (D) of this rule may work under the supervision (supervision means that a fully qualified technologist is on-site and readily available to answer questions or assist) of a technologist, meeting all of the requirements of this rule, for up to one year while waiting to take the certification test.
- (2) Interpreting Physician qualifications. All physicians interpreting mammograms shall meet MQSA qualifications and hold a current license to practice medicine in the State of Oregon.
- (3) Medical Physicist qualifications. All Medical Physicists conducting surveys and equipment evaluations of mammography facilities and providing oversight of their quality assurance programs shall;
- (a) Meet MQSA requirements; and
- (b) Be currently licensed as a vendor by the Authority.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 3-2003, f. & cert. cf. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PII 14-2008,

f. & cert. ef. 9-15-08; PII 10-2011, f. 9-30-11, cert. ef. 10-1-11

### 333-116-0130

## Records and Reports of Misadministrations

- (1) For a misadministration that meets the definition in OAR 333-116-0020 a licensec must:
- (a) Notify the Authority by telephone no later than the next calendar day after discovery of the misadministration and provide information as outlined in paragraphs (b)(A) through (b)(II).

NOTE: The 24-hour phone number of the Authority is (971) 673-0490.

- (b) The licensee must submit a written report to the Authority within 15 days after the discovery of the misadministration. The written report must include:
- (A) The licensee's name;
- (B) The prescribing physician's name;
- (C) A brief description of the event to include;
- (i) Prescribed dose
- (ii) Delivered dose
- (D) Why the event occurred;
- (E) The effect on the patient;
- (F) What improvements are needed to prevent recurrence;
- (G) Actions taken to prevent recurrence; and
- (II) Certification that the licensee notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the patient" in this section), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.
- (c) The licensee must notify the referring physician of the affected patient and the patient or a responsible relative or guardian, unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative or guardian would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee must notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee must not delay medical care for the patient because of this.
- (d) If the patient was notified, the licensee also must furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either:
- (A) A copy of the report that was submitted to the Authority; or

- (B) A brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the Authority can be obtained from the licensee.
- (2) Each licensee must retain a record of each misadministration in accordance with OAR 333-100-0057. The record must contain the names of all individuals involved in the event (including the physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.
- (3) Aside from the notification requirement, nothing in this rule must affect any rights or duties of licensees and physicians in relation to each other, patients or responsible relatives or guardians.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

## 333-116-0190

## Authorization for Calibration and Reference Source

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

- Sealed sources manufactured and distributed by persons specifically licensed pursuant to OAR 333-102-0290 or equivalent provisions of the U.S. Nuclear Regulatory Commission (NRC) Agreement State or Licensing State and that do not exceed 1.11GBq (30 mCi) each;
- (2) Any radioactive material listed in OAR 333-116-0300, 333-116-0320 or 333-116-0360 with a half-life of 100 days or less in individual amounts not to exceed 1.11GBq (30 mCi), except Y-90 sources not to exceed 2.8 GBq (75 mCi);
- (3) Any radioactive material listed in OAR 333-116-0300, 333-116-0320 or 333-116-0360 with a half-life greater than 100 days in individual amounts not to exceed 7.4 MBq (200 uCi) each; and
- (4) Technetium-99m in amounts as needed, individual amounts to exceed 1.85 GBq (50 mCi).

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & ccrt. cf. 1-8-91; PII 3-2003, f. & ccrt. cf. 3-27-03; PH 31-2004(Temp), f. & ccrt. cf. 10-8-04 thru 4-5-05; PH 36-2004, f. & ccrt. cf. 12-1-04; PH 12-2006, f. & ccrt. cf. 6-16-06; PH 4-2007, f. & ccrt. cf. 3-1-07; PII 14-2008, f. & ccrt. cf. 9-15-08; PH 4-2010, f. & ccrt. cf. 2-16-10; PH 24-2014, f. & ccrt. cf. 8-15-14

## 333-119-0010

### Definitions

- (1) "Authority" means the Oregon Health Authority.
- (2) "Customer" means any member of the public who is provided access to a tanning device in exchange for a fee or other compensation, or any individual who, in exchange for a fee or other compensation, is afforded use of a tanning device as a condition or benefit of membership or access.
- (3) "Employee" means any individual, including a minor whether lawfully or unlawfully employed, who engages to furnish services for remuneration, financial or otherwise, subject to the direction and control of an employer and includes any individual who is required to have workers' compensation coverage.
- (4) "EPA" means the U.S. Environmental Protection Agency.
- (5) "FDA" means the U.S. Food and Drug Administration.
- (6) "Fitzpatrick Skin Type Scale" means a numerical classification diagram used as a way to classify the response of different types of skin to ultraviolet (UV) light.
- (76) "Formal Training" means a course of instruction reviewed and approved by the Authority and which is conducted or presented under formal classroom conditions or online by a qualified expert possessing adequate knowledge and experience to offer a curriculum, associated training, and certification testing pertaining to and associated with the correct use of tanning equipment. Operator training shall cover ultraviolet radiation and effects on the skin, photosensitivity, FDA and State of Oregon regulations, eye protection, and equipment maintenance.
- (87) "Handrails" means a suitable physical aid that will help to maintain proper exposure distance.
- (98) "Identification" means:

- (a) A government-issued photo identification that displays the individual's date of birth;
  or
- (b) A government or non-government issued photo identification when submitted with a completed Oregon Underage Tanning Medical Recommendation form.
- (109) "Individual" means any human being.
- $(1\underline{1}\theta)$  "Minor" means any individual under the age of 18 years old.
- (124) "Operator" means the person who is an employee (defined by the Oregon Occupational Safety and Health Division, OAR 437-003-0011(2)) or contractor of the tanning facility who has received a certificate from an approved formal training course and who is responsible for any of the following:
- (a) Determining customer's skin type;
- (b) Determining the suitability for use of a tanning device;
- (c) Providing information regarding the dangers of ultraviolet radiation exposure including photoallergic reactions and photosensitizing agents;
- (d) Assuring that all required forms are understood and properly signed by the customer;
- (e) Maintaining required exposure records;
- Recognizing and reporting injuries or alleged injuries to the registrant;
- (g) Determining the customer's exposure schedule;
- (h) Setting timers which control the duration of exposure; and
- (i) Instructing the customer in the proper use of protective eyewear.
- (j) Verifying and documenting age of clients.
- K -Sanitizing tanning devices.
- (132) "Other Compensation" means the payment or exchange of goods, services or anything of value for use of the tanning device or devices.
- (143) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of these entities.

- (154) "Phototherapy Device" means equipment that emits Ultraviolet radiation used by a health care professional in the treatment of disease or illness.
- (165) "Program" means the Radiation Protection Services section of the Public Health Division.
- (176) "Protective Eyewear" means suitable cycwcar that protects the eye from Ultraviolet radiation and allows adequate vision.
- (187) "Public Places" means the area where members of the public may assemble and are not directly affected by tanning operations.
- (198) "Recommendation" means a written directive using a form provided by the Authority and signed by a licensed physician.
- (2019) "Registrant" means a tanning facility registered with the Authority as required by provisions of this division.
- (210) "Registration" means registration with the Authority in accordance with provisions of this division.
- (224) "Remote" means a timer that is placed away from the tanning device so it can only be programmed by the tanning facility soperatortaff
- (231) "Safe Level" means not more than 50 colonies of microorganisms per four square inches of equipment surface.
- (242) "Sanitize" means the effective bactericidal treatment of surfaces of equipment and devices by an EPA or FDA registered product that provides a sufficient concentration of chemicals, and enough time to reduce the bacterial count, including pathogens, to a safe level. Chemical germicides that are registered with EPA as hospital disinfectants when used at recommended dilutions and directions may be approved for sanitizing of tanning devices:
- (2<u>5</u>3) Skin Types:
- (a) "Type 1" means skin burns easily and severely (painful burn); tans little or none and peels.
- (b) "Type 2" means skin burns easily and severely (painful burn); tans minimally or lightly and also peels.
- (c) "Type 3" means skin burns moderately and tans about average.
- (d) "Type 4" means skin burns minimally, tans easily and above average with each exposure; exhibits immediate pigment darkening reaction.

- (e) "Type 5" means skin rarely burns, tans easily and substantial; always exhibits immediate pigment darkening reaction
- (264) Storage, means when a tanning device is not actively being used, as evidenced by the removal of all tanning lamps and lack of connection to a power supply
- (274) "Tanning Device" means any equipment used for tanning of the skin, that emits electromagnetic radiation with wavelengths in the air between 200 and 400 nanometers including, but not limited to, a sunlamp, Ultraviolet Lamp, tanning booth, facial unit, UVA wand, or tanning bed. "Tanning device" also means any accompanying equipment, including, but not limited to, protective eyewear, timers, ballasts, starters, lamps, reflectors, cooling fans, acrylics, comfort pillows and handrails.
- (285) "Tanning Facility" means any location, place, area, structure, or business that provides persons access to any tanning device.
- (296) "Timer" means an electronic device designed specifically to terminate tanning sessions at a preset time interval provided to terminate the exposure at a preset time interval.
- (3027) "Ultraviolet Radiation" means radiation that has a wavelength between two hundred nanometers and four hundred nanometers.

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.925 - 431.955

Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 14-2013, f. 12-26-13, cert. ef. 1-1-14

#### 333-119-0020

#### Registration

- (1) Prior to the operation of any tanning device used by the public for a fee or other compensation, the owner or operator shall file an application with the Authority and pay applicable fee(s) in the amount and in the manner specified in OAR 333-103-0025 to register each tanning device.
- (2) If the owner or operator owns or operates more than one such tanning facility, the owner or operator shall file a separate application for each such facility owned or operated.
- (3) Registration application shall be made on forms furnished by the Authority.

