# Radiation Advisory Committee
# Proposed Rule Making
# February 12, 2014

**333-100-0020(5)(d), Prohibited Uses: Revise reference number within the text of the rule.**

**333-102-0300(2)(c), Issuance of Specific Licenses: Change text from "of" to "or".**

**333-103-0010, Annual Fee for Specific Licenses: Increase fees by 25%.**

**333-103-0015, Annual Registration Fee for General Licenses and Devices: Increase fees by 25%.**

**333-103-0035, Fees for Radiological Analyses: Increase fees by 25%.**

**333-106-0055, X-Ray Operator Training (Draft), Removes training requirements.**

**333-106-0345 – 0368, New CT Rules.**

**333-116-0190(3), Authorization for Calibration Source: revise mCi to uCi.**

**333-116-0687, Qualifications for Authorized User for Oral Administration……..: Change title to match code of federal regulations.**

**333-118-0020(13) and (28), Add definitions referencing "Indian Tribe and Tribal Official".**

**333-120-0710(2)(A)(B) and (C), Notification of Incidents: Remove the term "sieverts or".**

**333-100-0020**

**Prohibited Uses**

(1) Hand-held fluoroscopic screens shall not be used unless they have been listed in the Registry of Sealed Source and Devices or accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health.

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

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

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

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

(a) Podiatrists, Chiropractors, Dentists, Naturopath, Osteopaths, Medical Doctors, and Veterinarians;

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

(c) Dental Professionals are permitted to prescribe and review intraoral radiographs, in accordance with the Oregon Board of Dentistry administrative rules, chapter 818.

(d) No person will be allowed to use X-ray producing equipment without first meeting the requirements of OAR 333-106-0045(1~~6~~5) or 333-106-0055.

(6) No person shall intentionally or unintentionally expose another individual to radiation other than ionizing radiation in such a way as to adversely affect the health or safety of that individual. Notwithstanding this restriction, the use of radiation other than ionizing radiation by persons licensed by the State of Oregon to practice the healing arts and who are authorized to use radiation will be allowed.

(7) Dental units with a Kilovolt peak (kVp) of 50 and below are prohibited from being sold, leased, transferred or lent.

(a) Existing diagnostic dental X-ray systems less than 55 kVp shall not be used on minors.

(b) After October 1, 2011, registrants may not use diagnostic dental X-ray systems with a fixed, nominal kVp of less than 55.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

**333-102-0300**

**Issuance of Specific Licenses**

(1) Upon a determination that an application meets the requirements of the Act and these rules, the Authority will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(2) The Authority may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this division as it deems appropriate or necessary in order to:

(a) Minimize danger to public health and safety or property;

(b) Require such reports and the keeping of such records and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(c) Prevent loss or~~of~~ theft of material subject to this division.

(3) Whenever the Authority denies an application for a new license or a license renewal, the Authority will notify the applicant in writing stating the grounds for denial. Upon denial, the applicant may request a hearing pursuant to OAR 333-102-0345.

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

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

**333-103-0010**

**Annual Fee for Specific Licenses**

(1)(a) Each specific license listed in section (2) of this rule, as defined in OAR 333-102-0203, shall be licensed pursuant to sections (2), (3), (4), (5), and (6) of this rule by a specific license fee.

(b) Upon written request and approval by the Authority, fees for new licenses or additional sources may be prorated on a quarterly basis for the current fiscal year.

(2) Each specific license type appearing in the following fee schedule shall be licensed separately with a specific license fee as indicated:

(a) Analytical/Leak Test/Fixed X-ray Fluorescence, $690~~552~~(F);

(b) Basic License, $1,220~~976~~(F);

(c) Brachytherapy, $2,755~~2,204~~(F);

(d) Broad Scope A, $3,000(F);

(e) Broad Scope B, $2,755~~2,204~~(F);

(f) Broad Scope C, $1,370~~1,096~~(F);

(g) Distribution, $1,370~~1,096~~ (F);

(h) Fixed Gauge, $345~~276~~(S);

(i) High, medium and low doserate brachytherapy, $3,445~~2,756~~(S);

(j) Imaging and Localization, $1,258~~1,096~~(F);

(k) In Vitro Laboratory, $455~~364~~(F);

(l) Industrial Radiography:

(A) Fixed Facility, $3,000(F);

(B) Field Use, $3,000(F);

(m) Instrument Calibration, $1,035~~828~~(S);

(n) Investigational New Drug, $2,065~~1,652~~(F);

(o) Irradiator Self-Shielded, $~~1,096~~(S);

(p) Manufacturing/Compounding, $3,670~~2,936~~(F);

(q) Mobile Nuclear Medicine, $3,670~~2,936~~(F);

(r) NORM (no processing), $920~~736~~(F);

(s) Nuclear Pharmacy, $3,000(F);

(t) Other Measuring Device, $200~~160~~(S). Six sources or more, for attenuation purposes, may apply for a basic license;

(u) Portable Gauge:

(A) X-ray Fluorescence, $690~~552~~(S);

(B) All other portable gauges, $920~~736~~(S);

(v) Radiopharmaceutical Therapy, $2,065~~1,652~~(F);

(w) RAM/NOS Facility, $3,000(F);

(x) Research & Development, $2,065~~1,652~~(F);

(y) Sealed Sources for Diagnosis, $690~~552~~(S);

(z) Source Material, $3,000(F);

(aa) Special Nuclear Material (sealed), $1,370~~1,096~~(S);

(bb) Special Nuclear Material (unsealed), $3,307~~2,756~~(F);

(cc) Teletherapy (external beam), $3,000(S);

(dd) Unique, $No Fee;

(ee) Uptake and Dilution, $920~~736~~(F);

(ff) Use of Xenon Gas, $920~~736~~(F);

(gg) Waste Packaging, $3,000(F);

(hh) Well Logging, $2,068~~1,652~~(S);

**NOTE**: (F) means facility; (S) means source.

(3) Each specific license validation fee shall be due and payable:

(a) Each specific license validation fee shall be due and payable based on the following fee schedule.

