

DIVISION 103

FEES

Purpose and Scope

333-103-0001 (1) The rules in this Division establish fees for sources of radiation and provide for their payment. Sources of radiation, as defined in OAR 333-100-0005(125), include, but are not limited to, radiation facilities, radiation producing machines, radiation producing devices, radioactive material in sealed and unsealed form (normal form and special form), and radioactive material uses.

(2) Except as otherwise specifically provided, the rules in this Division apply as follows:

(a) Radiation producing machines, radiation facility registration, radiation machine vendors and/or services, accredited hospital radiology inspectors, and non-ionizing sources of radiation are subject to OAR Chapter 333, Divisions 101, 105, 106, 108, 109, 112, 115, or 119;

(b) Radioactive materials pursuant to OAR Chapter 333 Division 102, 105, 110, 113, 115, 116, and 117;

(c) General licenses and registrations pursuant to Division 101 and 102 of these rules;

(d) Microwave Oven Service Licensees;

(e) Radiological Analyses; and

(f) Tanning Device Registrations.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 2-1995, f. & ef. 9-8-95; HD 1-1996, f. & cert. ef. 7-1-96

Definitions

333-103-0003 As used in this Division, the following definitions apply:

(1) "License" ("Acknowledgement of Validation," "Validation Certificate"; "Certificate of Validation") means the document issued that validates receipt of payment for a specific license or registration fee.

(2) "Registration Fee" means:

(a) The fee paid to the Agency for a license (certificate of validation) or acknowledgement of validation for Radiation Producing Machines; or

(b) The fee paid to the Agency to validate a general license registration issued pursuant to OAR 333-102-0101, 333-102-0103, 333-102-0115, 333-102-0130, or 333-102-0340

(3) "Specific License Fee" means:

(a) The annual fee payable July 1 of each year, to validate specific licenses for sources of radiation; or

(b) The fee paid upon application to the Agency for a Oregon Radioactive Materials License to license (validate) specific licensed sources of radiation pursuant to OAR 333-103-0010; or

(c) The fee paid to license additional sources of radiation pursuant to OAR 333-103-0010.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 2-1995, f. & ef. 9-8-95; HD 1-1996, f. & cert. ef. 7-1-96

Biennial Fee for Radiation Machines

333-103-0005 (1) For the purpose of this Division, a radiation machine is defined under OAR 333-100-0005.

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

- (a) Hospital, radiologist, chiropractic, osteopathic or medical X-ray machine \$173
- (b) Hospital X-ray machine when X-ray machine inspection is performed by an accredited hospital radiology inspector rather than an Agency inspector \$88
- (c) Industrial or podiatry X-ray machine \$115
- (d) Dental, academic or veterinary X-ray machine \$ 87

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

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

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

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.757

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & ef. 1-8-91; HD 15-1994, f. & ef. 5-6-94; HD 2-1995, f. & ef. 9-8-95; HD 1-1996, f. & cert. ef. 7-1-96

Annual Fee for Specific Licenses

333-103-0010 (1) Each specific license listed in section (2) of this rule, as defined in OAR 333-102-0203, shall be licensed (validated) pursuant to sections (2), (3), (4), (5), and (6) of this rule by a specific license fee.

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

- (a) Analytical/Leak Test \$ 348(F)
- (b) Basic License 696(F)
- (c) Brachytherapy 1,392(F)
- (d) Broad Scope A 2,900(F)
- (e) Broad Scope B 1,392(F)
- (f) Broad Scope C 696(F)
- (g) Distribution 696(F)
- (h) Fixed Gauge 174(S)
- (i) High dose rate brachytherapy 1,740(S)
- (j) Imaging and Localization 696(F)
- (k) In Vitro Laboratory 232(F)
- (l) Industrial Radiography 2,900(F)
- (m) Instrument Calibration 522(S)
- (n) Investigational New Drug 1,044(F)

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| (o) Irradiator Self-Shielded | 696(S) |
| (p) Manufacturing/Compounding | 1,856(F) |
| (q) Mobile Nuclear Medicine | 1,856(F) |
| (r) NORM (no processing) | 464(F) |
| (s) Nuclear Pharmacy | 2,320(F) |
| (t) Other Measuring Device | 116(S) |
| (u) Portable Gauge | 464(S) |
| (v) Radiopharmaceutical Therapy | 1,044(F) |
| (w) RAM/NOS Facility | 2,900(F) |
| (x) Research & Development | 1,044(F) |
| (y) Sealed Sources for Diagnosis | 348(S) |
| (z) Source Material | 2,320(F) |
| (aa) Special Nuclear Material (sealed) | 696(S) |
| (bb) Special Nuclear Material (unsealed) | 1,740(F) |
| (cc) Teletherapy (external beam) | 2,900(S) |
| (dd) Unique | No Fee |
| (ee) Uptake and Dilution | 464(F) |
| (ff) Use of Xenon Gas | 464(F) |
| (gg) Waste Packaging | 2,320(F) |
| (hh) Well Logging | 1,044(S) |

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

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

(a) On or before July 1 of each year;

(b) For each specific license source of radiation listed in section (2) of this rule for which application pursuant to OAR 333-102-0295 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 (certificate of validation) or acknowledgement of validation for each specific license issued pursuant to section (3) of this rule for the then or current fiscal year shall be provided by the Agency. The certificate of validation for the then or 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 10 working 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 \$696, pursuant to subsection (2)(b) of this rule.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.757

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & ef. 1-8-91; HD 15-1994, f. & ef. 5-6-94; HD 2-1995, f. & ef. 9-8-95; HD 1-1996, f. & cert. ef. 7-1-96

Annual Registration Fee for General Licenses and Devices

333-103-0015 (1) Any general license granted by the Agency shall 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. General License registration fees as defined in OAR 333-103-0003(2)(b) shall:

(a) Validate each general licensed source of radiation due July 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

(2) The general licenses appearing in the following fee schedule shall be registered on the appropriate Agency 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 \$100

(b) Each radiation source in a generally license measuring, gauging or controlling device authorized pursuant to OAR 333-102-0115(1), except for radioactive material contained in devices designed and manufactured for the purpose of producing light or an ionized atmosphere **pursuant to 333-102-105**
\$100

(c) 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 . . .
\$100

(d) Each General Licensee possessing or using source material for research, development, educational, commercial or operational purposed pursuant to OAR 333-102-0101 \$150

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

(f) 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 shall pay a registration validation fee as required by OAR 333-103-0030(6).

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

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

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.757

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & ef. 1-8-91; HD 15-1994, f. & ef. 5-6-94; HD 2-1995, f. & ef. 9-8-95; HD 1-1996, f. & cert. ef. 7-1-96

Biennial Fee for Microwave Oven Service Licensees

333-103-0020 (1) Each specific license issued by the Agency for microwave oven service shall be subject to a biennial \$87 specific license fee.

(2) The specific license fee shall be due and payable on or before July 1 of each biennium.

(3) A certificate of validation or acknowledgement of validation for the then current fiscal year shall be provided by the Agency. The current certificate of validation shall be retained by the licensee.

(4) Unless validated by the annual fee, each specific license shall be deemed to expire on June 30 of each year.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.757

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & ef. 1-8-91; HD 15-1994, f. & ef. 5-6-94; HD 2-1995, f. & ef. 9-8-95; HD 1-1996, f. & cert. ef. 7-1-96

Annual Fee For Tanning Devices

333-103-0025 (1) Each tanning device shall be validated annually by a tanning device fee of \$76.

(2) The tanning device fee shall be due and payable for each tanning device on or before October 1 of each year.

(3) A certificate of validation or acknowledgement of validation for the then current fiscal year shall be posted on or near the tanning device, by the registrant.

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

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.940

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

Reciprocal Recognition Fee

333-103-0030 (1) Any radiation machine or radioactive material source brought into the state for use under reciprocity shall pay a fee equal to 100 percent of the appropriate license or registration validation fee, listed in OAR 333-103-0005 or 333-103-0010, not to exceed \$3,000 in a year.

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

(3) An acknowledgement of fee payment, such as a certificate of validation, will be provided by the Agency. The acknowledgement of fee payment shall be retained by the licensee or registrant and attached to the license or registration.

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

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

(6) Notwithstanding section (5) of this rule, each out-of-state or NRC specific licensee authorized, pursuant to OAR 333-102-0340, shall pay upon each entrance into Oregon. Any use of radioactive material in Oregon pursuant to OAR 333-102-0340 exceeding 30 consecutive days or 180 calendar days shall require an application for an Oregon specific radioactive materials license pursuant to OAR 333-102-0295.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.665

Hist.: HD 1-1991, f. & ef. 1-8-91; HD 15-1994, f. & ef. 5-6-94; HD 2-1995, f. & ef. 9-8-95; HD 1-1996, f. & cert. ef. 7-1-96

Fees For Radiological Analyses

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333-103-0035 (1) An individual, agency, or company that requests that the Agency Radiation Laboratory perform radiological analyses on samples shall pay a fee to the Agency in accordance with the schedule in section (2) of this rule. The responsible individual submitting the sample(s) shall first obtain a request form from the Agency. This form contains the fee schedule and the types of radiological analyses offered. That individual shall then submit the completed form along with the sample and the appropriate fee to the Agency. The Agency will send the results by return mail in accordance with the estimated time as per section (3) of this rule.

(2) Fee Schedule:

| | Water | Solid |
|--|-------|-------|
| (a) Gamma Isotopic | \$156 | \$179 |
| (b) Gross Alpha | 72 | ---- |
| (c) Gross Beta | 72 | ---- |
| (d) Gross Alpha and Gross Beta | 83 | ---- |
| (e) Strontium-90 | 190 | ---- |
| (f) Strontium-89 and Strontium-90 | 202 | ---- |
| (g) Alpha Spectroscopy: | | |
| (A) Radium-226 and/or Radium-228 | 340 | 455 |
| (B) Thorium-230 | 432 | 547 |
| (C) Thorium-232 | 432 | 547 |
| (D) Uranium-235/238 | 432 | 547 |
| (E) Plutonium-239 | 432 | 547 |
| (h) Low-level Iodine-131 | 160 | ---- |
| (i) Tritium (H-3) | 68 | ---- |

(3) The analyses results will be available in approximately five working days for Gamma Isotopic analyses; for Strontium-90 or Strontium 89 and 90, approximately 20 working days. All other types of radiological analyses results will be available in approximately 15 working days.

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

NOTE: A \$100 surcharge shall be added to the fee for a one-day completion schedule for a Gamma Isotopic analysis.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & ef. 1-8-91; HD 15-1994, f. & ef. 5-6-94; HD 2-1995, f. & ef. 9-8-95; HD 1-1996, f. & cert. ef. 7-1-96

Fees for Accredited Hospital Radiology Inspectors

333-103-0050 (1) Each accreditation for a radiology inspector shall be subject to an accreditation fee of \$200.

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(2) Each accreditation issued by the Agency for a radiology inspector shall be subject to a biennial renewal fee of \$200.

(3) Each accreditation shall expire in the second year on the last day of the month of issuance unless renewed.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: NEW

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DIVISION 105

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Purpose ~~and Scope~~

333-105-0001 (1) ~~*{The rules in t}*~~ This Division prescribes ~~*{establish radiation safety}*~~ requirements for the industrial use of ~~*{persons using}*~~ sources of radiation and radiation safety requirements for persons using these sources of radiation in industrial radiography.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.665, 453.635

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

Scope

333-105-0003 The provisions and requirements of this Division are in addition to, and not in substitution for, other ~~*{applicable}*~~ requirements of these rules. ~~*{(2)The rules in this Division}*~~ In particular, the general requirements of Divisions 100, 101, 102, 111, 118, and 120 of this Chapter apply to applicants, ~~*{all}*~~ licensees, and ~~*{for}*~~ registrants subject to this Division ~~*{who use sources of radiation for industrial radiography}*~~. Division 102 and 118 of these rules apply to licensing and transportation of radioactive material and Division 101 of these rules applies to the registration of radiation machines. Except for sections that are ~~*{those rules in this Division clearly}*~~ applicable only to sealed radioactive sources, both radiation machines and sealed radioactive sources are covered by this Division. This rule does not apply to medical uses addressed in Division 116.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.665, 453.635

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

Definitions

333-105-0005 As used in this Division, the following definitions apply:

(1) "Annual refresher safety training" means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review shall include, as a minimum, a review of radiation safety aspects of industrial radiography, any results of internal audits, Agency inspections, new procedures or equipment, new or revised regulations, and accidents or errors that have been observed. The review shall also provide opportunities for employees to ask safety questions.

(2) "ANSI" means the American National Standards Institute.

(3) "Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, (e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator when it is used as an exposure head.

(4) "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet so shielded that ~~radiation levels at~~ every location on the exterior meets the **dose limits for individual members of the public as limitations** specified in OAR 333-120-0180;

~~(a)~~(5) "Cabinet X-ray system" means an X-ray system with the X-ray tube installed in an enclosure **hereinafter termed a cabinet**, which ~~is~~ **is** independent of existing architectural structures except the floor, ~~for which it may be placed,~~ **The cabinet x-ray system** is intended to contain at least that portion of a material being irradiated, provide radiation attenuation and exclude personnel from its interior during generation of ~~x-~~radiation. **This definition** ~~includes~~ **includes** ~~are all~~ X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad and bus terminals and in similar facilities. An X-ray tube used within a shielded part of a building, or X-ray equipment ~~which~~ **that** may temporarily or occasionally incorporate portable shielding, is not considered a cabinet X-ray system.

(6) "Camera" see "Radiographic exposure device".

~~(b)~~(7) "Certifiable cabinet x-ray system" means an existing uncertified x-ray system that has been **modified to meet the certification requirements specified in 21 CFR 1020.40.**

(8) "Certified cabinet X-ray system" means an X-ray system ~~which~~ **that** has been certified in accordance with ~~21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of~~ 21 CFR 1020.40.

(9) "Certifying entity" means an independent certifying organization meeting the requirements in Appendix A of Division 105 or an Agreement State regulatory program meeting the requirements in Appendix A, Sections II and III.

(10) "Collimator" means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the ~~device used to limit the~~ size, shape, and direction of the ~~primary~~ radiation beam when the sealed source is cranked into position to make a radiographic exposure.

~~(3)~~(11) "Control drive cable" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

(12) "Control drive mechanism" means a device that enables the source assembly to be moved into and out of the exposure device.

(13) "Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

(14) "Drive cable" see "Control cable".

(15) "Exposure head" means a device that locates the gamma radiography sealed source in the selected working position. An exposure head also is known as a source stop or end cap.

(16) "Field station" means a facility from which sources of radiation may be stored or used and from which equipment is dispatched.

(17) "Guide tube" (projection sheath) means a flexible or rigid tube, or "J" tube, for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

(15) "Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process, and includes taking radiographs, calibration of survey instruments, operational and performance testing of survey instruments and devices, film development, posting of radiation areas, preparing radiographic sources for transport, set-up of radiography equipment, posting of records and radiation area surveillance, etc., as applicable. In addition the Radiation Safety Officer experience shall include source exchange and source retrieval. Excessive time spent in only one or two of these areas, such as film development or radiation area

surveillance, should not be counted toward the 2000 hours of hands-on experience required for a radiation safety officer in 333-105-520 or the hands-on experience for a radiographer as required by 333-105-530.

(19) **“Independent certifying organization”** means an independent organization that meets all of the criteria of Appendix A of this part.

(20) "Industrial radiography" means ~~the~~ a nondestructive examination of the ~~macroscopic~~ structure of materials ~~by nondestructive methods~~ using ionizing radiation to make radiographic images ~~sources of radiation~~.

(21) **“Lay-barge radiography”** means industrial radiography performed on any water vessel used for laying pipe.

~~(4)~~(22) "Lixiscope" means a portable light-intensified imaging device using a sealed source.

(23) **“Offshore platform radiography”** means industrial radiography conducted from a platform over a body of water.

~~(5)~~(24) "Permanent radiographic installation" means an enclosed shielded room, cell, or vault, not located at a temporary jobsite, ~~installation or structure designed or intended for radiography and~~ in which radiography is ~~regularly~~ performed.

~~(6)~~ (25) "Personal supervision" means supervision in which the radiographer is physically present at the site where sources of radiation and associated equipment are being used, watching the performance of the radiographer's assistant and in such proximity that immediate assistance can be given if required.

(26) **“Pigtail”** see **“Source assembly”**.

(27) **“Pill”** see **“Sealed source”**.

(28) **“Practical examination”** means a demonstration through application of the safety rules and principles in industrial radiography including use of all procedures and equipment to be used by radiographic personnel.

(29) "Projection sheath" see "Guide tube".

(30) "Projector" see "Radiographic exposure device".

(31) **“Radiation safety officer for industrial radiography”** means an individual with the responsibility for the overall radiation safety program on behalf of the licensee or registrant and who meets the requirements of 333-105-0520.

~~(7)~~(32) "Radiographer" means any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of these rules and ~~all license conditions~~ the conditions of the license or registration.

~~(8)~~(33) **“Radiographer certification”** means written approval received from a certifying entity stating that an individual has satisfactorily met the radiation safety, testing, and experience criteria in 333-105-0530.

(34) "Radiographer's assistant" means any individual who, under the ~~personal~~ direct supervision of a radiographer, uses radiographic exposure devices, sources of radiation, related handling tools or radiation survey instruments in industrial radiography.

~~(9)~~(35) "Radiographer instructor" means any radiographer who has been authorized by the Agency to provide on-the-job training to radiographer trainees in accordance with OAR 333-105-~~0201(2)(b)~~0530(3).

~~(10)~~(36) "Radiographer trainee" means any individual who, under the ~~personal~~ direct supervision of a radiographer instructor, uses sources of radiation, related handling tools or radiation survey instruments during the course of his instruction.

~~(11)~~(37) "Radiographic exposure device" (also called a camera or a projector) means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding

thereof may be moved or otherwise changed from a shielded to unshielded position for purposes of making a radiographic exposure.

~~12~~(38) **"Radiographic operations" means all activities performed with a radiographic exposure device, or with a radiation machine. Activities include using, transporting (except when being transported by common or contract carriers), storing at a temporary job site, performing surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries. Transporting a radiation machine is not considered a radiographic operation.**

(39) "Radiographic personnel" means any radiographer, radiographer's assistant, radiographer instructor or radiographer trainee.

(40) "Radiography" see "Industrial radiography."

~~13~~(41) "Residential location" means any area where structures in which people lodge or live are located and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums and garages.

(42) **"S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.**

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

~~14~~(44) "Shielded position" means the location within the radiographic exposure device, **source changer**, or storage container ~~which~~ **that**, by manufacturer's design, is the proper location for storage of the sealed source.

~~15~~(45) "Shielded room radiography using radiation machines" means industrial radiography using radiation machines, which is conducted in an enclosed room, the interior of which is not occupied during radiographic operations, which is so shielded that every location on the exterior meets conditions for an unrestricted area as specified in OAR 333-120-0180, and the only access to which is through openings that are interlocked so that the radiation machine will not operate unless all openings are securely closed.

(46) **"Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.**

~~16~~(47) "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices. ~~including those source changers~~ **They also may be used for transporting and storing** ~~age of~~ sealed sources.

~~17~~(48) "Storage area" means any location, facility or vehicle ~~which~~ **that** is used to store ~~and to transport or to~~ secure a radiographic exposure device, **a radiation machine**, or a storage container ~~for a sealed source~~ when it is not ~~in~~ **used for radiographic operations. Storage areas are** ~~and which is~~ locked or ~~has~~ **have** a physical barrier to prevent accidental exposure, tampering with or unauthorized removal of the device, **container, source, or machine.**

~~18~~(49) "Storage container" means a device in which sealed sources are transported or stored.

~~19~~(50) "Temporary jobsite" means any location where ~~industrial~~ radiographic ~~y~~ **operations are** ~~is~~ performed **and where sources of radiation may be stored other than** ~~the~~ **those location(s) of use authorized** ~~listed in a specific~~ **on the license or** ~~certificate of~~ registration.

~~20~~(51) "Transport container" means a package that is designed to provide radiation safety and security when sealed sources are transported and which meets all applicable requirements of the U.S. Department of Transportation.

(52) **"Underwater radiography" means radiographic operations performed when the radiographic exposure device or radiation machine and/or related equipment are beneath the surface**

of the water.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605

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

Exemptions

333-105-0050 (1) Uses of certified and certifiable cabinet x-ray systems are exempt from the requirements of this Division except for the following:

(a) For certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals:

(A) No registrant shall permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit. Records that demonstrate compliance with this subparagraph shall be maintained for Agency inspection until disposal is authorized by the Agency.

(B) Tests for proper operation of interlocks must be conducted and recorded at intervals not to exceed six months. Records of these tests shall be maintained for Agency inspection until disposal is authorized by the Agency.

(C) The registrant shall perform an evaluation of the radiation dose limits to determine compliance with OAR 333-120-180, 333-120-190 and 21 CFR 1020.40, Cabinet X-Ray Systems (39 Federal Register 12986, April 10, 1974), at intervals not to exceed one year. Records of these evaluations shall be maintained for Agency inspection for two years after the evaluation.

(b) Certified cabinet X-ray systems shall be maintained in compliance with 21 CFR 1020.40, Cabinet X-Ray Systems (39 Federal Register 12986, April 10, 1974), and no modification shall be made to the system unless prior Agency approval has been granted.

(2) Industrial uses of liscopes are exempt from the requirements of this Division if the dose rate 18 inches from the source of radiation to any individual does not exceed 2 millirem per hour. Devices that exceed this limit shall meet the applicable requirements of this Division and the licensing or registration requirements of Division 101 or Division 102 of these rules, as applicable.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

Hist.:

Licensing and Registration Requirements for Industrial Radiography Operations.

333-105-0075 The Agency will approve an application for a specific license for the use of licensed material or a registration for use of radiation machines if the applicant meets the following requirements:

(1) The applicant satisfies the general requirements specified in OAR 333-101-005 for radiation machine facilities or 333-102-200 for radioactive material, as applicable, and any special requirements contained in this Division;

(2) The applicant submits an adequate program for training radiographers and radiographer's assistants that meets the requirements of 333-105-530:

(a) After August 31, 2004, the applicant need not describe the initial training and examination program for radiographers in the subjects outlined in 333-105-530(7).

(b) From August 31, 2002 to August 31, 2004, the applicant may affirm that all individuals acting as industrial radiographers will be certified in radiation safety by a certifying entity before commencing duty as radiographers. This affirmation substitutes for a description of its initial training and examination program for radiographers in the subjects outlined in 333-105-530(7).

(3) The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid;

(4) The applicant submits written operating and emergency procedures as described in 333-105-540;

(5) The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed 6 months as described in 333-105-530(5);

(6) The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility;

(7) The applicant submits the qualifications of the individual(s) designated as the radiation safety officer as described in 333-105-520(1);

(8) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing the test. The description must include the:

- (a) Methods of collecting the samples;
- (b) Qualifications of the individual who analyzes the samples;
- (c) Instruments to be used; and
- (d) Methods of analyzing the samples.

(9) If the applicant intends to perform calibrations of survey instruments and alarming ratemeters, the applicant must describe methods to be used and the experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 333-105-450 and 333-105-560(7)(d);

(10) The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations;

(11) The applicant identifies the location(s) where all records required by this and other Divisions of these rules will be maintained;

(12) If a license application includes underwater radiography, a description of:

- (a) Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;
- (b) Radiographic equipment and radiation safety equipment unique to underwater radiography; and

- (c) Methods for gas-tight encapsulation of equipment; and

(13) If an application includes offshore platform and/or lay-barge radiography, a description of:

- (a) Transport procedures for radioactive material to be used in industrial radiographic operations;
- (b) Storage facilities for radioactive material; and
- (c). Methods for restricting access to radiation areas.

(14) A license or registration will be issued if 333-105-410(1) through 333-105-410(13), as applicable, are met.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

Hist.:

~~_____~~ **Equipment Control**

~~Limits on Levels of Radiation for Radiographic Exposure Devices and Storage Containers~~

~~— 333-105-0101 Radiographic exposure devices measuring less than four inches (10 cm) from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of 50 milliroentgens (1.29×10^{-5} C/kg) per hour at six inches (15 cm) from any exterior surface of the device. Radiographic exposure devices measuring a minimum of four inches (10 cm) from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or outer containers for radiographic exposure devices, shall have no radiation level in excess of 200 milliroentgens (5.16×10^{-5} C/kg) per hour at any exterior surface and 10 milliroentgens (2.58×10^{-6} C/kg) per hour at 39.4 inches (1 m) from any exterior surface. The radiation levels specified are with the sealed source in the shielded position.~~

~~— Stat. Auth.: ORS Ch. 453.605 - 453.807~~

~~— Stats. Implemented: ORS 453.625, 453.635~~

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

Locking of Sources of Radiation

~~— 333-105-0105 (1) Each source of radiation shall be provided with a lock or lockable outer container designed to prevent unauthorized or accidental production of radiation or removal or exposure of a sealed source and shall be kept locked at all times except when under the direct surveillance of a radiographer or radiographer's assistant or as may be otherwise authorized in this Division. Each storage container and source changer likewise shall be provided with a lock and shall be kept locked when containing sealed sources except when the container is under the direct surveillance of a radiographer or radiographer's assistant.~~

~~— (2) Radiographic exposure devices, source changers and storage containers, prior to being moved from one location to another and also prior to being secured at a given location, shall be locked and surveyed to assure that the sealed source is in the shielded position.~~

~~— (3) The sealed source shall be secured in its shielded position by locking the exposure device or securing the remote control each time the sealed source is returned to its shielded position. Then a survey shall be performed to determine that the sealed source is in the shielded position pursuant to OAR 333-105-0315(2).~~

~~— Stat. Auth.: ORS Ch. 453.605 - 453.807~~

~~— Stats. Implemented: ORS 453.625, 453.635~~

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

Storage Precautions

~~— 333-105-0110 (1) Locked radiographic exposure devices, source changers, storage containers and radiation machines shall be physically secured to prevent tampering or removal by unauthorized personnel.~~

~~— (2) Radiographic exposure devices, source changers or transport containers that contain radioactive material shall not be stored in residential locations. This requirement does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the licensee complies with OAR 333-105-0110(3), and if the vehicle does not constitute a permanent storage location as described in OAR 333-105-0110(4).~~

~~— (3) If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in OAR 333-120-0180 of these rules at the exterior surface of the vehicle.~~

~~— (4) A storage or use location is permanent if radioactive material is stored at the location for more than 90 days and any one or more of the following applies to the location:~~

~~— (a) Telephone service is established by the licensee;~~

~~— (b) Industrial radiographic services are advertised for or from the location;~~

~~— (c) Industrial radiographic operations are conducted at other sites due to arrangements made from the location.~~

~~— (5) Each radiographic exposure device and all associated equipment must meet the minimum criteria for requirements specified in 10 CFR Part 34.20 "Performance requirements for radiography equipment," and 10 CFR Part 34.21 "Limits on levels of radiation for radiographic exposure devices and storage containers."~~

~~— NOTE: After January 10, 1996, radiographic equipment must meet the requirements of 10 CFR 34.20. Storage containers and source changers must meet the requirements of 10 CFR 34.21.~~

~~— Stat. Auth.: ORS Ch. 453.605 - 453.807~~

~~— Stats. Implemented: ORS 453.625, 453.635~~

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

Radiation Survey Instruments

~~— 333-105-0115 (1) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this Division and Division 120 of this chapter. Instrumentation required by this section shall have a range such that two milliroentgens (5.16×10^{-7} C/kg) per hour through one roentgen (2.58×10^{-4} C/kg) per hour can be measured.~~

~~— (2) Each radiation survey instrument shall be calibrated:~~

~~— (a) At energies appropriate for use and at intervals not to exceed three months and after each instrument servicing;~~

~~— (b) Such that accuracy within plus or minus 20 percent can be demonstrated; and~~

~~— (c) At two points located approximately 1/3 and 2/3 of full-scale on each scale for linear scale instruments; at midrange of each decade, at two points of at least one decade for logarithmic scale instruments and at appropriate points for digital instruments.~~

~~— (3) Records of these calibrations shall be maintained for inspection by the Agency.~~

~~— (4) Each radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly.~~

~~— Stat. Auth.: ORS Ch. 453.605 - 453.807~~

~~— Stats. Implemented: ORS 453.625, 453.635~~

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

Leak Testing, Repair, Tagging, Opening, Modification and Replacement of Sealed Sources

~~—333-105-0120 (1) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening or any other modification of any sealed source shall be performed only by persons specifically authorized to do so by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State.~~

~~—(2) Each sealed source shall be tested for leakage at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within the six-month period prior to the transfer, the sealed source shall not be put into use until tested.~~

~~—(3) The leak test shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to OAR 333-102-0225(5). Records of leak test results shall be kept in units of microcuries (Bq) and maintained for inspection by the Agency.~~

~~—(4) Any test conducted pursuant to section (2) and (3) of this rule which reveals the presence of 0.005 microcurie (185 Bq) or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with rules of the Agency. Within five days after obtaining results of the test, the licensee shall file a report with the Agency describing the equipment involved, the test results and the corrective action taken.~~

~~—(5) Each radiographic exposure device shall have permanently attached to it a durable label which has, as a minimum, the instruction: "**Danger - Radioactive Material - Do Not Handle - Notify Civil Authorities if Found.**"~~

~~—Stat. Auth.: ORS Ch. 453.605 - 453.807~~

~~—Stats. Implemented: ORS 453.625, 453.635~~

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

Quarterly Inventory

~~—333-105-0125 Each licensee shall conduct a quarterly physical inventory to account for all sealed sources received or possessed by the licensee. The records of the inventories shall be maintained for inspection by the Agency and shall include the quantities and kinds of radioactive material, the location of all sealed sources and the date of the inventory, the name of the individual making the inventory, the manufacturer, the model number and the serial number.~~

~~—Stat. Auth.: ORS Ch. 453.605 - 453.807~~

~~—Stats. Implemented: ORS 453.625, 453.635~~

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

Utilization Logs

~~—333-105-0130 Each licensee or registrant shall maintain current logs which shall be kept available for inspection by the Agency, showing for each source of radiation the following information:~~

