DRAFT October 10, 2012

Radiation Protection Services
Oregon Administrative Rule Revision for 2012
RAC Meeting, October 10, 2010

Oregon Administrative Rule

333-100-0005: Revise sum and ratio
333-102-0115: Add the word "consecutive days" for reciprocity
333-102-0203: Change rule reference to "333-103-0010(2)(r) for NORM licensing
333-102-0250: Delete extra rule title
333-102-0285: Revise rule reference in (2)(a)
333-102-0340: Add the term "180 consecutive days"
333-106-0045: Change web site address. Revise wording, add rule reference for ARRT registry exam, housekeeping and revise rule reference
333-106-0101: Change web site address
333-106-0110: Change Division 120 to OAR 333-106-0120. Change text from required to when requested.
333-106-0305: Change symbol, housekeeping
333-106-0315: Change symbol, housekeeping
333-106-0370(5): Housekeeping regarding term "technologist licensed by the board"
333-106-0720: Housekeeping, change web address.
333-116-0040: Addition to rule references for NRC compatibility, reword for rule clarity.
333-116-0050: Add OAR and reword (2)(a),(b),(c),(d), for NRC compatibility
333-116-0050: Add the word "or", housekeeping
333-116-0090: Revise rule title to match NRC, CFR.
333-116-0170: Housekeeping, separate sections (4) and (5).
333-116-0405: Delete duplicate rule. Current rule is 333-116-0710
333-116-0640: Add rule reference for NRC, CFR compatibility
333-116-0660: Add rule reference for NRC, CFR compatibility
333-116-0670: Revise text; add rule reference for NRC, CFR compatibility
333-116-0680: Revise rule title, revise rule reference for NRC, CFR compatibility
333-116-0683: Revise rule reference for NRC, CFR compatibility
333-116-0687: Revise rule reference for NRC, CFR compatibility
333-116-0690: Additional rules for Brachytherapy inserted for NRC, CFR compatibility
333-116-0700: Revise rule reference for NRC CFR compatibility
333-116-0715: Insert rules for reference for NRC, CFR compatibility
333-116-0720: Revise text and rule reference for NRC, CFR compatibility
333-116-0740: Revise rule reference and add rule for NRC, CFR compatibility
333-116-0880: Housekeeping, add the OBMI reference to rule
333-116-0905: Revise rule reference for NRC, CFR compatibility
333-119-0040: Added text for tanning facilities
333-119-0041: New rule for cleaning and sanitation
333-119-0080: Housekeeping, remove reference dates
333-120-0630: Change reference from Form Y to NRC form 4, remove historical note
333-120-0730: Revise "must submit to the Authority" to "have available for inspection"
333-123-0005(18) (20): Added definitions for electronic brachytherapy
333-123-0055: New rule for electronic brachytherarpy
333-123-0060: New rule for electronic brachytherarpy
333-123-0065: New rule for electronic brachytherarpy
333-123-0070: New rule for electronic brachytherarpy
333-123-0075: New rule for electronic brachytherarpy
333-123-0080: New rule for electronic brachytherarpy
333-123-0085: New rule for electronic brachytherarpy
333-123-0090: New rule for electronic brachytherarpy
333-123-0095: New rule for electronic brachytherarpy
333-123-0100: New rule for electronic brachytherarpy
333-123-0105: New rule for electronic brachytherarpy
333-123-0110: New rule for electronic brachytherarpy
333-123-0115: New rule for electronic brachytherarpy

333-100-0005, Definitions

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

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

333-102-0115, Certain Measuring, Gauging and Controlling Devices

(12) Persons generally licensed by an Agreement State with respect to devices meeting the criteria in section (9) of this rule are not subject to registration requirements if the devices are used in areas subject to NRC jurisdiction for a period less than 180 consecutive days in any calendar year. The Nuclear Regulatory Commission does not require registration information from such licensees.

333-102-0203, Definitions

(50) "NORM (no processing)" means a facility-specific license pursuant to OAR 333-103-0010(2)(m) authorizing possession, use, and transfer of NORM in accordance with division 117 of this chapter.

333-102-0250, Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under a General License

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

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

333-102-0285, Manufacture, Preparation, or Transfer for Commercial Distribution of Radiopharmaceutical Drugs Containing Radioactive Material for Medical Use Under Division 116

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radiopharmaceutical drugs containing radioactive material for use by persons authorized pursuant to division 116 of this chapter will be approved if:

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

(b) The applicant submits evidence that the applicant is at least one of the following:

(A) Registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

(B) Registered or licensed with a state agency as a drug manufacturer;

(C) Licensed as a pharmacy by a state Board of Pharmacy;

(D) Operating as a nuclear pharmacy within a federal medical institution; or

(E) A Positron Emission Tomography (PET) drug production facility registered with a state agency.

(c) The applicant submits information on the radionuclide, chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radiopharmaceutical drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radiopharmaceutical drugs by medical use licensees; and

(d) The applicant satisfies the following labeling requirements:

(A) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radiopharmaceutical drug to be transferred for commercial distribution. The label must include the radiation symbol and the words CAUTION, RADIOACTIVE MATERIAL or DANGER, RADIOACTIVE MATERIAL; the name of the radiopharmaceutical drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radiopharmaceutical drugs with a half life greater than 100 days, the time may be omitted.