(A) Validation fees for licenses expiring July through September are due by October 1 each year.

(B) Validation fees for licenses expiring October through December are due by January 1 each year.

(C) Validation fees for licenses expiring January through March are due by April 1 each year; and,

(D) Validation fees for licenses expiring April through June are due by July 1 each year.

(b) For each specific license source of radiation listed in section (2) of this rule for which application pursuant to OAR 333-102-0190 for an Oregon Radioactive Materials License has been made;

(c) For each additional specific license source of radiation in an amendment to an existing Oregon Radioactive Materials License pursuant to OAR 333-102-0320.

(4) A license for each specific license issued pursuant to section (3) of this rule shall be provided by the Authority. The certificate of validation for the current fiscal year shall be retained by the licensee and attached to the license pursuant to requirements in OAR 333-111-0005.

(5) The specific license fee that validates specific sealed sources also validates possession of one additional sealed source during source exchange (one new source and one spent source) for a period not to exceed 30 calendar days.

(6) Sealed sources manufactured and distributed as reference sources that do not exceed 100 times the quantity in 30.71 Schedule B of 10 CFR Part 30 are exempt from specific license fees and validation if used pursuant to a specific license listed in section (2) of this rule. The license validation fee for reference sources that exceed 100 times the quantity in 30.71 Schedule B of 10 CFR Part 30 or reference sources authorized alone without additional licensed radioactive material shall be $976, pursuant to subsection (2)(b) of this rule.

Stat. Auth.: ORS 453.757
Stats. Implemented: ORS 453.757
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 13-1988, f. 6-7-88, cert. ef. 7-1-88; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 2-1995(Temp), f. & cert. ef. 7-11-95; HD 4-1995, f. & cert. ef. 9-8-95; HD 3-1996, f. & cert. ef. 8-9-96; PH 11-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

**Annual Registration Fee for General Licenses and Devices**

(1) Any general license granted by the Authority must be validated annually by the general license registration fee listed in section (2) of this rule, unless otherwise exempted by subsection (2)(e) of this rule. Validation must be confirmed by verifying, correcting, and/or adding to the information provided in a request for registration received from the Authority. General License registration fees as defined in OAR 333-103-0003 shall:

(a) Validate each general licensed source of radiation due October 1 of each year for sources of radiation; and

(b) Validate each new application to register general license material pursuant to OAR 333-101-0007; and

(c) Registration.

(2) The general licenses appearing in the following fee schedule shall be registered on the appropriate Authority form and shall be validated annually by a general license registration fee:

(a) Each healing arts facility that uses radioactive material for In Vitro laboratory or clinical testing authorized by OAR 333-102-0130, $200~~160~~;

(b) Each radiation source in a generally licensed measuring, gauging or controlling device authorized pursuant to OAR 333-102-0115(1), $200~~160~~;

(c) For radioactive material contained in devices designed and manufactured for the purpose of producing light, except Tritium exit signs, or an ionized atmosphere that exceed the limits in OAR 333-102-0105, $66 per device for the first twelve devices after which a Basic Specific License is required.

(d) Each general licensee possessing or using depleted uranium for the purpose of providing a concentrated mass in a small volume of the product or device pursuant to OAR 333-102-0103, $200~~160~~;

(e) Each General Licensee possessing or using source material for research, development, educational, commercial or operational purposed pursuant to OAR 333-102-0101, $300~~240~~;

(f) General licenses not specifically identified in subsections (2)(a), (2)(b), (2)(c) and (2)(d) of this rule are exempt from the payment of an annual general license registration fee.

(g) Each out-of-state or NRC specific licensee granted a general license pursuant to OAR 333-102-0340 to conduct activities within the State of Oregon for a period not to exceed 180 days in a calendar year must pay a registration validation fee as required by OAR 333-103-0030(6).

(h) State and local government agencies are required to register each generally licensed device but are exempt from the fees required in this rule.

(3) Notwithstanding subsection (2)(g) of this rule, the general license fee shall be due and payable on or before October 1 of each year.

(4) A certificate of validation for the then current fiscal year shall be provided by the Authority. The certificate for the then current fiscal year must be retained by the licensee and attached to the general license.

(5) Upon written request and approval by the Authority, fees for new licenses or additional sources may be prorated on a quarterly basis for the fiscal year.

Stat. Auth.: ORS 453.757
Stats. Implemented: ORS 453.757
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 13-1988, f. 6-7-88, cert. ef. 7-1-88; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1991, f. & cert. ef. 10-1-91; HD 2-1995(Temp), f. & cert. ef. 7-11-95; HD 4-1995, f. & cert. ef. 9-8-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 11-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 20-2010, f. & cert. ef. 9-1-10

**333-103-0035**

**Fees For Radiological Analyses**

(1) An individual, agency, or company that requests that the Authority Radiation Laboratory perform radiological analyses on samples must pay a fee to the Authority in accordance with the schedule in section (2) of this rule. The responsible individual submitting the sample(s) must first obtain a request form from the Authority. This form contains the fee schedule and the types of radiological analyses offered. That individual must then submit the completed form along with the sample and the appropriate fee to the Authority. The Authority will send the results by return mail in accordance with the estimated time as per section (3) of this rule.