~~—(1) A description (or make and model number) of each source of radiation or storage container in which the sealed source is located;~~

- ~~— (2) The identity of the radiographer to whom assigned;~~
- ~~— (3) Locations where used and dates of use; and~~
- ~~— (4) The date(s) each source of radiation is removed from storage and returned to storage.~~
- ~~— Stat. Auth.: ORS Ch. 453.605 - 453.807~~
- ~~— Stats. Implemented: ORS 453.625, 453.635~~
- ~~— Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91~~

Inspection and Maintenance

- ~~— 333-105-0135 (1) Each licensee or registrant shall ensure that checks for obvious defects in radiation machines, radiographic exposure devices, storage containers and source changers are performed prior to each day of use.~~
- ~~— (2) Each licensee or registrant shall conduct a program of at least quarterly inspection and maintenance of radiation machines, radiographic exposure devices, storage containers and source changers to assure proper functioning of components important to safety. All appropriate parts shall be maintained in accordance with manufacturer's specifications. Records of inspection and maintenance shall be maintained for inspection by the Agency until their disposal is authorized by the Agency.~~
- ~~— (3) If any inspection conducted pursuant to section (1) or (2) of this rule reveals damage to components critical to radiation safety, the device shall be removed from service until repairs have been made and the device shall be tagged as "Defective - Out of Service."~~
- ~~— Stat. Auth.: ORS Ch. 453.605 - 453.807~~
- ~~— Stats. Implemented: ORS 453.625, 453.635~~
- ~~— Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95~~

Permanent Radiographic Installations

- ~~— 333-105-0140 (1) Permanent radiographic installations having high radiation area entrance controls of the type described in OAR 333-120-0410 also shall meet the requirements of this rule.~~
- ~~— (2) Each entrance that is used for personnel access to the high radiation area shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation. The audible signal shall be activated when an attempt is made to enter the installation while the source is exposed.~~
- ~~— (3) The control device or alarm system shall be tested for proper operation at the beginning of each period of use. If a control device or alarm system is operating improperly, it shall be immediately labeled as defective and repaired before industrial radiographic operations are resumed. Records of these tests shall be maintained for inspection by the Agency until their disposal is authorized.~~
- ~~— Stat. Auth.: ORS Ch. 453.605 - 453.807~~
- ~~— Stats. Implemented: ORS 453.625, 453.635~~
- ~~— Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95~~

~~Personal Radiation Safety
Requirements for
Radiographers and
Radiographers' Assistants~~

~~**Training and Testing**~~

~~333-105-0201 (1) The licensee or registrant shall not permit any individual to act as a radiographer, as defined in this Division until such individual:~~

~~(a) Has been instructed in the subjects outlined in OAR 333-105-0202;~~

~~(b) Has received copies of and instruction in the rules contained in this Division and the applicable rules of Divisions 120 and 111, Agency license(s) or certificate of registration and the licensee's or registrant's operating and emergency procedures, and shall have demonstrated understanding thereof;~~

~~(c) Has demonstrated competence to use the licensee's or registrant's sources of radiation, radiographic exposure devices, related handling tools and radiation survey instruments; and~~

~~(d) Has demonstrated an understanding of the instruction by successful completion of a written test and field examination on the subjects covered.~~

~~(2) The licensee or registrant shall not permit any individual to act as a radiographer's assistant, as defined in this Division, until such individual:~~

~~(a) Has received copies of and instruction in the licensee's or registrant's operating and emergency procedures and shall have demonstrated understanding thereof;~~

~~(b) Has demonstrated competence to use, under the personal supervision of the radiographer, the sources of radiation, radiographic exposure devices, related handling tools and radiation survey instruments which will be used; and~~

~~(c) Has demonstrated an understanding of the instructions in OAR 333-105-0201 (1) by successfully completing a written or oral test and a field examination on the subjects covered.~~

~~(3) Records of the above training, including copies of written tests and dates of oral tests and field examinations, shall be maintained for inspection by the Agency.~~

~~(4) Each licensee or registrant shall conduct an internal audit program to ensure that the Agency's radioactive material license conditions and the licensee's or registrant's operating and emergency procedures are followed by each radiographer and radiographer's assistant. These internal audits shall be performed at least quarterly, and each radiographer shall be audited at least annually. Records of internal audits shall be maintained for inspection by the Agency.~~

~~Stat. Auth.: ORS Ch. 453.605 - 453.807~~

~~Stats. Implemented: ORS 453.625, 453.635~~

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

Subjects to be Covered During the Instruction of Radiographers

~~333-105-0202 (1) Fundamentals of Radiation Safety:~~

~~(a) Characteristics of gamma and X-radiation;~~

~~(b) Units of radiation dose (millirem) and quantity of radioactivity (Curie);~~

~~(c) Hazards of excessive exposure of radiation;~~

~~(d) Levels of radiation from sources of radiation;~~

~~(e) Methods of controlling radiation dose;~~

~~(A) Working time;~~

- ~~—(B) Working distances;~~
- ~~—(C) Shielding;~~
- ~~—(2) Radiation detection instrumentation to be used:~~
 - ~~—(a) Use of radiation survey instruments:~~
 - ~~—(A) Operation;~~
 - ~~—(B) Calibration;~~
 - ~~—(C) Limitations;~~
 - ~~—(b) Survey techniques;~~
 - ~~—(c) Use of personnel monitoring equipment:~~
 - ~~—(A) Film badges and TLD dosimeters;~~
 - ~~—(B) Pocket dosimeters;~~
 - ~~—(C) Pocket chambers;~~
- ~~—(3) Radiographic equipment to be used:~~
 - ~~—(a) Remote handling equipment;~~
 - ~~—(b) Radiographic exposure devices and sealed sources;~~
 - ~~—(c) Storage containers;~~
 - ~~—(d) Operation and control of X-ray equipment.~~
- ~~—(4) Inspection and maintenance performed by the radiographers;~~
- ~~—(5) Case histories of radiography accidents;~~
- ~~—(6) The requirements of pertinent federal and state rules;~~
- ~~—(7) The licensee's or registrant's written operating and emergency procedures;~~

~~—Stat. Auth.: ORS Ch. 453.605 - 453.807~~

~~—Stats. Implemented: ORS 453.625, 453.635~~

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

Operating and Emergency Procedures

~~—333-105-0205 The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:~~

- ~~—(1) Handling and use of sources of radiation to be employed such that no individual is likely to be exposed to radiation doses in excess of the limits established in Division 120 of this chapter;~~
- ~~—(2) Methods and occasions for conducting radiation surveys;~~
- ~~—(3) Methods for controlling access to and posting of radiographic areas;~~
- ~~—(4) Methods and occasions for locking and securing sources of radiation;~~
- ~~—(5) Personnel monitoring and the use of personnel monitoring equipment, including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale;~~
- ~~—(6) Transportation to field locations, including packing of sources of radiation in the vehicles, posting (formerly placarding) of vehicles and control of sources of radiation during transportation;~~
- ~~—(7) Minimizing exposure of individuals in the event of an accident;~~
- ~~—(8) The procedure for notifying proper personnel in the event of an accident;~~
- ~~—(9) Maintenance of records; and~~
- ~~—(10) The inspection and maintenance of radiographic exposure devices, source changers, storage containers and radiation machines.~~

~~—Stat. Auth.: ORS Ch. 453.605 - 453.807~~

~~—Stats. Implemented: ORS 453.625, 453.635~~

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

Personnel Monitoring Control

~~— 333-105-0210 (1) The licensee or registrant shall not permit any individual to act as a radiographer, radiographer's assistant or as a radiographer's trainee unless, at all times during radiographic operations, each such individual wears a direct reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluminescent dosimeter (TLD).~~

~~— (2) Pocket dosimeters shall have a range from zero to at least 200 milliroentgens (5.16×10^{-5} C/kg) and shall be recharged daily or at the start of each shift. Each film badge or TLD shall be assigned to and worn by only one individual.~~

~~— (3) Pocket dosimeters shall be read and exposures recorded at least once daily.~~

~~— (4) Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters shall read within plus or minus 30 percent of the true radiation exposure.~~

~~— (5) Each alarm ratemeter must --~~

~~— (a) Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift;~~

~~— (b) Be set to give an alarm signal at a preset dose rate of 500 mR/hr.;~~

~~— (c) Require special means to change the preset alarm function; and~~

~~— (d) Be calibrated at periods not to exceed one year for correct response to radiation. Acceptable ratemeters must alarm within plus or minus 20 percent of the true radiation dose rate.~~

~~— (6) If an individual's pocket dosimeter is discharged beyond its range, industrial radiographic operations by that individual shall cease and the individual's film badge or TLD shall be processed immediately. The individual shall not return to work with sources of radiation until a determination of the radiation exposure has been made.~~

~~— (7) Reports received from the film badge or TLD processor and records of daily pocket dosimeter readings shall be kept for inspection by the Agency until the Agency authorizes disposition.~~

~~— (8) If a film badge or TLD is lost or damaged, the worker shall cease work immediately until a replacement film badge or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge or TLD.~~

~~— Stat. Auth.: ORS Ch. 453.605 - 453.807~~

~~— Stats. Implemented: ORS 453.625, 453.635, 453.695~~

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

Records Required at Temporary Job Sites

~~— 333-105-0301 Each licensee or registrant conducting industrial radiography at a temporary job site shall have the following records available at that site for inspection by the Agency:~~

~~— (1) Appropriate license or certificate of registration or equivalent document;~~

~~— (2) Operating and emergency procedures;~~

~~— (3) Applicable regulations;~~

~~— (4) Survey records required pursuant to OAR 333-105-0315 for the period of operation at the site;~~

~~— (5) Daily pocket dosimeter records for the period of operation at the site; and~~

~~— (6) The latest instrument calibration and leak test records for specific devices in use at the site.~~

~~Acceptable records include tags or labels which are affixed to the device or survey meter.~~

- ~~— Stat. Auth.: ORS Ch. 453.605 - 453.807~~
- ~~— Stats. Implemented: ORS 453.625, 453.635~~
- ~~— Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91~~

Security

~~— 333-105-0305 During each radiographic operation, the radiographer or radiographer's assistant shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Division 100 except:~~

- ~~— (1) Where the high radiation area is equipped with a control device or alarm system as described in OAR 333-120-0410; or~~
- ~~— (2) Where the high radiation area is locked to protect against unauthorized or accidental entry.~~

- ~~— Stat. Auth.: ORS Ch. 453.605 - 453.807~~
- ~~— Stats. Implemented: ORS 453.625, 453.635~~
- ~~— Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1995, f. & cert. ef. 4-26-95~~

Posting

~~— 333-105-0310 Notwithstanding any provisions in OAR 333-120-0420, areas in which radiography is being performed shall be conspicuously posted as required by OAR 333-120-0410.~~

- ~~— Stat. Auth.: ORS Ch. 453.605 - 453.807~~
- ~~— Stats. Implemented: ORS 453.625, 453.635~~
- ~~— Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1995, f. & cert. ef. 4-26-95~~

Radiation Surveys and Survey Records

~~— 333-105-0315 (1) No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in OAR 333-105-0115, is available and used at each site where radiographic exposures are made.~~

~~— (2) A survey with a radiation survey instrument shall be made after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall also include the guide tube.~~

~~— (3) A survey shall be made of the storage area as defined in OAR 333-105-0005(11) whenever a radiographic exposure device is being placed in storage.~~

~~— (4) A physical radiation survey shall be made to determine that each sealed source is in its shielded position prior to securing the radiographic exposure device, storage container or source changer as specified in OAR 333-105-0105.~~

~~— (5) A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is "off."~~

~~— (6) Records shall be kept of the surveys required by section (3) of this rule. Such records shall be maintained for inspection by the Agency after completion of the survey. If the survey was used to determine an individual's exposure, however, the records of the survey shall be maintained until the Agency authorizes their disposition.~~

~~Stat. Auth.: ORS Ch. 453.605 - 453.807~~

~~Stats. Implemented: ORS 453.625, 453.635~~

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

Supervision of Radiographer's Assistants or Trainees

~~333-105-0320 Whenever a radiographer's assistant or trainee uses radiographic exposure devices, uses sealed sources or related handling tools, or conducts radiation surveys required by OAR 333-105-0315(2) or (3) to determine that the sealed source has returned to the shielded position, the individual shall be under the personal supervision of a radiographer. The personal supervision shall include:~~

~~(1) The radiographer's personal presence at the site where the sealed sources are being used;~~

~~(2) The ability of the radiographer to give immediate assistance if required; and~~

~~(3) The radiographer's watching the assistant's performance of the operations referred to in this rule.~~

~~Stat. Auth.: ORS Ch. 453.605 - 453.807~~

~~Stats. Implemented: ORS 453.625, 453.635~~

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

Special Requirements and Exemptions for Enclosed Radiography

~~333-105-0325 (1) Systems for enclosed radiography designed to allow admittance of individuals shall:~~
~~(a) Comply with all applicable requirements of this section and OAR 333-120. If such a system is a certified cabinet X-ray system, it shall comply with all applicable requirements of this section and 21 CFR 1020.40;~~

~~(b) Be evaluated at intervals not to exceed one year to assure compliance with the applicable requirements as specified in OAR 333-105-0325(1)(a). Records of these evaluations shall be maintained for inspection by the Agency.~~

~~(2) Certified cabinet X-ray systems designed to exclude individuals are exempt from the requirements of this Division except that:~~

~~(a) Operating personnel must be provided with either a film badge or a thermoluminescent dosimeter; and reports of the results must be maintained for inspection by the Agency;~~

~~(b) No registrant shall permit any individual to operate a cabinet X-ray system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this subparagraph shall be maintained for inspection by the Agency until disposition is authorized by the Agency;~~

~~(c) Tests for proper operation of high radiation area control devices or alarm systems, where applicable, must be conducted, recorded and maintained in accordance with OAR 333-105-0140;~~

~~(d) The registrant shall perform an evaluation, at intervals not to exceed one year, to determine conformance with this section and OAR 333-120-0180. If such a system is a certified cabinet X-ray system, it shall be evaluated at intervals not to exceed one year to determine conformance with 21 CFR 1020.40. Records of these evaluations shall be maintained for inspection by the Agency.~~

~~(3) Certified cabinet X-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the Agency pursuant to OAR 333-100-0025.~~

~~Stat. Auth.: ORS Ch. 453.605 - 453.807~~

~~Stats. Implemented: ORS 453.625, 453.635~~

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

Specific Requirements for Radiographic Personnel Performing Industrial Radiography

~~— 333-105-0330 (1) At a jobsite, the following shall be supplied by the licensee or registrant:~~

~~— (a) At least one operable, calibrated survey instrument;~~

~~— (b) A current whole body personnel monitor (TLD or film badge) for each individual;~~

~~— (c) An operable, calibrated pocket dosimeter with a range of 0 to 200 milliroentgens (5.16×10^{-5} C/kg) for each worker; and~~

~~— (d) The appropriate barrier ropes and signs.~~

~~— (2) Industrial radiographic operations shall not be performed if any of the items in OAR 333-105-0330(1) are not available at the jobsite or are inoperable.~~

~~— (3) Each licensee or registrant shall provide as a minimum two radiographic personnel when sources of radiation are used at temporary jobsites. If one of the personnel is a radiographer trainee, the other shall be a radiographer instructor.~~

~~— (4) No individual other than a radiographer, radiographer's assistant or a radiographer trainee who is under the personal supervision of a radiographer instructor shall manipulate controls or operate equipment used in industrial radiographic operations.~~

~~— (5) No individual shall act as a radiographer instructor unless such individual:~~

~~— (a) Has met the requirements of OAR 333-105-0201(2);~~

~~— (b) Has one year of documented experience as a radiographer; and~~

~~— (c) Has been named as a radiographer instructor on the license issued by the Agency.~~

~~— (6) During an inspection by the Agency, the Agency inspector may terminate an operation if any of the items in section (1) of this rule are not available and operable or if the required number of radiographic personnel are not present. Operations shall not be resumed until such conditions are met.~~

~~— Stat. Auth.: ORS Ch. 453.605 - 453.807~~

~~— Stats. Implemented: ORS 453.625, 453.635~~

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

Prohibitions:

~~— 333-105-0335 Industrial radiography performed with a sealed source which is not fastened to or contained in a radiographic exposure device, known as fishpole radiography, is prohibited unless specifically authorized in a license issued by the Agency.~~

~~— Stat. Auth.: ORS Ch. 453.605 - 453.807~~

~~— Stats. Implemented: ORS 453.625, 453.635~~

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

Performance Requirements for Industrial Radiography Equipment

333-105-0420 Equipment used in industrial radiographic operations must meet the following minimum criteria:

(1) Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standard Institute, N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981);

(2) In addition to the requirements specified in 333-105-420(1), the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources;

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

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

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

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

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

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

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

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

(3) In addition to the requirements specified in 333-105-420(1) and 333-105-420(2), the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers;

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

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

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

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

"DANGER --RADIOACTIVE."

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

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

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

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

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

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

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

(5) As an exception to 333-105-420(1), equipment used in industrial radiographic operations need not comply with § 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque

that an individual using the radiography equipment can reasonably exert on the lever or crankshaft of the drive mechanism.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Limits on External Radiation Levels From Storage Containers and Source Changers

333-105-0430 The maximum exposure rate limits for storage containers and source changers are 2 millisieverts (200 mrem) per hour at any exterior surface, and 0.1 millisieverts (10 mrem) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Locking of Sources of Radiation, Storage Containers and Source Changers

333-105-0440 (1) Each radiographic exposure device must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device and/or its container must be kept locked (If a keyed lock, the key must be removed at all times) when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in 333-105-580 In addition, during radiographic operations the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

(2) Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked (If a keyed lock, the key must be removed at all times) when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

(3) The control panel of each radiation machine shall be equipped with a lock that will prevent the unauthorized use of an x-ray system or the accidental production of radiation. The radiation machine shall be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer or a radiographer's assistant.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Radiation Survey Instruments

333-105-0450 (1) The licensee or registrant shall keep sufficient calibrated and operable radiation survey instruments at each location where sources of radiation are present to make the radiation surveys required by this Division and by Division 120 of these rules. Instrumentation required by this section must be capable of measuring a range from 0.02 millisieverts (2 mrem) per hour through 0.01 sievert (1 rem) per hour.

(2) The licensee or registrant shall have each radiation survey instrument required under 333-105-450(1) calibrated:

- (a) At energies appropriate for use and at intervals not to exceed 6 months or after instrument servicing, except for battery changes;
 - (b) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 mrem) per hour; and
 - (c) So that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked.
- (3) The licensee or registrant shall maintain records of the results of the instrument calibrations in accordance with 333-105-620.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Leak Testing and Replacement of Sealed Sources

333-105-0460 (1) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source must be performed by persons authorized to do so by the Agency, the Nuclear Regulatory Commission, or another Agreement State.

(2) The opening, repair, or modification of any sealed source must be performed by persons specifically authorized to do so by the Agency, the Nuclear Regulatory Commission, or another Agreement State.

(3) Testing and recordkeeping requirements.

(a) Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed 6 months. The leak testing of the source must be performed using a method approved by the Agency, the Nuclear Regulatory Commission, or by another Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 becquerel (0.005 microCurie) of radioactive material on the test sample and must be performed by a person specifically authorized by the Agency, the Nuclear Regulatory Commission, or another Agreement State to perform the analysis.

(b) The licensee shall maintain records of the leak tests in accordance with 333-105-630.

(c) Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within 6 months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds 6 months.

(4) Any test conducted pursuant to 333-105-460(2) and 333-105-460(3) that reveals the presence of 185 becquerel (0.005 microCurie) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall have it decontaminated and repaired or disposed of in accordance with Agency rules. A report must be filed with the Agency within 5 days of any test with results that exceed the threshold in this paragraph, describing the equipment involved, the test results, and the corrective action taken.

(5) Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 185 becquerel (0.005 microCurie) of radioactive material on the

test sample and must be performed by a person specifically authorized by the Agency, the Nuclear Regulatory Commission, or another Agreement State to perform the analysis. Should such testing reveal the presence of DU contamination, the exposure device must be removed from use until an evaluation of the wear of the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while not in use and in storage. Before using or transferring such a device, however, the device must be tested for DU contamination, if the interval of storage exceeds 12 months. A record of the DU leak-test must be made in accordance with 333-105-630.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Quarterly Inventory

333-105-0470 (1) Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation, and for devices containing depleted uranium received and possessed under the license.

(2) The licensee or registrant shall maintain records of the quarterly inventory in accordance with 333-105-640.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.

333-105-0480 (1) The licensee or registrant shall perform visual and operability checks on survey meters, radiation machines, radiographic exposure devices, transport and storage containers, associated equipment and source changers before each day's use, or work shift, to ensure that:

- (a) The equipment is in good working condition;**
- (b) The sources are adequately shielded; and**
- (c) Required labeling is present.**

(2) Survey instrument operability must be performed using check sources or other appropriate means.

(3) If equipment problems are found, the equipment must be removed from service until repaired.

(4) Each licensee or registrant shall have written procedures for and perform inspection and routine maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed 3 months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment must be removed from service until repaired.

(5) The licensee's inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

(6) Records of equipment problems and of any maintenance performed under 333-105-480 must be made in accordance with 333-105-660.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Permanent Radiographic Installations.

333-105-0490 (1) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

(a) An entrance control of the type described in OAR 333-120-220 that causes the radiation level upon entry into the area to be reduced; or

(b) Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the source is exposed or the machine is energized. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed or the machine is energized.

(2) The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry as designated in 333-105-490(a)(1) must be tested monthly. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within 7 calendar days. The facility may continue to be used during this 7-day period, provided the licensee or registrant implements the continuous surveillance requirements of 333-105-580 and uses an alarming ratemeter. Test records for entrance controls and audible and visual alarms must be maintained in accordance with 333-105-670.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Labeling, Storage, and Transportation

333-105-0500 (1) The licensee may not use a source changer or a container to store radioactive material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording:

**CAUTION RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES [or " NAME OF COMPANY"]
or "DANGER"**

(2) The licensee may not transport radioactive material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with rules set out in Division 118.

(3) Radiographic exposure devices, source changers, storage containers, and radiation machines, must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store radioactive material in a manner that will minimize danger from explosion or fire.

(4) The licensee shall lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

(5) The licensee's or registrant's name and city or town where the main business office is located

shall be prominently displayed with a durable, clearly visible label(s) on both sides of all vehicles used to transport radioactive material or radiation machines for temporary job site use.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Radiation Safety Requirements

Conducting Industrial Radiographic Operations

333-105-0510 (1) Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of 333-105-530(3). The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

(2) All radiographic operations must be conducted in a permanent radiographic installation unless otherwise specifically authorized by the Agency.

(3) Except when physically impossible, collimators shall be used in industrial radiographic operations that use radiographic exposure devices that allow the source to be moved out of the device.

(4) A licensee or registrant may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the Agency, the Nuclear Regulatory Commission, or by another Agreement State.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Radiation Safety Officer

333-105-0520 The radiation safety officer shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant's program.

(1) The minimum qualifications, training, and experience for radiation safety officers for industrial radiography are as follows:

(a) Completion of the training and testing requirements of 333-105-530(1);

(b) 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

(c) Formal training in the establishment and maintenance of a radiation protection program.

(2) The Agency will consider alternatives when the radiation safety officer has appropriate training and experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

(3) The specific duties and authorities of the radiation safety officer include:

(a) Establishing and overseeing all operating, emergency, and ALARA procedures as required by Division 120 of these rules and reviewing them regularly to ensure that they conform to Agency rules and to the license or registration conditions;

(b) Overseeing and approving the training program for radiographic personnel to ensure that

appropriate and effective radiation protection practices are taught;

(c) Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the rules, including any corrective measures when levels of radiation exceed established limits;

(d) Ensuring that personnel monitoring devices are calibrated, if applicable, and used properly; that records are kept of the monitoring results; and that timely notifications are made as required by Division 120 of these rules; and

(e) Ensuring that operations are conducted safely and for implementing corrective actions including terminating operations.

(4) Licensees and registrants will have 2 years from the effective date of this rule to meet the requirements of 333-105-520(1) and 333-105-520(2).

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Training

333-105-0530 (1) The licensee or registrant may not permit any individual to act as a radiographer until the individual:

(a) Has received at least 40 hours of training in the subjects outlined in 333-105-530(7), in addition to on the job training consisting of hands-on experience under the supervision of a radiographer and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Appendix A of this Division. The on the job training shall include a minimum of 2 months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material and/or 1 month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on the job training (3 months or 480 hours); or

(b) The licensee or registrant may, until August 31, 2004, allow an individual who has not met the requirements of 333-105-530(1)(a), to act as a radiographer after the individual has received at least 40 hours of training in the subjects outlined in 333-105-530(7) and demonstrated an understanding of these subjects by successful completion of a written examination that was previously submitted to and approved by the Agency, the Nuclear Regulatory Commission, or another Agreement State, in addition to on the job training consisting of hands-on experience under the supervision of a radiographer. The on the job training shall include a minimum of 2 months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material and/or 1 month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on the job training (3 months or 480 hours).

(2) In addition, the licensee or registrant may not permit any individual to act as a radiographer until the individual:

(a) Has received copies of and instruction in the requirements described in the rules contained in this Division, and applicable sections of Divisions 120, 111, and 118 of these rules, in the license or registration under which the radiographer will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;

(b) Has demonstrated an understanding of items in 333-105-530(2)(a) by successful completion of a written or oral examination;

(c) Has received training in the use of the registrant's radiation machines, or the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

(d) Has demonstrated understanding of the use of the equipment described in 333-105-530(2)(c) by successful completion of a practical examination.

(3) The licensee or registrant may not permit any individual to act as a radiographer's assistant until the individual:

(a) Has received copies of and instruction in the requirements described in the rules contained in this Division, and applicable sections of Divisions 120, 111, and 118 of these regulation, in the license or registration under which the radiographer's assistant will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;

(b) Has demonstrated an understanding of items in 333-105-530(3)(a) by successful completion of a written or oral examination;

(c) Under the personal supervision of a radiographer, has received training in the use of the registrant's radiation machines, or the licensee's radiographic exposure devices and sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

(d) Has demonstrated understanding of the use of the equipment described in 333-105-530(3)(c) by successful completion of a practical examination.

(4) The licensee or registrant shall provide annual refresher safety training, as defined in 333-105-0005(1), for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

(5) Except as provided in 333-105-530(5)(d), the radiation safety officer or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Agency's rules, license or registration requirements, and operating and emergency procedures are followed. The inspection program must:

(a) Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed 6 months; and

(b) Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of 333-105-530(2)(c) and the radiographer's assistant must demonstrate knowledge of the training requirements of 333-105-530(3)(c) by a practical examination before these individuals can next participate in a radiographic operation.

(c) The Agency may consider alternatives in those situations where the individual serves as both radiographer and radiation safety officer.

(d) In those operations where a single individual serves as both radiographer and radiation safety officer, and performs all radiography operations, an inspection program is not required.

(6) The licensee or registrant shall maintain records of the above training to include certification documents, written, oral and practical examinations, refresher safety training and inspections of job performance in accordance with 333-105-680.

(7) The licensee or registrant shall include the following subjects required in 333-105-530(1):

(a) Fundamentals of radiation safety including:

(A) Characteristics of gamma and x-radiation;

(B) Units of radiation dose and quantity of radioactivity;

- (C) Hazards of exposure to radiation;
- (D) Levels of radiation from sources of radiation; and
- (E) Methods of controlling radiation dose (time, distance, and shielding);
- (b) Radiation detection instruments including:
 - (A) Use, operation, calibration, and limitations of radiation survey instruments;
 - (B) Survey techniques; and
 - (C) Use of personnel monitoring equipment;
- (c) Equipment to be used including:
 - (A) Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtailed);
 - (B) Operation and control of radiation machines;
 - (C) Storage, control, and disposal of sources of radiation; and
 - (D) Inspection and maintenance of equipment.
- (d) The requirements of pertinent state and federal rules; and
- (e) Case histories of accidents in radiography.
- (8) Licensees and registrants will have one year from the effective date of this rule to comply with the additional training requirements specified in 333-105-530(2)(a) and 333-105-530(3)(a).

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Operating and Emergency Procedures

333-105-0540 (1) Operating and emergency procedures must include, as a minimum, instructions in the following:

- (a) Appropriate handling and use of sources of radiation so that no person is likely to be exposed to radiation doses in excess of the limits established in Division 120 of these rules;
- (b) Methods and occasions for conducting radiation surveys;
- (c) Methods for posting and controlling access to radiographic areas;
- (d) Methods and occasions for locking and securing sources of radiation;
- (e) Personnel monitoring and the use of personnel monitoring equipment;
- (f) Transporting equipment to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when required, and control of the equipment during transportation as described in Division 118 of these rules;
- (g) The inspection, maintenance, and operability checks of radiographic exposure devices, radiation machines, survey instruments, alarming ratemeters, transport containers, and storage containers;
- (h) Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarming ratemeter alarms unexpectedly;
- (i) The procedure(s) for identifying and reporting defects and noncompliance, as required by 333-105-740;
- (j) The procedure for notifying proper persons in the event of an accident or incident;
- (k) Minimizing exposure of persons in the event of an accident or incident, including a source disconnect, a transport accident, or loss of a source of radiation;
- (l) Source recovery procedure if licensee will perform source recoveries; and
- (m) Maintenance of records.

(2) The licensee or registrant shall maintain copies of current operating and emergency procedures in accordance with 333-105-690 and 333-105-730.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Supervision of Radiographer's Assistants.