(B) A label is affixed to each syringe, vial, or other container used to hold a radiopharmaceutical drug to be transferred for commercial distribution. The label must include the radiation symbol and the words CAUTION, RADIOACTIVE MATERIAL or DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee described by paragraphs (1)(b)(C) or (D) of this rule:

(a) May prepare radiopharmaceutical drugs for medical use, as defined in OAR 333-116-0020, provided that the radiopharmaceutical drug is prepared either by an authorized nuclear pharmacist, as specified in subsections (2)(be) and (2)(d) of this rule, or an individual under the supervision of an authorized nuclear pharmacist as specified in OAR 333-116-0100.

333-102-0340, Reciprocal Recognition of Licenses

(1) Subject to these rules, any person who holds a specific license from the U.S. Nuclear Regulatory Commission, an Agreement State, or a licensing state, and issued by the Authority having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 consecutive days in any calendar year, provided that:

(6) If multiple work crews or persons work concurrently at more than one work location under a general license granted pursuant to this rule, each day worked at each location shall count toward the limit of 180 consecutive days in a calendar year.

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 is 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, 2 and 3. The referenced tables are available on the Program's website: ~~http://oregon.gov/DHS/ph/rps/index.shtml~~www.healthoregon.org/rps.

(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 due to the medical status of the patient or the inability of the patient to be left alone during the imaging procedure except as permitted under section (4) of this rule.

(16) Requirements for the operation of fluoroscopic X-ray equipment. The operation of fluoroscopic equipment shall be restricted to the following categories of properly trained operators:

(a) Radiologists;

(b) Non-Radiologist practitioners with proper training in the operation and use of fluoroscopic X-ray equipment;

(c) R.T.s, must be ARRT registered and in good standing with the Oregon Board of Medical Imaging ~~OBRT~~;

(d) R.P.A.s and R.R.A.s;

(e) ~~Technologists, who have successfully~~ completed an OBRT ~~approved program in radiologic technology as defined in ORS 688.405, may temporarily operate fluoroscopic equipment while waiting to take the A.R.R.T. registry examination:~~ Technologists, who have successfully completed an educational program in radiologic technology from an approved school as defined in ORS 688.405 may temporarily operate fluoroscopic equipment for up to one year while waiting to take the ARRT registry examination.

(A) The temporary period will expire when the individual has passed the registry examination and is considered an R.T.; or

(B) One year from the date when the technologist completed his/ her training, provided; and

(C) The technologist, while in the temporary status referred to in subsection (165)(e) of this rule, has a current temporary license issued by the Oregon Board of Medical Imaging.OBRT.

(17) Radiologists, R.A.s or R.P.A.s and R.T.s currently licensed in Oregon are considered to have met the training requirements in subsection (165)(l) of this rule.

(18) Fluoroscopic equipment operators who qualified to operate fluoroscopic X-ray equipment prior to April 11, 2005, will be considered as having met the training requirements in subsection (165)(l) of this rule.

(21) Facilities shall determine, or cause to be determined, the typical patient entrance exposure rate for their most common fluoroscopic examinations. The determination shall be made using an attenuation block as described in OAR 333-106-0005(78) of these rules using measurement protocol in compliance with OAR 333-106-0210 of these rules and expressed in Roentgens per minute (R/min.) or milliRoentgens per minute (mR/min.). In addition, these entrance exposure rates shall be posted in the room where fluoroscopic examinations are conducted so that they are readily available to administrators, X-ray operators, patients and practitioners.

333-106-0101, Diagnostic X-ray Systems

(7) Beam Quality:

(a) Half-Value Layer (HVL):

The HVL of the useful beam for a given X-ray tube potential shall not be less than the values shown in Table 4. If it is necessary to determine such HVL at an X-ray tube potential which is not listed in Table 4, linear interpolation or extrapolation may be made; The referenced table is available on the Program's website: www.healthoregon.org/rpshttp://www.oregon.gov/DHS/ph/rps/index.shtml

(A) The HVL required in subsection (7)(a) of this rule 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 5. The referenced table is available on the Program's website: www.healthoregon.org/rpshttp://www.oregon.gov/DHS/ph/rps/index.shtml

(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 relationship between temperature of the developer and development time indicated in Table 6 or the manufacturer's recommendations must be used with standard developing chemistry. The referenced table is available on the Program's website: www.healthoregon.org/rpshttp://www.oregon.gov/DHS/ph/rps/index.shtml

333-106-0110, Plan Review

When requestedired by the Authority, 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 must be availablebe submitted to the Authority for review, and approval. The required information is as set out in OAR 333-106-0120division 120.

(2) The Authority 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 reviewapproval 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 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08

333-106-0305, Radiation Exposure Control Devices

(4) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to five times the maximum exposure period (Tmax) minus the minimum exposure period (Tmin) when four timer tests are performed: (T)>=/- 5 (Tmax - Tmin).

333-106-0315, Exposure Reproducibility

The coefficient of variation of exposure shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to 5 times the maximum exposure (Emax) minus the minimum exposure (Emin). E ~~>=~~ 5 (Emax - Emin).

(3) Radiation Exposure Control (Timers). Means shall be provided to control the radiation exposure through the adjustment of exposure time in seconds, milliseconds (ms) or, number of pulses, or current/milliamps (mA), or the product of current and exposure time (mAs) or adjustment of kVp. In addition:

(a) Exposure Initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

(b) It shall not be possible to make an exposure when the timer is set to a "0" or "off" position if either position is provided;

(c) Exposure Indication. Means shall be provided for visual indication, observable at or from the operator's protected position, whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(d) Exposure termination.