(2) Fee Schedule:

(a) Gamma Isotopic:

(A) Liquid — $298~~248~~

(B) Solid — $341~~284~~

(b) Low-level Iodine-131 — $212;

(C) Tritium (H-3) — $92.

(3) The analyses results will be available in approximately five working days for Gamma Isotopic analyses.

**NOTE**: If the Authority cannot complete the analyses according to the schedule in section (3) of this rule, the Authority will notify the customer as soon as possible.

(4) A $100 surcharge shall be added to the fee for a one-day completion schedule for a Gamma Isotopic analysis.

Stat. Auth.: ORS 453.757
Stats. Implemented: ORS 453.757
Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 2-1995(Temp), f. & cert. ef. 7-11-95; HD 4-1995, f. & cert. ef. 9-8-95; PH 11-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

**333-106-0055**

**X-ray Operator Training DRAFT**

(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 documented adequate training in radiation safety.

(2) Adequate training in radiation safety means X-ray operators have completed a 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 an~~

(3) At a minimum an Authority approved training course 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;~~

~~(j) 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) 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

(B) How to develop an accurate chart

(C) Low dose techniques

(D) Pediatric techniques (does not apply to veterinary)

(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

(A) 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

(~~2~~4) Dental X-ray operators who meet the following requirements are considered to have met the requirements in section (1) of this rule:

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

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

(e) 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 (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:

**Comment [O1]:** Deleted based on meeting with Teresa at the Dental Board.

**Comment [O2]:** Deleted based on meeting with Teresa at the Dental Board.

**Comment [O3]:** I think we may need to add some wording here, to accommodate those who are applying for an Oregon certificate by credential…

**Comment [O4]:** Deleted based on meeting with Teresa at the Dental Board.

**Comment [O5]:** Covered under Dental Assistant Rules, based on meeting with Teresa at the Dental Board.

**Comment [MAK6]:** Does this say the same thing as (e)? It sounds like it to me, if you also agree I say we delete it.

**Comment [MAK7]:** This reference doesn't make much sense because 0035 says you can't take X-rays for demonstration purposes… I say delete this part

**Comment [O8]:** Propose moving this to Dental Rulse in 818-042-0050

**Comment [MAK9]:** Moved to a new section

**Comment [MAK10]:** Moved to a new section

**Comment [MAK11]:** Moved to a new section

**Comment [MAK12]:** Moved to a new section

~~(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.~~

**Comment [MAK13]:** Moved to a new section

~~(b) A dental radiation use and safety instructor is an individual who has:~~

**Comment [MAK14]:** Moved to a new section

~~(A) Passed the Radiation Health and Safety (RHS) or the Certified Dental Assistant (CDA) examination administered DANB; or~~

**Comment [MAK15]:** Moved to a new section

~~(B) Has been evaluated and approved as a qualified Dental radiation use and safety instructor by the Oregon Board of Dentistry; and~~

**Comment [MAK16]:** Moved to a new section

~~(C) Is currently licensed by the Oregon Board of Dentistry as a dentist; or~~

**Comment [MAK17]:** Moved to a new section

~~(D) Is a dental hygienist; or~~

**Comment [MAK18]:** Moved to a new section

~~(E) Is a dental assistant certified in Radiologic proficiency and has a minimum of two years of experience in taking dental radiographs.~~

**Comment [MAK19]:** Moved to a new section

~~(c) A veterinarian radiation use and safety instructor is an individual who is:~~

**Comment [MAK20]:** Moved to a new section

~~(A) Currently credentialed with the Oregon Veterinary Medical Examining Board, or licensed as a Radiologic Technologist by the Oregon Board of Medical Imaging; and~~

**Comment [MAK21]:** Moved to a new section

~~(B) Has completed training specific to veterinarian radiography, including training in animal restraint; and~~

**Comment [MAK22]:** Moved to a new section

~~(C) Have a minimum of two years of experience in taking veterinary radiographs.~~

**Comment [MAK23]:** Moved to a new section

~~(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~~

**Comment [MAK24]:** Moved to a new section

~~(B) The individual meets the requirements of a qualified expert as defined in OAR 333-100-0005(80).~~

**Comment [MAK25]:** Moved to a new section

~~(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~~.

**Comment [MAK26]:** Moved to the dental section

~~(6) The operator shall be able to demonstrate competency in the safe use of the X-ray equipment and associated X-ray procedures.~~

**Comment [MAK27]:** Moved to the end, so it's clear it applies to EVERYONE

(~~7~~5) ~~Any d~~Diagnostic 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 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), 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.

~~(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:~~

**Comment [MAK28]:** Moved up to Dental section

~~(a) They are enrolled in an Oregon Board of Dentistry approved radiology course; or~~

**Comment [MAK29]:** Moved up to Dental section

~~(b) A student studying under an Oregon Board of Dentistry approved radiology instructor; and~~

**Comment [MAK30]:** Moved up to Dental section

~~(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~~

**Comment [MAK31]:** Moved up to Dental section

~~(d) Demonstrated to the instructor that they are ready to take dental radiographs on human patients through:~~

**Comment [MAK32]:** Moved up to Dental section

~~(A) The use of manneguins under indirect supervision; or~~

**Comment [MAK33]:** Moved up to Dental section

~~(B) Taking dental radiographs of human patients while under the direct supervision of the instructor; and~~

**Comment [MAK34]:** Moved up to Dental section

~~(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 clinical training and available for review by the Oregon Health Authority, Public Health Division inspection staff at the time of inspection.~~

**Comment [MAK35]:** Moved up to Dental section

~~(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.~~

**Comment [MAK36]:** Moved up to dental section

~~(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.~~

**Comment [MAK37]:** Moved up to dental section

(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 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.