- (4) A validation certificate or acknowledgement of validation will be issued by the Authority.
- (5) The certificate issued by the Authority shall be effective for one year beginning January 1 through December 31.
- (6) The certificate shall be displayed in a conspicuous open public area of the tanning facility.
- (7) The Authority will provide an identification number that will be affixed by a Authority inspector to each tanning device during the initial or follow-up facility inspection:
- (a) Identification numbers shall not be removed without written permission of the Authority; and
- (b) Identification numbers shall not be defaced.
- (8) The registrant shall notify the Authority in writing before making any change that would render the information contained in the application for registration or the validation of registration no longer accurate.
- (9) No registration may be transferred from one person to another person, from one tanning facility to another tanning facility, or from one tanning device to another tanning device.
- (10) In the event of a change in ownership, the new owner will be required to apply for a registration of the tanning device within 30 days after taking possession of the property.
- (11) Tanning facilities already in existence at the time of the effective date of this rule may continue to operate. Such facility shall be given priority in the inspection process by the Authority. However, should those tanning facilities fail to meet the standards, they may be prohibited from continuing to operate until such time as they have met those standards through evaluation by the Authority's inspectors or through a hearing held by the Authority.
- (102) Failure to properly register a tanning device is subject to the imposition of a civil penalty per ORS 431.950 and ORS 431.262.
- (113) The Authority may require tanning facility registrants to complete and update application forms and information concerning tanning devices.

Stat. Auth.: ORS 431.925 - 431.955

Stats, Implemented: ORS 431.925 - 431.955

Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10

#### **General Requirements**

#### 333-119-0030

#### Administrative Responsibilities

- (1) The registrant shall be responsible for directing the operation of the tanning facility that has been registered with the Authority. That individual or individual's agent shall assure that the provisions of these rules are met in the operation of tanning devices.
- (2) A tanning device which does not meet the provisions of these rules shall not be operated and may be tagged "Out of Service for Non-compliance with OΛR 333-119 Requirements" by Authority inspectors. Devices tagged as non-compliant shall not be operated until written authorization is received by the registrant from the Authority.
- (3) The registrant shall assure that the tanning facility will comply with all applicable federal laws and regulations.
- (4) In addition to the requirements of this division, all registrants are subject to the applicable requirements of divisions 100, 103 and 111 of this chapter.
- (5) The Authority Inspection Findings report and facility response letter(s)o shall be conspicuously posted in public view until all items of non-compliance have been corrected and a written Authority release from this requirement is received by the registrant.
- (6) The registrant shall post in a conspicuous place the Authority "Notice To The Public".
- (7) The registrant shall assure that the "Warning", "Notice to the Public" and "Persons Under Age 18" signs are not covered or obscured, and are easily seen by clients at either the main reception area of the establishment or in each tanning device room.
- (8) The registrant shall notify the Authority of any injury for which medical attention was sought or obtained from the use of registered tanning device within one tworking day after learning of the occurrence, and provide the Authority any information about the incident the Authority deems necessary.

#### 333-119-0040

#### Construction and Operation of Tanning Facilities

Unless otherwise ordered or approved by the Authority, each tanning facility shall be constructed, operated and maintained to meet the following minimum requirements:

(1) All tanning facilities shall be equipped with convenient toilet facilities and dressing rooms. Such toilet facilities shall include a water-eloset toilet and hand washing sinks.

Such toilet and dressing rooms shall be properly maintained, as well as meet all state and local codes.

- (2) All areas of the tanning facility shall be ventilated with at least six air changes per hour or as required by local code.
- (23) Rooms or other enclosures containing tanning devices Tanning booth temperature shall be maintained below 100 degrees Fahrenheit (38 degrees Centigrade) during booth operation.
- \_(4) The tanning device shall meet the National Fire Protection Association's National Electrical Code, or be approved by the Underwriter Laboratories (UL) or Electrical Testing Laboratories (ETL).
- (35) Except as otherwise noted by the Authority, each tanning Tanning facility facilities shall be constructed, operated and maintained in accordance with applicable city, county and state codes.
- (46) Clean sanitary towels shall be provided to all patrons using tanning facilities.
- (57) A hamper or receptacle must be provided for all soiled towels and linen.
- (68) No pets or animals are permitted in tanning facilities other than service animals.

Stat. Auth.: ORS 431.925 - 431.955 Stats. Implemented: ORS 431.930

Hist.: HD 15-1991, f. & ccrt. cf. 10-1-91; IID 15-1994, f. & ccrt. cf. 5-6-94; PH 3-2003, f. & ccrt. cf. 3-27-03; PH 31-2004(Tcmp), f. & ccrt. cf. 10-8-04 thru 4-5-05; PH 36-2004, f. & ccrt. cf. 12-1-04; PH 14-2008, f. & ccrt. cf. 9-15-08; PH 4-2013, f. & ccrt. cf. 1-29-13

#### 333-119-0041

#### Cleaning and Sanitation

- All areas of the tanning facility, including tanning devices, equipment and apparatus, shall be maintained in a clean and sanitary manner by the facility operator.
- (2) The tanning device(s) and protective eyewear shall be cleaned sanitized after each client use, by the facility operator.
- (3) A clean paper or cloth towel shall be used each time the tanning device is elemed and sanitized.
- (4) The sanitizer must be specifically manufactured for sanitizing ultraviolet light emitting equipment and protective eyewear, and must not damage the acrylic lamp covers

of the device. The ultraviolet light produced by the tanning device itself is not considered an adequate sanitizing agent.