(e) Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure time (T) shall be greater than or equal to five times the minimum exposure time (Tmax) minus the minimum exposure time (Tmin) when four timer tests are performed:

(T) ~~>=~~ 5 (Tmax Tmin).

(A) Means shall be provided to terminate the exposure at a preset, time interval, mAs, number of pulses, or radiation to the image receptor.

(B) An X-ray exposure control shall be incorporated into each system such that an exposure can be terminated by the operator at any time, except for exposures of 0.5 second or less.

(C) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "0".

(4) Radiation Exposure Control Location and Operator Protection. Each X-ray control must be located in such a way as to meet the following requirements:

(a) The exposure switch shall be able to be operated in a protected area, as defined in OAR 333-106-0005(80~~)(1)(a)(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.

(5) Exposure Reproducibility. The coefficient of variation shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to five times the maximum exposure (Emax) minus the minimum exposure (Emin): E ~~>=~~ 5 (Emax - Emin)

333-106-0370, Operator Requirements

(1) Computed Tomography (CT) X-ray systems shall be operated by individuals who:

(a) Are registered with the American Registry of Radiologic Technologists (A.R.R.T); and

(b) Have received additional CT system training; and

(c) Meet the clinical experience requirements for C.T. established by A.R.R.T.; and

(d) Are currently licensed by the Oregon Board of Medical Imaging.

(2) Individuals who are registered with the A.R.R.T. and credentialed as an R.T.(R) and (CT) are considered to have met the CT training requirement in 333-106-0370(1) of this rule and clinical experience requirement in subsection (1)(a) of this rule.

(3) Those individuals who have met the requirements of section (1) of this rule prior to the effective date of this rule are considered to have met subsection (1)(a) of this rule.

(4) Technologists operating CT systems must do so under the direction of a radiologist.

(5) Positron Emission-Computed Tomography (PET/CT) or Single Photon Emission-Computed Tomography (SPECT/CT) systems shall be operated by technologist licensed by the Oregon Board of Medical Imaging who are::

(a) Any registered radiographer with the credential R.T. (R); or

(b) Registered radiation therapist with the credential R.T. (T); and

~~(c)~~ Who are ~~currently licensed~~ by ~~the Oregon~~ Board of ~~Medical Imaging~~; or

(cd) Registered certified nuclear medicine technologist with the credentials R.T. (N); or

(de) Certified Nuclear Medicine Technologist (CNMT) by the Nuclear Medicine Technologist Certification Board (NMTCB).

(6) The individuals mentioned in section (5) of this rule must also have successfully completed appropriate additional education and training and demonstrated competency in the use and operation of PET/CT or SPECT/CT systems.

(7) Appropriate additional training is considered training that covers the topic areas outlined in the PET/CT curriculum developed by the Multi-Organizational Curriculum Project Group sponsored by the American Society of Radiologic Technologists and the Society of Nuclear Medicine Technologists, or equivalent training approved by the Authority and:

(a) Includes the content specified in the PET/CT curriculum for the area(s) that the individual is not already trained or certified in; or

(b) Individuals meeting the requirements of section (5) of this rule and who have successfully completed training that the Authority has evaluated and judged to be substantially equivalent to that specified in subsection (7)(a) of this rule.

(8) R.T.(N)s or CNMTs who have become certified in Computed Tomography through the American Registry of Radiologic Technologists are considered to have met the training requirements in section (5) of this rule.

(9) Technologists operating PET/CT or SPECT/CT systems must do so under the direction of an authorized user licensed to perform imaging and localization studies in accordance with OAR 333-116-0320 of these rules.

333-106-0720, Quality Assurance Program

(5) Equipment quality control tests frequency. The registrant shall ensure that the following quality control test are performed when applicable equipment or components are initially installed or replaced and performed thereafter at least as often as the frequency specified in Table 7. The referenced table is available on the Program's website: www.healthoregon.org/rpshttp://www.oregon.gov/DHS/ph/rps/index.shtml

333-116-0040, License Amendments

A licensee must apply for and must receive a license amendment:

(1) Before receiving or using radioactive material for a method or type of medical use not permitted by the license issued under this division;

(2) Before permitting anyone, except a visiting ~~authorized user described in OAR 333-116-0110~~, to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license except:. A visiting authorized user is an ~~individual who:~~

(a) ~~Meets the requirements of OAR 333-116-0660, 333~~-116-0670, 333-116-0680, ~~333-116-0683, 333-116-0687, 333-116-0690, 333-116-0700, 333-116-0710~~ or 333-116-0720, ~~333-116-0740 and 333-116-0760 of these rules; or~~ For an authorized user, an individual who meets the requirements in OAR 333-116-0760, 333-116-0660, 333-116-0670, 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0690, 333-116-0710 and 333-116-0720

(b) For an authorized nuclear pharmacist; an individual who meets the requirements in OAR 333-116-0910 and 333-116-0760.Is a nuclear pharmacist ~~who meets the requirements in OAR 333~~-116-0910 and 333-116-0760; or

(c) For an authorized medical physicist; an individual who meets the requirements in OAR 333-116-0905 and 333-116-0760.~~Is a medical physicist, who meets the requirements in OAR 333-116-0730, 333-116-0740, 333-116-0760 and 333-116-0905; or~~

(d) An individual: Is identified as an authorized user, ~~or an~~ authorized nuclear pharmacist, or an authorized medical physicist on a Nuclear Regulatory Commission or Agreement State license that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy,, respectively, or

(3) Before changing the Radiation Safety Officer except as provided in OAR 333-116-0090;~~or Teletherapy Physicist~~;

(4) Before receiving radioactive material in excess of the amount authorized on the license;

(5) Before adding to or changing the areas of use or mailing address identified on the license; and

(6) Before revising procedures required by OAR 333-116-0495, 333-116-0580, 333-116-0583, and 333-116-0587 as applicable where such revision reduces radiation safety, ~~changing statements, representations and procedures which are~~ incorporated ~~into the license~~.