333-105-0550 The radiographer's assistant shall be under the direct visual supervision of a radiographer when using radiographic exposure devices, associated equipment or sources of radiation, or when conducting radiation surveys required by 333-105-570(2) to determine that the sealed source has returned to the shielded position or the radiation machine is off after an exposure. The personal supervision must include:

- (1) The radiographer's physical presence at the site where the sources of radiation are being used;**
- (2) The availability of the radiographer to give immediate assistance if required; and**
- (3) The radiographer's direct observation of the assistant's performance of the operations referred to in this section.**

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Personnel Monitoring

333-105-0560. (1) The licensee or registrant may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of direct reading dosimeter, an alarming ratemeter, and either a film badge or a TLD or other NAVLAP approved technologies. At permanent radiographic installations where other appropriate alarming or warning devices are in routine use, or during radiographic operations using radiation machines, the use of an alarming ratemeter is not required.

(a) Pocket dosimeters must have a range from zero to 2 millisieverts (200 mrem) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

(b) Each film badge and TLD must be assigned to and worn by only one individual.

(c) Film badges and TLD's must be exchanged at periods not to exceed one month.

(d) After replacement, each film badge or TLD must be returned to the supplier for processing within 14 calendar days of the end of the monitoring period, or as soon as practicable. In circumstances that make it impossible to return each film badge or TLD in 14 calendar days, such circumstances must be documented and available for review by the Agency.

(2) Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with 333-105-700.

(3) Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with 333-105-700. Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure.

(4) If an individual's pocket dosimeter is found to be off-scale, or the electronic personal dosimeter reads greater than 2 millisieverts (200 mrem), the individual's film badge or TLD must be sent for processing within 24 hours. In addition, the individual may not resume work associated with the use of sources of radiation until a determination of the individual's radiation exposure has been made. This determination must be made by the radiation safety officer or the radiation safety officer's designee. The results of this determination must be included in the records maintained in accordance with 333-105-700.

(5) If a film badge or TLD is lost or damaged, the worker shall cease work immediately until a replacement film badge or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge or TLD. The results of the calculated exposure and the time period for which the film badge or TLD was lost or damaged must be included in the records maintained in accordance with 333-105-700.

(6) Reports received from the film badge or TLD processor must be retained in accordance with 333-105-700.

(7) Each alarming ratemeter must:

- (a) Be checked to ensure that the alarm functions properly before using at the start of each shift;
- (b) Be set to give an alarm signal at a preset dose rate of 5 millisieverts (500 mrem per hour; with an accuracy of plus or minus 20 percent of the true radiation dose rate;
- (c) Require special means to change the preset alarm function; and
- (d) Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee shall maintain records of alarming ratemeter calibrations in accordance with 333-105-34

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Radiation Surveys

333-105-0570 The licensee or registrant shall:

(1) Conduct all surveys with a calibrated and operable radiation survey instrument that meets the requirements of 333-105-450;

(2) Conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or the guide tube. The survey must determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment. Radiation machines shall be surveyed after each exposure to determine that the machine is off;

(3) Conduct a survey of the radiographic exposure device whenever the source is exchanged and whenever a radiographic exposure device is placed in a storage area as defined in 333-105-0005, to ensure that the sealed source is in its shielded position; and

(4) Maintain records in accordance with 333-105-710.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Surveillance

333-105-0580 During each radiographic operation, the radiographer shall ensure continuous

direct visual surveillance of the operation to protect against unauthorized entry into a radiation area or a high radiation area, as defined in Division 100 of these rules, except at permanent radiographic installations where all entryways are locked and the requirements of 333-105-490 are met.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Posting

333-105-0590 All areas in which industrial radiography is being performed must be conspicuously posted as required by OAR 333- 120-410. The exceptions listed in 333-120-420 do not apply to industrial radiographic operations.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Recordkeeping Requirements

Records for Industrial Radiography

333-105-0600 Each licensee or registrant shall maintain a copy of its license or registration, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Agency, or until the Agency terminates the license or registration.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Records of Receipt and Transfer of Sources of Radiation

333-105-0610 (1) Each licensee or registrant shall maintain records showing the receipts and transfers of sealed sources, devices using DU for shielding, and radiation machines, and retain each record for 3 years after it is made.

(2) These records must include the date, the name of the individual making the record, radionuclide, number of becquerels (curies) or mass (for DU), and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Records of Radiation Survey Instruments

333-105-0620 Each licensee or registrant shall maintain records of the calibrations of its radiation survey instruments that are required under 333-105-450 and retain each record for 3 years after it is made.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Records of Leak Testing of Sealed Sources and Devices Containing DU

333-105-0630 Each licensee shall maintain records of leak test results for sealed sources and for devices containing DU. The results must be stated in units of becquerels (microCuries). The licensee shall retain each record for 3 years after it is made or until the source in storage is removed.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Records of Quarterly Inventory

333-105-0640 (1) Each licensee or registrant shall maintain records of the quarterly inventory of sources of radiation, including devices containing depleted uranium as required by 333-105-470, and retain each record for 3 years.

(2) The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sources of radiation and/or devices, and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Utilization Logs

333-105-0650 (1) Each licensee or registrant shall maintain utilization logs showing for each source of radiation the following information:

- (a)** A description, including the make, model, and serial number of the radiation machine or the radiographic exposure device, transport, or storage container in which the sealed source is located;
 - (b)** The identity and signature of the radiographer to whom assigned;
 - (c)** The location and dates of use, including the dates removed and returned to storage; and
 - (d)** For permanent radiographic installations, the dates each radiation machine is energized.
- (2)** The licensee or registrant shall retain the logs required by 333-105-29a. for 3 years.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Records of Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments

333-105-0660 (1) Each licensee or registrant shall maintain records specified in 333-105-480 of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments; and retain each record for 3 years after it is made.

(2) The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was performed.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Records of Alarm System and Entrance Control Checks at Permanent Radiographic Installations
333-105-0670 Each licensee or registrant shall maintain records of alarm system and entrance control device tests required by 333-105-490 and retain each record for 3 years after it is made.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Records Of Training and Certification

333-105-0680 Each licensee or registrant shall maintain the following records for 3 years after the individual terminates employment:

(1) Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, the names of individuals conducting and receiving the oral and practical examinations, and a list of items tested and the results of the oral and practical examinations; and

(2) Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliance observed by the radiation safety officer or designee.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Copies of Operating and Emergency Procedures

333-105-0690 Each licensee or registrant shall maintain a copy of current operating and emergency procedures until the Agency terminates the license or registration. Superseded material must be retained for 3 years after the change is made.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Records of Personnel Monitoring

333-105-0700 Each licensee or registrant shall maintain the following exposure records specified in 333-105-560:

- (1) Direct reading dosimeter readings and yearly operability checks required by 333-105-20b. and 333-105-560(3) for 3 years after the record is made;**
- (2) Records of alarming ratemeter calibrations for 3 years after the record is made;**
- (3) Reports received from the film badge or TLD processor until the Agency terminates the license or registration; and**
- (4) Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged film badges or TLD's, until the Agency terminates the license or registration.**

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Records of Radiation Surveys

333-105-0710 Each licensee shall maintain a record of each exposure device survey conducted before the device is placed in storage as specified in 333-105-570(3) Each record must be maintained for 3 years after it is made.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Form of Records

333-105-0720 Each record required by this Division must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Location Of Documents and Records.

333-105-0730 (1) Each licensee or registrant shall maintain copies of records required by this Division and other applicable Divisions of these rules at the location specified in 333-105-410(11).

(2) Each licensee or registrant shall also maintain current copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary job site:

- (a) The license or registration authorizing the use of sources of radiation;**
- (b) A copy of Divisions 100, 120, 105 & 111 of this Chapter;**
- (c) Utilization logs for each source of radiation dispatched from that location as required by 333-105-650.**
- (d) Records of equipment problems identified in daily checks of equipment as required by 333-**

105-660(1);

- (e) Records of alarm system and entrance control checks required by 333-105-670, if applicable;
- (f) Records of dosimeter readings as required by 333-105-700;
- (g) Operating and emergency procedures as required by 333-105-690;
- (h) Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by 333-105-620;
- (i) Evidence of the latest calibrations of alarming ratemeters and operability checks of dosimeters as required by 333-105-700;
- (j) Survey records as required by 333-105-710 and OAR 333-120-0620 as applicable, for the period of operation at the site;
- (k) The shipping papers for the transportation of radioactive materials required by Division 118 of these rules; and
- (l) When operating under reciprocity pursuant to OAR 333-102-340, a copy of the applicable State license or registration, or Nuclear Regulatory Commission license authorizing the use of sources of radiation.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Notifications

Notifications

333-105-0740 (1) In addition to the reporting requirements specified in 10 CFR 30.50 and in Division 120 of these rules, each licensee or registrant shall provide a written report to the Agency within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

- (a) Unintentional disconnection of the source assembly from the control cable;
- (b) Inability to retract the source assembly to its fully shielded position and secure it in this position;
- (c) Failure of any component, which is critical to safe operation of the device, to properly perform its intended function; or
- (d) An indicator on a radiation machine fails to show that radiation is being produced, an exposure switch fails to terminate production of radiation when turned to the off position, or a safety interlock fails to terminate x-ray production.

(2) The licensee or registrant shall include the following information in each report submitted under 333-105-740(1)38a., and in each report of overexposure submitted under OAR 333-120-0720 which involves failure of safety components of radiography equipment:

- (a) Description of the equipment problem;
 - (b) Cause of each incident, if known;
 - (c) Name of the manufacturer and model number of equipment involved in the incident;
 - (d) Place, date, and time of the incident;
 - (e) Actions taken to establish normal operations;
 - (f) Corrective actions taken or planned to prevent recurrence; and
 - (g) Names and qualifications of personnel involved in the incident.
- (3) Any licensee or registrant conducting radiographic operations or storing sources of radiation at any location not listed on the license or registration for a period in excess of 180 days in a calendar

year, shall notify the Agency prior to exceeding the 180 days.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Reciprocity

333-105-0750 (1) All reciprocal recognition of licenses and registrations by the Agency will be granted in accordance with OAR 333-102-340.

(2) Reciprocal recognition by the Agency of an individual radiographer certification will be granted provided that:

(a) The individual holds a valid certification in the appropriate category issued by a certifying entity, as defined in 333-105-0005;

(b) The requirements and procedures of the certifying entity issuing the certification affords the same or comparable certification standards as those afforded by 333-105-530(1);

(c) The applicant presents the certification to the Agency prior to entry into the state; and

(d) No escalated enforcement action is pending with the Nuclear Regulatory Commission or in any other state.

(3) Certified individuals who are granted reciprocity by the Agency shall maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, shall meet the requirements of 333-105-530(1).

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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

Specific Requirements for Radiographic Personnel Performing Industrial Radiography

333-105-0760 (1) At a job site, the following shall be supplied by the licensee or registrant:

(a) At least one operable, calibrated survey instrument for each exposure device or radiation machine in use;

(b) A current whole body personnel monitor (TLD or film badge) for each person performing radiographic operations;

(c) An operable, calibrated pocket dosimeter with a range of zero to 200 milliroentgens for each person performing radiographic operations ;

(d) An operable, calibrated, alarming ratemeter for each person performing radiographic operations using a radiographic exposure device; and

(e) The appropriate barrier ropes and signs.

(2) Each radiographer at a job site shall have on their person a valid certification ID card issued by a certifying entity.

(3) Industrial radiographic operations shall not be performed if any of the items in 333-105-780(1) and 333-105-780(2) are not available at the job site or are inoperable.

(4) During an inspection, the Agency may terminate an operation if any of the items in 333-105-780(1) and 333-105-780(2) are not available or operable, or if the required number of radiographic personnel are not present. Operations shall not be resumed until all required conditions are met.

APPENDIX A

I. Requirements for an Independent Certifying Organization.

An independent certifying organization shall:

- 1. Be an organization such as a society or association, whose members participate in, or have an interest in, the field of industrial radiography;**
- 2. Make its membership available to the general public nationwide. Membership shall not be restricted because of race, color, religion, sex, age, national origin or disability;**
- 3. Have a certification program open to nonmembers, as well as members;**
- 4. Be an incorporated, nationally recognized organization, that is involved in setting national standards of practice within its fields of expertise;**
- 5. Have an adequate staff, a viable system for financing its operations, and a policy and decision-making review board;**
- 6. Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;**
- 7. Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;**
- 8. Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;**
- 9. Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;**
- 10. Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;**
- 11. Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;**
- 12. Exchange information about certified individuals with the Nuclear Regulatory Commission and other independent certifying organizations and/or Agreement States and allow periodic review of its certification program and related records; and**
- 13. Provide a description to the Nuclear Regulatory Commission of its procedures for choosing examination sites and for providing an appropriate examination environment.**

II. Requirements for Certification Programs.

All certification programs must:

- 1. Require applicants for certification to (a) receive training in the topics set forth in 333-105-530. or equivalent State or Nuclear Regulatory Commission rules, and (b) satisfactorily complete a written examination covering these topics;**
- 2. Require applicants for certification to provide documentation that demonstrates that the applicant has:**
 - (a) Received training in the topics set forth in 333-105-530. or equivalent State or Nuclear Regulatory Commission regulations;**

(b) Satisfactorily completed a minimum period of on-the-job training as specified in 333-105-17a.;
and

(c) Received verification by a State licensee or registrant or a Nuclear Regulatory Commission licensee that the applicant has demonstrated the capability of independently working as a radiographer.

- 3. Include procedures to ensure that all examination questions are protected from disclosure;**
- 4. Include procedures for denying an application and revoking, suspending, and reinstating a certification;**
- 5. Provide a certification period of not less than 3 years nor more than 5 years;**
- 6. Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training; and**
- 7. Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.**

III. Requirements for Written Examinations

All examinations must be:

- 1. Designed to test an individual's knowledge and understanding of the topics listed in 333-105-17g. or equivalent State or Nuclear Regulatory Commission requirements;**
- 2. Written in a multiple-choice format;**
- 3. Have test items drawn from a question bank containing psychometrically valid questions based on the material in 333-105-530(7).**

**DEPARTMENT OF HUMAN SERVICES, OREGON HEALTH DIVISION
DIVISION 106
X-RAYS IN THE HEALING ARTS**

Purpose and Scope

333-106-0001

This Division establishes requirements, for which a registrant is responsible, for use of X-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of this Division are in addition to, and not in substitution for, other applicable provisions of these rules.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0005

Definitions

As used in this Division, the following definitions apply:

- (1) "Accessible Surface" means the external surface of the enclosure or housing provided by the manufacturer;
- (2) "Added Filtration" means any filtration which is in addition to the inherent filtration~~f, f.~~
- (3) "Aluminum Equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

[NOTE: The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.]

(4) "Agency approved Instructor" means an individual who has been evaluated and approved by the Agency to teach Radiation Safety.

(5) "Agency approved training course" means a course of training that has been evaluated and approved by the Agency.

(6) "A.R.R.T. means the American Registry of Radiologic Technologists.

~~f(4)}~~**(7) "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an X-ray system or subsystem. The term includes the owner of an X-ray system or his or her employee or agent who assembles components into an X-ray system that is subsequently used to provide professional or commercial services.**

~~f(5)}~~**(8) "Attenuation Block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.**

~~f(6)}~~**(9) "Automatic Exposure Control (AEC)" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation. (See also**

"Photo timer".)

~~f(7)~~ (10) "Barrier" (see "Protective Barrier").

~~f(8)~~ (11) "Beam Axis" means a line from the source through the centers of the X-ray fields.

~~f(9)~~ (12) "Beam-Limiting Device" means a device which provides a means to restrict the dimensions of the X-ray field.

~~f(10)~~ (13) "Beam Monitoring System" means a system designed to detect and measure the radiation present in the useful beam.

(14) "C-arm x-ray system" means an x-ray system in which the image receptor and x-ray tube housing are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

~~f(11)~~ (15) "Cephalometric Device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

~~f(12)~~ (16) "Certified Components" means components of X-ray systems which are subject to the X-ray Equipment Performance Standard promulgated under Public Law 90-602, the Radiation Control Agency for Health and Safety Act of 1968.

~~f(13)~~ (17) "Certified System" means any X-ray system which has one or more certified component(s).

~~f(14)~~ (18) "Changeable Filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical or physical process.

[(15)] (19) "Coefficient of Variation [σ] ~~f~~ (C) ~~f~~] means the ratio of the standard deviation to the mean value of a *[population]* set of observations. It is estimated using the following equation:

~~$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}} \left[\frac{\sum_{i=1}^n (X_i - \bar{X})^2}{n-1} \right]^{1/2}$$~~

$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}} \left[\frac{\sum_{i=1}^n (X_i - \bar{X})^2}{n-1} \right]^{1/2}$$

where

s = Estimated standard deviation of the ~~population~~ **observed values**

~~\bar{X}~~ \bar{x} = Mean value of observations in sample.

X_i = i_{th} observation in sample.

n = Number of observations in sample.

(20) "Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

~~16~~**(21)** "Contact Therapy System" means an X-ray system used for therapy with the tube port placed in contact with or within five centimeters of the surface being treated.

~~17~~**(22)** "Control Panel" means that part of the X-ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.

~~18~~**(23)** "Cooling Curve" means the graphical relationship between heat units stored and cooling time.

~~19~~**(24)** "Dead-Man Switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

~~20~~**(25)** "Detector" (see "Radiation detector").

(26) "Diagnostic x-ray imaging system" means an assemblage of components for the generation, emission, and reception of x-rays and the transformation, storage, and visual display of the resultant x-ray image.

~~21~~**(27)** "Diagnostic Source Assembly" means the tube housing assembly with a beam-limiting device attached.

~~22~~**(28)** "Diagnostic-Type Protective Tube Housing" means a tube housing so constructed that the leakage radiation measured at a distance of one meter from the source does not exceed 100 milliroentgens in one hour when the tube is operated at its leakage technique factors.

~~23~~**(29)** "Diagnostic X-Ray System" means an X-ray system designed for irradiation of any part of the human body or animal body for the purpose of diagnosis or visualization.

~~24~~**(30)** "Direct Scattered Radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (see "Scattered radiation").

~~25~~**(31)** "Entrance Exposure Rate" means the exposure ~~[per unit time at the point where the center of the useful beam enters the patient]~~ **free in air per unit of time .**

~~26~~**(32)** "Field Emission Equipment" means equipment which uses a tube in which electron emission from the cathode is due solely to the action of an electric field.

~~27~~**(33)** "Filter" means material placed in the useful beam to absorb preferentially selected radiations.

~~28~~**(34)** "Fluoroscopic Imaging Assembly" means a subsystem in which X-ray photons produce a ~~fluoroscopic~~ **visible** image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

(35) "Fluoroscopic x-ray equipment operator" means any individual who handles, adjusts technique factors, activates the exposure switch/ or button of a fluoroscopic x-ray machine or physically positions patients or animals.

~~29~~**(36)** "Focal Spot" means the area projected on the anode of the tube by the electrons accelerated from the cathode and from which the useful beam originates.

~~[(30)]~~(37) "General Purpose Radiographic X-Ray System" means any radiographic X-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

~~[(31)]~~(38) "Gonad Shield" means a protective barrier for the testes or ovaries.

~~[(32)]~~(39) "Half-Value Layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

(40) "Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by an Oregon licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

~~[(33)]~~(41) "Heat Unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes and seconds, i.e., kVp x mA x second.

~~[(34)]~~(42) "HVL" (see "Half-value layer").

~~[(35)]~~(43) "Image Intensifier" means a device, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy density.

~~[(36)]~~(44) "Image Receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident photons either into a visible image or into another form which can be made into a visible image by further transformations.

~~[(37)] "Image Receptor Support" means, for mammographic systems, that part of the system designed to support the image receptor during a mammographic examination.~~

~~[(38)]~~(45) "Inherent Filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

~~[(39)]~~(46) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

~~[(40)]~~(47) "Irradiation" means the exposure of matter to ionizing radiation.

~~[(41)]~~(48) "Kilovolt-Peak" (see "Peak tube potential").

~~[(42)]~~(49) "kV" means kilovolts.

~~[(43)]~~(50) "kVp" (see "Peak tube potential").

~~[(44)]~~(51) "kWs" means kilowatt second. It is equivalent to 10³ kV.mA.s, i.e., (A)kWs =

(X)kV x (Y)mA x (Z)s x kWs = XYZ kWs

10³kV x mA x 10³

~~[(45)]~~(52) "Lead Equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

~~[(46)]~~(53) "Leakage Radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for:

(a) The useful beam; and

(b) Radiation produced when the exposure switch or timer is not activated.

~~[(47)]~~(54) "Leakage Technique Factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

(a) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated

peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

(b) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of X-ray pulses in an hour for operation at the maximum-rated peak tube potential.

(c) For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

~~48~~(55) "Light Field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

~~49~~(56) "Line-Voltage Regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

$$\text{Percent line-voltage regulation} = 100 \frac{(V_n - V_l)}{V_l}$$

where

V_n = No-load line potential and

V_l = Load line potential.

~~50~~(57) "mA" means milliampere.

~~51~~(58) "mAs" means milliampere second.

~~52~~(59) "Maximum Line Current" means the root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.

~~53~~(60) "Mobile Equipment" (see "Equipment").

~~54~~(61) "Operator" means an individual who, under the supervision of a practitioner of the healing arts, **uses ionizing radiation upon a human being for diagnostic or therapeutic purposes including** ~~handles ionizing radiation equipment, physically positions patients or animals, determines exposure parameters or applies the radiation for the diagnostic or therapeutic purposes intended. (See the definition of "supervision" in OAR 333-100-0005(78).)~~ **the physical positioning of the patient, the determination of exposure parameters, and the handling of ionizing radiation equipment.**

~~55~~(62) "Patient" means an individual subjected to healing arts examination, diagnosis, or treatment.

~~56~~(63) "Peak Tube Potential" means the maximum value of the potential difference across the X-ray tube during an exposure.

~~57~~(64) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. **This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.**

~~58~~(65) "Photo timer" means a method for controlling radiation exposures to image receptors by measuring the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is a part of an electronic circuit which controls the duration of time the tube is activated (see also

"Automatic exposure control").

~~65~~ (66) "PID" (see "Position indicating device").

~~66~~ (67) "Portable Equipment" (see "X-Ray Equipment").

~~67~~ (68) "Position Indicating Device" means a device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

~~68~~ (69) "Primary Dose Monitoring System" means a system which will monitor useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been acquired.

~~69~~ (70) "Primary Protective Barrier" (see "Protective barrier").

~~70~~ (71) "Protective Apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.

~~71~~ (72) "Protected Area" means an area shielded with primary or secondary protective barriers or an area removed from the radiation source such that the exposure rate within the area due to normal operating procedures and workload does not exceed any of the following limits:

- (a) Two milliroentgens in any one hour; or
- (b) One hundred milliroentgens in any one year.
- (c) See OAR 333-120-0180 for additional information.

~~72~~ (73) "Protective Barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

- (a) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure;
- (b) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

~~73~~ (74) "Protective Glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

~~74~~ (75) "Qualified Expert" means an individual who has demonstrated to the satisfaction of the Agency that such individual possesses the knowledge, ~~and~~ training, **and experience** to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs.

~~75~~ (76) "Quality Control Program" means a program directed at film processing and radiographic image quality whereby periodic monitoring of film processing is performed. Test films are compared against a control film, either visually or by use of a densitometer, to determine if density or contrast have changed. Steps can then be taken to investigate such change and correct the problem. The X-ray machine itself can also be involved in the quality control program, as can other components of the imaging chain.

~~76~~ (77) "Radiation Detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

~~77~~ (78) "Radiation Therapy Simulation System" means a radiographic or fluoroscopic system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

~~78~~ (79) "Radiograph" means an image receptor on which the image is created directly or indirectly by a

pattern and results in a permanent record.

~~73~~ "Radiographic Imaging System" means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.

~~74~~ (80) "Radiological Physicist" means an individual who:

(a) Is certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x- and gamma-ray physics; or

(b) Has a bachelor's degree in one of the physical sciences or engineering and three years full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American Board of Radiology. The work duties must include duties involving the calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or

(c) Has a Master's or a Doctor's degree in physics, biophysics, radiological physics, health physics, or engineering; has had one year's full-time training in therapeutic radiological physics; and has had one year's full-time work experience in a radiotherapy facility where the individual's duties involve calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.

~~75~~ (81) "Rating" means the operating limits as specified by the component manufacturer.

~~76~~ (82) "Recording" means producing a permanent form of an image resulting from X-ray photons.

~~77~~ (83) "Registrant", as used in this Division, means any person who owns or possesses and administratively controls an X-ray system which is used to deliberately expose humans or animals to the useful beam of the system and is required by the provisions contained in Divisions 100 and 101 of this chapter to register with the Agency.

~~78~~ (84) "Response Time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero, sufficient to provide a steady state midscale reading.

~~79~~ (85) "Scattered Radiation" means radiation that, during passage through matter, has been deviated in direction (see "Direct Scattered Radiation").

~~80~~ (86) "Screening" means the use of a systematic approach to obtain cursory examinations of a person or group of persons without regard to specific clinical indications.

~~81~~ (87) "Secondary Dose Monitoring System" means a system which will terminate irradiation in the event of failure of the primary system.

~~82~~ (88) "Secondary Protective Barrier" (see "Protective barrier").

~~83~~ (89) "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

~~84~~ (90) "SID" (see "Source-image receptor distance").

~~85~~ (91) "Source" means the focal spot of the X-ray tube.

~~86~~ (92) "Source-Image Receptor Distance" means the distance from the source to the center of the input surface of the image receptor.

~~87~~ (93) "Spot Check" means a procedure which is performed to assure that a previous calibration continues to be valid.

~~88~~ (94) "Spot Film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

~~89~~ (95) "Spot-Film Device" means a device intended to transport and/or position a radiographic image

receptor between the X-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

~~90~~ (96) "SSD" means the distance between the source and the skin of the patient.

(91) ~~97~~ "Stationary Equipment" (see "X-Ray Equipment").

(92) ~~98~~ "Stray Radiation" means the sum of leakage and scattered radiation.

(93) ~~99~~ "Technique Factors" means the conditions of operation. They are specified as follows:

(a) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

(b) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of X-ray pulses;

(c) For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

~~94~~ (100) "Termination of Irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

~~95~~ (101) "Traceable to a National Standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

~~96~~ (102) "Tube" means an X-ray tube, unless otherwise specified.

~~97~~ (103) "Tube Housing Assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

~~98~~ (104) "Tube Rating Chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

~~99~~ (105) "Unprotected Area" means any area in which the exposure rate, due to the use of the radiation machine under normal operating procedures and workload, exceeds any of the following limits:

(a) Two milliroentgens in any one hour; or

(b) One hundred milliroentgens in any seven consecutive days; or

(c) Five hundred milliroentgens in any one year.

~~100~~ (106) "Useful Beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.

~~101~~ (107) "Variable-Aperture Beam-Limiting Device" means a beam-limiting device which has capacity for stepless adjustment of the X-ray field size at a given SID.

~~102~~ (108) "Visible Area" means that portion of the input surface of the image receptor over which the incident X-ray photons are producing a visible image.

~~103~~ (109) "Wedge Filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

~~104~~ (110) "X-Ray Control" means a device which controls input power to the X-ray high-voltage generator and/or the X-ray tube. It includes equipment such as exposure switches (control), timers, photo timers, automatic brightness stabilizers and similar devices, which control the technique factors of an X-ray exposure.

~~105~~ (111) "X-Ray Equipment" means an X-ray system, subsystem, or component thereof. Types of equipment are as follows:

- (a) "Mobile equipment" means X-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;
- (b) "Portable equipment" means X-ray equipment designed to be hand-carried;
- (c) "Stationary equipment" means X-ray equipment which is installed in a fixed location;
- (d) "Transportable" means X-ray equipment installed in a vehicle or trailer.

(112) "X-ray equipment operator" means any individual who handles, adjusts technique factors, activates the exposure switch/ or button of an x-ray machine, or physically positions patients or animals for an x-ray.

~~[(106)]~~ **(113) "X-Ray Field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.**

~~[(107)]~~ **(114) "X-Ray High-Voltage Generator" means a device which transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the X-ray tube(s), high-voltage switches, electrical protective devices and other appropriate elements.**

~~[(108)]~~ **(115) "X-Ray System" means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.**

~~[(109)]~~ **(116) "X-Ray Subsystem" means any combination of two or more components of an X-ray system for which there are requirements specified in this Division.**

~~[(110)]~~ **(117) "X-Ray Tube" means any electron tube which is designed to be used primarily for the production of X-rays.**

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

General Requirements

333-106-0010

Administrative Controls

- (1) The registrant shall be responsible for directing the operation of the X-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of this section are met in the operation of the X-ray system(s).
- (2) An X-ray system and/or the operation of the X-ray system which does not meet the provisions of these rules shall not be operated for diagnostic or therapeutic purposes.
- (3) For X-ray equipment manufactured after July 31, 1974, the registrant shall assure that the equipment will remain in compliance with the Code of Federal Regulations, Title 21.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0015

Technique Chart

A useable up-to-date chart shall be provided in the vicinity of the diagnostic X-ray system's control panel which specifies, for all examinations performed with that system, the following information:

- (1) Patient's anatomical size versus technique factors to be utilized.
- (2) Film-screen combination to be used.
- (3) Type and focal distance of the grid to be used, if any.
- (4) Source to image receptor distance to be used.
- (5) Indication of radiographic examinations requiring gonad shielding, except in the case of veterinary use.
- (6) Units utilizing photo timers shall have a chart indicating cell choice, optimum kVp and density setting as well as other applicable requirements of this rule.
- (7) Units utilizing automatic techniques that are incorporated in the X-ray machine are considered to meet the requirements of sections (1), (2), (3) and (4) of this rule.
- (8) In cases where machine use is restricted to intraoral radiography, or one operator and less than three techniques, the registrant is exempt from the requirements of this rule.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0020

Protection of Patients and Personnel

For safe operation of the registrants X-ray system the following apply when required in writing by the Agency:

- (1) Written safety procedures:
 - (a) Shall be mandatory for hospitals and radiologists;
 - (b) Shall include any equipment limitations or restrictions;
 - (c) Shall include any restrictions of the operating technique required for the safe operation of the X-ray system.
- (2) Written procedures shall be available for review at any time to all individuals operating X-ray equipment.