- (45) An operator cannot require the consumer to sanitize the tanning equipment or protective eyewear and shall not post any signs requesting such sanitation be performed by the consumer.
- (56) The sanitizer must contain a concentration of Quaternary Ammonium between 400ppm-800ppm.
- (7a) A test kit that accurately measures the concentration of the sanitizing solution in parts per million (ppm) shall be used to measure the strength of the sanitizing solution when the concentrate and water dilution is initially prepared and tested weekly thereafter to ensure sufficient strength remains within the sanitizing solution.
- (7) A written policy for cleaning and sanitizing shall be available for employees and the consumer. Written policies need to address the following:
- (a) Tanning device manufacturer's recommended sanitizer solution and eleaning guidelines. If the manufacturer does not recommend a specific sanitizer then the written policy shall contain the name of the sanitizer that is being used on the tanning device and eyewear.
- (b) Materials Safety-Data Sheets referring to the sanitizing agent used by the operator.
- (c) Location of the sanitizer and the application instructions.

Stat. Auth.: ORS 431.925 - 431.955 Stats. Implemented: ORS 431.930 Hist.: PH 4-2013, f. & ccrt. ef. 1-29-13

#### Specific Requirements

#### 333-119-0050

#### Warning Statement

At each customer's initial visit to a tanning facility, and at least annually thereafter, the customer shall be provided the following written statement to review and sign which warns the customer that (a Authority approved tanning client card may be used to satisfy this requirement) The warning language must be in 14 point or larger font.:

- (1) Not wearing the appropriate protective eyewear provided to each customer by the tanning facility may cause damage to the eyes; and
- (2) Overexposure to the tanning process may cause burns; and

- (3) Repeated exposure to the tanning process may cause skin cancer or premature aging of the skin or both; and
- (4) Abnormal skin sensitivity or burning may result from the tanning process if the customer is also consuming or using certain foods, cosmetics or medications (such as tranquilizers, antibiotics, diuretics, blood pressure medication or birth control pills):
- (a) Foods:
- (b) Cosmeties; or
- (e) Medications such as tranquilizers, antibiotics, diaretics, high blood pressure medication, antineoplastics or birth control pills; and
- (5) Any person taking a prescription or over-the-counter drug should consult a physician before using a tanning device.
- (6) The frequency and duration of tanning sessions must not exceed tanning device manufacturer recommendations.
- (7) Frequent users should be regularly screened for skin cancer by a physician.

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.925 - 431.955

Hist.: HD 15-1991, f. & ccrt. cf. 10-1-91; HD 15-1994, f. & ccrt. cf. 5-6-94; PH 14-2008,

f. & cert. cf. 9-15-08

#### 333-119-0060

#### Warning Sign

- (1) The registrant shall conspicuously post the warning sign described in section (2) of this rule within one meter (39.37 inches) of each tanning device and in such a manner that the sign is clearly visible, not obstructed by any barrier, equipment or other object, and can be easily viewed by the customer before operating the tanning device.
- (2) The warning sign in section (1) of this rule shall meet the following requirements:
- (a) The sign shall be printed on paper or similar material no smaller than 8.5 inches by 11 inches. Signs are available for printing on the Authority's website.
- (b) The major sign heading shall be labeled "DANGER" and the section entitled "FAILURE" shall be a minimum of Times New Roman, bold with a minimum font size of 40.

(c) The body text shall be a minimum of Times New Roman with a minimum font size of 20.

#### DANGER -- ULTRAVIOLET RADIATION

Follow instructions.

Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and/or skin cancer.

Frequent users should be regularly screened for skin cancer.

## FAILURE TO USE PROTECTIVE EYEWEAR MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES.

Medications or cosmetics may increase your sensitivity to the Ultraviolet radiation. Consult a physician before using sunlamp or tanning device if you are using medications or have a history of skin problems or believe yourself to be especially sensitive to sunlight.

If you do not tan in the sun, you are unlikely to tan from the use of this product

# Tanning session frequency and time shall not exceed the device manufacturer's recommendations

Stat. Auth.: ORS 431,925 - 431,955

Stats, Implemented: ORS 431,925 - 431,955

Hist.: IID 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; PII 14-2008,

f. & cert. cf. 9-15-08; PH 20-2010, f. & cert. cf. 9-1-10

#### 333-119-0070

#### Protective Eyewear

- (1) The registrant shall provide <u>make available</u> protective eyewear to each customer for use during <u>only use of tanning sessions devices</u>.
- (2) The protective eyewear in section (1) of this rule shall meet the requirements of 21 Code of Federal Regulations (CFR) Part 1040, Section 1040.20(c)(4).
- (3) Tanning facility operators shall ensure before each tanning session, that clients have approved protective evewear."

hat customers wear the protective eyewear required by this rule.

Stat. Auth.: ORS 431.925 - 431.955

Stats, Implemented: ORS 431.925 - 431.955

Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 14-2008,

f. & cert. ef. 9-15-08

#### 333-119-0080

#### Training of Personnel

- (1) The registrant shall maintain documentation to verify that all tanning device operators are adequately trained in the following:
- (a) The rules of this division;
- (b) Procedures for correct operation of the tanning facility and tanning devices:
- (e) Recognition of injury or overexposure to Ultraviolet radiation;
- (d) The tanning device manufacturer's procedures for operation and maintenance of the tanning devices;
- (e) The determination of skin type of customers and appropriate determination of duration of exposure to registered tanning devices;
- (f) Emergency procedures to be followed in case of injury; and
- (g) Potential photosensitizing foods, cosmetics, and medientions[D2]:
- (12) The registrant shall ensure that tanning devices are operated only while an adequately trained operator is present at the tanning facility.
- (23) All operators of registered tanning devices must successfully complete an Authority approved tanning training course in the State of Oregon prior to commencement of tanning operations.
- (34) Approved training will include, at a minimum, content covering the rules of this division, skin typing, recognition of overexposure, as well as any other topic determined by the Authority to be critical to client protection.