333-116-0050, Notifications

(1) A licensee must provide to the Authority a copy of the board certification, the Nuclear Regulatory Commission or Agreement State license, or the permit issued by a licensee of Broad Scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, or an authorized nuclear pharmacist, pursuant to OAR 333-116-0040(2)(a) through (d).

333-116-0090, ~~Statement of~~ Authorityies and Responsibilities for the Radiation Protection Program

(1) In addition to the radiation protection program requirements of OAR 333-120-0020, a licensee's management must approve in writing:

(a) Requests for a license application, renewal, or amendment before submittal to the Authority;

(b) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(c) Radiation protection program changes that do not require a license amendment and are permitted under OAR 333-116-0123.

~~333-116-0405, Training for Use of Sealed Sources for Diagnosis.~~

~~Except as provided in OAR 333-116-0710, the licensee must require the authorized user of a diagnostic sealed source for use in a device authorized under OAR 333-116-0400 to be a physician,~~ dentist, or podiatrist ~~who:~~

~~(1) Is certified~~ by a specialty board ~~whose certification process includes all~~ of the requirements ~~in~~ sections ~~(2) and (3)~~ of this rule and whose ~~certification~~ has been ~~recognized by~~ the Nuclear ~~Regulatory Commission or an Agreement~~ State; or

(2) Has ~~completed eight hours~~ of classroom ~~and laboratory~~ training in ~~basic radionuclide~~ handling techniques ~~specifically applicable~~ to the ~~use of the device~~. The training ~~must include~~:

~~(a)~~ Radiation physics and ~~instrumentation~~;

(b) Radiation ~~protection~~;

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

(d) ~~Radiation biology; and~~

(e) Has ~~completed training in~~ the use of the ~~device for the~~ uses requested.

~~Stat. Auth.:~~ ORS 453.635
~~Stats. Implemented: ORS 453.605 - 453.807~~
~~Hist.:~~ PH 12-2006, ~~f. & cert. ef. 6-16-06~~; PH 4-2007, ~~f. & cert.~~ ef. 3-1-07; ~~PH 11-2008, f. &~~ cert. ef. ~~9-15-~~08

333-116-0640, Radiation Safety Officer Training and Experience Requirements

Except as provided in OAR 333-116-0740~~0650~~, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in OAR 333-116-0090 to be an individual who:

(1) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in sections (4) and (5) of this rule. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a)(A) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(B) Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

(C) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(b)(A) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(B) Have two years of full-time practical training and/or supervised experience in medical physics:

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(ii) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in OAR 333-116-0740, 333-116-0670 orand 333-116-0680;

(C) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(2) Has completed a structured educational program consisting of 200 hours of classroom and laboratory training as follows:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology;

(e) Radiopharmaceutical chemistry;

(f) Radiation dosimetry; and

(g) One year of full time experience in radiation safety at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Authority, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license that authorizes similar type(s) of medical use of radioactive material involving the following:

(A) Shipping, receiving, and performing related radiation surveys;

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

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material; and

(G) Disposing of radioactive material; or

(3)(a) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under OAR 333-116-0905(1) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in sections (4) and (5) of this rule; or

(b) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and

(4) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in section (5) and in paragraphs (1)(a)(A) and (1)(b)(B) or paragraphs (1)(b)(A) and (1)(b)(B) or section (2) or subsections (3)(a) or (3)(b) of this rule, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

(5) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

333-116-0660, Training for Uptake, Dilution or Excretion Studies

Except as provided in OAR 333-116-0740, the licensee shall ~~must~~ require the authorized user of a radiopharmaceutical listed in OAR 333-116-0300 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in section (1~~3~~) of this rule (The names of board certifications recognized by the NRC or an Agreement State are posted on the NRC's website). To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Complete 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include paragraphs (3)(a)(A) through (3)(b)(F) of this rule; and

(b) Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in radiation safety, radionuclide handling and quality control; or

(2) Is an authorized user under OAR 333-116-0670 or, 333-116-0680 and 333-116-0740 or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(3) Has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include:

(a) Classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in this rule, OAR 333-116-0660, 333-116-0670, 333-116-0680 and 333-116-0740 or Nuclear Regulatory Commission or equivalent Agreement State requirements, involving:

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

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

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

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

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

(F) Administering dosages of radiopharmaceutical drugs to patients or human research subjects; and

(4) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this rule, OAR 333-116-0660, 333-116-0670, and 333-116-0680, 333-116-0740 or Nuclear Regulatory Commission or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection (1)(a) or section (3) of this rule and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under OAR 333-116-0300.