(3) The operator shall be able to demonstrate familiarity with these procedures.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0025

Protection of Patients and Personnel

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:

(1) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.

(2) 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 millimeter lead equivalent.

(3) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter 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 - ORS 453.755

Stats. Implemented:

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

333-106-0030

Gonad Shielding

(1) Gonad shielding of not less than 0.5 millimeter lead equivalent shall be used for patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure. In addition:

(a) Collimation shall not be used as a substitute for proper shielding;

(b) Should the situation arise where by gonadal shielding would compromise the diagnosis, a sticker stating "Gonadal shielding would interfere with the diagnostic procedure" (or the equivalent) shall be placed on the film to identify the reason this procedure does not comply with section (1) of this rule.

(2) A written policy regarding gonad shielding shall be provided to each individual operating X-ray equipment. This policy shall include but not be limited to:

(a) Definition of age of patients requiring gonad shielding;

(b) A listing of radiographic procedures requiring gonad shielding for both males and females;

(c) Other pertinent data that would help insure compliance, such as type and location of placement of gonad shielding.

(3) The registrant shall provide a means to assure that the requirements of section (1) of this rule are followed.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0035

Deliberate Exposures Restricted

Persons shall not be exposed to the useful beam except for healing art purposes[; unless] **until the patient has been evaluated, and a medical need for the x-ray/s is determined, and** ~~[each exposure of which,]~~ has been authorized by a physician licensed to practice the healing arts in Oregon . Any useful diagnostic information obtained from each exposure shall be reviewed by a practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

- (1) Exposure of an individual for training, demonstration or other purposes unless there are also healing arts requirements and proper prescription has been provided.
- (2) Exposure of an individual for the purpose of healing arts screening :
 - (a) Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Agency;
 - (b) When requesting such approval, that person shall submit the following information. If any information submitted to the Agency becomes invalid or outdated, the Agency shall be immediately notified:
 - (A) Name and address of the applicant and, where applicable, the names and addresses of agents within this state;
 - (B) Diseases or conditions for which the X-ray examinations are to be used in diagnoses;
 - (C) A detailed description of the X-ray examinations proposed in the screening program;
 - (D) Description of the population to be examined in the screening program, i.e., age, sex, physical conditions, and other appropriate information;
 - (E) An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the X-ray examinations;
 - (F) An evaluation by a qualified expert of the X-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these rules;
 - (G) A description of the diagnostic film quality control program;
 - (H) A copy of the technique chart for the X-ray examination procedures to be used;
 - (I) The qualifications of each individual who will be operating the X-ray system(s);
 - (J) The qualifications of the individual who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified;
 - (K) The name and address of the individual who will interpret the radiograph(s);
 - (L) A description of the procedures to be used in advising the individuals screened and their private

practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated;

(M) A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X-ray examinations.

(3) Mammography screening shall be exempt from the requirements of section (2) of this rule if the following conditions are met:

~~[(a) Only dedicated mammography X-ray systems are used,]~~

~~[(b) Each dedicated mobile mammography X-ray system shall have a dedicated film processor located in the mobile van,]~~

~~[(c) Each exposure is authorized by a practitioner of the healing arts who is licensed to practice in Oregon, and produced by an individual who is A.R.R.T. registered and certified in mammography]~~

~~[(d) All radiographs are interpreted by a Board Certified Radiologist,]~~

~~[(e) All radiographs will be kept for the patient's future reference or given to a physician named by the patient for future reference,]~~

~~[(f) A complete quality control program as outlined in OAR 333-106-0710 must be implemented for the entire X-ray and processing system,]~~

~~[(g) Guides established by N.E.X.T. (or equivalent) must be followed routinely to keep patient exposures as low as possible and maintain high quality radiographs.~~

~~[NOTE: Nationwide Evaluation of X-ray Trends (N.E.X.T.) as established by the Conference of Radiation Control Program Directors, Inc.]]~~

~~[(h)]~~

(a) The requirements set forth in OAR 333-106-0700 are satisfied.

(b) All other applicable rules are met.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0040

Patient Holding and Restraint

When a patient or film must be provided with auxiliary support during a radiation exposure:

(1) Mechanical holding devices shall be provided and used when the technique permits. The safety rules, required by OAR 333-106-0020, shall list individual projections where holding devices cannot be used.

(2) Written safety procedures, as required by OAR 333-106-0020, shall indicate the requirements for selecting a holder and the procedure the holder shall follow.

(3) The human holder shall be protected, as required by OAR 333-106-0025(1) and (2).

(4) No individual shall be used routinely to hold film or patients.

(5) Occupationally exposed personnel are prohibited from holding human patients during radiographic examination.

- (6) The Agency 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).
- (7) 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.
- (8) Holding of patients shall be permitted only when it is otherwise impossible to obtain the necessary radiograph.
- (9) Individuals stressing joints shall be exempt from section (5) of this rule.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0045

Use of Best Procedures and Equipment

Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This is interpreted to include, but not limited to:

- (1) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.
- (2) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality, see Tables 1 [~~and~~], 2 and 3.

~~[TABLE 1~~

~~Conference of Radiation Control Program Directors~~

~~AVERAGE PATIENT EXPOSURE GUIDE~~

~~1988 (or the most current)~~

~~MEDICAL ESE's~~

~~Patient ESE (mR)~~

~~Projection Thickness Grid SID Speed Speed~~

~~Abdomen (A/P) 23 Yes 40 410-200-~~

~~490-300-~~

~~620-433-~~

~~Lumbar Spine (A/P) 23 Yes 40 350-252-~~

~~450-350-~~

~~600-487-~~

~~Full Spine (A/P) 23 Yes 72 260 145~~

~~Cervical Spine (A/P) 13 Yes 40 135 95~~

~~Skull (Lat) 15 Yes 40 145 70~~

~~Chest (P/A) 23 No 72 8- 4-~~

~~15-5-~~

~~18-11-~~

~~Chest (P/A) 23 Yes 72 14- 10-~~

~~25-15-~~

~~33-18-~~

~~{NOTES:-~~

~~-1- Patient thickness expressed in centimeters (cm).~~

~~-2- Source to Image Receptor Distance (SID) expressed in inches (in).~~

~~-3- All measurements made in air (no phantom).~~

~~-4- Generally, the PA Chest with a grid represents high kVp techniques, and without a grid represents lower kVp techniques.~~

~~-5- If the facility uses a wedge filter, measure the exposure in the center of the X-ray field.~~

~~-6- ESE's are not necessarily proportional to imaging systems speed differences. }~~

TABLE 1

MEDICAL PATIENT EXPOSURE GUIDE

Maximum Entrance Skin Exposures (ESE) in mR

| Projection | Patient Thickness in centimeters (cm) | Grid | SID | 200 speed | 400 speed |
|----------------------------|--|-------------|------------|------------------|------------------|
| A.P. Abdomen | 23 | Yes | 40" | 620 | 433 |
| A.P. Lumbar Spine | 23 | Yes | 40" | 640 | 487 |
| A.P. Full Spine | 23 | Yes | 72" | 350 | 200 |
| A.P. Cervical Spine | 13 | Yes | 40" | 185 | 130 |
| Lat. Skull | 15 | Yes | 40" | 195 | 95 |
| P.A. Chest | 23 | No | 72" | 25 | 12 |
| P.A. Chest | 23 | Yes | 72" | 32 | 20 |

Note:

- 1) "SID" means source to image receptor distance.
- 2) All measurements were made in air without a phantom.

- 3) Generally, a P.A. Chest using a grid is done at high kVp (i.e. 120), whereas a non grid P.A. Chest is most often done at lower kVp (i.e. 75).
- 4) If a facility uses a wedge type filter, the exposure should be measured in the center of the x-ray field.
- 5) ESE's are not necessarily proportional to imaging systems speed differences.

~~[TABLE 2
Conference of Radiation Control Program Directors
AVERAGE PATIENT EXPOSURE GUIDES
1988 (or the most current)
DENTAL CEPHALOMETRIC~~

~~30mR (patient thickness 15 cm, SID = 66 inches, without grid)~~

~~NOTE: Exam is normally conducted with the source (focal spot) at a distance of 60 inches from the mid-sagittal plane and with the image receptor at approximately 15 cm from that plane yielding an SID of about 66 inches. (Average ESE from NEXT 1984)~~

Table 2

DENTAL CEPHALOMETRIC PATIENT EXPOSURE GUIDE

Maximum Entrance Skin Exposures (ESE) in mR

| Projection | Part Thickness | Grid | SID | ESE |
|-------------------|-----------------------|-------------|------------|------------|
| Lat. Skull | 15 cm | No | 66" | 30 |

~~fTable 3~~

~~DENTAL INTRAORAL (BITEWING)~~

~~kVp "D" Speed Film "E" Speed Film
ESE ESE~~

~~-
50 425-575 220-320
55 350-500 190-270
60 310-440 165-230
65 270-400 140-200~~

70 240-350 120-170
 75 170-260 100-140
 80 150-230 90-120
 85 130-200 80-105
 90 120-180 70-90
 95 110-160 60-80
 100 100-140 50-70

NOTES:-

-1- *The bitewing guides represent the range of exposures (under the indicated conditions) that will produce, in the judgment of a panel of experienced dental radiologists, acceptable quality radiographs. The radiographs, of the 3M dental phantom, were produced under well controlled conditions (in terms of both exposure and processing). The radiographs were taken at 10mA at the indicated kVp's using a GE 90 H X-ray machine. In the 50-70 kVp range there was 1.5 mm Al filtration and in the 75-100 kVp range the filtration was 2.5 mm Al.*

-2- *Exposures are specified as free-in-air exposures without backscatter.*

-3- *Note that the indicated kVp is often significantly different from the actual kVp. Such a difference could result in the application of an inappropriate exposure range.*

Table 3

**ADULT DENTAL INTRAORAL BITEWING EXPOSURE GUIDE
 Maximum Entrance Skin Exposures (ESE) in mR**

| kVp | "D" Speed Film | "E" Speed Film | "F" Speed Film |
|------------|-----------------------|-----------------------|-----------------------|
| 50 | 575 | 320 | 256 |
| 55 | 500 | 270 | 216 |
| 60 | 440 | 230 | 184 |
| 65 | 400 | 200 | 160 |
| 70 | 350 | 170 | 136 |
| 75 | 260 | 140 | 112 |
| 80 | 230 | 120 | 96 |
| 85 | 200 | 105 | 84 |

| | | | |
|------------|------------|-----------|-----------|
| 90 | 180 | 90 | 72 |
| 95 | 160 | 80 | 64 |
| 100 | 140 | 70 | 56 |

Note:

- 1) Exposures indicated in table 3 are free-in-air without backscatter.**
- 2) The indicated kVp is often significantly different from the actual kVp. Such a difference could result in the use of an exposure that exceeds the maximum allowed.**
- 3) Manufacturer’s technical data indicates that “F” speed film requires 20% less exposure than “E” speed film.**
- 4) For children and small adults, the maximum ESE should be approximately 30% less than indicated in table 3.**
- 5) Anterior teeth in the maxillary region require the same amount of exposure as a bitewing.**
- 6) Anterior teeth in the mandibular region require approximately 25% less exposure than a bitewing.**

(3) 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.

(4) 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.

(5) Cardboard cassettes without screens shall not be used (dental intraoral excluded).

(6) Fluoroscopy:

(a) Use shall be restricted to those properly trained, and deemed competent in the safe use of fluoroscopy by a hospital radiation safety committee, radiologist or roentgenologist:

(A) Physician here means a MD, DO, DC, DPM or DVM only;

(B) Technologist here means A.R.R.T. -- Registered only:

(i) The use of fluoroscopy by technologists shall be performed under the direction of a radiologist or roentgenologist and is restricted to the healing arts exclusively for the purpose of localization and/or to assist physicians in obtaining images for diagnostic purposes;

(ii) Allowing technologists to assist in the use of fluoroscopy is not to be interpreted as giving the technologist the authority to do fluoroscopic studies on patients on their own accord.

(c) Proper training to meet the requirements of subsection (a) of this section shall include but not be limited to the following:

(i) Principles and operation of the fluoroscopic X-ray machine;

(ii) Biological effects of X-ray;

(iii) Radiation units;

(iv) Typical fluoroscopic outputs;

(v) High level control options;

(vi) Dose reduction techniques for fluoroscopy;

(vii) Protective devices;

(viii) Radiation monitoring;

(ix) Applicable radiation rules and regulations.

(D) Physicians or technologists using fluoroscopy prior to the effective date of these rules will be considered to have met the requirements of paragraph (6)(a)(C) of this rule if they have a written statement attesting that they have been evaluated and deemed competent in the safe use of fluoroscopy. Such evaluation and attestation must include the input of a radiologist or roentgenologist. In addition such attestation could be used as the basis of establishing proper training and competency in the safe use of fluoroscopy by other registrants that the individual may be associated with.

(b) All images formed by the use of stationary fluoroscopy shall be viewed, directly or indirectly, and interpreted by a radiologist, cardiologist or other qualified specialist;

(c) Mobile fluoroscopy shall meet the requirements of subsection (6)(a) and (b) of this rule;

(d) Written procedures for technologists performing fluoroscopy shall be available and include:

(A) A description of the examinations that the technologist is allowed to perform;

(B) A description of the qualifications to be met by a technologist who is performing fluoroscopy;

(C) A list of all technologists who are qualified and who are performing fluoroscopy.

(e) At no time will any student be allowed to perform fluoroscopy unless directly supervised by a radiologist or qualified technologist;

(f) Overhead fluoroscopy is not to be routinely used as a positioning tool for radiographic exams.

(7) 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.

(8) Filter slot covers shall be provided when necessary.

(9) All patients' radiographs, or copies shall be made available for review by any practitioner of the healing arts upon request of the patient.

(10) 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 Agency. 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.

(11) 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 values must then be compared to existing guidelines, and if such values are significantly higher than such guidelines, action must be taken to reduce the values while at the same time maintaining or improving diagnostic image quality. In addition, typical patient exposure values shall be posted or made readily available to administrators, X-ray operators, patients and practitioners.

(12) 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) Effective twelve (12) months after the effective date of this rule, establish cumulative fluoroscopic on-time benchmarks for each type of fluoroscopic examination performed at their site ;

- (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 on-time benchmarks established for individual fluoroscopic examinations ;**
- (c) Take appropriate action, when the established benchmarks are consistently exceeded, and provide written documentation of such actions when requested by the Agency.**
- (13) Dental X-ray machines designed and manufactured to be used for dental purposes shall be restricted to dental use only.
- (14) An X-ray quality control program shall be administered when appropriate.
- (15) The number of radiographs taken for any radiographic examination should be the minimum number needed to adequately diagnose the problem.
- (16) All X-ray equipment must be capable of functioning at the manufacturer's intended specifications.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0050

Personnel Monitoring

All individuals who are associated with the operation of an X-ray system are subject to the requirements of OAR 333-120-0100 and 333-120-0140. In addition:

- (1) When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:
- (a) When an apron is worn, the monitoring device shall be worn at the collar outside of the apron;
- (b) The dose to the whole body based on the maximum dose attributed to the most critical organ (which are the gonads, the blood-forming organs, head and truck or lens of the eye), shall be recorded in the reports required by OAR 333-120-0650(3). If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.
- (2) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0055

X-ray Operator Training

(1) The registrant shall assure that individuals who will be operating the X-ray equipment shall have adequate training in radiation safety. Adequate training in radiation safety means a **minimum of forty (40) hours [or more] of didactic instruction for medical X-ray equipment operators, thirty (30) hours for dental X-ray equipment operators, and twenty (20) hours [or more] for veterinary X-ray equipment operators from an Agency approved training course covering [in] 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 radiation regulations;
- (i) Darkroom and film processing;
- (j) Film critique.

(2) In addition to the above[;] ; ~~[and after the effective date of these rules, medical X-ray operators using diagnostic radiographic x-ray equipment on human patients must meet the following:-]~~

(a) **Medical X-ray equipment operators using diagnostic radiographic equipment on human patients, and who are not responsible to the Oregon Board of Radiologic Technology. Must have [Have] 100 hours or more of instruction in radiologic technology including but not limited to anatomy and physiology, patient positioning, exposure and technique all of which must be appropriate to the types of X-ray examination that the individual will be involved with; and**

(b) **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**

(c) ~~[All persons taking X-rays on humans must]~~ **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; and

(d) **The training required in OAR 333-106-0055 (1) and (2) must [Be] be taught by an Agency approved [radiologic technologist] Instructor. Approval will be based the following criteria;**

(A) Medical

(i) **Currently licensed as a Radiologic Technologist and approved as an education provider by the Oregon Board of Radiologic Technology.**

(B) Dental

(i) **Passed the Dental Assisting National Board (DANB) written radiation health and safety**

examination; And

(ii) Currently licensed, by the Oregon Board of Dentistry as a dentist; Or

(iii) Dental hygienist; Or

(iv) Is a dental assistant certified in Radiologic proficiency; And

(v) Has a minimum of two years of experience in taking dental radiographs.

(C) Veterinarian-

(i) Currently credentialed with the Oregon Veterinary Medical Examining Board, or

**(ii) Currently licensed as a Radiologic Technologist by the Oregon Board of Radiologic Technology;
And**

(iii) Have training specific to veterinarian radiography; And

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

(D) On a case by case basis, if an evaluation by the Agency reveals that the individual has alternative qualifications that are substantially equivalent to the qualifications listed in sections (2)(d)(A),(B),or (C) of this rule.

(3) In addition to the requirements in sections (1),(2)(d)(B) of this rule, dental X-ray equipment operators must also;

(a) Satisfy any requirements established by the Oregon Board of Dentistry;

(4) Dental X-ray students are permitted to expose a human patient to X-ray during their clinical instruction only under direct supervision of licensed dentist, or licensed dental hygienist, or a dental assistant certified by the Oregon Board of Dentistry in Radiologic proficiency, or an Agency approved instructor.

~~f(3)f~~ **(5) The operator shall be able to demonstrate competency in the safe use of the X-ray equipment and associated X-ray procedures.**

~~[4]~~ **(6) Any operator is deemed to have adequate training to meet the requirements of section (1) of this rule if they meet any of the following:**

(a) Hold a current license from the Oregon Board of Radiologic Technology;

(b) Hold a current limited permit from the Oregon Board of Radiologic Technology;

(c) Are 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 [~~an instructor who is either~~] a radiologist who is

currently licensed with the Oregon Medical Examiners Board or a [*registered and licensed*] radiologic technologist who is currently registered with the American Registry of Radiologic Technologists and licensed with the Oregon Board of Radiologic Technology;

(d) Are a student in an Oregon Board of Radiologic Technology **approved** limited permit program under a [*licensed*] Radiologic Technologist **who is currently registered with the American Registry of Radiologic Technologists and licensed by the Oregon Board of Radiologic Technology;** or

(e) [*For*] **Medical X-ray equipment** operators not responsible to the Oregon Board of Radiologic Technology, [*you must hold a certificate from an agency-approved training course that covers the items listed in section (1) of this rule*] **who have met the training requirements listed in section (1) of this rule prior to September 1995, will be considered to have met the requirements of section (2) of these rules [;] ;**

~~[(f) X-ray operators not responsible to the Oregon Board of Radiologic Technology who have met the 20-hour requirement prior to March 1, 1994, will be considered to have met the requirements of section (1) of this rule.]~~

(f) **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 (1) or (2) as applicable of this rule, if the Agency's evaluation of their training indicates that it is equivalent to or exceeding the requirements in the applicable section of the X-ray operator training requirements.**

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0101

Diagnostic X-ray Systems

Additional Requirements. In addition to other requirements of this Division, all diagnostic X-ray systems shall meet the following requirements:

(1) **Warning Label.** The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed".

(2) The state will attach an identification number to each X-ray control panel:

(a) Identification numbers shall not be removed without written permission of the Agency;

(b) Identification numbers shall not be defaced.

(3) Mobile and portable X-ray systems shall meet the requirements of a stationary system when used for greater than seven consecutive days in the same location.

(4) **Battery Charge Indicator.** On battery-powered X-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(5) Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 milliroentgens (25.8 $\mu\text{C}/\text{kg}$) in one hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(6) Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed two milliroentgens (0.516 $\mu\text{C}/\text{kg}$) in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(7) Beam Quality:

(a) Half-Value Layer:

(A) The half-value layer of the useful beam for a given X-ray tube potential shall not be less than the values shown in Table [3] 4. If it is necessary to determine such half-value layer at an X-ray tube potential which is not listed in Table [3] 4, linear interpolation or extrapolation may be made;

[TABLE 3

HALF VALUE LAYER CRITERIA

X-ray Tube Voltage Minimum HVL

(Kilovolt Peak) (mm of Al)

| <i>Design Operating Range</i> | <i>Measured Operating Potential</i> | <i>Special Dental Systems</i> | <i>Other X-Ray Systems</i> |
|-------------------------------|-------------------------------------|-------------------------------|----------------------------|
| <i>Below 50</i> | <i>30</i> | <i>1.5</i> | <i>0.3</i> |
| | <i>40</i> | <i>1.5</i> | <i>0.4</i> |
| | <i>49</i> | <i>1.5</i> | <i>0.5</i> |
| <i>50 to 70</i> | <i>50</i> | <i>1.5</i> | <i>1.2</i> |
| | <i>60</i> | <i>1.5</i> | <i>1.3</i> |
| | <i>70</i> | <i>1.5</i> | <i>1.5</i> |
| <i>Above 70</i> | <i>71</i> | <i>2.1</i> | <i>2.1</i> |
| | <i>80</i> | <i>2.3</i> | <i>2.3</i> |
| | <i>90</i> | <i>2.5</i> | <i>2.5</i> |
| | <i>100</i> | <i>2.7</i> | <i>2.7</i> |
| | <i>110</i> | <i>3.0</i> | <i>3.0</i> |
| | <i>120</i> | <i>3.2</i> | <i>3.2</i> |
| | <i>130</i> | <i>3.5</i> | <i>3.5</i> |
| | <i>140</i> | <i>3.8</i> | <i>3.8</i> |

150 4.1 4.1

NOTE: The above HVL criteria will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table 4.

TABLE 4
HALF VALUE LAYER (HVL) CRITERIA

| Design Operating Range | Measured Potential (kVp) | Half Value Layer In mm of Aluminum |
|-------------------------------|---------------------------------|---|
|-------------------------------|---------------------------------|---|

| | | Dental Intra-Oral Manufactured Before Aug. 1, 1974 and On or After Dec. 1, 1980 | All Other Diagnostic X-ray Systems |
|-----------------|------------|--|---------------------------------------|
| Below 51 | 30 | N/A | 0.3 |
| | 40 | N/A | 0.4 |
| | 50 | 1.5 | 0.5 |
| 51 to 70 | 51 | 1.5 | 1.2 |
| | 60 | 1.5 | 1.3 |
| | 70 | 1.5 | 1.5 |
| Above 70 | 71 | 2.1 | 2.1 |
| | 80 | 2.3 | 2.3 |
| | 90 | 2.5 | 2.5 |
| | 100 | 2.7 | 2.7 |
| | 110 | 3.0 | 3.0 |
| | 120 | 3.2 | 3.2 |
| | 130 | 3.5 | 3.5 |
| | 140 | 3.8 | 3.8 |
| | 150 | 4.1 | 4.1 |

Note: The above HVL criteria will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table 4.

[TABLE 4
 FILTRATION REQUIRED vs OPERATING VOLTAGE
 Total Filtration:-
 inherent plus added. (mm Al equivalent)

*Operating Dental Other
Voltage X-ray X-ray
(kVp) Systems Systems
Below 50 0.5 millimeters
50-70 1.5 1.5 millimeters
Above 70 2.5 2.5 millimeters]*

TABLE 5

FILTRATION REQUIRED versus OPERATING VOLTAGE

| Total Filtration: Inherent + Added (in mm Al equivalent) | | |
|---|-----------------------------|----------------------------|
| Operating Voltage (kVp) | Dental X-ray Systems | Other X-ray Systems |
| Below 50 | | 0.5 |
| 50-70 | 1.5 | 1.5 |
| > 70 | 2.5 | 2.5 |

(B) In addition to the requirements of section (5) of this rule, all intraoral dental radiographic systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent filtration permanently installed in the useful beam;

(C) Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam;

(D) For capacitor energy storage equipment, compliance with the requirements of section (5) of this rule shall be determined with the maximum quantity of charge per exposure;

(E) The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

(b) Filtration Controls. For X-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by subsection (5)(a) of this rule is in the useful beam for the given kVp which has been selected.

(8) Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly which has been selected.

(9) Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the X-ray system.

(10) Technique Indicators:

(a) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated;

(b) The requirement of subsection (10)(a) of this rule may be met by permanent marking on equipment having fixed technique factors.

(11) There shall be provided for each X-ray machine a means for determining the proper S.I.D.

(12) X-ray film developing requirements. Compliance with this section is required of all healing arts registrants and is designed to ensure that patient and operator exposure is minimized and to produce optimum image quality and diagnostic information:

(a) Manual processing of films:

(A) The following relationship between temperature of the development and development time must be used (standard chemistry only) or manufacturer's recommendations:

*[Thermometer Readings Minimum Developing Times
(Degrees) (Minutes)]*

~~C-F~~

~~27-80 2~~

~~79 2~~

~~78 2 1/2~~

~~77 2 1/2~~

~~24-76 3~~

~~75 3~~

~~74 3 1/2~~

~~73 3 1/2~~

~~22-72 4~~

~~71 4~~

~~70 4 1/2~~

~~69 4 1/2~~

~~20-68 5~~

~~67 5 1/2~~

~~66 5 1/2 65 6 18 - 64 6 1/2 63 76 2 8 61 8 1/2 16 - 60 9 1/2 }~~

| THERMOMETER READINGS IN DEGREES | | MINIMUM DEVELOPING TIME |
|--|-------------------|--------------------------------|
| Centigrad | Fahrenheit | Minutes |

| | | |
|-----------|-----------|------------|
| <u>27</u> | <u>80</u> | <u>2</u> |
| | <u>79</u> | <u>2</u> |
| | <u>78</u> | <u>2.5</u> |
| | <u>77</u> | <u>2.5</u> |
| <u>24</u> | <u>76</u> | <u>3</u> |
| | <u>75</u> | <u>3</u> |
| | <u>74</u> | <u>3.5</u> |
| | <u>73</u> | <u>3.5</u> |
| <u>22</u> | <u>72</u> | <u>4</u> |
| | <u>71</u> | <u>4</u> |
| | <u>70</u> | <u>4.5</u> |
| | <u>69</u> | <u>4.5</u> |
| <u>20</u> | <u>68</u> | <u>5</u> |
| | <u>67</u> | <u>5.5</u> |
| | <u>66</u> | <u>5.5</u> |
| | <u>65</u> | <u>6</u> |
| <u>18</u> | <u>64</u> | <u>6.5</u> |
| | <u>63</u> | <u>7</u> |
| | <u>62</u> | <u>8</u> |
| | <u>61</u> | <u>8.5</u> |
| <u>16</u> | <u>60</u> | <u>9.5</u> |

(B) Processing of film. All films shall be processed in such a fashion as to achieve adequate sensitometric performance. This criterion shall be adjudged to have been met if:

- (i) Film manufacturer's published recommendations for time and temperature are followed; or
- (ii) Each film is developed in accordance with the time-temperature chart (see subsection (a) of this section).

(C) Chemical-film processing control:

- (i) Chemicals shall be mixed in accordance with the chemical manufacturer's recommendations;
- (ii) Developer replenisher shall be periodically added to the developer tank based on the recommendations of

the chemical or film manufacturer. Solution may be removed from the tank to permit the addition of an adequate volume of replenisher.

(D) All processing chemicals shall be completely replaced at least every two months or as indicated by the manufacturer;

(E) Devices shall be available which will:

(i) Give the actual temperature of the developer; and

(ii) Give an audible or visible signal indicating the termination of a preset development time (in minutes or seconds).

(b) Automatic film processing. Films shall be processed in such a manner that the degree of film development is the same as would be achieved by proper adherence to subsection (a) of this section (manual processing);

(c) Darkrooms. Darkrooms shall be constructed so that film being processed, handled, or stored will be exposed only to light which has passed through an appropriate safelight filter;

(d) Safelights shall be properly mounted to eliminate film fogging;

(e) Safelights shall be properly matched to the type of film being used;

(f) Rapid film processing. Special chemicals have been designed for use in Endodontics. These chemicals have special development requirements and do not permit as large of a margin of error in darkroom technique as do standard developing chemicals. Failure to precisely follow manufacturer's recommendations can easily lead to overexposure and underdevelopment. Darkroom procedures shall include:

(A) The manufacturer's time temperature development is crucial and shall be followed exactly;

(B) Caution: A timer capable of accurately measuring the short development times required shall be used;

(C) If rapid chemical processing is used for general radiography all applicable requirements of section (12) of this rule shall be followed.