Stat. Auth.: ORS 431,925 - 431,955 Stats. Implemented: ORS 431,930

Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. cf. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004,

f. & cert. ef. 12-1-04; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. cf. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 4-2013, f. & cert. ef. 1-29-13

#### 333-119-0090

#### Protection of Consumers

The registrant and operators are responsible for protecting the customers from overexposure to Ultraviolet Light by assuring that; shall establish and use a procedure manual that will aid in the protection of the customer to excessive or unnecessary exposure to Ultraviolet Light. This manual shall include, but not be limited to, the following instructions:

- (1) Only one customer may occupy the tanning room. In the case of a customer using a tanning device who may need the aid or assistance from another person, that individual must also be provided with and wear protective cycwcar.
- (2) No customer under the age of 18 years shall be allowed to use a tanning device without a completed Oregon Underage Tanning Medical Recommendation form completed by a licensed physician and identification. The recommendation:
- (a) Must identify the physician and client and describe the recommended tanning session frequency(s) and duration(s);
- (b) Must identify dates for starting and ending of the tanning sessions; and
- (c) Cannot exceed the exposure scheduled per OAR 333-119-0100(14)(b).
- (3) A sign shall be posted in conspicuous view at or near the reception area with the following text in a minimum of at least 36 point type:

"PERSONS UNDER AGE 18 ARE NOT ALLOWED TO USE A TANNING DEVICE WITHOUT A WRITTEN RECOMMENDATION FROM A LICENSED PHYSICIAN"

- (4) Each person using a tanning device shall be instructed by the operator on the maximum exposure time and proper exposure distance, as recommended by the manufacturer of the device. The operator shall also instruct the customer as to the location and proper operation of the tanning device's emergency shut off switch.
- (5) Infants and minors are not permitted to be in the tanning device room during exposure by parents or guardians.
- (6) Tanning operators shall limit exposure time to the exposure time recommendation provided by the the device manufacturer's recommendations on the tanning device or in the device operating manual.

The maximum exposure time recommended by the manufacturer of the device shall not be exceeded in any 24-hour period.

- (7) A copy of the manufacturer's recommended exposure schedule shall be maintained at the remote timer controls for each device.
- (8) At the time of their initial visit, all clients shall have their skin type determined according to the Fitzpatrick Skin Type Scale, and their skin type recorded in the client record.
- (7) Tanning facilities shall post the following signs visible to the customer:
- (a) "In Case Of An Emergency, Dial 911";
- (b) "Oregon Radiation Protection Services at (971) 673-0490[D3]".
- (89) Tanning operators shall maintain a list of the common photosensitizing agents as provided by the Public Health Division, FDΛ, or other appropriate authorities, available for review by customers.
- (910) Tanning facilities are prohibited from controlling the use of tanning devices solely with token timer systems or a mechanical timer system.

Stat. Auth.: ORS 431.925 - 431.955 Stats. Implemented: ORS 431.930

Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. cf. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PII 14-2008, f. & cert. ef. 9-15-08; PII 4-2010, f. & cert. ef. 2-16-10; PII 10-2011, f. 9-30-11, cert. cf. 10-1-11; PH 14-2013, f. 12-26-13, cert. ef. 1-1-14

#### 333-119-0100

#### Equipment

- (1) The registrant shall use only tanning devices manufactured in accordance with the specifications set forth in 21 CFR Part 1040, Section 1040,20, "Sunlamp Products and Ultraviolet Lamps Intended for Use in Sunlamp Products."
- (2) Each sunlamp product or Ultraviolet Lamp used in these facilities shall not emit measurable Ultraviolet C radiation.
- (3) Each Ultraviolet Lamp contained within the sunlamp product shall be shielded so as to not come into contact with the customer. A transparent acrylic cover shall be used for this purpose.

- (4) Tanning booths in which the customer is in a standing position shall be provided with a handrail for the customer to hold onto during operation of the booth.
- (a) The construction of the booth shall be such that it will have the strength to withstand the stress of use and the impact of a falling person.
- (b) Entry to stand-up-booths shall be of rigid construction with doors which are non-latching and open outwardly.
- (5) Each tunning device shall have, clearly marked, the appropriate position the customer is to assume prior to operation [D4].
- (26) Each tanning device shall-be labeled in accordance with 21 CFR Part 1040, prominently display the following label or equivalent warning/information label:

DANGER - ULTRAVIOLET RADIATION.