333-116-0670, Training for Imaging and Localization Studies

Except as provided in OAR 333-116-0740, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under OAR 333-116-0320 to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in section 3 of this rule and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State; or ~~has been recognized by the Commission or an Agreement State and who meets the requirements in section (3) of this rule. (The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's website).~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies as described in subsection (3)(a) through paragraph (2)(b)(G) of this rule; and

(b) Pass an examination administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling and quality control; or

(2) Is an authorized user under OAR 333-116-0680 and meets the requirements in OAR 333-116-0670(3)(b)(G) or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(3) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies.

(a) The training and experience must include at a ~~minimum: (a) classroom~~minimum classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

(b) Work experience, under the supervision of an authorized user, who meets the requirements in this rule or OAR 333-116-0670, 333-116-0680, 333-116-0740 and 333-116-0670(3)(b)(G) or equivalent Nuclear Regulatory Commission or Agreement State requirements, involving:

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

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

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

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

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

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radiopharmaceutical drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radiopharmaceutical drugs; and

(4) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this rule or OAR 333-116-0670(3)(b)(G), 333-116-0680, 333-116-0740 or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection (1)(a) or section (3) of this rule and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under ~~this rule or~~ OAR 333-116-0300 and 333-116-0320, 0680.

333-116-0680, Training for Use of Unsealed Byproduct Material for Which a Written Directive is Required ~~Therapeutic Use of Radiopharmaceuticals~~

Except as provided in OAR 333-116-0740, the licensee must require an authorized user of unsealed byproduct material for the uses authorized under OAR 333-116-0360 to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in section (2) of this rule and whose certification has been recognized by the Commission or an Agreement State; or

(2)~~(a)~~ Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include:

(aA) Classroom and laboratory training in the following areas:

(Ai) Radiation physics and instrumentation;

(B~~ii~~) Radiation protection;

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

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

(Ev) Radiation biology; and

(b~~B~~) Work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0740, ~~sections (1)~~ and (2) of this rule, or Nuclear Regulatory Commission or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in section (2) of this rule, must have experience in administering dosages in the same dosage category or categories (i.e., OAR 333-116-0680(2)(a)(A) as the individual requesting authorized user status. The work experience must involve:

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

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

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

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

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

(F~~vi~~) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radiopharmaceutical drugs; and

(G~~vii~~) Administering dosages of radiopharmaceutical drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

(iI) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

(ii~~II~~) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

NOTE: Experience with at least three cases in Category (vii)(2) also satisfies the requirement in Category (vii)(A).

(iii~~III~~) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or

(ivIV) Parenteral administration of any other radionuclide; and

(c~~b~~) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (2)(a) and (2)(b)(G) or (2)(a) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under OAR 333-116-0360. The written attestation ~~certification~~ must be signed by a preceptor authorized user who meets the requirements in sections OAR 333-116-0740, 333-116-0680 (1), (2), of ~~this rule~~ or equivalent Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user, who meets the requirements in section (2) of this rule, must have experience in administering dosages in the same dosage category or categories (i.e., OAR 333-116-0680(2)~~(a)~~(bB)(Gvii)(iI), (ii~~II~~), (iii~~III~~), or (ivIV) as the individual requesting authorized user status.

333-116-0683, Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 millicuries)

Except as provided in OAR 333-116-0740, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive and the total treatment quantity is less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in section (3) of this rule and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State; or

(2) Is an authorized user under OAR 333-116-0680 ~~section (1) or (2)~~ for uses listed in OAR 333-116-0680 or 333-116-0687, or equivalent Agreement State requirements; or

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

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0740 or equivalent Nuclear Regulatory Commission or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in OAR 333-116-0680(2) must have experience in administering dosages as specified in OAR 333-116-0680(2)(ba)(~~B~~)(Gvii)(~~i~~) or (ii~~H~~). The work experience must involve:

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

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

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

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

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

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

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (3)(a) and (3)(b) of this rule and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under OAR 333-116-0360. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR ~~333-116-~~0680, 333-116-0740, 333-116-0680, 333-116-0683, 333-116-0687(1) and ~~(2)~~, of this rule, ~~333-116-0687,~~ or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized

user, who meets the requirement in OAR 333-116-0680(2), must also have experience in administering dosages as specified in OAR 333-116-0680(2)(ba)(GB)(~~vii~~)(il) or (iiH).

333-116-0687, Qualifications for Authorized User for Oral Administration When a Written Directive is Required

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

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in subsection (3)(a) (3)(b) and (3)(c) of this rule and whose certification has been recognized by the Commission or an Agreement State; or

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

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

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0687, 333-116-0740 ~~section (1) or (2)~~, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in OAR 333-116-0680(2)(a), must have experience in administering dosages as specified in OAR 333-116-0680. The work experience must involve:

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

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

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

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

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

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

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (3)(a) and (3)(b) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under OAR 333-116-0360. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0680, 333-116-0687, 333-116-0740 ~~section~~ (1) or (2), or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in OAR 333-116-0680(2)(a), must have experience in administering dosages as specified in OAR 333-116-0680(2)(a)(B)(vii)(II).