(g) The department shall make such tests as may be necessary to determine compliance with this section.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0105

Information and Maintenance Record and Associated Information

(1) The registrant shall maintain the following information for each x-ray **and automatic film processing** system for inspection by the Agency:

(a) Model ~~and~~ , serial numbers~~, and~~ **and manufacturer's user manuals for** ~~of~~ all ~~major components~~ **x-ray systems and automatic film processors** ~~and user manuals for those components~~ ;

(b) Tube rating charts and cooling curves;

(c) Records of surveys, calibrations maintenance, and modification performed on the x-ray system(s) with names of persons who perform such services;

(d) A scale drawing of the room in which a stationary x-ray system is located with such drawing indicating the current use of areas adjacent to the room and an estimate of the extent of occupancy by individuals in such areas. In addition, the drawing shall include:

- (A) The result of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or
 - (B) The type and thickness of materials, or lead equivalency, of each protective barrier.
 - (e) A copy of all correspondence with this Agency regarding that x-ray system;
 - (f) Provisions in section (1) of this rule shall pertain to X-ray systems placed in service after the effective date of these rules.
- (2) X-ray Log. Each facility shall maintain an x-ray log containing the patient's name, the type of examinations, and the dates the examinations were performed and the name of the x-ray operator. The following facilities are exempt from this requirements:
- (a) Dental facilities that maintain patient records showing the type and date of the examination and the operator's name;
 - (b) Industrial facilities doing industrial X-ray only;
 - (c) Veterinary facilities;
 - (d) Hospitals or clinics who employ only fully licensed X-ray operators;
 - (e) Doctors' offices or clinics with only one X-ray operator, or one X-ray exam;
 - (f) Academic, when not X-raying humans.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0110

Plan Review

When required by the Agency, and:

- (1) Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing X-rays for diagnostic or therapeutic purposes shall be submitted to the Agency for review and approval. The required information is as set out in Division 20.
- (2) The Agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.
- (3) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in Division 120.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0120

Information on Radiation Shielding for Plan Reviews -- Optional

In order to provide an evaluation or technical advice on shielding requirements for a radiation installation, the following information must be submitted:

- (1) The plans should show, as a minimum, the following:
 - (a) The normal location of the X-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the X-ray control panel;
 - (b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;
 - (c) The dimensions of the room(s) concerned;
 - (d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present;
 - (e) The make and model of the X-ray equipment and the maximum technique factors;
 - (f) The type of examination(s) or treatment(s) which will be performed with the equipment.
- (2) Information on the anticipated workload of the X-ray system(s).
- (3) If the services of a qualified expert have been utilized to determine the shielding requirements, a report, including all basic assumptions used, shall be submitted with the plans.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0130

Design Requirements for an Operator's Booth

- (1) Space Requirements when required by OAR 333-106-0110:
 - (a) The operator shall be allotted not less than 7.5 square feet (0.697 m²) of unobstructed floor space in the booth;
 - (b) The operator's booth may be any geometric configuration with no dimension of less than two feet (0.61 m);
 - (c) The space shall be allotted excluding any encumbrance by the X-ray control panel, such as overhang, cables, or other similar encroachments;
 - (d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette not reach the operator's station in the booth.
- (2) Structural Requirements:
 - (a) The booth walls shall be permanently fixed barriers of at least seven feet (2.13 m) high;
 - (b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed;
 - (c) Shielding shall be provided to meet the requirements of Division 120 of these rules.
- (3) X-ray Exposure Control Placement: The X-ray exposure control for the system shall be fixed within the booth and:
 - (a) Shall be at least 40 inches (1.02 m) from any open edge of the booth wall which is nearest to the examining

table;

(b) Shall allow the operator to use the majority of the available viewing windows.

(4) Viewing System Requirements:

(a) Each booth shall have at least one viewing device which will:

(A) Be so placed that the operator can view the patient during any exposure; and

(B) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

(b) When the viewing system is a window, the following requirements also apply:

(A) The viewing area shall be at least one square foot (0.0929 m²);

(B) The design of the booth shall be such that the operator's expected position when viewing the patient and operating the X-ray system is at least 18 inches (0.457 m) from the edge of the booth;

(C) The material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.

(c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of subsection (4)(a) of this rule;

(d) When the viewing system is by electronic means:

(A) The camera shall be so located as to accomplish the general requirements of subsection (4)(a) of this rule;

(B) There shall be an alternate viewing system as a backup for the primary system.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

Fluoroscopic X-ray Systems Requirements

333-106-0201

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 centimeters 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 centimeters 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 centimeters or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of five centimeters by five centimeters 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:

(A) 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, five centimeters by five centimeters;

(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 (2) 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 - ORS 453.755

Stats. Implemented:

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

333-106-0205

Activation of the Fluoroscopic Tube

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.

Stat. Auth.: ORS 453

Stats. Implemented:

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

333-106-0210

Entrance Exposure Rates ~~{Limits}~~

~~{Entrance Exposure Rate Allowable Limits}~~

(1) For fluoroscopic equipment manufactured before May 19, 1995, the following apply:

~~{(1) a}~~ **Fluoroscopic equipment that is provided with Automatic Exposure Rate Control (AERC) shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of [~~The exposure rate measured at the point where the center of the useful beam enters the patient shall not exceed~~] ten (10) roentgens (2.58 mC/kg) per minute, ~~{except during recording of fluoroscopic images or when provided with optional high level control.}~~ at a point where the center of the useful beam enters the patient, except ;**

(A) During the recording of fluoroscopic images, or;

(C) When optional high-level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of five (5) roentgens (1.29 mC/kg) per minute at a point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(2) Fluoroscopic equipment that is not provided with AERC shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of five (5) roentgens (1.29 mC/kg) per minute at a point where the center of the useful beam enters the patient, except;

(a) During the recording of fluoroscopic images, or;

(A) When optional high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(3) Equipment with both an AERC mode and a manual mode. Fluoroscopic equipment that is provided with both an AERC and a manual mode shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of ten (10) roentgens (2.58 mC/kg) per minute in either mode at a point where the center of the useful beam enters the patient, except;

(a) During the recording of fluoroscopic images, or;

(A) When the mode or modes have an optional high-level control, in which case that mode or modes shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of five (5) roentgens (1.29 mC/kg) per minute at a point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(4) Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in sections 1, 2, and 3 of this rule.

(5) For fluoroscopic equipment manufactured on and after May 19, 1995, the following requirements will apply:

(a) Fluoroscopic equipment operable at any combination of tube potential and current that will result in an exposure rate in excess of five (5) roentgens (1.29 mC/kg) per minute at a point where the center of the useful beam enters the patient shall be equipped with AERC. Provision for manual selection of the technique factors may be provided.

(b) Fluoroscopic equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of ten (10) roentgens (2.58 mC/kg) per minute at a point where the center of the useful beam enters the patient except ;

(i) During the recording of fluoroscopic images from an x-ray image- intensifier tube using photographic film or a video camera when the x-ray source is operated in a pulsed mode.

(ii) When an optional high-level control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of twenty (20) roentgens per minute at a point where the center of the useful beam enters the patient. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

[(2) When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.]

~~[(a) Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator;~~

~~(b) A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.~~

~~(3) In addition to the other requirements of OAR 333-106-0201, certified systems which do not incorporate an automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient except during recording of fluoroscopic images or when an optional high level control is provided and is activated.]~~

(4) **Measuring compliance.** Compliance with the requirements of this rule shall be determined as follows:

~~[(a) Movable grids and compression devices shall be removed from the useful beam during the measurement;]~~

~~f(b)}~~ **(a)** If the source is below the table, exposure rate shall be measured one **(1)** centimeter above the tabletop or cradle;

~~f(c)}~~ **(b)** If the source is above the table, the exposure rate shall be measured at **thirty (30)** centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

~~f(d)}~~ **(c)** For a C-arm type of fluoroscope, the exposure rate shall be measured **thirty (30)** centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than **thirty (30)** centimeters from the input surface of the fluoroscopic imaging assembly;

~~f(e)}~~ **(d)** For a lateral type fluoroscope, the exposure rate shall be measured at a point **fifteen (15)** centimeters from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is moveable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than **fifteen (15)** centimeters to the centerline of the X-ray table.

(5) Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirement set forth in section 5 of this rule.

~~f(5)}~~ **(6)** Periodic measurement of entrance exposure rate shall be performed as follows:

(a) Such measurement shall be made annually or after any maintenance of the system which might affect the exposure rate;

(b) Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in OAR 333-106-0105(1)(c). The measurement results shall be stated in roentgens per minute and include the technique factors used in determining such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results;

(c) Personnel monitoring devices may be used to perform the measurements required by subsection (5)(a) of this rule, provided the measurements are made as described in subsection (5)(d) of this rule;

(d) Conditions of periodic measurement of entrance exposure rate are as follows:

(A) The measurement shall be made under the conditions that satisfy the requirements of section (4) of this rule;

(B) The kVp shall be the kVp typical of clinical use of the X-ray system;

- (C) The X-ray system(s) that incorporates automatic exposure control shall have sufficient material placed in the useful beam to produce a milliamperage typical of the use of the X-ray system or the worst case; and
(D) X-ray system(s) that do not incorporate an automatic exposure control shall utilize a milliamperage typical of the clinical use of the X-ray system.

[NOTE: Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.]

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0215

Barrier Transmitted Radiation Rate Limits

(1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed two milliroentgens (0.516 $\mu\text{C}/\text{kg}$) per hour at ten centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(2) Measuring Compliance of Barrier Transmission:

(a) The exposure rate due to transmission through the primary protective barrier combine with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters;

(b) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop;

(c) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters;

(d) Movable grids and compression devices shall be removed from the useful beam during the measurement;

(e) The attenuation block shall be positioned in the useful beam ten centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0220

Indication of Potential and Current

During fluoroscopy and cinefluorography [~~the kV and the mA~~] x-ray tube potential and current shall be continuously indicated. **Deviation of x-ray tube potential and current from the indicated values shall not exceed the maximum deviation stated by the manufacturer.**

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0225

Source-to-Skin Distance

The source-to-skin distance shall not be less than:

- (1) Thirty-eight centimeters on stationary fluoroscopes manufactured on or after August 1, 1974;
- (2) 35.5 centimeters on stationary fluoroscopes manufactured prior to August 1, 1974;
- (3) Thirty centimeters on all mobile fluoroscopes; and
- (4) Twenty centimeters 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 - ORS 453.755

Stats. Implemented:

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

333-106-0230

Fluoroscopic Timer

- (1) Means shall be provided to present the cumulative on-time of the fluoroscopic tube.
- (2) The maximum cumulative time of the timing device shall not exceed five minutes without resetting.
- (3) A signal audible to the fluoroscopist, or the appropriate operator, shall indicate the completion of any preset cumulative on-time; or if no audible signal is provided, the exposure shall terminate.

Stat. Auth.: ORS 453

Stats. Implemented:

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

333-106-0235

Mobile Fluoroscopes

In addition to the other requirements of OAR 333-106-0201 through 333-106-0245, mobile fluoroscopes shall

provide intensified imaging.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0245

Radiation Therapy Simulation Systems

Radiation therapy simulation systems shall be exempt from all the requirements of OAR 333-106-0201 through 333-106-0245 provided that:

- (1) 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
- (2) Systems which do not meet the requirements of OAR 333-106-0230 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.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, Veterinary Systems, or Computed Tomography X-ray Systems

333-106-0301

Beam Limitation

- (1) The useful beam shall be limited to the area of clinical interest.
- (2) General Purpose Stationary and Mobile X-ray Systems:
 - (a) There shall be provided a means for stepless adjustment of the size of the X-ray field, where the adjustment of each dimension of the field is independent of the other;
 - (b) A method shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam;
 - (c) Evidence of compliance with subsections (2)(a) and (b) of this rule shall be shown on each radiograph taken, either by imaging part of the collimator on the radiograph or by imaging collimator nubs or pointers;
 - (d) Beam-defining lights used for visually defining perimeters of the X-ray field shall have an illumination

great enough to be visualized by the operator under ambient light conditions;

(e) The Agency may grant an exemption on noncertified X-ray systems to subsection (2)(a) and (b) of this rule provided the registrant makes a written application for such exemption and in that application:

(A) Demonstrates it is impractical to comply with subsection (2)(a) and (b) of this rule; and

(B) The purpose of subsection (2)(a) and (b) of this rule will be met by other methods.

(3) Additional Requirements for Stationary General Purpose X-ray Systems. In addition to the requirements of section (2) of this rule, all stationary general purpose X-ray systems shall meet the following requirements:

(a) A method shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within two percent of the SID, and to indicate the SID to within two percent;

(b) The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

(c) Indication of field size dimensions and SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(4) X-ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of the image receptor to within two percent of the SID, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(5) Special Purpose X-ray Systems:

(a) Means shall be provided to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the X-ray beam is perpendicular to the plane of the image receptor;

(b) Means shall be provided to align the center of the X-ray field with the center of the image receptor to within two percent of the SID, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

Compliance shall be determined with the axis of the X-ray beam perpendicular to the plane of the image receptor;

(c) Subsection (5)(a) and (b) of this rule may be met with a system that meets the requirements for a general purpose X-ray system as specified in section (2) of this rule or, when alignment means are also provided, may be met with either:

(A) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(B) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

Stat. Auth.: ORS 453.605 - ORS 753.755

Stats. Implemented:

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

333-106-0305

Radiation Exposure Control Devices

(1) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. In addition:

(a) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero;

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

(2) X-Ray Exposure Control:

(a) An X-ray exposure control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time except for:

(A) Exposure of 1/2 second or less; or

(B) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

(b) Each X-ray exposure control shall be located in such a way as to meet the following requirements:

(A) Stationary X-ray systems shall be required to have the X-ray exposure control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and

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

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

(i) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of paragraph (2)(b)(A) of this rule;

(ii) Used for greater than one hour and less than one week at the same location, i.e., a room or suite, shall meet the requirement of subparagraph (2)(b)(C)(i) of this rule or be provided with a 6.5 foot (1.98 m) high protective barrier which is placed at least six feet (1.83 m) from the tube housing assembly and at least six feet (1.83 m) from the patient; or

(iii) Used to make an exposure(s) of a patient at the use location shall meet the requirement of subparagraph (2)(b)(C)(i) or (ii) of this rule or be provided with a method of X-ray control which will permit the operator to be at least 12 feet (3.66 m) from the tube housing assembly during an exposure.

(c) The X-ray control shall provide visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(3) Automatic Exposure Controls. When an automatic exposure control is provided:

(a) Indication shall be made on the control panel when this mode of operation is selected;

(b) If the X-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field

emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;

(c) The minimum exposure time for all equipment other than that specified in subsection (3)(b) of this rule shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver five mAs, whichever is greater;

(d) Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than 60 kW per exposure, or the product of X-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the X-ray tube potential is less than 50 kVp, the product of X-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(e) A visible signal shall indicate when an exposure has been terminated at the limits required by subsection (3)(d) of this rule, and manual resetting shall be required before further automatically timed exposures can be made.

(4) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (\bar{T}) shall be greater than or equal to five times the maximum exposure period (T_{\max}) minus the minimum exposure period (T_{\min}) when four timer tests are performed:

$$\bar{T} \geq 5(T_{\max} - T_{\min})$$

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0310

Source-to-Skin Distance

(1) All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters. This is considered to have been met when the collimator or cone provides the required limits.

(2) Any device provided to limit the SSD must be durable and securely fastened to the system.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0315

Exposure Reproducibility

The coefficient of variation of exposure shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (\bar{E}) is greater than or equal to five times the maximum exposure (E_{\max}) minus the minimum exposure (E_{\min}).

$$\bar{E} \geq 5(E_{\max} - E_{\min}).$$

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0320

Radiation from Capacitor Energy Storage Equipment in Standby Status

Radiation emitted from the X-ray tube when the exposure switch or timer is not activated shall not exceed a rate of two milliroentgens ($0.516 \mu\text{C}/\text{kg}$) per hour at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0325

Intraoral Dental Radiographic Systems

In addition to the provisions of OAR 333-106-0010 through 333-106-0101, the requirements of this rule apply to X-ray equipment and associated facilities used for intraoral dental radiography. Requirements for extraoral dental radiographic systems are covered in OAR 333-106-0301 through 333-106-0320 . **Only systems meeting the requirements of OAR 333-106-0325 shall be used.**

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

(a) 18 centimeters if operable above 50 kVp; or

(b) 10 centimeters if ~~[not operable above]~~ **operable at 50 kVp only .**

(2) ~~[Field]~~ **Beam** Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that **the beam at the minimum SSD shall be containable in a circle having a diameter of no more than seven (7) centimeters:**

~~[(a) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 7.0 centimeters; and~~

~~(b) If the minimum SSD is less than 18 centimeters, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 6 centimeters.]~~

(3) **Radiation Exposure Control (Timers).** Means shall be provided to **Control the radiation exposure by through the adjustment of** ~~[terminate the exposure at a preset]~~ **exposure time** ~~[interval]~~, ~~[preset product of current and time]~~ **number of pulses, and / or current / milliamps (mA),** ~~[a preset number of pulses]~~, or ~~[a preset radiation exposure to the image receptor]~~ **the product of current and exposure time (mAs).** In addition]:

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

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

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

(d) **Exposure termination.**

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

(B) An x-ray exposure control shall be incorporated into each system such that an exposure can be terminated by the operator at any time, except for exposures of 1/2 second or less.

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

~~[(b) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure time (T) shall be greater than or equal to five times the maximum exposure time (T_{max}) minus the minimum exposure time (T_{min}) when four timer tests are performed.]~~

$$T > 5(T_{max} - T_{min})$$

(4) ~~[X-ray Control]~~ **Radiation Exposure Control Location and Operator Protection.**

(a) ~~[An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time, except for exposures of 1/2 second or less ;]~~

(b) Each X-ray control shall be located in such a way as to meet the following requirements:

(A) The exposure switch shall be able to be operated in a protected area which shall be located behind a secondary protective barrier as defined in OAR 333-106-0005(66)(b) and the operator shall remain in that

protected area during the entire exposure; and

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

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

(i) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of paragraph (4)(b)(A) of this rule;

(ii) Used for ~~[greater than one hour and]~~ less than one week at the same location, i.e., a room or suite, shall ~~[meet the requirements of subparagraph (4)(b)(B)(i) of this rule or]~~ be provided with **either a protective barrier of at least six and one half (6.5) [foot] feet ~~[(1.98 m)] (2 meters) high for operator protection, or a means to allow the operator to be [protective barrier which is placed]~~ at least [six] **nine (9) feet ~~[(1.83 m)] (2.7 meters)~~ from the tube housing assembly [and at least six feet (1.83 m) from the patient] while making exposures. ~~f, or~~****

~~[(iii) Used to make an exposure(s) of a patient at the use location shall meet the requirement of subparagraph (4)(b)(B)(i) or (ii) of this rule or be provided with a method of X-ray control which will permit the operator to be at least 12 feet (3.66 m) from the tube housing assembly during an exposure.~~

~~(c) The X-ray control shall provide visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.]~~

(5) Exposure Reproducibility. **When the equipment is operated on an adequate power supply as specified by the manufacturer, ~~fF~~ the estimated coefficient of variation of radiation exposures shall [not exceed $\theta.1\theta$] be no greater than 0.05 [when all technique factors are held constant] for any specific combination of technique factors.** This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to five times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}):

$$E \geq 5(E_{max} - E_{min}).$$

(6) Accuracy. Deviation of technique factors from the indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed ten (10) percent of the indicated value for kVp and twenty (20) percent for exposure time.

(a) kVp Limitations. Dental x-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs on humans.

~~f(6)f~~ **(7) Administrative Controls:**

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

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

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

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

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

(f) Pointed cones shall not be utilized unless specific authorization has been granted by the Agency.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

Computed Tomography X-ray Systems

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) "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, that is:

where:

$$CTDI = \frac{1}{nT} \int_{-7T}^{+7T} D(z) dz$$

z = Position along a line perpendicular to the tomographic plane.

D(z) = Dose at position z.

T - Nominal tomographic section thickness.

n = 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.

(2) "Contrast Scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$CS = \frac{\mu_x - \mu_w}{(CTN)_x - (CTN)_w}$$

where:

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

$(CTN)_x$ = CTN of the material of interest.

$(CTN)_w$ = CTN of water.

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

(4) "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.

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

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

(7) "CTN" (see "CT number").

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

$$CTN = \frac{k (\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant.*

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

[*NOTE: The constant has a normal value of 1,000 when the Hounsfield scale of CTN is used.]

(9) "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".)

(11) "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.

(12) "Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the

attenuation coefficient of water. Its estimate (S_n) is calculated using the following expressions:

$$s_n = \frac{100 \times CS \times s}{\mu_w}$$

where:

CS = Contrast scale.

μ_w = Linear attenuation coefficient of water.

s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

(13) "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.

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

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

(16) "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.

(17) "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.

(18) "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.

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

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

(21) "Tomographic Plane" means that geometric plane which is identified as corresponding to the output tomogram.

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

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0355

Requirements for Equipment

(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;
- (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) 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).

(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 centimeters, 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.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0360

Facility Design Requirements

(1) Aural Communication. Provisions shall be made for two-way aural communication between the patient and the operator at the control panel.

(2) 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.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

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 Agency 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;

(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 plus or minus 0.01 grams per cubic centimeter or a reasonable substitute. The phantom(s) shall be at least 14 centimeters 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 centimeters 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 centimeter 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 centimeter 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 Agency.

(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 Agency.
- (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 - ORS 453.755

Stats. Implemented:

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

333-106-0370

Operator Requirements

CT X-ray systems shall be operated by individuals who are registered with A.R.R.T., who have received additional CT system training, and licensed by the state.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

Therapeutic X-ray Systems of Less Than One MeV

333-106-0401

Additional Requirement

Notwithstanding other provisions of this rule, the use of contact therapy X-ray machines shall be in accordance with OAR 333-106-0420 of these rules.

Stat. Auth.: ORS 453

Stats. Implemented:

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

333-106-0405

Equipment Requirements

- (1) Leakage Radiation. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified at the distance specified for the classification of that X-ray system:
- (a) Contact Therapy Systems. Leakage radiation shall not exceed 100 milliroentgens (25.8 $\mu\text{C}/\text{kg}$) per hour at five centimeters from the surface of the tube housing assembly;
 - (b) 0-150 kVp Systems. Systems which were manufactured or installed prior to the effective date of this rule shall have a leakage radiation which does not exceed one roentgen (0.258 mC/kg) in one hour at one meter from the source;
 - (c) 0-150 kVp Systems. Systems which are manufactured on or after the effective date of this rule shall have a leakage radiation which does not exceed 100 milliroentgens (25.8 $\mu\text{C}/\text{kg}$) in one hour at one meter from the source;
 - (d) 151 to 999 kVp Systems. The leakage radiation shall not exceed one roentgen (0.258 mC/kg) in one hour at one meter from the source except systems that operate in excess of 500 kVp may have a leakage radiation at one meter from the source not to exceed 0.1 percent of the useful beam one meter from the source.
- (2) Permanent Beam Limiting Devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or higher degree of protection as required for the tube housing assembly.
- (3) Removable and Adjustable Beam Limiting Devices:
- (a) Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than one percent of the useful beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient;
 - (b) Adjustable beam limiting devices installed after May 1, 1983, shall meet the requirements of subsection (a) of this section;
 - (c) Adjustable beam limiting devices installed before May 1, 1983, shall, for the portion of the X-ray beam to be blocked by these devices, transmit not more than five percent of the useful beam at the maximum kilovoltage and maximum treatment filter.
- (4) Filter System. The filter system shall be so designed that:
- (a) The filters cannot be accidentally displaced at any possible tube orientation;
 - (b) The radiation at five centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/kg) per hour under any operating conditions; and

- (c) Each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.
- (5) Tube Immobilization. The tube housing assembly shall be capable of being immobilized for stationary treatments.
- (6) Focal Spot Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.
- (7) Beam Block. Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.
- (8) Beam Monitor System. Systems of greater than 150 kVp manufactured after the effective date of this rule shall be provided with a beam monitor system which:
- (a) Shall have the detector of the monitor system interlocked to prevent incorrect positioning;
 - (b) Shall not allow irradiation until a preselected value of exposure has been made at the treatment control panel;
 - (c) Shall independently terminate irradiation when the preselected exposure has been reached;
 - (d) Shall be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;
 - (e) Shall have a display at the control panel from which the dose at a reference point in soft tissue can be calculated;
 - (f) Shall have a control panel display which maintains the administered dose reading until intentionally reset to zero; and
 - (g) Shall have a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.
- (9) Timer:
- (a) A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset timer selector and an elapsed time indicator;
 - (b) The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero;
 - (c) The timer shall terminate irradiation when a preselected time has elapsed if any dose monitoring system present has not previously terminated irradiation;
 - (d) The timer shall permit accurate presetting and determination of exposure times as short as one second;
 - (e) The timer shall not permit an exposure if set at zero;
 - (f) The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism.
- (10) Control Panel Functions. The control panel, in addition to the displays required in other provisions of this rule, shall have:
- (a) An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible;
 - (b) An indication of whether X-rays are being produced;
 - (c) Means for indicating X-ray tube potential and current;

- (d) Means for terminating an exposure at any time;
 - (e) A locking device which will prevent unauthorized use of the X-ray system; and
 - (f) For X-ray systems manufactured after the effective date of this rule, a positive display of specific filter(s) in the beam.
- (11) Multiple Tubes. When a control panel may energize more than one X-ray tube:
- (a) It shall be possible to activate only one X-ray tube at any time;
 - (b) There shall be an indication at the control panel identifying which X-ray tube is energized;
 - (c) There shall be an indication at the tube housing assembly when that tube is energized.
- (12) Source-to-Skin Distance. There shall be means of determining the SSD to within one centimeter.
- (13) Shutters. Unless it is possible to bring the X-ray output to the prescribed exposure parameters within five seconds, the beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition:
- (a) After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel; and
 - (b) An indication of shutter position shall appear at the control panel.
- (14) Low-Filtration X-ray Tubes. Each X-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0410

Facility Design Requirements for X-ray Systems Capable of Operating Above 50 kVp

- (1) Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.
- (2) Viewing Systems:
 - (a) Windows, mirrors, closed-circuit television, or an equivalent system 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) Additional requirements for X-ray systems capable of operation above 150 kVp:
 - (a) All protective barriers shall be fixed except for entrance doors or beam interceptors;
 - (b) The control panel shall be located outside the treatment room;
 - (c) Entrance Interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and re-initiating irradiation by manual action at the control panel;

(d) When any door referred to in subsection (3)(c) of this rule is opened while the X-ray tube is activated, the exposure at a distance of one meter from the source shall be reduced to less than 100 milliroentgens (25.8 $\mu\text{C}/\text{kg}$) per hour.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0415

Surveys, Calibrations, Spot Checks, and Operating Procedures

(1) Surveys:

(a) All new facilities, and existing facilities 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 transmitted by the registrant to the Agency within 30 days of the receipt of the report;

(c) The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable rules.

(2) Calibrations:

(a) The calibration of an X-ray system shall be performed at intervals not to exceed one year and after any change or replacement of components which could cause a change in the radiation output;

(b) The calibration of the radiation output of the 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;

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

(d) The calibrations shall be such that the dose at a reference point in soft tissue can be calculated to within an uncertainty of five percent;

(e) The calibration of the X-ray system shall include, but not be limited to, the following determinations:

(A) Verification that the X-ray system is operating in compliance with the design specifications;

(B) The exposure rates as a function of field size, technique factors, filter, and treatment distance used;

(C) The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present; and

(D) An evaluation of the uniformity of the largest radiation field used.

(f) Records of calibration shall be maintained by the registrant for five years after completion of the calibration;

(g) A copy of the most recent X-ray system calibration shall be available at or in the area of the control panel.

(3) Spot Checks. Spot checks shall be performed on X-ray systems capable of operation at greater than 150 kVp. Such spot checks shall meet the following requirements:

(a) The spot-check procedures shall be in writing and shall have been developed by a qualified expert. A copy

- of the procedures shall be submitted to the Agency prior to its implementation;
- (b) If a qualified expert does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a qualified expert within 15 days;
 - (c) The spot-check procedures shall specify the frequency at which tests or measurements are to be performed. The spot-check procedures shall specify that the spot check shall be performed during the calibration specified in section (2) of this rule. The acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in section (2) of this rule shall be stated;
 - (d) The cause for a parameter exceeding a tolerance set by the qualified expert shall be investigated and corrected before the system is used for patient irradiation;
 - (e) Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the qualified expert's spot-check procedures, the system shall be recalibrated as required in section (2) of this rule:
 - (A) Records of spot-check measurements shall be maintained by the registrant for two years after completion of the spot-check measurements and any necessary corrective actions;
 - (B) Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of section (2) of this rule or which has been intercompared with a system meeting those requirements within the previous year.
- (4) Operating Procedures:
- (a) X-ray systems shall not be left unattended unless the system is secured against unauthorized use;
 - (b) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;
 - (c) The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed 50 kVp. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 mm lead equivalency at 100 kVp;
 - (d) No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of Division 120 of these rules. No individual other than the patient shall be in the treatment room during exposures from X-ray systems operating above 150 kVp;
 - (e) The X-ray system shall not be used in the administration of radiation therapy unless the requirements of sections (2) and (3)(e) of this rule have been met.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0420

Requirements for Contact Grenz Ray Therapy X-ray Installations

(1) Leakage Radiation. When the tube of a contact Grenz ray therapy system is operated at its leakage technique factors, the leakage radiation in any direction shall not exceed 100 mR/hr at five centimeters from the tube housing.

(2) Timer. A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset timer selector and an elapsed time indicator. It shall be necessary to zero the elapsed time indicator and the preset time selector after irradiation is terminated.

(3) Control Panel. The control panel shall have:

- (a) An indication of whether electrical power is present and activation of the X-ray tube is possible;
- (b) An indication of whether X-rays are being produced;
- (c) The means for indicating kVp and X-ray tube current;
- (d) The means for terminating an exposure at any time;
- (e) A locking device which will prevent unauthorized use of the X-ray system, or the room in which X-ray machine is used or stored shall be secured against unauthorized entry.

(4) Control Panel with Multiple Tubes. When a control panel may energize more than one X-ray tube:

- (a) It shall be possible to activate only one X-ray tube during any one time interval;
- (b) There shall be an indication at the control panel identifying which X-ray tube can be energized;
- (c) There shall be an indication at the X-ray tube if that tube head can be energized.

(5) Target-to-Patient Distance. There shall be means for determining the target-to-patient distance to within one centimeter.

(6) Facility Design Requirements. In addition to shielding adequate to meet requirements of Division 120 of these rules, the following treatment room design requirements shall be met: Treatment rooms shall be provided with warning lights, in a readily observable position near the outside of all access doors (preferably at eye level), which will indicate when the useful beam is "on" or when the room is in use for Grenz ray therapy purposes.