~~(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.~~

(~~13~~9) ~~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 section~~s~~ (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 section~~s~~ ~~(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. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 24-1994, f. & cert. ef. 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. ef. 9-15-08; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-106-0056 Radiation Use and Safety Instructor Qualifications

(1) The training required in chapter 0055 (1) of this rule must be taught by an Authority approved instructor. Approval will be based upon the following criteria:

(a) An individual who meets the requirements of a qualified expert as defined in OAR 333-100-0005(80).

(b) A medical use and safety instructor is an individual who is:

(A) Currently licensed as a Radiologic Technologist and approved as an education provider by the Oregon Board of Medical Imaging.

(c) 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 (CDA) 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.

(d) 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.

(2) 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 (1)(a), (1)(b) or (1)(c) of this rule or is an individual who is qualified under OAR 333-101-0230 as a Hospital Radiology Inspector; or

**333-106-0345**

**Purpose and scope**

(1) This part establishes requirements governing the use of computed tomography (CT) scanners in the healing arts.

(2) This part applies to all registrants who use a CT scanner for the intentional exposure of humans for diagnostic imaging.

~~(4) In addition to the requirements of this part, all registrants are subject to chapter 333, divisions 100-124 as appropriate.~~

**333-106-0350**

**Definitions**

In addition to the definitions provided in division 100 and 106 of these rules, the following definitions shall be applicable to this rule.

(1) “Annual” means a period of 12 consecutive months, not to exceed a period of 14 months.

(2) “Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data. Computed tomography includes the capability of producing axial tomograms.

(3) “CT scanner” means a CT machine capable of performing CT scans of the head, other body parts, or full body patient procedures including PET/CT and SPECT/CT hybrid scanners if used for diagnostic CT procedures.

(~~4~~1) "Computed Tomography Dose Index" means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan. This definition assumes that the dose profile is centered around z = 0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

(~~5~~2) "Contrast Scale" means the change in the linear attenuation coefficient per CTN relative to water.

(~~6~~3) "CS" (see Contrast scale).

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**Comment [O38]:** This statement is covered at the beginning of the division.

**Comment [ML39]:** This refers to all other general rules like registering the machine, dosimetry, etc. I’m not sure what the official way to site this is but this will be the place holder language for now.

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**Comment [ML40]:** Reworded for final draft.

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(74) "CT Conditions of Operation" means all selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in OAR 333-106-0005.

(85) "CTDI" (see Computed tomography dose index).

(96) "CT Gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

(107) CTN (see CT number).

(118) CT Number means the number used to represent the X-ray attenuation associated with each elemental area of the CT image.

(12) "Dose-length product (DLP)" is the CTDI multiplied by the scan length (image thickness multiplied by the number of adjacent, non-overlapped images in the acquisition) in centimeters.

(139) "Dose Profile" means the dose as a function of position along a line.

(10) "Elemental Area" means the smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted (see also Picture element.)

(141) "Multiple Tomogram System" means a computed tomography X-ray system which obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

(152) "Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water.

(163) "Nominal Tomographic Section Thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which X-ray transmission data are collected.

(17) "Positron emission tomography (PET)"means an imaging technique that uses positron-emitting radionuclides to produce 3-dimensional images of functional processes in the body.

(184) "Picture Element" means an elemental area of a tomogram.

(19) "Qualified CT Medical Physicist" means an individual qualified in accordance with OAR 333-106-0367

(2015) "Reference Plane" means a plane which is displaced from and parallel to the tomographic plane.

(2116) "Scan" means the complete process of collecting X-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

(2217) "Scan Increment" means the amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of such displacement.

(2318) "Scan Sequence" means a preselected set of two or more scans performed consecutively under preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

(2419) "Scan Time" means the period of time between the beginning and end of X-ray transmission data accumulation for a single scan.

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**Comment [ML41]:** Suggested wording change.

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(25) “Single photon emission computed tomography (SPECT)”means an imaging technique that uses radionuclides to produce3-dimensional images of functional processes in the body.

(2~~6~~0) "Single Tomogram System" means a CT X-ray system which obtains X-ray transmission data during a scan to produce a single tomogram.

(27) “Tomogram” means the depiction of the attenuation properties of a section through a body.

(2~~8~~1) "Tomographic Plane" means that geometric plane which is identified as corresponding to the output tomogram.

(2~~9~~2) "Tomographic Section" means the volume of an object whose X-ray attenuation properties are imaged in a tomogram.

(30) “Traceable to a national standard” means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with the NIST at least once every 2 years and the results of the proficiency test conducted within 24 months of calibration show agreement within ± 3% of the national standard in the appropriate energy range.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08

**333-106-0355**

**Requirements for Equipment**

**CT Equipment requirements**

(1) CT Equipment requirements shall comply with the Food and Drugs 21 CFR in the following areas:

(a) Information to be provided for users – Part 1020.33(c).

(b) Quality Assurance – Part 1020.33(d).

(c) Control and indication of conditions of operation – Part 1020.33(f).

(d) Tomographic plane indication and alignment - Part 1020.33(g).

(e) Beam-on and status indicators – Part 1020.33(h).

(f) Scan increment accuracy – Part 1020.33(i).

(g) CT number mean and standard deviation – Part 1020.33(j).

~~(1) Termination of Exposure:~~

~~(a) Means shall be provided to terminate the X-ray exposure automatically by either de-energizing the X-ray source or shuttering the X-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function;~~

~~(b) A visible signal shall indicate when the X-ray exposure has been terminated through the means required by subsection (1)(a) of this rule;~~

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**Comment [ML42]:** The federal performance standards apply to the manufacture and installation of ionizing radiation emitting products. Most of these rules were written into OR’s rules but have now been taken out so all the federal rules can be referenced instead.