333-116-0690, Training for Therapeutic Use of Brachytherapy Source

Except as provided in OAR 333-116-0740, the licensee must require the authorized user using manual brachytherapy sources specified in OAR 333-116-0420 for therapy to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in section (2) of this rule and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State; or

(a) Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by ~~diplomates~~diplomats of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(2)~~(1)~~ Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(a~~A~~) 200 hours of classroom and laboratory training in the following areas:

(A~~i~~) Radiation physics and instrumentation;

(B~~ii~~) Radiation protection;

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

(D~~iv~~) Radiation biology; and

(b~~B~~) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this rule or equivalent Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving:

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

(B~~ii~~) Checking survey meters for proper operation;

(C~~iii~~) Preparing, implanting, and removing brachytherapy sources;

(D~~iv~~) Maintaining running inventories of material on hand;

(E~~v~~) Using administrative controls to prevent a medical event involving the use of byproduct material; and

(F~~vi~~) Using emergency procedures to control byproduct material; and

(ch) Has ~~obtained~~ completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this rule OAR 333-116-0740, 333-116-0690, or equivalent Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (2)(a)(B) of this rule; and

(c) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this rule OAR 333-116-0740, 333-116-0690, or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection (1)~~(a)~~, or subsections (2)(a) and (2)(b) of this rule and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under OAR 333-116-0420.

333-116-0700, Training for Ophthalmic Use of Strontium-90

Except as provided in OAR 333-116-0740, the licensee must require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

(1) Is an authorized user under OAR 333-116-0690 or equivalent Nuclear Regulatory eCommission or Agreement State requirements; or

(2)~~(a)~~ Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy.

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Radiation biology; and

(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

(A) Examination of each individual to be treated;

(B) Calculation of the dose to be administered;

(C) Administration of the dose;

(D) Follow up and review of each individual's case history; and

(E) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in OAR 333-116-0740, 333-116-0690, 333-116-0700~~this rule~~, or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in subsections ~~(1) and~~ (2)(a) of this rule and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

333-116-0715, Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive

Except as provided in OAR 333-116-0740, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

(1) Is an authorized user under OAR 333-116-~~03~~600680 for uses listed in OAR 333-116-0680(2)(b)(G)(iii) or 333-116-0680(2)(b)(G)iv) or equivalent Agreement State requirements; or

(2) Is an authorized user under OAR 333-116-0690 or 333-116-0720, or equivalent Agreement State or Nuclear Regulatory Commission requirements and who meets the requirements in section (4) of this rule; or

(3) Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under OAR 333-116-0690 or 333-116-0720, and who meets the requirements in section (4) of this rule.

(4)(a) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required.

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0680 333-116-0715, 333-116-0740 or this rule, or equivalent Nuclear Regulatory Commission or Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in OAR 333-116-0680 must have experience in administering dosages as specified in OAR 333-116-0680(2)(ba)(B)(G~~vii~~)(iii) and/or 333-116-0680(2)(b)(G)(iv). The work experience must involve:

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

(B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

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

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

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

(F) Administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least three cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in sections (2) or (3) of this rule,subsections (4)(b) or (4)(c) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0680, 333-116-0715, 333-116-0740 or this rule, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in OAR 333-116-0680, must have experience in administering dosages as specified in OAR 333-116-0680(2)(ba)(GB)(vii)(iii) and/or 333-116-0680(2)(b)(G)(iv).

333-116-0720, Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Except as provided in OAR 333-116-0740, the licensee must require the authorized user of a sealed source specified in OAR 333-116-0480 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission (NRC) or an Agreement State and who meets the requirements in subsection (2)(c) and section (3) of this rule. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(2)(a) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit. ~~that includes:~~

(a) Which includes the following:

(A) 200 hours of classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

(B) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0740, 333-116-0720,this rule or equivalent Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving:

(i) Reviewing full calibration measurements and periodic spot-checks;

(ii) Preparing treatment plans and calculating treatment doses and times;

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

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(v) Checking and using survey meters; and

(vi) Selecting the proper dose and how it is to be administered; and

(b) Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in OAR 333-116-0740, 333-116-0720,this rule or equivalent Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (2)(a)(B) of this rule; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (1)(a) or (2)(a) and (2)(b), and section (3) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0740, 333-116-0720, this rule or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(3) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

333-116-0740, Training for Experienced Authorized User, Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Nuclear Pharmacist or Authorized Nuclear Pharmacist

(1) An individual identified as a Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist on a Nuclear Regulatory Commission or Agreement State license before July 1, 2006 ~~who perform only those methods of use for which they were authorized on that date~~ need not comply with the training requirements of OAR 333-116-0640, through 333-116-0760 ~~and~~ 333-116-0905 or 333-116-0740 through 333-116-0915.

(2) Practitioners of the healing arts identified as authorized users for the human use of radioactive material on a Authority, Nuclear Regulatory Commission or Agreement State or Licensing State license before July 1, 2006 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of or use under OAR 333-116-0300640 through 333-116-04800760.

(3) Individuals who need not comply with training requirements as described in this rule may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

333-116-0880, Training and Experience for PET, PET/CT and SPECT/CT Personnel

(1) Pharmacy or chemistry personnel must have 40 extra hours above Nuclear Pharmacy requirements and 40 hours specific to PET. The 40 hours should be divided equally between didactic and practical applications.

(2) Authorized users who meet training requirements for human use in OAR 333-116-0670 must complete an additional 40 hours at an accepted PET training center.

(3) Technical personnel working under an authorized user must have basic radiation safety training, plus 40 additional hours specific to PET.