FOLLOW-INSTRUCTIONS CAREFULLY

#### DO NOT ENTER WITHOUT PROTECTIVE EYEWEAR

- (37) Adequate means shall be provided to enable a customer to summon assistance from the exposure position.
- (48) All persons hired for servicing and repair of tanning devices shall be an Authority licensed service technician or State of Oregon licensed electricians.
- (59) Original Equipment Manufacturer (OEM) replacement parts (or equivalent) shall be used, if available, to prevent UL/ETL delisting of tanning devices. All local, State of Oregon, and National Electrical Codes codes must be observed during service and repair actions.
- (610) Replacement lamps shall be certified by the manufacturer as equivalent to Defective or burned out tanning lamps or bulbs shall be replaced with a type intended for use in the device and shall be of the same Ultraviolet range (A or B) as the manufacturer specifies, and shall be the original lamp type as specified by the manufacturer, or certified as an equivalent lamp per 21 CFR 1040,20.
- (744) If equivalent lamps are used instead of the Original Equipment Manufacturer (OEM) required lamps, a copy of the equivalency certification, provided by the lamp supplier, shall be maintained on file for review by the Authority during inspections, inspectors.
- (812) Lamps removed from a tanning device Defective or burned out tanning lamps and tanning lamps which have been operated in a tanning device for the manufacturer's maximum rated lamp hour life, shall be disposed of in a safe and proper manner to

prevent unauthorized and unsafe use as lighting devices. Used tanning lamps are prohibited from being resold for any purpose.

- (439) If the Ultraviolet tanning device is not in an individual cubicle, then a suitable screen, curtain, or other shield shall be provided, maintained, and used to prevent unnecessary exposure to Ultraviolet radiation of persons not using the device.
- (14) The facility operator shall ensure that customers do not exceed the exposure time indicated by the manufacturer.
- (4510) Each tanning device shall have a timer that complies with the requirements of 21 CFR Part 1040, Section 1040.20 (c)(2).
- (a11) The maximum timer interval shall not exceed the manufacturer's maximum recommended exposure time, or 20 minutes, whichever is less.
- (12b) A tanning facility shall use the following exposure schedule or an equivalent schedule to accommodate for on tanning devices originally designed with a 30 minute maximum exposure timers that are have been reduced to a 20 minute maximum exposure timers: A copy of this exposure schedule must be affixed to the tanning device, and a copy maintained at the timer controls.
- (A) Skin type 1:
- (i) Week 1: 1-3 minutes;
- (ii) Week 2: 4-6 minutes;
- (iii) Week 3: 7-10 minutes;
- (iv) Week 4: 11-15 minutes.
- (B) Skin type 2 and 3:
- (i) Week 1: 4 minutes;
- (ii) Week 2: 8 minutes;
- (iii) Week 3: 12 minutes;
- (iv) Week 4: 16 minutes;
- (v) Weekly maintenance: 20 minutes.
- (C) Skin Type 4 and 5:

- (i) Week 1: 4 minutes;
- (ii) Week 2: 12 minutes;
- (iii) Week 3: 16 minutes;
- (iv) Week 4: 20 minutes;
- (v) Weekly maintenance: 20 minutes.
- (e)13) Tanning device timers shall be controlled by a properly trained operator. A remote timer control system shall be used for this purpose.
- (d14) Each tanning device shall be equipped with a functional an emergency shut-off mechanism to allow manual termination of the UV exposure by the customer, as required by 21 CFR 1040.20(c)(3).
- (4615) Each timer must be functional and accurate to within  $\pm$  10 percent.
- (1716) The registrant shall ensure that the timer is checked annually for accuracy and the results recorded:
- (1817)The registrant shall ensure that the emergency shut-off is tested annually for proper function and results recorded.
- (18) All tanning devices shall be maintained to the minimum requirements of the manufacturer.
- (19) Each tanning device shall be equipped with an hour meter to accurately determine lamp hour use and recording of maintenance service on each device.

Stat. Auth.: ORS 431,925 - 431,955

Stats. Implemented: ORS 431.655, 431.930 & 431.945

Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. cf. 5-6-94; PII 3-2003, f. & cert. cf. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 14-2008, f. & cert. cf. 9-15-08; PH 4-2010, f. & cert. cf. 2-16-10; PII 10-2011, f. 9-30-11, cert. ef. 10-1-11

#### 333-119-0110

#### Records and Reports

(1) The registrant shall maintain a record of each customer's total number of tanning visits, dates and durations of tanning exposures.

- (2) The registrants shall maintain a record of each customer's signature and acknowledgement that they understand the potential risks involved with exposure to Ultraviolet radiation and overexposure, and that they have reviewed a photosensitizing drug list.
- (3) The registrant shall maintain and have available when requested by the Authority, all completed Oregon Underage Tanning Medical Recommendation forms with copies of the identification used for each minor allowed to use a tanning device.
- (4) Upon their initial visit, all tanning clients must present acceptable identification as proof of age. Any tanning client who appears to be under the age of 26 years shall be required to show identification. The type of identification, identification number, client's name, and date of birth shall be recorded by the registrant in the client's record. When requested by the Authority, records shall be available for review.
- (5) The registrant shall submit to the Authority a written report of injury for which medical attention was sought or obtained from the use of registered tanning devices within five working days after occurrence. The report shall include:
- (a) The name, address and phone number of the affected individual:
- (b) The name, location and phone number of the tanning facility involved:
- (c) The nature of the actual or alleged injury; and
- (d) Any other information relevant to the actual or alleged injury to include the date and duration of exposure and any documentation of medical attention sought or obtained [D5].
- (6) The registrant shall maintain records showing the results of annual timer and emergency shut off button tests.
- (7) The registrant shall maintain a record of operator training as required in OAR 333-119-0080(43).
- (8) The registrant shall maintain a copy of the ownersowner's manual for each tanning device, the following information for each tanning device:
- (a) Manufacturer's equipment manual and any other service related material or instruction; and
- (b) The exposure schedule developed by the manufacturer; and
- (e) Records of surveys, inspections, maintenance, and modifications performed on the tanning device with names of persons performing such services, the date of service, and the hour meter reading of the device serviced.