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~~(c) The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under CT X-ray system control, of greater than one-half second duration.~~

(2) CT equipment shall be maintained in compliance with the requirements of section (1) of this rule.

~~(2) Tomographic Plane Indication and Alignment:~~

~~(a) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane;~~

~~(b) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes;~~

~~(c) If a device using a light source is used to satisfy subsection (2)(a) or (b) of this rule, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.~~

~~(3) Beam-On and Shutter Status Indicators and Control Switches:~~

~~(a) The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed;~~

~~(b) Each emergency button or switch shall be clearly labeled as to its function.~~

~~(4) Indication of CT Conditions of Operation. The CT X-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operations at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.~~

~~(5) Extraneous Radiation. When data are being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by OAR 333-106-0101(5) of these rules.~~

~~(6) Maximum Surface CTDI Identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.~~

~~(7) Additional Requirements Applicable to CT X-ray Systems Containing a Gantry Manufactured After September 3, 1985:~~

~~(a) The total error in the indicated location of the tomographic plane or reference plane shall not exceed five millimeters;~~

~~(b) If the X-ray production period is less than one-half second, the indication of X-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible;~~

~~(c) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus one millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 cm, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel;~~

~~(d) Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.~~

**Comment [ML43]:** This subrule states that the equipment must be kept in the same condition as when it was installed.

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Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08

**333-106-0360**

**Facility Design Requirements**

(1) ) A fixed CT scanner room shall be a permanent part of the building or equipment. Portable shields shall not be used for permanent installations. ~~Aural Communication. Provisions shall be made for two-way aural communication between the patient and the operator at the control panel.~~

(2) The CT scanner shall be situated in a protected area and is subject to design approval by a qualified expert. National Council on Radiation Protection and measurements (NCRP) Report #147 shall be used as guidance for determining adequate shielding. ~~Viewing Systems:~~

~~(a) Windows, mirrors, closed-circuit televisions, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel;~~

~~(b) When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.~~

(3) The control panel for a fixed CT scanner shall be in a protected area.

(4) Movable barriers with electrical interlocks shall not be approved in lieu of compliance with section (3) of this rule.

(5) The operator of a fixed CT scanner shall be able to see and communicate with the patient from the protective area at the control panel. When an observation window is provided, it shall have a lead equivalence at least equal to that required of the control barrier in which it is installed.

(6) Mobile or portable CT scanners used routinely in 1 location shall be considered a fixed installation and shall comply with the requirements of sections (1) to (5) of this rule.

(7) CT scanners mounted in a vehicle or trailer must meet requirements of sections 1–5.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.775
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

**333-106-0361**

***Radiation Protection Surveys***

(1) The registrant must ensure that radiation protection surveys are performed at new facilities, at existing facilities not previously surveyed, and anytime the CT scanner is replaced, moved or structural changes are made in the room.

(2) In new facilities, a radiation protection survey must be completed prior to the first clinical use following installation.

(3) The radiation protection survey must be performed by a Qualified CT Medical Physicist as defined in 333-106-0367) or a Qualified Expert as defined in 333-100-0005.

(4) Surveys must be conducted with an operable radiation survey instrument that has been calibrated according to manufacturer's specifications, not to exceed 24 months. If manufacturer specifics are not available, then the radiation survey instrument shall be calibrated every 12 months.

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**Comment [ML44]:** The term "protected area" is defined in 333-106-0005.
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(5) The Qualified CT Medical Physicist or Qualified Expert must verify that:

(a) Radiation levels in restricted areas are not likely to cause personnel to receive exposures in excess of the limits specified in 333-120-0100(1); and

(b) Radiation levels in unrestricted areas do not exceed the limits specified in 333-120-0180 and 333-120-0190.

(6) The radiation protection survey record must be documented and indicate all instances where the facility, in the opinion of the Qualified Medical Physicist or a Qualified Expert, is in violation of applicable regulations. The survey record must also include the:

(a) Date of the measurements;

(b) Reason the survey is required;

(c) Manufacturer's name, model number and serial number of the CT scanner;

(d) Manufacturer and model of the instrument(s) used to measure radiation levels and date last calibrated;

(e) A floor plan of the areas surrounding the exam room that were surveyed;

(f) Measured dose rate at several points in each area expressed in mSv/hr or mR/hr.;

(g) Calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area;

(h) Signature of the individual responsible for conducting the survey; and

(i) The survey must be available for review at the time of inspection.

**333-106-0362**

**Operating Procedure and Conditions of Operation**

(1) Within six months following the effective date of these rules, the CT facility shall establish default scanning protocols in consultation with a Qualified CT Medical Physicist.

(2) Default scanning protocols shall be either password protected or a written policy shall be in place that prohibits anyone from changing protocols without documented approval from the CT medical director, lead CT technologist or supervising CT Radiologist.

(a) Each facility shall establish a policy to review all of their CT default protocols at least annually to ensure they are correct and are the intended protocols.

(b) Written and signed documentation of this annual review shall be kept and made available for inspection for each CT unit at the facility.

(3) The CT operator shall ensure all technique factors and dose indices are appropriate for the protocol being used and the patient being imaged. This may be accomplished by reviewing dose indicator devices if available or dose indices such as the technique factors.

(4) The facility shall establish a written policy for retaking CT exams on patients.

(5) Staff shall not be required by the licensee or registrant to hold patients during CT examinations.