(7) Operating Procedures, Surveys and Calibration:

(a) All new facilities and existing facilities not previously surveyed shall have a radiation protection survey made by a qualified expert. This shall also be done after any change in the facility which might produce a radiation hazard. The expert shall report the findings in writing to the person in charge of the facility, and a copy of this report shall be transmitted by the registrant to the Agency;

(b) The radiation output of each therapeutic X-ray machine shall be calibrated by a qualified expert. The calibration shall be repeated after any change in, or replacement of, components of the X-ray generating equipment which could cause a change in X-ray output. Calibration of the therapy beam shall be performed with a measurement instrument, the calibration of which is directly traceable to national standards of exposure or absorbed dose, and which shall have been calibrated within the preceding year. Records of such calibrations shall be provided to and maintained by the registrant. In addition:

(A) Each therapeutic X-ray machine shall have the calibrations repeated at time intervals not exceeding one year. The calibration shall include at least the following determinations:

- (i) The accurate determination of the air dose rate for a sufficient number of operating parameters for each normally used effective energy to permit the determination of the dose received by the patient;
- (ii) Verification that the equipment is operating in accordance with the design specifications;
- (iii) The effective energy (e.g., half-value layer when appropriate) for every combination of kVp and mA used for radiation therapy; and
- (iv) The calibration determinations above shall be provided in sufficient detail such that the absorbed dose in rads to tissue adjacent to, as well as in the useful beam, may be calculated to within plus or minus five percent of the intended absorbed dose.

(B) In the therapeutic application of X-ray equipment constructed with beryllium or other low-filtration windows, the registrant shall assure that the unfiltered radiation reaches only the part intended and that the useful beam port is blocked at all times except when actually being used;

(C) Therapeutic X-ray machines shall not be left unattended unless the security measures required by subsection (3)(e) of this rule are met to prevent activation of the useful beam;

(D) Except as provided in OAR 333-106-0025, no individual other than the patient shall be in the treatment room during exposures unless the individual is protected by a barrier sufficient to meet the requirements of Division 120, and no individual other than the patient and operator shall be in the treatment room during exposures except in emergency situations;

(E) The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding, and the peak tube potential of the system does not exceed 50 kVp. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 mm lead equivalency at 100 kVp.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0480

X-ray and Electron Therapy Systems with Energies of One MeV and Above

Division 109 except OAR 333-109-0040(3) and (4) shall apply to medical facilities using therapy systems with energies one MeV and above.

NOTE: In addition all items in Division 106 starting with OAR 333-106-0480 and ending with 333-106-0580 shall meet the requirements of any item referenced as OAR 333-106-0480.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0485

Definitions

In addition to the definitions provided in OAR 333-106-0005, the following definitions shall be applicable to OAR 333-106-0480:

- (1) "Applicator" means a structure which determines the extent of the treatment field at a given distance from the virtual source.
- (2) "Beam Scattering Filter" means a filter used in order to scatter a beam of electrons.
- (3) "Central Axis of the Beam" means a line passing through the virtual source and the center of the plane

figure formed by the edge of the first beam limiting device.

(4) "Dose Monitoring System" means a system of devices for the detection, measurement, and display of quantities of radiation.

(5) "Dose Monitoring System" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

(6) "Existing Equipment" means therapy systems subject to OAR 333-106-0480 which were manufactured on or before January 1, 1985.

(7) "Field-Flattening Filter" means a filter used to provide dose uniformity over the area of a useful beam of X-rays at a specified depth.

(8) "Field Size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

(9) "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.

(10) "Interruption of Irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

(11) "Isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the beams passes in all conditions.

(12) "Moving Beam Therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation. It includes arc therapy, skip therapy, and rotational therapy.

(13) "New Equipment" means systems subject to OAR 333-106-0480 which were manufactured after January 1, 1985.

(14) "Normal Treatment Distance" means:

(a) For electron irradiation, the virtual source to surface distance along the central axis of the useful beam as specified by the manufacturer for the applicator;

(b) For X-ray irradiation, the virtual source to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

(15) "Radiation Head" means the structure from which the useful beam emerges.

(16) "Shadow Tray" means a device attached to the radiation head to support auxiliary beam limiting material.

(17) "Stationary Beam Therapy" means radiation therapy without relative displacement of the useful beam and the patient during irradiation.

(18) "Target" means that part of a radiation head which by design intercepts a beam of accelerated particles with subsequent emission of other radiation.

(19) "Virtual Source" means a point from which radiation appears to originate.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0490

Requirements for Equipment

(1) Leakage Radiation to the Patient Area. New equipment shall meet the following requirements:

(a) For operating conditions producing maximum leakage radiation, the absorbed dose in rad (gray) due to leakage radiation, including X-rays, electrons, and neutrons, at any point in a circular plane of two meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size shall not exceed 0.1 percent of the maximum absorbed dose in rad (gray) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be average over an area up to but not exceeding 200 square centimeters;

(b) For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in subsection (1)(a) of this rule for the specified operating conditions. Records on leakage radiation measurements shall be maintained for inspection by the Agency.

(2) Existing equipment shall meet the following requirements:

(a) For operating conditions producing maximum leakage radiation, the absorbed dose in rad (gray) due to leakage radiation excluding neutrons at any point on a circle of two meters radius. The center of the circle shall be one meter from the virtual source, and the plane defined by the circle shall be perpendicular to the central ray of the radiation beam, and shall not exceed 0.1 percent of the maximum absorbed dose in rad (gray) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and surface of the circular plane. Measurements shall be average over an area up to but not exceeding 100 square centimeters at the positions specified;

(b) For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in subsection (2)(a) of this rule for the specified operating conditions. Records on radiation leakage shall be maintained for inspection by the Agency.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0501

Leakage Radiation Outside the Patient Area for New Equipment

(1) The absorbed dose in rad (gray) due to leakage radiation except in the area specified in OAR 333-106-0490(1)(a) when measured at any point one meter from the path of the charge particle, before the charge particle strikes the target or window, shall not exceed 0.1 percent for X-ray leakage nor 0.05 percent for neutron leakage of the maximum absorbed dose in rad (gray) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in OAR 333-106-0490(1)(a).

(2) The registrant shall determine or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in section (1) of this rule, for specified operating conditions. Radiation measurements

excluding neutrons shall be averaged over an area up to but not exceeding 100 square centimeters. Neutron measurements shall be averaged over an area up to but not exceeding 200 square centimeters.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0505

Beam Limiting Devices

Adjustable or interchangeable beam limiting devices shall be provided, and such devices shall transmit no more than two percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement. The beam limiting devices referred to here do not include the partial transmission-blocking devices.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0510

Filters

- (1) Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.
- (2) If the absorbed dose rate data required by OAR 333-106-0547 relates exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools.
- (3) For new equipment which utilizes a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:
 - (a) Irradiation shall not be possible until a selection of filter has been made at the treatment control panel;
 - (b) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
 - (c) A display shall be provided at the treatment control panel showing the filter(s) in use; and
 - (d) An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0512

Beam Quality

The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:

- (1) The absorbed dose resulting from X-rays in a useful electron beam at a point on the central axis of the beam ten centimeters greater than the practical range of the electrons shall not exceed the values stated in Table 5. Linear interpolation shall be used for values not stated.
- (2) Compliance with section (1) of this rule shall be determined using:
 - (a) A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;
 - (b) The largest field size available which does not exceed 15 by 15 centimeters; and

Table 5

| Maximum Energy of Electron Beam in MeV | X-ray Absorbed Dose as a fraction of Maximum Absorbed Dose |
|--|--|
| 1 | 0.03 |
| 15 | 0.05 |
| 35 | 0.10 |
| 50 | 0.20 |

- (c) A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least five centimeters and whose depth is sufficient to perform the required measurement.
- (3) The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during X-ray irradiation, shall not exceed the limits stated in Table 6. Linear interpolation shall be used for values not stated.
- (4) Compliance with section (3) of this rule shall be determined by measurements made:
 - (a) Within a phantom using an instrument which will allow extrapolation to the surface absorbed dose;
 - (b) Using a phantom whose size and placement meet the requirements of section (2) of this rule;
 - (c) After removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam flattening filters; and
 - (d) Using the largest field size available which does not exceed 15 by 15 centimeters.
- (5) The registrant shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose in the useful beam due to neutrons, excluding stray neutron radiation, for specified operating conditions.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0515

Beam Monitors

All therapy systems shall be provided with radiation detectors in the radiation head.

- (1) New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose monitoring systems.
- (2) Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.
- (3) The detector and the system into which that detector is incorporated shall meet the following requirements:
 - (a) Each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning;
 - (b) Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated;
 - (c) Each dose monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation;

Table 6

| Maximum Photon Energy Surface in MeV | Absorbed Dose at the as a fraction of the Maximum Absorbed Dose |
|--------------------------------------|--|
| 1 | 0.80 |
| 2 | 0.70 |
| 5 | 0.60 |
| 15 | 0.50 |

| | |
|----|------|
| 35 | 0.40 |
| 50 | 0.20 |

(d) For new equipment, the design of the dose monitoring systems shall assure that:

- (A) The malfunctioning of one system shall not affect the correct functioning of the second system; and
- (B) The failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.

(e) Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall:

- (A) Maintain a reading until intentionally reset to zero;
- (B) Have only one scale and no scale multiplying factors;
- (C) Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined; and
- (D) In the event of power failure, the dose monitoring information required in subsection (3)(e) of this rule displayed at the control panel at the time of the failure shall be retrievable in at least one system for a 20-minute period of time.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0517

Beam Symmetry

In new equipment inherently capable of producing useful beams with asymmetry exceeding five percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds five percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds 10 percent, the irradiation is terminated.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0520

Selection and Display of Dose Monitors Units

(1) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the

treatment control panel.

(2) The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.

(3) After termination of irradiation, it shall be necessary to reset the dosimeter display to zero before subsequent treatment can be initiated.

(4) For new equipment after termination of irradiation, it shall be necessary to manually reset the preselect dose monitor units before irradiation can be initiated.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0525

Termination of Irradiation by the Dose Monitoring System or Systems During Stationary Beam Therapy

(1) Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.

(2) If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.

(3) For new equipment, a second dose monitoring system shall be present. That system shall be capable of terminating irradiation when not more than ten percent of 25 dose monitoring units above the preselected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.

(4) For new equipment, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0526

Interruption Switches

It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any re-selection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0527

Termination Switches

It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0530

Timer

(1) A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator.

(2) The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be re-initiated, it shall be necessary to reset the elapsed time indicator to zero.

(3) For new equipment after termination of irradiation and before irradiation can be re-initiated, it shall be necessary to manually reset the preset time selector.

(4) The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0535

Selection of Radiation Type

Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:

(1) Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.

(2) An interlock system shall be provided to insure that the equipment can emit only the radiation type which has been selected.

- (3) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
- (4) An interlock system shall be provided to prevent irradiation with X-rays except to obtain a port film when electron applicators are fitted.
- (5) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted.
- (6) The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0540

Selection of Energy

Equipment capable of generating radiation beams of different energies shall meet the following requirements:

- (1) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.
- (2) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
- (3) The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.
- (4) For new equipment, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the X-ray target or electron window deviates by more than 20 percent or three MeV, whichever is smaller, from the selected nominal energy.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0545

Selection of Stationary Beam Therapy or Moving Beam Therapy

Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:

- (1) Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.
- (2) An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected.
- (3) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

- (4) The mode of operation shall be displayed at the treatment control panel.
- (5) For new equipment, an interlock system shall be provided to terminate irradiation if:
- (a) Movement of the gantry occurs during stationary beam therapy; or
 - (b) Movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function.
- (6) Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement:
- (a) For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than 20 percent from the selected value;
 - (b) For new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than five percent from the value calculated from the absorbed dose per unit angle relationship.
- (7) Where the dose monitor system terminate the irradiation in arc therapy, the termination of irradiation shall be as required by OAR 333-106-0525.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0547

Absorbed Dose Rate

For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. In addition:

[NOTE: The radiation detectors specified in OAR 333-106-0515 may form part of this system.]

- (1) The dose monitor unit rate shall be displayed at the treatment control panel.
- (2) If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameters utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated shall be in a record maintained by the registrant.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0550

Location of Focal Spot and Beam Orientation

The registrant shall determine or obtain from the manufacturer the location with reference to an accessible point on the radiation head of:

- (1) The X-ray target or the virtual source of X-rays; and
- (2) The electron window or the virtual source of electrons if the system has electron beam capabilities.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0555

System Checking Facilities

Capabilities should be provided so that all radiation safety interlocks can be checked for correct operation. When preselection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operation in both locations have been completed.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0560

Facility and Shielding Requirements

In addition to Division 120 of these rules the following design requirements shall apply:

- (1) Protective Barriers. All protective barriers shall be fixed except for entrance doors or beam interceptors.
- (2) Control Panel. The control panel shall be located outside the treatment room.
- (3) Viewing Systems:
 - (a) Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may 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.
- (4) Aural Communications. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements makes aural communication impractical, other methods of communication shall be used.
- (5) Room Entrances. Treatment rooms entrances shall be provided with warning lights in readily observable position near the outside of all access doors to indicate when the useful beam is "on".
- (6) Entrance Interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be

possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

Surveys, Calibrations, Spot Checks, and Operating Procedures

333-106-0565

Surveys

- (1) All new facilities, and existing facilities 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.
- (2) The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be transmitted by the registrant to the Agency within 30 days of receipt of the report.
- (3) The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable rules.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0570

Calibrations

- (1) The calibration of each therapeutic X-ray machine shall be performed in accordance with an established calibration protocol acceptable to the Agency before the system is first used for irradiation of a patient and thereafter at time intervals which do not exceed 12 months and after change which might significantly alter the

calibration, spatial distribution, or other characteristics of the therapy beam.

NOTE: The calibration protocol published by the American Association of Physicists in Medicine is accepted as an established protocol. For other protocols, the user shall submit that protocol to the Agency for concurrence that the protocol is acceptable.

(2) The calibration shall be performed under the direct supervision of a radiological physicist who is physically present at the facility during the calibration.

(3) Calibration radiation measurements required by section (1) of this rule shall be performed using a dosimetry system:

(a) Having a calibration factor for cobalt-60 gamma rays traceable to a national standard;

(b) Which has been calibrated within the previous two years and after any servicing that may have affected its calibration;

(c) Which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and

(d) Which has had constancy checks performed on the system as specified by a radiological physicist.

(4) Calibrations shall be in sufficient detail that the dose at a reference point in soft tissue may be calculated to within an uncertainty of five percent.

(5) The calibration of the therapy beam shall include but not be limited to the following determinations:

(a) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, side light, and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry, and jaw system, and beam flatness and symmetry at the specified depth;

(b) The absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilizes with that therapy beam;

(c) The uniformity of the radiation field and any dependency upon the direction of the useful beam;

(d) Verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions;

(e) Verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators.

(6) Records of calibration measurements under section (1) of this rule and dosimetry system calibrations under section (3) of this rule shall be maintained for five years after completion of the full calibration.

(7) A copy of the latest calibration performed pursuant to section (1) of this rule shall be available in the area of the control panel.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0575

Spot Checks

Spot checks shall be performed on systems subject to OAR 333-106-0480 during calibrations and thereafter at intervals not to exceed one month. Such spot checks shall meet the following requirements:

- (1) The spot-check procedures shall be in writing and shall have been developed by a radiological physicist. A copy of the procedure shall be submitted to the Agency prior to its implementation.
- (2) If a radiological physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a radiological physicist within 15 days.
- (3) The spot-check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.
- (4) At intervals not to exceed one week, spot checks shall be made [~~of absorbed dose measurements at a minimum of 2 depths in a phantom~~] **to ensure that the energy remains within ± 3 percent.**
- (5) Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot-check measurement.
- (6) The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.
- (7) Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist's spot-check procedures, the system shall be recalibrated as required in OAR 333-106-0570(1).
- (8) Records of spot-check measurements shall be maintained by the registrant for a period of 2 years after completion of the spot-check measurements and any necessary corrective actions.
- (9) Where a spot check involves a radiation measurement, such measurements shall be obtained using a system satisfying the requirements of OAR 333-106-0570(3) or which has been intercompared with a system meeting those requirements within the previous year.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0580

Qualified Expert

- (1) For the purpose of meeting the requirements set forth in OAR 333-106-0480 through 333-106-0585 the registrant shall determine if a person is an expert qualified by training and experience to calibrate an X-ray and electron therapy equipment (one MeV and above) and establish procedures for (and review the results of) spot-check measurements. The registrant shall determine that the qualified expert:
 - (a) Is certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, Roentgen ray and physics, or X-ray and radium physics; or
 - (b) Has the following minimum training and experience:
 - (A) A Master's or Doctor's degree in physics, biophysics, radiological physics or health physics;
 - (B) On year of full-time training in therapeutic radiological physics; and
 - (C) One year of full-time experience in a radiation therapy facility including personal calibration and spot-check of at least one X-ray and electron therapy equipment (one MeV and above).

(2) Registrants that have their therapy units calibrated by persons who do not meet these criteria for minimum training and experience may request (from the Agency) an exemption from the requirements of subsection (1)(b) of this rule. The request must include the name of the proposed qualified expert, a description of the individual's training and experience, information similar to that specified in subsection (1)(b) of this rule, reports of at least one calibration and spot-check program based on measurements personally made by the proposed expert within the last ten years and written endorsement of the technical qualifications of the proposed expert from personal knowledge by a physicist certified by the American Board of Radiology in one of the specialties listed in subsection (1)(a) of this rule.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

333-106-0585

Operating Procedures

(1) No individual other than the patient shall be in the treatment room during treatment of a patient.

(2) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

(3) The system shall not be used in the administration of radiation therapy unless the requirements of OAR 333-106-0565, 333-106-0570 and 333-106-0575 have been met.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

Veterinary Medicine Radiographic Installations

333-106-0601

Additional Requirements

(1) Equipment:

(a) The protective tube housing shall be of the diagnostic type;

(b) Collimating devices shall be provided and used for collimating the useful beam to the area of clinical interest;

(c) All X-ray equipment sold (etc.) after October 1991 must be equipped with a variable adjustable collimator and beam-defining light that meets all of the requirements of OAR 333-106-0301(1), (2) and (3);

(d) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum

equivalent for machines operating up to 50 KVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp;

(e) A device shall be provided to terminate the exposure after a preset time or exposure;

(f) A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least 12 feet (3.66 m) from the animal during all X-ray exposures.

(2) Structural Shielding: All wall, ceiling and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with Division 120.

(3) Operating Procedures:

(a) The operator shall stand well away from the useful beam and the animal during radiographic exposures;

(b) No individual other than the operator shall be in the X-ray room while exposures are being made unless such individual's assistance is required;

(c) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and that individual shall be so positioned that no part of the body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored with appropriate personnel monitoring devices.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

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

Mammography X-Ray Systems

333-106-0700

The rules set forth in this part are in addition to, and supplement the most current version of the Mammography Quality Standards Act (MQSA) 3.21 Code of Federal Regulations (CFR) Part 900. Registrants will be surveyed by a state surveyor representing the Food and Drug Administration, to determine if the requirements of MQSA are met. The same surveyor will also determine if the requirements of the Oregon Rules for the Control of Radiation are met. The surveyor will leave two survey reports, one indicating the findings of the federal survey and one indicating the findings of the state survey.

As indicated above, the registrant will be presented with two separate survey reports. The registrant is required to deal with each report individually and required to respond to each report separately. The two reports may deal with the same issue(s) or separate issues. Violations may be noted on one report and not the other. The surveyor will give detailed instructions at the time of the survey on how to respond to each report.

333-106-07[00]10

Definitions

In addition to the definitions provided in Division 100 and 106 of these rules, the following definitions shall be applicable to ~~[this rule]~~ **the rules in this section** .

~~[(1) Mammographic screening means the use of radiation to test women for the detection of diseases of the breast when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such tests for the purposes of diagnosis. Screening is considered as self-referral by asymptomatic women without physicians orders (see OAR 333-100-020(5)(6) and 333-106-036(3))]~~

~~[(2) Mammography means radiography of the breast.]~~

~~[(3) Phantom means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer. (The ACR-recommended phantom meets this requirements.)]~~

(1) Air Kerma means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a given mass of air. The unit used to measure the quantity of kerma is the Gray (Gy). For x-rays with energies below 300 kiloelectronvolts (keV), 1Gy=100 rad and is equivalent to 114 Roentgens (R) of exposure.

(2) FDA means the Food and Drug Administration.

(3) An Image receptor support surface means that portion of the image receptor support which is the x-ray input surface and is used to support the patient's breast during mammography.

(4) Interpreting physician means a licensed physician who interprets mammographic images and meets the qualifications of OAR 333-106-0750(2)

(5) Lead Interpreting Physician means a physician who interprets mammographic images, meets the qualifications of OAR 333-106-0750(2), and who has the general responsibility for ensuring that the registrant's quality assurance program meets all applicable rules and regulations.

(6) Mammographic screening means the use of radiation to test women for the detection of diseases of the breast when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such tests for the purposes of diagnosis. Screening is considered as self-referral by asymptomatic women without physicians orders

(see OAR 333-100-0020(5)(6) and 333-106-003 ~~f6~~ 5(3))

(7) Mammography means radiography of the breast.

(8) Mammography equipment evaluation means an onsite assessment of a mammography unit/s or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable state and federal standards.

(9) Mammography unit/s means an assemblage of components for the production of X-rays for use during mammography, including, at a minimum; An X-ray generator, an X-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.

(10) Medical Physicist means a person trained in evaluating the performance of mammography equipment and quality assurance programs and meets the qualifications of OAR 333-106-0750(3).

(11) MQSA means the Mammography Quality Standards Act of 1992.

(12) Phantom means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer. (The "FDA accepted phantom" meets this requirement.)

(13) Quality Assurance is a comprehensive concept that comprises all of the management practices instituted by the registrant or the registrant's representative/s to ensure that:

- (a). every imaging procedure is necessary and appropriate to the clinical problem at hand;**
- (b). the images generated contain information critical to the solution of that problem;**
- (c). the recorded information is correctly interpreted and made available in a timely fashion to the patient's physician;**
- (d). the examination results in the lowest possible radiation exposure, cost, and inconvenience to the patient, consistent with objective (b) noted above.**

(14) Quality Assurance Program includes such facets as efficacy studies, continuing education, quality control, preventive maintenance, and calibration of equipment.

(15) Quality Control means a series of distinct technical procedures that ensure the production of a satisfactory product, e.g., a high quality screening or diagnostic image.

(16) Quality Control Technologist means an individual who is qualified under MQSA, and who is responsible for those quality assurance responsibilities not assigned to the Lead Interpreting Physician or to the Medical Physicist.

(17) Resting period means the period of time necessary to bleed out air that has been trapped between the radiographic film and intensifying screen during the loading process in the darkroom. This period of time is usually measured in minutes and determined by the individual manufacturer of the intensifying screen/mammography cassette combination.

(18) Standard Breast means a 4.2 centimeter(cm) thick compressed breast, consisting of 50 percent adipose, and 50 percent glandular tissue.

(19) Survey means an onsite physics consultation and evaluation of a registrant's mammography equipment, and quality assurance program performed by a medical physicist.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

Hist.: HD 15-1994, f. & cert. ef. 5-6-94

333-106-07{10}20

Equipment Standards

Only x-ray systems meeting the [~~following standards~~] **design and performance standards required under MQSA shall be used, unless otherwise specified in the following rules.**

(1) System design. The x-ray system shall be specifically designed for mammography.

(2) Image receptor.

~~(a)[The] fi~~ Image receptor systems [~~and their individual components~~] shall be specifically designed [~~for~~], or appropriate for mammography.

(b) Systems using screen-film image receptors shall provide, at a minimum, image receptor sizes of 18X24, and 24X30 centimeters (cm).

(c) An adequate number of image receptors shall be provided to accommodate the resting period recommended by the manufacturer.

(3) Target/filter. The x-ray system shall have the capability of providing kVp/target/filter combinations

compatible with image receptor systems meeting the **following** requirements ; *[of section (2) of this rule.]*

(a) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(b) When more than one target is provided, the system shall indicate, prior to exposure, the preselected target material.

(c) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after exposure, the target material and/or focal spot actually used during the exposure.

(4) Beam quality:~~{(a)}~~ When used with screen-film image receptors, and the contribution to filtration made by the compression device is included, the useful beam shall have a **minimum** half-value layer (HVL) ₂ *[between the values of: measured kVp/100 and measured kVp/100 +0.1 millimeters aluminum]*. **The minimum HVL, for mammography equipment designed to operate below 50 kVp, is determined by dividing the actual kVp by 100, and is expressed in millimeters (mm) of aluminum equivalent.**

~~{(b) For Xeroradiography, the HVL of the useful beam with the compression device in place shall be at least 1.0 and not greater than 1.6 mm aluminum, measured at 49 kVp with a tungsten target tube.]~~

(5) Resolution. ~~[The combination of focal spot size, source-to-image receptor distance and magnification shall result in a resolution of at least 12 line pairs per millimeter (cycles/mm) measured at the image plane with a bar resolution pattern positioned 4.5 cm above the breast support and when the bar resolution pattern is either perpendicular to or parallel with the chest wall. The kVp shall be in the range of 26-30 and the mA shall be the highest available for a one second duration.]~~ Until October 28, 2002, focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. After October 28, 2002, facilities shall evaluate focal spot condition only by determining system resolution.

(a) Each X-ray system used for mammography, in combination with the mammography screen-film combination used, shall provide a minimum resolution of 11 Cycles/millimeters (mm)(line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis .

(b) The bar pattern shall be placed 4.5 centimeters (cm) above the image receptor support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 centimeter (cm) of the chest wall edge of the image receptor.

(6) Compression.

(a) ~~[The x-ray system shall be capable of compressing the breast with a force of at least 25 pounds and shall be capable of maintaining this compression for at least 15 seconds. The maximum force shall be no greater than 40 pounds.]~~ All mammography systems shall incorporate a compression device capable of compressing the breast with a force of at least 25 pounds.

(b)~~[The chest wall edge of the compression paddle shall be aligned with the chest wall edge of the image receptor to within " (1) one percent of the Source-to-Image Receptor Distance with the compression paddle placed 4.5 cm above the breast support device.]~~ Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 25 pounds and 45 pounds.

(c)All mammography systems shall be equipped with different sized compression paddles that match the sizes of all full field image receptors provided for the system. The compression paddle shall:

(A) Be flat and parallel to the image receptor support and shall not deflect from parallel by more than 1.0 centimeter (cm) at any point on the surface of the compression paddle when compression is applied.

If the compression paddle is not designed to be flat and parallel to the image receptor support during compression, it shall meet the manufacturer's design specifications and maintenance requirements;

(B) Have a chest wall edge that is straight and parallel to the edge of the image receptor support;

(C) Clearly indicate the size and available positions of the detector at the x-ray input surface of the compression paddle;

(D) Not extend beyond the chest wall edge of the image receptor support by more than one (1) percent of the SID when tested with the compression paddle placed above the support surface at a distance equivalent to a standard breast thickness;

(E) Shall not be visible, at its vertical edge, on the image.

(c) When equipped with a compression paddle height digital display, the display shall accurately represent the actual height of the compression paddle to within + or - 0.5 centimeter (cm). Testing shall be performed according to manufacturer's specifications.

(7) System capabilities. A mammographic x-ray system utilizing screen-film image receptors shall ~~have~~:

(a) ~~[the capability of using anti-scatter grids that are:]~~

~~[(A) integral to the x-ray system, and]~~

~~[(B) available for all image receptor sizes.]~~ Be equipped with moving grids matched to all image receptor sizes provided.

(b) ~~[the capability of automatic exposure control, for systems installed after the effective date of these regulations.]~~ Provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, non-grid, magnification; and various target-filter combinations.

~~[(c) the capability of registering post-exposure mAs after an exposure made using an automatic exposure control device, for systems installed after the effective date of these regulations.]~~

(A) The automatic exposure control shall be capable of maintaining film optical density (OD) within + or - 0.30 of the mean optical density when thicknesses of a homogeneous material are varied over a range of 2 to 6 centimeters (cm) and the kVp is varied appropriately for such thicknesses over the kVp range used clinically. If this requirement can not be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different thicknesses and compositions that must be used so that optical densities within + or - 0.30 of the average under photo-timed conditions can be produced ;

(B) After October 28, 2002, the AEC shall be capable of maintaining film optical density (OD) to within + or - 0.15 of the mean optical density when thicknesses of a homogeneous material are varied over a range of 2 to 6 centimeters (cm) and the kVp is varied appropriately for such thicknesses over the kVp range used clinically.

(8) ~~[Milliamperes-Second Read-Out Accuracy. For those mammographic x-ray systems equipped with automatic exposure control and post-exposure mAs read-out, the accuracy of such mAs read-out shall be within " 10 percent of the actual mAs delivered.]~~ Breast entrance kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

~~[(10)]~~ (9) Collimation.

(a) ~~[The mammographic system shall be provided with means to limit the useful beam such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than two (2) percent of the SID.]~~ All mammography

systems shall have beam limiting devices that allow the entire chest wall edge of the X-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the X-ray field does not extend beyond any edge of the image receptor by more than two (2) percent of the SID. Under no circumstances, shall the X-ray field extend beyond the non-chest wall edges of the image receptor support.

(b) The total misalignment of the edges of the visually defined light field with the respective edges of the X-ray field either along the length or width of the visually defined field shall not exceed two (2) percent of the SID.