- (9) Records shall be maintained showing the receipt, transfer, repair and method of disposal of all tanning devices and lamps.
- (10) All required records shall be maintained in a location and format until inspected by the Authority and shall be so filed as to be readily available for review during inspections conducted by the Authority.

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431,925 - 431,955

Hist.: IID 15-1991, f. & cert. ef. 10-1-91; IID 15-1994, f. & cert. ef. 5-6-94; PH 14-2008,

f. & cert. cf. 9-15-08; PH 14-2013, f. 12-26-13, cert. ef. 1-1-14

#### 333-119-0120

#### Advertising

- (1) Registrants shall not claim or distribute promotional materials that claim using a tanning device is safe, free from risk or that using the device will result in medical or health benefits. Only cosmetic claims can be promoted.
- (2) No person, in any advertisement, shall refer to the fact that such person, or such person's facility is registered with the Authority pursuant to the provisions of this division, and no person shall state or imply that any activity under such registration has been approved by the Authority.
- (3) Advertisements for tanning packages shall include the disclaimer that tanning session frequency and duration shall not exceed device manufacturer recommendations.
- (3) No person or facility shall advertise or promote tanning packages labeled as "unlimited".
- (4) Tanning packages shall include the following written tunning guidelines for all clients:
- (a) Initial tanning sessions (three to five) are limited to intervals of at least 48 hours between sessions to allow adequate time for melanin activation and transit to occur prior to subsequent exposures. The manufacturer's recommended exposure schedule posted on tanning devices or listed in the operating manual for the tanning device shall be followed by tanning operators advising new clients during initial tanning sessions.
- (b) After the initial (three to five) tanning exposures, tanning sessions are limited to one tanning session per 24-hour period (or one tanning session per 48 hours on tanning devices so labeled) with customers being properly advised of the manufacturer's recommended exposure schedule posted on tanning devices or listed in the operating manual for the tanning device.

(e) Promotion of annual tanning packages shall include a written statement listing the total number of sessions allowed per person, per year (recommendations should generally not exceed two sessions per week and the maximum of 30-50 sessions per year as recommended by the International Radiation Protection Association (IRPA) and other authorities).

Stat. Auth.: ORS 431.925 - 431.955 Stats. Implemented: ORS 431.930

Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. cf. 5-6-94; PII 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PII 14-2008, f. & cert. ef. 9-15-08; PH 20-2010, f. & cert. cf. 9-1-10

#### 333-119-0130

#### Exemptions

- (1) The Authority may, upon application therefore or upon its own initiative, grant such exemptions or exceptions from the requirements of the rules in this section as it determines are authorized by law and will not result in undue hazard to public health and safety.
- (2) A phototherapy device used by or under the direct supervision of a physician licensed under ORS chapter 677 is exempt from the requirements of this division.
- (3) Any individual is exempt from the provisions of this division to the extent that such individual owns a tanning device exclusively for personal use.
- (4) Tanning devices, while in transit or storage incidental thereto, are exempt from the registration provisions of this division.
- (a) (add storage to definitions) power disconnect and lamps removed.
- (5) Tanning devices located in any facility having public access are required to have the power supply physically disconnected from the device and lamps removed in order to qualify for a no-fee required storage designation. Tanning devices with lamps installed and power active to the device are required to be registered with the Authority and pay applicable fees.

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.925 - 431.955

Hist.: HD 15-1991, f. & cert. cf. 10-1-91; HD 15-1994, f. & cert. cf. 5-6-94; PH 14-2008,

f. & cert. cf. 9-15-08

#### Surveys and Monitoring

#### 333-120-0200

#### General

- (1) Each licensee or registrant must make or cause to be made, surveys that:
- (a) Are necessary for the licensee or registrant to comply with the rules in this division;
  and
- (b) Arc reasonable under the circumstances to evaluate:
- (A) The magnitude and extent of radiation levels; and
- (B) The concentrations or quantities of radioactive material; and
- (C) The potential radiological hazards that could be present.
- (2) Notwithstanding 333-120-0620, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning. Records must be retained in accordance with 10 CFR parts 30.35(g), 40.36(f), and 70.25
- (32) The licensee or registrant must ensure that instruments and equipment used for quantitative radiation measurements (e.g. dose rate and effluent monitoring) are calibrated at intervals not to exceed 12 months for the radiation measured, except when a more frequent interval is specified in another applicable division or a license condition.
- (43) All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees or registrants to comply with OAR 333-120-0100, with other applicable provisions of this division or with conditions specified in a license must be processed and evaluated by a dosimetry processor;
  - (a) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

- (b) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.
- (54) The licensee or registrant must ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