(6) When a patient must be held in position for CT, mechanical supporting or restraining devices shall be used unless contraindicated. If the patient must be held by an individual, this individual shall wear a

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protective apron of 0.5 millimeter minimum lead equivalence and be so positioned that no part of his or her body will be in the path of the primary beam and that his or her body is as far as possible from the edge of the primary beam.

(7) Only individuals whose presence is necessary are allowed in a CT scan room during exposure. Each individual, except the patient, shall be protected by at least 0.5 millimeter lead equivalent aprons or a whole body protective barrier.

(8) A CT scanner shall not be left unattended without locking the apparatus, room, or building in some manner which will prevent use of the apparatus by unauthorized persons.

**333-106-0363**

**Quality Control Program**

(1) The registrant shall ensure that a CT quality assurance phantom is available for testing the CT system.

(2) Instructions on the use of the phantom shall be provided. The instructions shall include a schedule of tests appropriate for the CT system, the allowable variations for the test parameters, and a method to store the test results.

(3) Within six months following the effective date of these rules, a CT facility shall establish and implement a quality control program under the supervision of a CT Medical Physicist.

(4) Evaluations and tests shall be performed following written procedures and methods. Corrective action shall be taken and documented according to instructions provided by the Qualified CT Medical Physicist if the results of an evaluation or test fall outside the control limits.

(5) The Qualified CT Medical Physicist shall determine the frequency of each test. An on-site CT Radiologic Technologist shall be identified to be responsible for the ongoing quality control testing.

(6) The ongoing quality control evaluation should include, at a minimum, the following:

(a) Water CT number accuracy check and standard deviation (Noise);

(b) Artifact evaluation;

(c) Visual checklist; and

(d) Printer quality control (if used for primary interpretation)

**333-106-0364**

**Initial and Annual Qualified CT Medical Physicist Scanner Performance Evaluations**

(1) A CT Medical Physicist shall complete an initial performance evaluation of the CT scanner before use on patients and annually thereafter.

(2) Surveys shall be performed after any change in the facility or equipment which might cause an increase in radiation exposure or any changes in the image quality of the images.

(3) A calibrated dosimetry system shall be used to measure the radiation output of a CT scanner. Calibration of the dosimetry system shall be within the preceding 24 months, or per manufacturer's specifications, and shall be traceable to a national standard.

(4) A performance evaluation shall include the following:

(a)Alignment light accuracy

(b) Alignment of table to gantry.

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**Comment [ML48]:** This sections indicates what the physicist should test for during annual surveys. I believe most of these requirements are what ACR requires.

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(c) Gantry tilt, as appropriate

(d) Slice localization from scanned projection radiograph.

(e) Table travel accuracy.

(f) Image thickness

(g) Radiation Beam Width

(h) Image quality, including the following:
(A) Gray level performance of CT Acquisition display monitors;

(B) Low-contrast performance;

(C) Image uniformity;

(D) Noise;

(E) Artifact evaluation; and

(F) Spatial Resolution

(i) CT number uniformity

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(j) Dosimetry, including the following:

(A) Dose indicator such as computed tomography dose index (CTDI); and

(B) Patient radiation dose for representative examinations.

(k) Safety evaluation, including the following:

(A) Visual inspection:

(B) Audible and visual signals: and

(C) Posting requirements.

(l) Review of clinical protocols shall include at a minimum:

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(A) An evaluation of scanner features, including kV, mAs, detector configuration, reconstructed scan width, pitch, reconstruction algorithm, and other features such as dose reduction options, including automatic exposure controls, iterative reconstruction techniques, etc. to ensure they are being properly utilized; and

(B) Review the following clinical protocols, if they are used on the CT scanner:

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(i) Pediatric head (1 year old)

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(ii) Pediatric abdomen (5 years old; 40-50 lb or approx. 20 kg)

(iii) Adult head

(iv)Adult abdomen (70 kg)

(v) High-Resolution chest
(vi) Brain perfusion, and

(vii) Low dose lung cancer screening exam

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(m) The CTDI for the following CT examinations on standard phantoms shall not exceed the dose limits listed below:

(A) Adult Head, 80 mGy

(B) Adult Abdomen, 30 mGy

(C) Pediatric Abdomen (5 years of age or 40 lbs.), 20 mGy

(D) Pediatric Head, 40 mGy

(n) Review of the facility's ongoing quality control program, including test results and corrective action.

(o) Evaluations and tests shall be performed following written procedures and methods found in the latest ACR CT Quality Control Manual. Corrective action shall be taken and documented according to instructions provided by the medical physicist if the results of an evaluation or test fall outside the control limits.

(5) The Qualified Expert shall prepare a report must include the following:

(a) A summary of the performance evaluation required under section (1) of this rule.

(b) Recommendations for necessary improvements.

(c) Type of dosimetry system used, including the date of the last calibration.

(6) The report required under section (5) of this rule shall be provided to the CT facility within 30 days after completion of the evaluation and shall be made available to the Agency upon request.

(7) The facility shall keep written documentation of action taken to recommended items from the survey report.

(8) Records of preventive maintenance and repair shall be retained for each CT scanner and be made available to the Agency upon request.