(4) Positron Emission-Computed Tomography (PET/CT) or Single Photon Emission-Computed Tomography (SPECT/CT) systems must be operated by technologists licensed by the Oregon Board of Medical Imaging who are:

(a) Any registered radiographer with the credential R.T. (R); or

(b) Registered radiation therapist with the credential R.T. (T); ~~and~~

~~(c) Who are currently licensed by the Oregon Board of Radiologic Technology; or~~

(cd) Registered certified nuclear medicine technologist with the credentials R.T. (N); or

(de) Certified Nuclear Medicine Technologist (CNMT) by the Nuclear Medicine Technologist Certification Board (NMTCB).

(5) The individuals mentioned in section (4) of this rule must also have successfully completed appropriate additional education and training and demonstrated competency in the use and operation of PET/CT or SPECT/CT systems.

333-116-0905, Training for Authorized Medical Physicist

Except as provided in OAR 333-116-0740, the licensee shall require the authorized medical physicist to be an individual who:

(1) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in subsection (2)(b) and section (3) of this rule. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(b) Have two years of full-time practical training and/or supervised experience in medical physics:

(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(B) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in OAR 333-116-0650, ~~333-116-0720~~, 333-116-0690 or ~~,~~ 333-116-0720 or ~~333-116-0740~~; and

(c) Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(2)~~(a)~~ Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization.

(a) This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services and must include:

(A) Performing sealed source leak tests and inventories;

(B) Performing decay corrections;

(C) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(D) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(b) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections ~~(1)~~(a) ~~and (1)(b) and~~ section (3) and subsections (1)(a) and (1)(b) ~~of this~~ rule, or subsection (2)(a) and section (3) of this rule, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in this rule, in OAR 333-116-0905, 333-116-0650~~10 CFR part 35~~ or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(3) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training

requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

333-119-0040, Construction and Operation of Tanning Facilities

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

(1) Physical facilities:

(a) All tanning facilities shall be equipped with convenient toilet facilities and dressing rooms. Such toilet facilities shall include a water closet and hand washing sinks. Such toilet and dressing rooms shall be properly maintained, as well as meet all state and local codes.

(b) All areas of the tanning facility shall be ventilated with at least six air changes per hour or as required by local code.

(c) Tanning booth temperature shall be maintained below 100 degrees Fahrenheit (38 degrees Centigrade) during booth operation.

(d) The tanning device shall meet the National Fire Protection Association's National Electrical Code, or be approved by the Underwriter Laboratories (UL) or Electrical Testing Laboratories (ETL).

(e) Except as otherwise noted by the Authority, each tanning facility shall be constructed, operated and maintained in accordance with applicable city, county and state codes.

(f) Clean sanitary towels shall be provided to all patrons using tanning facilities.

(g) A hamper or receptacle must be provided for all soiled towels and linen.

(h) No pets or animals are permitted in tanning facilities other than service animals.

333-119-004, 1(2) Cleaning and Sanitation~~maintenance~~:

(1a) All areas of the tanning facility, including tanning devices, equipment and apparatus, shall be maintained in a clean and sanitary manner by the facility operator, ~~in accordance with manufacturer's instructions.~~

(2b) The tanning device(s) and protective eyewear shall be cleaned with an ~~approved sanitizer~~ after each use by the facility operator in accordance with the manufacturer's instructions. ~~A listing of approved sanitizers is maintained by the Authority and is available upon request of registrants. This listing may change at any time due to updating of state or federal sanitation guidelines. The operator shall use a sanitizer that sanitizes to a safe level of microorganisms as required by these rules.~~

(3) A clean paper or cloth towel shall be used each time the tanning device is cleaned and sanitized.

(4) The sanitizer, ~~as described in these rules~~, is ~~one~~ specifically manufactured for sanitizing ultraviolet light emitting equipment and protective eyewear, and that it does not damage the acrylic lamp covers of the device.

(a) The Ultraviolet Light produced by the tanning device itself is not considered an adequate sanitizing agent.

(5c) Protective eyewear and tanning devices shall be sanitized after each use with a sanitizing agent, that is registered by EPA and approved by the Authority using the following procedures:

(A) Immerse protective eyewear for at least one minute in a clean solution (or spray tanning device acrylic surfaces and allow at least one to two minutes of surface contact time with a solution) containing at least 400 ppm (parts per million) of available quaternary ammonium compound at a temperature of at least 75 degrees Fahrenheit; or

(B) Immerse protective eyewear for at least one minute in a clean solution (or spray tanning device acrylic surfaces and allow at least one to two minutes of surface contact time with the solution) containing at least 100 ppm (parts per million) of available chlorine as a hypochlorite and at a temperature of at least 75 degrees Fahrenheit.

(d) A test kit that accurately measures the concentration of the sanitizing solution in parts per million (ppm) shall be used to measure the strength of the sanitizing solution when the concentrate and water dilution is initially prepared and at least weekly thereafter to ensure sufficient strength of the sanitizing solution. If a suitable test kit is not available for an approved sanitizer, the laboratory analysis data shall be provided by the product manufacturer, and a copy of it be on file with the Authority. Written procedures at the facility using sanitizer shall include proper mixing and handling instructions to assure proper concentration of the sanitizer.

(6) An operator cannot require the consumer to sanitize the tanning equipment or protective eyewear and shall not post any signs requesting such sanitation be performed by the consumer.

(7) The sanitizer must contain a concentration of Quaternary Ammonium between 400ppm-800ppm. A test kit that accurately measures the concentration of the sanitizing solution in parts per million (ppm) shall be used to measure the strength of the sanitizing solution when the concentrate and water dilution is initially prepared and tested weekly thereafter to ensure sufficient strength remains within the sanitizing solution.