~~[(H)] (10) [Accuracy of kVp. Deviation of actual kVp from the indicated kVp shall not exceed the limits specified by the manufacturer of the x-ray system, or, where such limits are not specified, the actual kVp shall be within +2 kVp of the indicated kVp]~~ Kilovoltage peak (kVp) accuracy and reproducibility;

(a) The kVp, shall be accurate within + or - five (5) percent of the indicated or selected kVp at the lowest clinical kVp that can be measured by a kVp test device, and the most commonly used, and highest available clinical kVp, and;

(b) At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

~~[(I2)Automatic Exposure Control Performance. In addition to 333-106-315, mammographic systems in the Automatic Exposure Control (AEC) mode shall be able to maintain constant film density to within an optical density of "0.3 of the average optical density over the range of clinically used kVp=s, using BR-12 or other breast equivalent material phantom thicknesses of 2 to 6 centimeters.]~~

~~[(I3)Radiation Output Minimum. At 28 kVp, with a focal spot meeting the requirements of section (5) of this rule, the mammographic system shall be capable of sustaining a minimum output of 129 µC/kg/sec (500 mR/sec) for at least three (3) seconds and producing a minimum output of 2.1 µC/kg/mAs (8 mR/mAs). These outputs shall be measured at a point 4.5 centimeters from the surface of the breast support device when the SID is at its maximum and the effect of compression paddle attenuation is included.]~~

~~[(I4)Screen-film Contact. Cassettes shall not be used for mammography if one or more large areas (>1 cm) of poor contact can be seen in a 40 mesh test.]~~

~~[(I5)Image quality. The mammographic x-ray imaging system shall be capable of providing an image of a 0.75mm fiber, 0.32mm speck group, and a 0.75mm mass from an American College of Radiology (ACR) phantom (or equivalent) on the standard mammographic image receptor system in use at facility. No mammogram shall be taken on patients if this minimum is not met.]~~

~~(II) [(I6)] Dose. [The mean glandular dose for one craniocaudal view, based on exposure measured at the breast entrance location, and using dose conversion factors specified by the Health Care Financing Administration in their Medicare Mammography Survey Protocols, shall not exceed the following values:~~

~~(a) One (1) mGy (100 millirad) for no-grid screen film systems.]~~ The average glandular dose delivered during a single cranio-caudal view of an FDA accepted phantom simulating a standard breast, shall not exceed 200 millirad (2.0 mGy). The dose shall be determined with technique factors and conditions used, by the registrant, clinically for a standard breast. The testing protocol used shall be the same as used by MQSA.

~~[(b) Two (2) mGy (200 millirad) for screen-film systems with grid.]~~

~~[(c) Four (4) mGy (400 millirad) for Xerography systems.]~~

(a) If the average glandular dose exceeds 200 millirad (2.0 mGy) but is no greater than 250 millirad (2.5

mGy), patient mammography may be continued until the cause of the problem is determined and corrected. Correction must be completed within thirty (30) working days of when the registrant became aware of the problem. If correction has not been completed within thirty (30) working days, and the registrant has not requested an extension in writing from the agency, patient mammography must cease until correction of the dose problem has occurred.

(b) If the average glandular dose exceeds 250 millirad (2.5 mGy), patient mammography must cease until the cause of the dose problem is determined and corrected.

~~[(17)Technique settings. The technique settings used for section [s (15) and (16)] 12 of this rule, shall be those used by the facility for its clinical images of a 50 percent adipose/50 percent glandular 4.5 centimeter (cm) compressed breast.]~~

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95

333-106-07 [20] 30 (1)

Quality Assurance Program

~~[Quality assurance program required.]~~ The registrant shall have a written, on-going equipment quality assurance program specific to mammographic imaging, covering all components of the diagnostic x-ray imaging system~~[.]~~. **The quality assurance program shall include the testing required in section (5) of this rule, as well as the evaluation of the test results and corrective actions necessary to ensure consistently high-quality images with minimum patient exposure. Responsibilities under this requirement**

~~[include providing qualified individuals who are to]~~ are as follows:

~~[(a) Conduct equipment monitoring functions;]~~

(a)The registrant shall identify in policy/procedure, by name, a Lead Interpreting Physician meeting the requirements of OAR 333-106-0750(2), whose responsibilities at a minimum must include:

(A)Ensuring that the registrant's quality assurance program meets all associated rules and regulations;

(B)Ensuring that an effective quality assurance program exists;

(C)Providing frequent feedback to mammography technologists regarding film quality and quality control procedures ;

(D)Reviewing the Quality Control Technologist's test data at least every three months, or more if consistency has not been shown or problems are evident ;

(E)Reviewing the Medical Physicist's annual survey report/ or equipment evaluation results.

~~[(b) Analyze the monitoring results to determine if there are problems requiring correction;]~~

(b)The registrant shall identify in policy/procedure, by name, and have the services of, a Medical Physicist who meets the requirements of OAR 333-106-0750(3). The Medical Physicist shall assist in overseeing the equipment quality assurance practices of the registrant. At a minimum, the Medical Physicist shall be responsible for the annual surveys, mammography equipment evaluations, and associated reports meeting all the requirements of MQSA.

~~[(c) Carry out or arrange for the necessary corrective actions when results of quality control tests including those specified in section (3) of this rule, indicate the need, and]~~

(c) The registrant shall identify in policy/procedure, by name, a single qualified Quality Control Technologist meeting the requirements of OAR 333-106-0750(1), who shall be responsible for:

(A) equipment performance monitoring functions;

(B) Analyzing the monitoring results to determine if there are problems requiring correction;

(C) Carrying out or arranging for the necessary corrective actions when results of quality control tests including those specified in section (5) of this rule, indicate the need; and

~~[(d) Maintain records documenting that subsections (1)(a)(b) and (c) of this rule have been done for a minimum of two years.]~~

(D) The Quality Control Technologist may be assigned other tasks associated with the quality assurance program that are not assigned to the Lead Interpreting Physician or Medical Physicist. These additional tasks must be documented in written policy/procedure.

(2) ~~[Quality assurance program review]~~ Annual Survey. At intervals not to exceed 12-14 months, the registrant shall have a Medical Physicist meeting the requirements of OAR 333-106-0750(3) conduct a ~~[review]~~ survey to evaluate the mammography equipment, and ~~[of]~~ the effectiveness of the quality assurance program required in section (1) of this rule ~~[.]~~. ~~[and maintain a written report of such review.]~~ Records of annual ~~[reviews]~~ surveys shall be maintained for a minimum of two years, and shall be available on-site for agency review.

~~[(3) Equipment quality control tests. The registrant shall ensure that the following quality control tests are performed when applicable equipment or components are initially installed or replaced and performed thereafter at least as often as the frequency specified. If such tests indicate the need for corrective action, based on limits defined here, or in 333-106-0710, no patient mammography may be performed until correction is accomplished:~~

~~(a) Processor performance by sensitometric means daily, or day of use, prior to the first patient exposure. For any mammography registrant using film processors at multiple locations, such as a mobile service, each processor shall be subject to this requirement. Corrective action shall be taken when:~~

~~(A) deviations of " 0.10 or more in optical density from established operating levels occur for readings of mid-density (MD) and density difference (DD) on the sensitometric control charts:~~

~~(B) base plus fog (B+F) exceeds the established operating level by more than 0.03 in optical density.~~

~~(b) Resolution and/or focal spot size - upon tube installation or replacement only.~~

~~(c) Half-value-layer 12 months.~~

~~(d) kVp accuracy - 12 months. _____~~

~~(e) Output reproducibility, mA linearity, and mR/mAs - 12 months.~~

~~(f) Automatic exposure control reproducibility and performance (response to kVp and phantom thickness) - 12 months.~~

~~(g) Screen-film contact and screen artifact detection - six (6) months.~~

~~(h) Compression device performance (releases, level of force, etc.) - six (6) months.~~

~~(I) Collimator alignment - 12 months.~~

~~(j) Primary/secondary barrier transmission - upon initial x-ray system installation and significant modification of the system or the facility.~~

~~(k) Image quality (using a test "phantom," which mimics the composition of the breast and includes simulations of breast structures) - monthly for stationary systems and prior to performing mammography at each new location for mobile systems.]~~

(3) Annual survey /or equipment evaluation corrective actions. Corrective action shall be completed within thirty (30) working days of when the registrant received written or verbal notice of recommendations or failures on their annual survey /or equipment evaluation report, unless otherwise noted in these rules or a written request for extension has been submitted to and approved by the Agency;

(a) Correction of equipment related failures or recommendations shall be demonstrated by a repeat test using the same test methodology and documentation, or a test accepted as the equivalent by the Agency, that was used to initially identify the problem.

(b) When the results of a quality control test/s fail to meet applicable action limits defined in these rules, the appropriate action regarding the suspension or continuation of mammography as defined in these rules or in MQSA, shall be taken.

~~*{(4) Additional Quality Control Requirements. The registrant shall perform the following observations and procedures according to the frequency noted and record the results. Corrections of problems noted shall be made and recorded. Records shall be maintained over the most recent two-year period.*~~

~~*(a) Reject rate - three (3) months.*~~

~~*(b) View box uniformity - six (6) months.*~~

~~*(c) Darkroom integrity (safelight condition, light leaks, etc.) - six (6) months.*~~

~~*(d) Screen cleaning - weekly.*~~

(4) Quality assurance records. The registrant shall ensure that;

(a) Records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, policies, previous inspection findings, and radiation protection are maintained until inspected by the agency.

(b) Quality control monitoring data and records, problems detected by the analysis of that data, corrective actions, and records of the Lead Interpreting Physician's periodic reviews of the Quality Control Technologist's monitoring data taken must be maintained for a minimum of two years.

(5) Equipment quality control tests frequency. The registrant shall ensure that the following quality control tests are performed when applicable equipment or components are initially installed or replaced and performed thereafter at least as often as the frequency specified as follows;

| FREQUENCY OF TEST | NAME OF TEST |
|-------------------------------------|---|
| Daily | Processor Quality Control |
| Weekly | Phantom Image |
| Quarterly | Fixer Retention |
| | Repeat Analysis |
| | Darkroom Fog |
| Semi-Annual | Screen/Film Contact |
| | Compression |
| | Medical Physicist Survey to include at a minimum; |
| Annual | AEC Performance |
| | kVp Accuracy and Reproducibility |
| | Evaluation of System Resolution |
| | Beam Quality (Half Value Layer) Assessment |
| | Breast Entrance Exposure |
| | Average Glandular Dose |
| | Radiation Output Rate |
| | X-ray to Light Field Alignment |
| | X-ray to Image Receptor alignment |
| | Compression Paddle Extension at Chest Wall |
| | System Artifacts |
| | Uniformity of Screen Speed |
| | Unit Assembly Evaluation |
| | Decompression |
| | View box luminance and room Illuminance |
| Review of Technologist's QC Records | |

(6) Testing methods and action limits for quality control tests shall meet the most current requirements of MQSA, in addition to the following;

(7) Screen/film contact. Screen film contact tests shall be performed on all screens used clinically, using a 40 mesh test tool and 4 cm thick sheet of acrylic. Screens demonstrating one or more areas of poor contact that are greater than 1 cm in diameter, that are not eliminated by screen cleaning, and remain in the same location during subsequent tests, shall not be used for mammography. Screen/film contact shall be such that any areas of poor contact, regardless of size, shall not detract from image quality.

(8) Processor performance. A processor performance test shall be performed by sensitometric means and evaluated daily, after the solution temperature in the processor has reached proper temperature, and just prior to processing any clinical mammograms. The test shall be an assessment of the base plus fog, mid-density, density difference, and developer temperature .

(a) Sensitometers and densitometer used to evaluate processor performance shall be calibrated every

- twelve (12) months and a record of the calibration shall be maintained until inspected by the Agency.
- (b) The mid-density and density difference action limits must be within + or - 0.15 of the control operating level.
 - (c) The base plus fog (B+F) action limit must be within + or - 0.03 of the control operating level.
 - (d) If the mid-density and/or the density difference fall outside of the + or - 0.10 control limit but within the + or - 0.15 control limit for a period of three (3) days (a trend), steps must be taken to determine the cause and correct the problem ;
 - (e) If the mid-density and/or the density difference falls outside of the + or - 0.15 control limit, mammograms must not be processed through the processor until the cause of the problem is determined, corrected, and a repeat test is done demonstrating that the mid-density and/or density difference are within the + or - 0.15 control limit ;
 - (f) Processor quality control graphs must be in the format of the registrant's accrediting body or equivalent, and indicate test date/s, mid-density and density difference action limits, base plus fog action limit, film brand, type and emulsion number in use, as well as high-lighting the date column when chemistry changes occurred, and noting corrective action taken when limits are exceeded ;
 - (g) Cross over records and calculations must be maintained for agency review. New mid-density and /or density difference operating levels must be charted on a new graph page.
 - (h) Re-establishment of operating levels must be done in accordance with the accrediting body's protocol regarding the appropriateness of this procedure or at the specific direction of the facility's medical physicist.
 - (i) While re-establishing operating levels (five day average), the facility must chart each day's results against it's old operating control levels. At the end of the of the five days, a new chart must be established, indicating the new calculated operating limits. During the five day average, the facility will not be cited for having exceeded the old processor operating levels, and must also do a phantom image test each day. Should the phantom image test exceed either the +- 0.20 background optical density limit or the +- 0.05 density difference limit, mammography must be suspended until the cause of the problem is identified and corrected, and a repeat phantom image test is shown to be within limits.
- (9) Primary/secondary barrier transmission - upon initial x-ray system installation and significant modification of the system or the facility.
- (10) Image quality. The mammography system must be capable of producing an image of the phantom demonstrating the following;
- (a) A minimum score of four (4.0) fibrils, three (3.0) speck groups, and three (3.0) masses (or the most current minimum score established by the accrediting body and accepted by the FDA).
 - (b) Background density action limits within + or - 0.20 of the control level ;
 - (c) Density difference action limits within + or - 0.05 of the control level ;
 - (d) Milliampere seconds (mAs) within + or - 15% of the control level ;
 - (e) Demonstrating a level of contrast sufficient enough to clearly help define fibril, speck, and mass edges.
 - (f) Without objectionable levels of image noise or quantum mottle that obscure the visualization of fibrils, specks, or masses.
 - (g) Demonstrating reasonably sharp fibril, and mass margins.
 - (h) With a minimum optical density (measured at the center of the phantom) of 1.20.

(i) Phantom image test records must be in the most current format of the registrant's accrediting body or the equivalent, and indicate the exposure mode, kVp, and photo-cell used for the test as well as remarks indicating the corrective action that was taken when limits were exceeded.

(j) When phantom image results do not meet the requirements defined in sections (a),(b),(c), (d),(e), (f),(g),or (h) of this rule, corrective action must occur, and a repeat phantom image test must be performed demonstrating compliance, before further mammography examinations are performed using the x-ray machine.

(11) Darkroom fog. Darkroom fog levels shall not exceed 0.05 in optical density when sensitized film is exposed to darkroom conditions with safelight on for two (2) minutes. Film shall be sensitized by exposing it to sufficient light from an appropriate intensifying screen so that after processing, an optical density of at least 1.20 is achieved.

(a) If the darkroom fog level exceeds 0.05 in optical density but is less than 0.10, mammography may be continued until the problem is corrected.

(b) If the darkroom fog level exceeds 0.10 in optical density, mammography must be curtailed until the problem is corrected and the fog level no longer exceeds 0.05 in optical density.

(12) Repeat rate. Corrective actions shall be recorded and the results of these corrective actions shall be assessed if the reject rate exceeds five (5) percent or changes by +2% from the previously measured rate. The reject rate shall be based on repeated clinical images.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

Hist.: HD 15-1994, f. & cert. ef. 5-6-94

333-106-07 ~~f30~~ 40 (1)

Additional [Facility] Requirements

Masks. Masks shall be provided on the view boxes to block extraneous light from the viewer's eye when the illuminated surface of the view box is larger than the area of clinical interest.

(2) Film processing. Film processors utilized for mammography shall be ~~[adjusted to and operated at the specifications recommended by the mammographic film manufacturer, or at other settings such that the sensitometric performance is at least equivalent.]~~ ;

(a) Used with x-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.

(b) Use chemical solutions that are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.

(c) Be adjusted to and operated at the specifications recommended by the mammographic film manufacturer, or at other settings such that the sensitometric performance is at least equivalent.

(3) Instruments and devices. ~~[An image quality phantom, sensitometer, and a calibrated densitometer shall be available to each facility in order to comply with the quality control test frequencies specified in 333-106-730 and 740. The calibration of the densitometer shall be checked and documented every twelve (12) months.]~~

The following instruments and devices shall be available and properly maintained;

(a) FDA accepted image quality phantom ;

(b) 21 step sensitometer that is calibrated every 12 months ;

(c) Densitometer that is calibrated every 12 months and checked against the instrument control strip at least monthly.

~~[(4) Operator qualifications. In order to use any mammography X-ray machine the operator of the mammography X-ray unit must have the following qualifications:~~

~~Have a current license issued by the Oregon Board of Radiologic Technology, and~~

~~(b) Be currently registered and in good standing with the American Registry of Radiologic Technologists, and~~

~~(c) Be certified in mammography by the American Registry of Radiologic Technology, or~~

~~(d) Provide documented evidence of mammography certification in progress, or~~

~~(e) Provide documented evidence of mammography certification student status. Student status shall not exceed a period of one year prior to certification~~

~~NOTE: In order to meet this rule, a one-year moratorium from the effective date of this rule will be allowed.~~

~~(5) Physician qualifications. The physician interpreting the mammogram shall be certified by the Board of Radiology, the American Osteopathic Board of Radiology, or be Board eligible, or equivalent, and have had specialized training in mammography and image interpretation.~~

~~(6) Physicist qualifications. The person performing evaluation of mammographic system performance in accordance with these regulations, shall be certified by the American Board of Radiology, or be Board eligible, or equivalent, or recognized as competent by the Oregon Health Division.]~~

~~[(7)] (4) Image retention. Clinical images shall be retained for a minimum of five (5) years or not less than ten (10) years if no additional mammograms of the patient are performed.~~

~~[(8) Reject rate. Corrective action shall be taken if the reject rate exceeds five (5) percent. The reject rate shall be based on repeated clinical images.~~

~~(9) Darkroom fog. Darkroom fog levels shall not exceed 0.05 in optical density when sensitized film is exposed to darkroom conditions with safelight on for two (2) minutes. Film shall be sensitized by exposing to sufficient light from an appropriate intensifying screen so that after processing, an optical density of 1.0 is achieved.]~~

(5) Mobile Mammography. In addition to meeting the requirements of this section as well as OAR 333-106-0700, 333-106-0710, 333-106-0720, 333-106-0730, and 333-106-0750, registrants shall ensure that for a mammography system that is used at more than one location:

(a) The film processor is operated in accordance with the requirements of OAR 333-106-0740(2)(a)(b)(c)(d), and is located where the mammography examinations are performed (batch processing is prohibited).

(b) The following tests are conducted, evaluated and documented after every move and before any mammography examinations are conducted, in order to verify that the unit's performance continues to meet quality requirements:

(A) Phantom image;

(B) The measured radiation output or the data from the post exposure mAs display does not deviate by more than + or - 10 % of the established operating level.

(6) Technique charts. Mammography technique charts shall be posted in the vicinity of the mammography system's X-ray control. The technique chart shall indicate;

(a) Technique factors for 3, 3-5, 5-7, and > 7 centimeter compressed breast thicknesses for fatty, 50

- percent fatty-50 percent dense, and dense breast tissue;
- (b) The target/ filter combination to be used;
 - (c) The kVp to be selected for the patient sizes and breast tissue compositions indicated in section (a) of this rule, or if an auto-kVp mode is used, indicate the post kVp that is selected;
 - (d) The exposure mode to be used (i.e. auto-kVp, manual, etc.);
 - (e) The manual technique factors to be used for small, medium, and large sized breast tissue specimens, and Implanted breasts;
 - (f) The film/ screen combination to be used;
 - (g) The date that the technique chart was last reviewed for accuracy and the name of the reviewer.

Stat. Auth.: ORS CH. 453 . 605 - 453.755

Stat. Imp.:

Hist.: HD

333-106-0750 (1)

Personnel Qualifications

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 Radiologic Technology; and
 - (b) Have prior to the effective date of these rules qualified as a radiologic technologist under the MQSA interim rules or completed forty (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 supervision of an individual qualified under this section; and
 - (C) At least 8 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 (ARRT); 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 sections (1)(a)(b)(A)(B)(C)(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

(a) 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 agency.

Stat. Auth.: ORS 453.605 - ORS 453.755

Stats. Implemented:

Hist.: HD 15-1994, f. & cert. ef. 5-6-94

DIVISION 111

NOTICES, INSTRUCTIONS
AND REPORTS
TO WORKERS; INSPECTIONS

Purpose and Scope

333-111-0001 This Division establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in activities under a license or registration and options available to such individuals in connection with Agency inspections of licensees or registrants to ascertain compliance with the provisions of the act and rules, orders and licenses issued thereunder regarding radiological working conditions. The rules in this Division apply to all persons who receive, possess, use, own or transfer sources of radiation registered with or licensed by the Agency pursuant to Division 100, 101 and 102.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

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

Posting of Notices to Workers

333-111-0005 (1) Each licensee or registrant shall post current copies of the following documents:

- (a) The rules in this Division and in Division 120;
- (b) The license, certificate of validation, conditions or documents incorporated into the license by reference and amendments thereto;
- (c) The operating procedures applicable to activities under the license or registration; and
- (d) Any notice of noncompliance involving radiological working conditions, proposed imposition of civil penalty or order issued pursuant to Division 100, and any response from the licensee or registrant.

(2) If posting of a document specified in subsection (1)(a), (b) or (c) of this rule is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined, provided that such document is readily available to workers at the licensee's or registrant's facility.

(3) Agency "Notice to Employees" shall be posted by each licensee or registrant as required by these rules.

(4) Documents, notices or forms posted pursuant to this rule shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous and shall be replaced if defaced or altered.

(5) Agency documents posted pursuant to subsection (1)(d) of this rule shall be posted within two working days after receipt of the documents from the Agency: The licensee's or registrant's response, if any, shall be posted within two working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

OREGON ADMINISTRATIVE RULES
CHAPTER 333, DIVISION 111 - HEALTH DIVISION

.imp 7/15/2 Time:944

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.745

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

Instructions to Workers

333-111-0010 All individuals working in or frequenting any portion of a restricted area:

- (1) Shall be kept informed of the storage, transfer or use of sources of radiation in such portions of the restricted area;
- (2) Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material, in precautions or procedures to minimize exposure and in the purposes and functions of protective devices employed;
- (3) Shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of these rules and licenses for the protection of personnel from exposures to radiation or radioactive material occurring in such areas;
- (4) Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to or cause a violation of Agency rules and licenses or unnecessary exposure to radiation or radioactive material;
- (5) Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and
- (6) Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to OAR 333-111-0015.

(7) Refresher training shall be provided at intervals not to exceed three (3) years covering the topics identified in 333-111-0010.

NOTE: The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.745

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

Notification and Reports to Individuals

333-111-0015 (1) Radiation exposure data for an individual and the results of any measurements, analyses and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this rule. The information reported shall include data and results obtained pursuant to these rules, orders or license conditions, as shown in records maintained by the licensee or registrant pursuant to OAR 333-120-0650. Each notification and report shall:

- (a) Be in writing;
- (b) Include the appropriate identifying data such as the name of the licensee or registrant, the name of the individual and the individual's social security number;
- (c) Include the individual's exposure information; and

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(d) Contain the following statement:

"This report is furnished to you under the provisions of rules entitled Oregon Rules for the Control of Radiation, Division 111. You should preserve this report for further reference."

(2) Each licensee or registrant shall advise each worker annually in writing of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to OAR 333-120-0650. Prior to January 1, 1994, licensees are required to provide this information only upon request of the worker.

(3) At the request of a worker formerly engaged in work controlled by the licensee or registrant, each licensee or registrant shall furnish to the worker a report of the worker's exposure to radiation or radioactive material. Such report shall be furnished within thirty (30) days from the time the request is made or within thirty (30) days after the exposure of the individual has been determined by the licensee or registrant, whichever is later; shall cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation machines registered with the Agency; and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

(4) When a licensee or registrant is required pursuant to Division 120 of these rules to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on the exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Agency.

(5) At the request of a worker who is terminating employment in a given calendar quarter with the licensee or registrant in work involving radiation dose, or of a worker who, while employed by another person, is terminating assignment to work involving radiation dose in the licensee's or registrant's facility in that calendar quarter, each licensee or registrant shall provide to each such worker, or to the worker's designee, at termination, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during that specifically identified calendar quarter or fraction thereof, or provide a written estimate of that dose if the finally determined personnel monitoring results are not available at that time. Estimated doses shall be clearly indicated as such.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.695

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

Presence of Representatives of Licensees or Registrants and Workers During Inspection

333-111-0020 (1) Each licensee or registrant shall afford to the Agency at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises and records pursuant to these rules.

(2) During an inspection, Agency inspectors may consult privately with workers as specified in OAR 333-111-0025. The licensee or registrant may accompany Agency inspectors during other phases of an inspection.

(3) If, at the time of inspection, an individual has been authorized by the workers to represent them during Agency inspections, the licensee or registrant shall notify the inspectors of such

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authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(4) Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in OAR 333-111-0010.

(5) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(6) With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany Agency inspectors during the inspection of physical working conditions.

(7) Notwithstanding the other provisions of this rule, Agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.745

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

Consultation with Workers During Inspections

333-111-0025 (1) Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these rules and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(2) During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Act, these rules or license condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of OAR 333-111-0030(1).

(3) The provisions of section (2) of this rule shall not be interpreted as authorization to disregard instructions pursuant to OAR 333-111-0010.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.745

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

Requests by Workers for Inspections

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333-111-0030 (1) Any worker or representative of workers believing that a violation of the Act, these rules or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the Agency. Any such notice shall be in writing, shall set forth the specific grounds for the notice and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the Agency no later than at the time of inspection except that, upon the request of the worker giving such notice, their name and the name of individuals referred to therein shall not appear in such copy or on any record published, released or made available by the Agency, except for good cause shown.

(2) If, upon receipt of such notice, the Agency determines that the complaint meets the requirements set forth in section (1) of this rule, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to this rule need not be limited to matters referred to in the complaint.

(3) No licensee, registrant or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these rules or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by this Division.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.745

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

Inspections Not Warranted; Informal Review

333-111-0035 (1) If the Agency determines, with respect to a complaint under OAR 333-111-030, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Agency shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the Administrator of the Health Division. Such agency will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the Administrator of the Health Division. Such agency will provide the complainant with a copy of such statement by certified mail.

(2) Upon the request of the complainant, the Administrator of the Health Division may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Administrator of the Health Division shall affirm, modify or reverse the determination of the Agency and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

(3) If the Agency determines that an inspection is not warranted because the requirements of OAR 333-111-0030(1) have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint

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meeting the requirements of OAR 333-111-030(1).

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.745

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

DIVISION 112

REQUIREMENTS FOR MICROWAVE OVEN USE AND SERVICE

Purpose and Scope

333-112-0001 (1) The purpose of this Division is to assure adequate servicing and repair of microwave ovens and to prevent public and occupational exposure to microwave radiation from leaking microwave ovens which the Agency has determined to present a biological hazard to occupational and public health and safety.

(2) The requirements of this Division apply to any person or facility that operates microwave ovens or that provides repair or other service for microwave ovens used in homes, restaurants, hospitals, schools or other establishments where the public could be exposed.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

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

Definitions

333-112-0005 As used in this Division, these terms have the definitions set forth below:

(1) "Microwave oven" means an electronic product designed to heat or cook food through the application of electromagnetic energy at frequencies assigned by the Federal Communications Commission in the normal industrial, scientific and medical heating bands ranging from 890 megahertz to 6,000 megahertz.

(2) "Cavity" means that portion of the microwave oven in which food may be heated or cooked.

(3) "Door" means the movable barrier which prevents access to the cavity during operation and the function of which is to prevent emission of microwave energy from the passage or opening which provides access to the cavity.

(4) "External surface" means the outside surface of the cabinet or enclosure provided by the manufacturer as part of the microwave oven, including doors, door handles, latches and control knobs.

(5) "Licensee" means any person (facility) that provides service for microwave ovens.

(6) "Service" means the testing, repair, maintenance, modification, replacement or adjustment of any microwave oven or any part or component thereof.

(7) "Stirrer" means that feature of a microwave oven which is intended to provide uniform heating of the load by constantly changing the standing wave pattern within the cavity or moving the load.

(8) "Technician" means any individual that performs service on microwave ovens.

Stat. Auth.: ORS Ch. 453

Stats. Implemented: ORS 453.605

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

Licensing of Microwave Oven Repair Facilities

333-112-0010 (1) No person or facility shall provide service for microwave ovens except as authorized by a specific license issued by the Agency. A license application will be approved or an annual

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validation certificate issued when the Agency determines that:

- (a) The applicant's proposed test equipment satisfies the requirements of OAR 333-112-0020;
 - (b) The applicant's proposed procedures pertaining to oven repair and instruction of personnel are adequate to ensure compliance with these rules.
- (2) License applications shall be made on forms furnished by the Agency.
 - (3) In addition to the requirements of this Division, all licensees are subject to the requirements of Division 100 and 111 of these rules.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.665

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

Requirements for Microwave Oven Service Licensees

Service Responsibilities

333-112-0015 (1) The licensee shall test each microwave oven serviced for leakage in accordance with measurement and test procedures described in OAR 333-112-0020. The test shall be performed before, if the oven is operational, and after servicing of the oven has been completed.

(2) No licensee shall provide service for a microwave oven in such a manner as to cause leakage from the oven in excess of those limits specified in OAR 333-112-0040.

(3) The licensee shall notify the Agency within 20 days of any microwave oven that is found to be leaking microwave radiation in excess of the limits specified in OAR 333-112-0040. The notification shall include:

- (a) The maximum power density measured with procedures described in OAR 333-112-0020;
 - (b) The name of the manufacturer of the oven;
 - (c) The date the leakage was corrected and the oven was brought into compliance with OAR 333-112-0040; or
 - (d) The reason why the leakage was not corrected and brought into compliance with OAR 333-112-0040;
 - (e) The name and address of the owner.
- (4) A copy of the notification required by section (3) of this rule shall be supplied to the owner or user of the microwave oven at the time the notification is sent to the Agency.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625

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

Measurement and Test Procedures

333-112-0020 (1) Leakage levels shall be determined by measurements of microwave power density made with an instrument system which:

- (a) Reaches 90 percent of its steady-state reading within three seconds when the system is subjected to a stepped input signal;
- (b) Has a radiation detector with an effective aperture of 25 square centimeters or less as measured

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in a plane wave, having no dimension exceeding ten centimeters;

(c) Is capable of measuring microwave oven leakage levels with an accuracy of plus 25 percent and minus 20 percent (plus or minus one decibel);

(d) Has been calibrated at least within the last 12 months.