**~~333-106-0365~~**

**~~Surveys, Calibrations, Spot Checks, and Operating Procedures~~**

~~(1) Surveys:~~

~~(a) All CT X-ray systems installed after December 1990 and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard;~~

~~(b) The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the Authority upon request.~~

~~(2) Radiation Calibrations:~~

~~(a) The calibration of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration;~~

~~(b) The calibration of a CT X-ray system shall be performed at intervals specified by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output;~~

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(c) The calibration of the radiation output of a CT X-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years;

(d) CT dosimetry phantom(s) shall be used in determining the radiation output of a CT X-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

(A) CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 +- 0.01 grams per cubic cm or a reasonable substitute. The phantom(s) shall be at least 14 cm in length and shall have diameters of 32.0 centimeters for testing CT X-ray systems designed to image any section of the body and 16.0 cm for systems designed to image the head or for whole body scanners operated in the head scanning mode;

(B) CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation along a line parallel to the axis of rotation 1.0 cm from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided;

(C) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom;

(D) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(3) The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

(4) Calibration shall meet the following requirements:

(a) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness;

(b) The CTDI along the two axes specified in paragraph (2)(d)(B) of this rule shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 cm from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant.

**NOTE:** For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.

(c) The spot checks specified in section (5) of this rule shall be made;

(d) Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the Authority.

(5) Spot Checks:

(a) The spot check procedures shall be in writing and shall have been developed by a qualified expert;

(b) The spot-check procedures shall incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material;

~~(c) Spot checks shall be included in the calibration required by section (2) of this rule and at time intervals and under system conditions specified by a qualified expert;~~

~~(d) Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operations as are used to perform calibrations required by section (2) of this rule. The images shall be retained, until a new calibration is performed, in two forms as follows:~~

~~(A) Photographic copies of the images obtained from the image display device; and~~

~~(B) Images stored in digital form on a storage medium compatible with the CT X-ray system.~~

~~(e) Written records of the spot checks performed shall be maintained for inspection by the Authority.~~

~~(6) Operating Procedures:~~

~~(a) The CT X-ray system shall not be operated except by an individual who has been specifically trained in its operation;~~

~~(b) Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following:~~

~~(A) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;~~

~~(B) Instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variation for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;~~

~~(C) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and~~

~~(D) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.~~

~~(7) If the calibration or spot check of the CT X-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified expert, use of the CT X-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.~~

~~Stat. Auth.: ORS 453.605 - 453.807~~
~~Stats. Implemented: ORS 453.605 - 453.807~~
~~Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08~~

**333-106-0366**

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**Records and Report Retention**

(1) A facility with a CT scanner shall maintain records and reports on file and shall make the records and reports available for review by the Agency as follows:

(a) Records documenting the qualifications of all personnel who worked at the facility as an operator or CT Medical Physicist. Records of personnel no longer employed by the facility shall be kept on file until the next inspection following the employee's termination has been completed and the Agency has determined that the facility is in compliance with the CT personnel requirements.

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(b) A report of a CT medical event required under 333-106-0368 shall be maintained on file for at least 7 years.

(c) Initial and annual CT Medical Physicist performance evaluation reports required under 333-106-0364 shall be maintained on file for at least 5 years.

(d) Records of the results from the ongoing quality control evaluation required under R 333-106-0363 shall be maintained on file for at least 3 years.

**333-106-0367**

**Qualified CT Medical Physicist**

(1) In order to perform a CT survey or provide consultative services on a CT unit, a person must be approved by the Authority, under the provisions of 333-101-0020, as a provider of radiation services in CT. In addition, they must qualify as a CT medical physicist by following the requirements outlined below:

(a) Initial qualifications. Before beginning to independently provide consultation to a CT facility, a medical physicist shall meet one of the following:

(A) Be certified in diagnostic radiological physics or radiological physics by the American Board of Radiology, or in diagnostic imaging physics by the American Board of Medical Physics, or in diagnostic radiology physics by the Canadian College of Physicists in Medicine; or

(B) Have a graduate degree in medical physics, radiological physics, physics, or other relevant physical science or engineering discipline from an accredited institution and have formal coursework in the biological sciences with at least 1 course in biology or radiation biology and 1 course in anatomy, physiology, or similar topics related to the practice of medical physics, and have 3 years of documented experience in a clinical CT environment. An accredited institution is a college or university accredited by a regional accrediting organization that has been recognized either by the U.S. department of education (USDE) or by the council for higher education accreditation (CHEA) or both. Individuals with non-U.S. degrees shall provide documentation that their foreign degrees are equivalent to those granted from an approved institution in the U.S. and that the granting institution is equivalent to a regionally accredited institution in the USA; or

(C) CT Medical Physicists who, prior to (*expected effective date of rule*), have been actively working in the area of CT in the state of Oregon and are specifically approved by the Authority to provide CT medical physics services in Oregon, are exempt from the requirements in section (i) and (ii) of this rule.

(b) Continuing experience. After the second anniversary of the date when the requirements of subdivision (a) of this rule were completed, the medical physicist shall have evaluated at least 2 CT scanners in the prior 24-month period.

(c) Continuing education. After the third anniversary of the date when the requirements of subdivision (a) of this rule were completed, the CT medical physicist shall have earned at least 15 continuing medical education units; at least half shall be category 1, in the prior 36-month period. The continuing education shall include credits pertinent to CT.

(d) Re-establishing qualifications. A CT medical physicist who fails to maintain the required continuing experience or continuing education requirements shall reestablish his or her qualifications before resuming the independent evaluation of CT scanners and facilities, as follows:

(A) A CT medical physicist who fails to meet the continuing experience requirements of subdivision (c) of this rule shall evaluate a sufficient number of CT scanners, under the supervision of a medical physicist, to meet the requirements of subdivision (c) of this rule.

(B) A CT medical physicist who fails to meet the continuing education requirements of subdivision (d) of this rule shall obtain a sufficient number of additional continuing education credits to meet the requirements of subdivision (d) of this rule.

(e) Documentation of continuing education and continuing experience shall be kept on file and made available to an inspector upon request.