333-120-0210

Conditions Requiring Individual Monitoring of External and Internal Occupational Dose

Fach licensee or registrant must monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dosc limits of this division. As a minimum:

- Each licensee or registrant must monitor occupational exposure to radiation and must supply and require the use of individual monitoring devices by:
- (a) Adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in OAR 333-120-0100(1);
- (b) Minors likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in OAR 333-120-0160 or 333-120-0170;
- (c) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of one mSv (0.1 rem);
- (d) Individuals entering a high or very high radiation area; and
- (e) Individuals working with medical fluoroscopic equipment.
- (A) An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to OAR 333-120-0170(1), must be located under the protective apron at the waist.
- (B) An individual monitoring device used for lens dose equivalent must be located at the neck, or an unshielded location closer to the lens, outside the protective apron.
- (C) When only one individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to OAR 333-120-0100(3)(b) it must be located at the neck outside the protective apron. When a second individual monitoring device is used, for the same purpose, it must be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.

- (2) Each licensee or registrant must monitor (OAR 333-120-0130) the occupational intake of radioactive material by and assess the committed effective dose equivalent to:
- (a) Adults likely to receive, in one year, an intake in excess of 10 percent of the applicable ΛLI(s) in 10 CFR Part 20 Table 1, Columns 1 and 2, of Appendix B to 20.1001 to 20.2401; and
- (b) Minors likely to receive, in one year, from radiation sources external to the body, a deep dose equivalent in excess of one mSv (0.1 rem), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv).
- (c) Declared pregnant women likely to receive, during the entire pregnancy, from radiation sources external to the body, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

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

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PII 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PII 12-2006, f. & cert. ef. 6-16-06; PII 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

#### 333-120-0670

#### Records of Waste Disposal

- (1) Each licensee shall must maintain records of the disposal of licensed materials made under divisions OAR 333-120-0510, 333-120-0520, 333-120-0530, 333-120-0540, 10 CFR Part 61, and disposal by burial in soil, including burials authorized before January 28, 1981.
- (2) The licensee shall maintain the records required by section 1 of this rule until the Authority terminates each pertinent license requiring the record. Requirements for disposition of these records, prior to license termination are located in OAR 333-100-0055, 333-102-0355 and 10 CFR Part 72.80 for licensed activities.
- (32) The licensee shallmust retain the records required by section (1) of this rule until the Authority terminates each pertinent license requiring the record.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. cf. 5-6-94; PH 3-2003, f. & cert. cf. 3-27-03; PH 31-

2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

#### 333-121-0010

#### Definitions

- (1) "Annually" means at intervals not to exceed one year.
- (2) "Commencement of construction" means taking any action defined as "construction" or any other activity at the site of a facility subject to the regulations in this division that has a reasonable nexus to radiological health and safety.
- (3) "Construction" means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the regulations in this part that are related to radiological safety or security. The term "construction" does not include:
- (a) Changes for temporary use of the land for public recreational purposes;
- (b) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;
- (c) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;
- (d) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this part;

#### (e) Excavation;

- (1) Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;
- (g) Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);
- (h) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or
- (i) Taking any other action that has no reasonable nexus to radiological health and safety

- (42) "Doubly encapsulated sealed source" means a sealed source in which the radioactive material is sealed within an inner capsule and that capsule is sealed within an outer capsule.
- (53) "Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the scaled radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.
- (64) "Irradiator operator" means an individual who has successfully completed the training and testing described in OAR 333-121-0300 and is authorized by the terms of the license to operate the irradiator without a supervisor present.
- (75) "Irradiator operator supervisor" means an individual who meets the requirements for an irradiator operator and who physically oversees operation of the irradiator by an individual who is currently receiving training and testing described in OAR 333-121-0300.
- (86) "Panoramic dry-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type drysource-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.
- (97) "Panoramic irradiator" means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.
- (108) "Panoramic wet-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.
- (119) "Pool irradiator" means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.
- (120) "Product conveyor system" means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.
- (134) "Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

- (142) "Scaled source" means any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the byproduct material.
- (153) "Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10%, as designated by the US Geological Survey.
- (164) "Underwater irradiator" means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

Stat. Auth.: ORS 453.675

Stats. Implemented: ORS 453.675 Hist.: PH 5-2005, f. & cert. ef. 4-11-05

333-121-0020

#### Application for a Specific License

- (1) Applications for specific licenses shall be filed on a form prescribed by the Authority and satisfy the general requirements specified in 333-102-0200..
- (2) The Authority may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Authority to determine whether the application should be granted or denied or whether a license should be modified or revoked.
- (3) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.
- (4) An application for a license may include a request for a license authorizing one or more activities.
- (5) In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Authority provided such references are clear and specific.
- (6) Applications and documents submitted to the Authority may be made available for public inspection except that the Authority may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

Stat. Auth.: ORS 453.675

Stats. Implemented: ORS 453.675 Hist.: PH 5-2005, f. & cert. cf. 4-11-05

333-122-0005

#### Definitions

As used in this division, the following definitions apply:

(16) "Radiation safety officer for industrial x-ray" means an individual with the responsibility for the overall radiation safety program on behalf of the registrant and who meets the requirements of 333-122-0175200 of these rules.