(2) Measurements shall be made in accordance with the manufacturer's leakage test procedures or with the microwave oven operating at its maximum output and containing a load of 275 plus or minus 15 milliliters of tap water, initially at room temperature, placed within the cavity at the center of the load-carrying surface provided by the manufacturer. The water container for the latter procedure shall be a low form 600 milliliter beaker, or substantially similar vessel, having an inside diameter of approximately 8.5 centimeters and made of an electrically nonconductive material, such as glass or plastic.

(3) Measurements shall be made with the door fully closed, as well as with the door fixed in any other position which allows the oven to operate.

(4) Measurements shall be made at points five centimeters or less from external surfaces of the oven.

Stat. Auth.: ORS Ch. 453

Stats. Implemented: ORS 453.625, 453.635

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

Training of Service Personnel

333-112-0025 The licensee shall ensure that each technician who services microwave ovens in his or her employ is instructed in the test procedures, compliance criteria and all requirements of this Division.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

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

Personnel Monitoring for Cataracts

333-112-0030 It is recommended that each individual who performs servicing of microwave ovens have his or her eyes examined for cataract formations. The testing for cataracts should be by a licensed ophthalmologist and should be performed at the beginning of employment and annually thereafter.

Stat. Auth.: ORS Ch. 453

Stats. Implemented: ORS 453.625, 453.635

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

Records

333-112-0035 The licensee shall maintain records showing the results of leakage measurements on each microwave oven serviced. The records shall be maintained for inspection by the Agency and shall be so filed as to be readily available for review. The records shall contain at least the following information:

(1) The name of the individual who performed the service;

(2) The date the service was completed;

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- (3) The maximum leakage levels before and after servicing as applicable;
- (4) The location of the maximum leakage levels.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

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

Operation of Microwave Ovens

333-112-0040 (1) No person shall operate or direct the operation of a microwave oven that has been determined to leak microwave radiation in excess of the following limits:

(a) For ovens manufactured after October 1, 1971, leakage in excess of five milliwatts per square centimeter at any point five centimeters or more from the external surface of the oven;

(b) For ovens manufactured before October 1, 1971, leakage in excess of ten milliwatts per square centimeter at any point five centimeters or more from the external surface of the oven.

(2) Microwave ovens shall be considered to be in compliance with section (1) of this rule if the maximum power density of microwave radiation leakage measured in the test procedures specified in OAR 333-112-0020 does not exceed the microwave radiation leakage limits specified in section (1) of this rule measured through at least one stirrer cycle.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

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

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DIVISION 113

RADIATION SAFETY
REQUIREMENTS FOR WIRELINE
SERVICE OPERATIONS AND
SUBSURFACE TRACER STUDIES

Purpose and Scope

333-113-0001 (1) The rules in this Division establish radiation safety requirements for persons using sources of radiation for wireline service operations including mineral logging, radioactive markers and subsurface tracer studies. The requirements of this Division are in addition to, and not in substitution for, the requirements of Division 100, 102, 120 and 111 of these rules.

(2) The rules in this Division apply to all licensees or registrants who use sources of radiation for wireline service operations including mineral logging, radioactive markers or subsurface tracer studies.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625

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

Definitions

333-113-0005 As used in this Division, the following definitions apply:

(1) "Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary jobsites.

(2) "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

(3) "Logging supervisor" means the individual who provides the personal supervision of the use of sources of radiation at the well site.

(4) "Logging tool" means a device used subsurface to perform well-logging.

(5) "Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.

(6) "Personal supervision" means guidance and instruction by the supervisor who is physically present at the jobsite and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required.

(7) "Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

(8) "Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

(9) "Subsurface tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.

(10) "Temporary jobsite" means a location where radioactive materials are present for the purpose of performing wireline service operations or subsurface tracer studies.

(11) "Uranium sinker bar" means a weight containing depleted uranium used to pull a logging tool down toward the bottom of a well.

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(12) "Well-bore" means a drilled hole in which wireline service operations and subsurface tracer studies are performed.

(13) "Well-logging" means all operations involving the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well and/or adjacent formations.

(14) "Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

(15) "Wireline service operation" means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605

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

Prohibition

333-113-0010 No licensee shall perform wireline service operations with a sealed source(s) unless, prior to commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor or land owner that:

(1) In the event that a well to be logged, using radioactive material, penetrates a potable aquifer or contains potable water, that well shall be cased from top to bottom prior to the well-logging;

(2) In the event a sealed source is lodged downhole, a reasonable effort at recovery will be made; and

(3) In the event a decision is made to abandon the sealed source downhole, the requirements of OAR 333-113-0501(3) shall be met.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.665, 453.635

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

Equipment Control**Limits on Levels of Radiation**

333-113-0101 Sources of radiation shall be used, stored and transported in such a manner that the requirements of Division 120 of these rules are met.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.665

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

Storage Precautions

333-113-0105 (1) Each source of radiation, except accelerators, shall be provided with a storage and/or transport container. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.

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(2) Sources of radiation shall be stored in a manner which will minimize danger from explosion and/or fire.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.665

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

Transport Precautions

333-113-0110 Transport containers shall be physically secured to the transporting vehicle to prevent accidental loss, tampering or unauthorized removal.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

Radiation Survey Instruments

333-113-0115 (1) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each field station and temporary jobsite to make physical radiation surveys as required by this Division and by OAR 333-1200-200 of these rules. Instrumentation shall be capable of measuring **1 μ Sv** (0.1 milliroentgen) ~~{(25.8 nanocoulombs/kg)}~~ per hour through at least **0.5 mSv** (50 milliroentgens) ~~{(12.9 microcoulombs/kg)}~~ per hour.

(2) Each radiation survey instrument shall be calibrated:

(a) At intervals not to exceed six months and after each instrument servicing;

(b) For linear scale measurements, at least two points located approximately 1/3 and 2/3 of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade and at two points of at least one decade; and for digital instruments, at appropriate points; and

(c) So that accuracy within 20 percent of the true radiation level can be demonstrated on each scale.

(3) Calibration records shall be maintained until inspected by the Agency.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

Leak Testing of Sealed Sources

333-113-0120 (1) Requirements. Each licensee using sealed sources of radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of **Bq** (microcuries) (Bq) and maintained for inspection by the Agency for six months after the next required leak test is performed or until transfer or disposal of the sealed source.

(2) Method of Testing. Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The test sample shall be taken from the surface of the source, source holder or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. The test sample shall be analyzed for radioactive contamination and the

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analysis shall be capable of detecting the presence of **185 Bq** (0.005 microcurie) ~~185 Bq~~ of radioactive material on the test sample.

(3) Interval of Testing. Each sealed source of radioactive material shall be tested at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source shall not be put into use until tested. If, for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

(4) Leaking or Contaminated Sources. If the test reveals the presence of **185 Bq** (0.005 microcurie) ~~185 Bq~~ or more leakage or contamination, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired or disposed of in accordance with these rules. A report describing the equipment involved, the test results and the corrective action taken shall be filed with the Agency.

(5) Exemptions. The following sources are exempted from the periodic leak test requirements of sections (1) through (4) of this rule:

(a) Hydrogen-3 sources;

(b) Sources of radioactive material with a half-life of 30 days or less;

(c) Sealed sources of radioactive material in gaseous form;

(d) Sources of beta and/or gamma emitting radioactive material with an activity of **3.7 MBq** (100 microcuries) ~~3.7 MBq~~ or less; and

(e) Sources of alpha emitting radioactive material with an activity of **0.370 MBq** (ten microcuries) ~~0.370 MBq~~ or less;

(f) Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer unless it has been tested for leakage within six months before the date of use or transfer.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

Physical Inventory

333-113-0125 Each licensee or registrant shall conduct a semiannual physical inventory to account for all sources of radiation. Records of inventories shall be maintained until inspection by the Agency and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory and the name of the individual conducting the inventory. Physical inventory records may be combined with leak test records.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

Utilization Records

333-113-0130 Each licensee or registrant shall maintain current records, which shall be kept available until inspection by the Agency, showing the following information for each source of radiation:

(1) Make, model number and a serial number or a description of each source of radiation used;

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- (2) The identity of the well-logging supervisor or field unit to whom assigned;
- (3) Locations where used and dates of use; and
- (4) In the case of tracer material and radioactive markers, the utilization record shall indicate the radionuclide and activity used in a particular well.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

Design, Performance and Certification Criteria for Sealed Sources Used in Downhole Operations

333-113-0135 (1) Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations and manufactured after May 1, 1983 shall be certified by the manufacturer, or other testing organization acceptable to the Agency, to meet the following minimum criteria:

- (a) Be of doubly encapsulated construction;
- (b) Contain radioactive material whose chemical and physical forms are as insoluble and nondispersible as practical; and
- (c) Has been individually pressure tested to at least 24,600 pounds per square inch absolute (1.695×10^7 pascals) without failure.

(2) For sealed sources, except those containing radioactive material in gaseous form, acquired after May 1, 1984 in the absence of a certificate from a transfer certifying that an individual sealed source meets the requirements of section (1) of this rule, the sealed source shall not be put into use until such determinations and testing have been performed.

(3) Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations after May 1, 1985 shall be certified by the manufacturer, or other testing organization acceptable to the Agency, as meeting the sealed source performance requirements for oil well-logging as contained in the **American National Standard N43.6**, "Classification of Sealed Radioactive Sources," (formerly N542, ANSI/NBS 126).

(4) After source disposal certification documents shall be maintained for inspection by the Agency, if the source is abandoned downhole, the certification documents shall be maintained until the Agency authorizes disposition.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

Labeling

333-113-0140 (1) Each source, source holder or logging tool containing radioactive material shall bear a durable, legible and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

**DANGER
RADIOACTIVE
OR
CAUTION**

RADIOACTIVE

This labeling shall be on the smallest component transported as a separate piece of equipment.

(2) Each transport container shall have permanently attached to it a durable, legible and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

**DANGER
RADIOACTIVE
OR
CAUTION
RADIOACTIVE
NOTIFY CIVIL AUTHORITIES
OR
(NAME OF COMPANY)**

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

Inspection and Maintenance

333-113-0145 (1) Each licensee or registrant shall conduct, at intervals not to exceed six months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers and injection tools to assure proper labeling and physical condition. Records of inspection and maintenance shall be maintained for inspection by the Agency.

(2) If any inspection conducted pursuant to section (1) reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made.

(3) If a sealed source is stuck in the source holder, the licensee shall not perform any operation, such as drilling, cutting or chiseling, on the source holder unless the licensee is specifically approved by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform this operation.

(4) The repair, opening or modification of any sealed source shall be performed only by persons specifically authorized to do so by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

Use of a Sealed Source in a Well Without a Surface Casing

333-113-0150 The licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedure must be approved by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.

Stat. Auth.: ORS Ch. 453.605 - 453.807

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Stats. Implemented: ORS 453.635, 453.665

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

Requirements for Personnel Safety**Requirements for Personnel Safety Training Requirements**

333-113-0201 (1) No licensee or registrant shall permit any individual to act as a logging supervisor as defined in this Division until such individual has:

(a) Received, in a course recognized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, instruction in the subjects outlined in OAR 333-113-0203 and demonstrated an understanding thereof;

(b) Read and received instruction in the rules contained in this Division and the applicable sections of Divisions 100, 120 and 111 of these rules or their equivalent, conditions of appropriate license or certificate of registration, and the licensee's or registrant's operating and emergency procedures, and demonstrated an understanding thereof; and

(c) Demonstrated competence to use sources of radiation, related handling tools and radiation survey instruments which will be used on the job.

(2) No licensee or registrant shall permit any individual to assist in the handling of sources of radiation until such individual has:

(a) Read or received instruction in the licensee's or registrant's operating and emergency procedures and demonstrated an understanding thereof; and

(b) Demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools and radiation survey instruments which will be used on the job;

(c) The licensee shall provide safety reviews for logging supervisors and logging assistants at least once during each calendar year.

(3) The licensee or registrant shall maintain employees training records until inspection by the Agency following termination of the individual's employment.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

Subjects to be Included in Training Courses for Logging Supervisors

333-113-0203 (1) Fundamentals of radiation safety.

(a) Characteristics of radiation.

(b) Units of radiation dose and quantity of radioactivity.

(c) Significance of radiation dose:

(A) Radiation protection standards;

(B) Biological effects of radiation dose.

(d) Levels of radiation from sources of radiation.

(e) Methods of minimizing radiation dose:

(A) Working time;

(B) Working distances;

(C) Shielding.

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(f) Radiation safety practices including prevention of contamination and methods of decontamination.

(2) Radiation detection instrumentation to be used.

(a) Use of radiation survey instruments:

(A) Operation,

(B) Calibration,

(C) Limitations.

(b) Survey techniques.

(c) Use of personnel monitoring equipment.

(3) Equipment to be used.

(a) Handling equipment.

(b) Sources of radiation.

(c) Storage and control of equipment.

(d) Operation and control of equipment.

(4) The Requirements of pertinent federal and state regulations.

(5) The licensee's or registrant's written operating and emergency procedures.

(6) The licensee's or registrant's record keeping procedures.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

Operating and Emergency Procedures

333-113-0205 The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

(1) Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in Division 120 of these rules;

(2) Methods and occasions for conducting radiation surveys;

(3) Methods and occasions for locking and securing sources of radiation;

(4) Personnel monitoring and the use of personnel monitoring equipment;

(5) Transportation to temporary jobsites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles and securing sources of radiation during transportation;

(6) Minimizing exposure of individuals in the event of an accident;

(7) Procedures for notifying proper personnel in the event of an accident;

(8) Maintenance of records;

(9) Use, inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers and injection tools;

(10) Procedures to be followed in the event a sealed source is lodged downhole;

(11) Procedures to be used for picking up, receiving and opening packages containing radioactive material;

(12) For the use of tracers, decontamination of the environment, equipment and personnel;

(13) Maintenance of records generated by logging personnel at temporary jobsites;

(14) Notifying proper persons in the event of an accident; and

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(15) Actions to be taken if a sealed source is ruptured, including actions to prevent the spread of contamination and minimize inhalation and ingestion of radioactive material and actions to obtain suitable radiation survey instruments as required by OAR 333-113-0115.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

Personnel Monitoring

333-113-0210 (1) No licensee or registrant shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears either a film badge or a thermoluminescent dosimeter (TLD). Each film badge or TLD shall be assigned to and worn by only one individual. Film badges must be replaced at least monthly and TLDs replaced at least quarterly. After replacement, each film badge or TLD must be promptly processed.

(2) Personnel monitoring records shall be maintained for inspection until the Agency authorizes disposition.

**Precautionary Procedures
in Logging and Subsurface
Tracer Studies****Security**

333-113-0301 During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized or unnecessary entry into a restricted area, as defined in Division 100 of these rules.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

Handling Tools

333-113-0305 The licensee shall provide and require the use of tools that will assure remote handling of sealed sources other than low activity calibration sources.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

Subsurface Tracer Studies

333-113-0310 (1) Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.

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(2) No licensee shall cause the injection of radioactive material into potable aquifers without prior written authorization from the Agency.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

Particle Accelerators

333-113-0315 No licensee or registrant shall permit above-ground testing of particle accelerators, designed for use in well-logging, which results in the production of radiation, except in areas or facilities so controlled or shielded that the requirements of OAR 333-120-0100 and 333-105-0030 as applicable, are met.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

Radiation Survey and Records**Radiation Surveys**

333-113-0401 (1) Radiation surveys or calculations shall be made and recorded for each area where radioactive materials are stored.

(2) Radiation surveys or calculations shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys and calculations shall include each source of radiation or combination of sources to be transported in the vehicle.

(3) If the sealed source assembly is removed from the logging tool before departing the jobsites, the logging tool detector shall be energized, or a survey meter used, to assure that the logging tool is free of contamination.

(4) Radiation surveys shall be made and recorded at the jobsite or well-head for each tracer operation, except those using hydrogen-3, carbon-14 and sulfur-35. These surveys shall include measurements of radiation levels before and after the operation.

(5) Records required pursuant to sections (1) through (4) of this rule shall include the dates, the identification of individual(s) making the survey, the identification of survey instrument(s) used and an exact description of the location of the survey. Records of these surveys shall be maintained for inspection by the Agency.

(6) If the licensee has reason to believe that, as a result of any operation involving a sealed source, the encapsulation of the sealed source could be damaged by the operation, the licensee shall conduct a radiation survey, including a contamination survey, during and after the operation.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

Documents and Records Required at Field Stations

333-113-0405 Each licensee or registrant shall maintain, for inspection by the Agency, the following documents and records for the specific devices and sources used at the field station:

- (1) Appropriate license, certificate of registration or equivalent document(s);
- (2) Operating and emergency procedures;
- (3) Applicable rules;
- (4) Records of the latest survey instrument calibrations pursuant to OAR 333-113-0115;
- (5) Records of the latest leak test results pursuant to OAR 333-113-0120;
- (6) Records of quarterly inventories required pursuant to OAR 333-113-0125;
- (7) Utilization records required pursuant to OAR 333-113-0130;
- (8) Records of inspection and maintenance required pursuant to OAR 333-113-0145;
- (9) Survey records required pursuant to OAR 333-113-0401; and
- (10) Training records required pursuant to OAR 333-113-0201.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

Documents and Records Required at Temporary Jobsites

333-113-0410 Each licensee or registrant conducting operations at a temporary jobsite shall have the following documents and records available at that site for inspection by the Agency:

- (1) Operating and emergency procedures;
- (2) Survey records required pursuant to OAR 333-113-0401 for the period of operation at the site;
- (3) Evidence of current calibration for the radiation survey instruments in use at the site;
- (4) When operating in the state under reciprocity, a copy of the appropriate license, certificate of registration or equivalent document(s);
- (5) Shipping papers for the transportation of radioactive material;
- (6) Copy of the license;
- (7) Current leak test; and
- (8) Validation certificate.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

Notification

Notification of Incidents, Abandonment and Lost Sources

333-113-0501 (1) Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of Division 120 of these rules.

(2) Whenever a sealed source or device containing radioactive material is lodged downhole the licensee shall:

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(a) Monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations; and

(b) Notify the Agency immediately by telephone and subsequently, within 30 days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. This letter shall identify the well or other location, describe the magnitude and extent of the escape of radioactive material, assess the consequences of the rupture and explain efforts planned or being taken to mitigate these consequences.

(3) When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:

(a) Advise the well-operator of requirements specified in these rules regarding abandonment and an appropriate method of abandonment, which shall include:

(A) The immobilization and sealing in place of the radioactive source with a cement plug;

(B) The setting of a whipstock or other deflection device; and

(C) The mounting of a permanent identification plaque at the surface of the well, containing the appropriate information required by section (4) of this rule;

(b) Notify the Agency by telephone, giving the circumstances of the loss and request approval of the proposed abandonment procedures; and

(c) File a written report with the Agency within 30 days of the abandonment. The report shall contain the following information:

(A) Date of occurrence;

(B) A description of the well logging source involved, including the radionuclide and its quantity, chemical and physical form;

(C) Surface location and identification of the well;

(D) Results of efforts to immobilize and seal the source in place;

(E) A brief description of the attempted recovery effort;

(F) Depth of the source;

(G) Depth of the top of the cement plug;

(H) Depth of the well;

(I) Any other information, such as a warning statement, contained on the permanent identification plaque; and

(J) The names of state agencies receiving a copy of this report.

(4) Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque for posting the well or well-bore. This plaque shall:

(a) Be constructed of long-lasting material, such as stainless steel or monel; and

(b) Contain the following information engraved on its face:

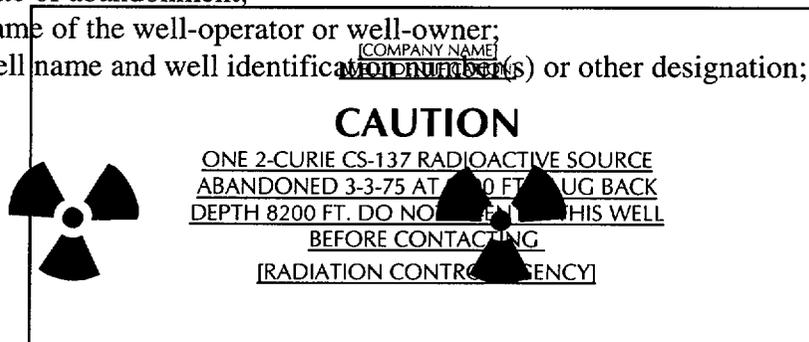
(A) The word **CAUTION**;

(B) The radiation symbol without the conventional color requirement;

(C) The date of abandonment;

(D) The name of the well-operator or well-owner;

(E) The well name and well identification number(s) or other designation;



The size of the plaque should be convenient for use on active or inactive wells, e.g., a 7-inch square. Letter size of the word "CAUTION" should be approximately twice the letter size of the rest of the information, e.g., 1/2-inch and 1/4-inch letter size, respectively.

(F) The sealed source(s) by radionuclide and activity;

(G) The source depth and the depth to the top of the plug; and

(H) An appropriate warning, depending on the specific circumstances of each abandonment.

(5) The licensee shall immediately notify the Agency by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable aquifer. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss and explain efforts planned or being taken to mitigate these consequences.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.635, 453.665

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

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DIVISION 114

**TRAINING FOR EMERGENCY RESPONSE TO
RADIOACTIVE MATERIAL INCIDENTS**

General

333-114-0001 The purpose of these rules is to insure that the response to a radioactive material accident be both swift and appropriate to minimize damage to any person, property, domestic animals, wildlife or the environment.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

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

Definitions

333-114-0005 For the purpose of ORS 469.611 and these rules:

(1) "Certified Training" means radiological safety training in which performance has been demonstrated through the satisfactory completion of an authorized exam.

(2) "Authorized Exam" means an exam, either written or oral; or a performance demonstration that has been authorized by the Agency as adequate to demonstrate the competency of a particular skill level. Whenever possible authorized exams will be developed consistent with the programs and policies with the Oregon Department of Energy, Oregon Department of Environmental Quality, State Fire Accreditation Board and the Board on Police Standards and Training.

(3) "Skill Level" means:

(a) "Radiological Monitor (RM)" means a person who has demonstrated competency through the satisfactory completion of an authorized (RM) exam and therefore is qualified to be a member of a radiological response team. An RM must be recertified every four years.

(b) "Regional Radiological Technical Assistant (RRTA)" means a person who has demonstrated competency through the satisfactory completion of an authorized RRTA, exam. An RRTA is also qualified to instruct employees of emergency services agencies in the proper response to transportation accidents involving radioactive materials. An RRTA must be recertified every two years.

(c) "Radiological Officer (RO)" means a person who has demonstrated competency through the satisfactory completion of an authorized RO exam and therefore is qualified to advise a community before during and after a nuclear attack and/or incident. A RO must be recertified every three years.

(d) "Radiological Monitor Instructor (RMI)" means a person who has demonstrated competency through the satisfactory completion of an authorized RMI exam and therefore is qualified to be an instructor of "Radiological Monitoring" as defined in these rules. An RMI must be recertified every three years.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

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

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Training

333-114-0010 In order to receive certification in radiological safety training from ~~the~~ Oregon ~~State~~ Health ~~Division~~ **Services, Radiation Protection Services** a person must satisfactorily complete the authorized exam administered by an authorized Health Division representative. A county will receive certification of training after it has qualified two Regional Radiological Technical Assistants, and completed a radioactive/hazardous materials emergency response exercise as defined in these rules. An "emergency services agency" as defined in ORS 401.025, will receive certification of training after it has qualified one Radiological Monitor per duty shift.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

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

Radioactive/Hazardous Materials Emergency Response Exercise

333-114-0015 This is defined as a practice response to an accident involving radioactive or other hazardous materials. The exercise should involve all organizations that would normally be present in a real incident, including but not limited to: Firefighting, law enforcement, prehospital and hospital emergency medical care, highway maintenance and state technical support agencies.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

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

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DIVISION 115

RADIATION SAFETY REQUIREMENTS FOR X-RAY AND HYBRID GAUGES

Purpose and Scope

333-115-0001 This Division provides special requirements for X-ray and hybrid gauges. The requirements of this Division are in addition to, and not substitutions for, applicable requirements in Division 100, 101, 102, 111, and 120 of these rules.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 10-1985, f. & ef. 7-28-87; HD 1-1995, f. & cert. ef. 4-26-95

Definitions

333-115-0005 (1) "X-ray gauge" means an X-ray producing device designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density level or interface location.

(2) "Fail-safe characteristics" mean design features which cause beam port shutters to close or which otherwise prevent emergence of the primary beam upon failure of a safety or warning device.

(3) "Primary beam" means ionizing radiation which passes through an aperture of the source housing by a direct path from the X-ray tube or a radioactive source located in the radiation source housing.

(4) "Hybrid Gauge" means a gauging device utilizing both X-ray and radioactive material sources.

(5) "Open-beam configuration" means a gauging system which an individual could accidentally place some part of the body in primary beam path during normal operation.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.605

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

Equipment Requirements

Safety Device

333-115-0010 (1) Except where impractical, an interlocking device which prevents the entry of any portion of an individual's body into the primary beam, or causes the primary beam to be shut off upon entry into its path, shall be provided.

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(2) In cases where the primary radiation beam is not intercepted by the detector device under all conditions of operation, protective measures shall be provided, such as auxiliary shielding, to avoid exposure to any individual from the transmitted primary radiation.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 10-1987, f. & ef. 7-28-87

Warning Devices

333-115-0015 A sign bearing the words, "Warning - X-rays (or ionizing radiation) - Do not place hands in jaws of gauge", or equivalent, shall be so located that it is visible to any person operating, aligning or adjusting a gauging device.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

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

Ports

333-115-0020 Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 10-1987, f. & ef. 7-28-87

Labeling

333-115-0025 All gauges shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

(1) CAUTION - HIGH INTENSITY X-RAY BEAM, or words having a similar intent on the X-ray source housing; and

(2) CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED, or words having a similar intent, near any switch that energizes an X-ray tube if the radiation source is an X-ray tube; and

(3) CAUTION - RADIOACTIVE MATERIAL, on the source housing if the radiation source is a radionuclide.

Stat. Auth.: ORS Ch. 453.605 - 453.807

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Stats. Implemented: ORS 453.625, 453.635

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

Shutters

333-115-0030 A visible indication of the status of the shutter shall be provided, e.g., red light indicating beam on, green light indicating beam off. This device shall be tested to ensure operations will not continue without a proper functioning warning device. On equipment installed after January 1, 1978, this device shall be of fail-safe design.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 10-1987, f. & ef. 7-28-87

Warning Lights

333-115-0035 (1) An easily visible light labeled with the words "BEAM ON" or words having a similar intent, shall be located:

(a) Near any switch that energizes an X-ray tube and shall be illuminated only when the tube is energized; or

(b) In the case of a radioactive source, near any switch that opens a housing shutter and which shall be illuminated only when the shutter is open.

(2) On equipment installed after January 1, 1978, warning lights shall have fail-safe characteristics.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 10-1987, f. & ef. 7-28-87

Area Requirements**Radiation Levels**

333-115-0101 The local components of a gauge shall be so located and arranged and shall include sufficient shielding or access control that no radiation levels exists in any area surrounding the local component groups which could result in a dose to an individual present therein in excess of the dose limits given in OAR 333-120-0180. For systems using X-ray tubes, these levels shall be met at any specified tube rating.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

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Hist.: HD 10-1987, f. & ef. 7-28-87; HD 1-1995, f. & cert. ef. 4-26-95

Surveys

333-115-0105 (1) Radiation surveys, as required by OAR 333-120-0200, of all X-ray and Hybrid gauges sufficient to show compliance with OAR 333-115-0101 shall be performed:

- (a) Upon installation of the equipment;
 - (b) A review of all safety devices shall be performed at least quarterly to insure their proper operation (i.e., signs, labels, interlocks, etc.);
 - (c) Annual surveys and monitoring to insure that operations are conducted safely;
 - (d) Following any change in the initial arrangement, number or type of local components in the system;
 - (e) Following any maintenance requiring the disassembly or removal of a local component in the system;
 - (f) Any time a visual inspection of the local components in the system reveals an abnormal condition;
 - (g) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or when the readings are approaching the radiation dose limits specified in OAR 333-120-0100.
- (2) Records of all reviews and surveys shall be maintained for inspection by the Agency.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

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

Posting

333-115-0110 Each area or room containing any gauge shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words CAUTION - X-RAY EQUIPMENT, or words having similar intent.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 10-1987, f. & ef. 7-28-87

Security

333-115-0115 When not in operation, the equipment shall be secured in such a way as to be accessible to, or operable by, only authorized personnel.

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Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 10-1987, f. & ef. 7-28-87

Operating Requirements

333-115-0120 Normal and Emergency operating procedures shall be written and available to all X-ray and Hybrid gauge equipment workers.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

Hist.: HD 10-1987, f. & ef. 7-28-87

Personnel Requirements**Instructions**

333-115-0201 (1) No person shall be permitted to operate or maintain X-ray or Hybrid gauges unless such person has received instruction in and demonstrated competence with regard to:

(a) Identification of radiation hazards associated with the use of the equipment;

(b) Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precaution required in such cases;

(c) Proper operating procedures for equipment;

(d) Symptoms of an acute localized exposure; and

(e) Proper procedures for reporting and active or suspected exposure.

(2) Each licensee or registrant shall maintain, for inspection by the Agency, records of training which demonstrate that the requirements of this rule have been met.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635

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

Personnel Monitoring

333-115-0205 Finger or wrist dosimetric devices shall be provided to and shall be used by all personnel working with open beam gauging equipment.

Stat. Auth.: ORS Ch. 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635, 453.695

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Hist.: HD 10-1987, f. & ef. 7-28-87

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