**Comment [ML49]:** Refers to CT medical event section. Will update once rule numbers are known

**Comment [ML50]:** Refers to report issued by physicist (qualified expert). Will update once rule numbers are found.

**Comment [ML51]:** Refers to QC section of CT rules

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**333-106-0368**

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**Report and Notification of a CT Medical Event**

(1) A CT facility shall notify the Agency within 48 hours of any CT medical event in which a patient who has undergone a CT study has incurred a deterministic radiation injury, such as epilation or erythema.

(2) The registrant shall submit a written report to the Agency within 30 days after the CT medical event is discovered.

(3) The written report shall include all of the following:

(a) The registrant's name, address, facility registration number, and machine registration tag number as they appear on the registration certificate.

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(b) The name of the individual who determined a CT medical event occurred.

(c) The dates of occurrence and discovery of the CT medical event.

(d) A narrative description of the CT medical event, including an estimated dose to the patient, if possible, and body part involved.

(e) The cause of the CT medical event.

(f) The effect on the individual who received the exposure.

(g) A narrative detailing corrective action taken or planned to prevent a recurrence.

(h) Certification that the registrant notified the individual or the individual's responsible relative or guardian and, if not, why not.

(i) The name and signature of the person preparing the report.

(4) The report shall not contain the name of the individual who is the subject of the CT medical event or any other information that could lead to identification of the individual.

(5) The registrant shall consult with the referring physician prior to notifying the individual that they were involved in a CT medical event.

(A) The registrant shall ensure that the individual was notified of the CT medical event no later than 1 week after the discovery unless unforeseen circumstances exist.

(B) The registrant shall not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the CT medical event,

(C) If verbal notification is necessary, the registrant shall inform the individual or legal guardian that a written description of the CT medical event can be obtained from the registrant.

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**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:

(1) 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, 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 um~~m~~Ci) each; and

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(4) Technetium-99m in 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. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10

**333-116-0687**

~~**Qualifications for Authorized User for Oral Administration When a Written Directive is Required**~~

**Training for oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).**

Except as provided in OAR 333-116-0740, the licensee must require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in subsection (3)(a) and (3)(b) of this rule and whose certification has been recognized by the Commission or an Agreement State, and who meets the requirements in subsection (3)(c) of this rule. (The names of board certifications which have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the Nuclear Regulatory Commission webpage); or

(2) Is an authorized user under OAR 333-116-0680 for uses listed in OAR 333-116-0680(2)(b)(G)(ii), or equivalent Nuclear Regulatory commission or Agreement State requirements; or

(3) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0687, 333-116-0740, or equivalent Nuclear Regulatory Commission or Agreement

State requirements. A supervising authorized user, who meets the requirements in OAR 333-116-0680(2), must have experience in administering dosages as specified in OAR 333-116-0680. The work experience must involve:

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

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

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

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

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

(F) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (3)(a) and (3)(b) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under OAR 333-116-0360. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0680, 333-116-0687, 333-116-0740, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in OAR 333-116-0680(2)(a), must have experience in administering dosages as specified in OAR 333-116-0680(2)(a)(B)(vii)(II).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 4-2013, f. & cert. ef. 1-29-13

**333-118-0020**

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**Definitions**

As used in this division, the following definitions apply:

(1) "A1" means the maximum activity of special form radioactive material permitted in a Type A package. This value is either listed in Appendix A to10 CFR Part 71, Table A-1, or may be derived in accordance with the procedures prescribed in Appendix A to10 CFR Part 71.

(2) "A2" means the maximum activity of radioactive material, other than special form material, LSA, and SCO material, permitted in a Type A package. This value is either listed in **Appendix A** to10 CFR Part 71, **Table A-1**, or may be derived in accordance with the procedures prescribed in Appendix A to10 CFR Part 71.

(3) "Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

(4) "Closed transport vehicle" means a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the radioactive material. The enclosure may be either temporary or permanent but shall limit access from top, sides, and ends. In the case of packaged materials, it may be of the "see-through" type.

(5) “Consignment” means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

(6) “Conveyance” means for transport by public highway or rail any transport vehicle or large freight container; or for transport by water any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; or for transport by aircraft.

(7) “Criticality Safety Index (CSI)” means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages containing fissile material during transportation. Determination of criticality safety index is described in 10 CFR 71.22, 71.23, and 71.59.

(8) “Deuterium” means for the purposes of 10 CFR Parts 71.15 and 71.22, deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.

(9) "Exclusive use" means the sole use of a conveyance by a single consignor and for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.

**NOTE:** The term "exclusive use" is used interchangeably with the terms "sole use" or "full load" in other regulations, such as Title 49 of the Code of Federal Regulations.

(10) "Fissile material" means the radionuclides plutonium-239, plutonium-241, uranium-233, and uranium-235, or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only, are not included in this definition. Certain exclusions from fissile material controls are provided in 10 CFR 71.15.NOTE: Authority jurisdiction is limited to special nuclear material in quantities not sufficient to form a critical mass as defined in division 100 of this chapter.

(11) "Fissile material package" means a fissile material packaging together with its fissile material contents.

(12) “Graphite” means for the purposes of 10 CFR 71.15 and 71.22 and graphite with a boron equivalent content less than five parts per million and density greater than 1.5 grams per cubic centimeter.

(13) *“Indian tribe”* means an Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.

(28) “Tribal official” means the highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership.

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**333-120-0710**

**Notification of Incidents**

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

(a) An individual to receive:

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

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

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

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

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

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

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

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

(C) A shallow-dose equivalent to the skin or extremities exceeding 0.15 Sv (~~15 sieverts or~~ rems); or

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

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

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

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

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