(8) A written policy for cleaning and sanitizing will be available for employees and the consumer. Written policies need to address the following:

(a) Tanning device manufacturer's recommended sanitizer solution and cleaning guidelines.

(B) If the manufacturer does not recommend a specific sanitizer then the written policy will contain the name of the sanitizer that is being used on the tanning device and eyewear.

(b) Materials Safety Data Sheets referring to the sanitizing agent used by the operator.

(c) Location of the sanitizer and the application instructions.

(e) Clean sanitary towels shall be provided to all patrons using tanning facilities.

(f) A hamper or receptacle must be provided for all soiled towels and linen.

(g) No pets or animals are permitted in tanning facilities other than service animals.

333-119-0080, Training of Personnel

(1) The registrant shall maintain documentation to verify that all tanning device operators are adequately trained in the following:

(a) The rules of this division;

(b) Procedures for correct operation of the tanning facility and tanning devices;

(c) Recognition of injury or overexposure to Ultraviolet radiation;

(d) The tanning device manufacturer's procedures for operation and maintenance of the tanning devices;

(e) The determination of skin type of customers and appropriate determination of duration of exposure to registered tanning devices;

(f) Emergency procedures to be followed in case of injury; and

(g) Potential photosensitizing foods, cosmetics, and medications.

(2) The registrant shall ensure that tanning devices are operated only while an adequately trained operator is present at the tanning facility.

(3) ~~On or after July 1, 2011,~~ All operators of registered tanning devices must successfully complete a Authority approved tanning training course in the State of Oregon prior to commencement of tanning operations.

~~(4) Prior to July 1, 2011:~~

~~(a)~~ At least one ~~owner, manager,~~ or operator ~~from each~~ tanning ~~facility with four~~ or less ~~tanning~~ devices, shall ~~successfully~~ complete one ~~of the vendor~~-provided ~~formal training~~ courses authorized by ~~the Authority.~~

~~(b) At least~~ two operators ~~from each~~ tanning facility ~~with five~~ or more ~~tanning devices~~ shall ~~successfully~~ complete one of ~~the vendor~~ provided ~~formal training~~ courses ~~authorized~~ by the ~~Authority.~~

(c) Training ~~of other full or~~ part-time operators ~~shall~~ be by means ~~of a~~ Authority-~~authorized and~~ vendor-provided ~~training~~ course, or by ~~materials~~ received by ~~an owner or~~ primary operator ~~from a~~ Authority-~~authorized and~~ vendor-provided ~~training~~ course, ~~or by a Authority~~-authorized ~~correspondence course.~~

~~(5)~~ Staff training shall ~~be documented~~ by the ~~facility owner~~ or operator ~~and include~~ copies ~~of training~~ certificates.

333-120-0630, Determination of Prior Occupational Dose

(1) For each individual likely to receive, in a year, an occupational dose requiring monitoring pursuant to OAR 333-120-0210, the licensee or registrant must:

(a) Determine the occupational radiation dose received during the current year; and

(b) Attempt to obtain the records of lifetime cumulative occupational radiation dose.

(2) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant must determine:

(a) The internal and external doses from all previous planned special exposures; and

(b) All doses in excess of the limits (including doses received during accidents and emergencies) received during the lifetime of the individual.

(3) In complying with the requirements of section (1) or 2 of this rule, a licensee or registrant may:

(a) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual may have received during the current year; or

(b) Accept, as the record of lifetime cumulative radiation dose, an up-to-date NRC~~Authority~~ Form 4~~Y~~, or equivalent, signed by the individual and counter-signed by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee or registrant); and

(c) Obtain reports of the individual's dose equivalent(s) from the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee or registrant) by telephone, telegram, electronic media, or letter. The licensee or registrant must request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(4) The licensee or registrant must record the exposure history, as required by section (1) of this rule, on NRC Form 4~~Authority Form Y~~, or other clear and legible record, of all the information required on NRC Form 4~~Y~~. The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant must use the dose shown in the report in preparing NRC~~Authority~~ Form 4Y. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant must place a notation on Authority Form Y indicating the periods of time for which data are not available.

NOTE: ~~Licensees are not required to reevaluate~~ the separate ~~external dose equivalents and~~ internal committed ~~dose equivalents or intakes of~~ radionuclides assessed ~~under OAR 333-104~~ (repealed 1994). Further, occupational ~~exposure histories obtained~~ and recorded on Authority ~~Form Y before~~ January 1, 1994, would ~~not have included effective dose~~ equivalent, but may be ~~used in the absence of~~ specific information ~~on the intake of radionuclides by~~ the individual.

(5) If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant must assume:

(a) In establishing administrative controls under OAR 333-120-0100(6) for the current year, that the allowable dose limit for the individual is reduced by 1.25 rem (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

(b) That the individual is not available for planned special exposures.

(6) The licensee or registrant must retain the records on NRC~~Authority~~ Form 4~~Y~~ or equivalent until the Authority terminates each pertinent license or registration requiring this record. The licensee or registrant must retain records used in preparing NRC~~Authority~~ Form 4~~Y~~ in accordance with 333-100-0057.

333-120-0730, Reports of Planned Special Exposures and Individual Monitoring

(1) The licensee must submit a written report to the Authority within 30 days following any planned special exposure conducted in accordance with OAR 333-120-0150 informing the Authority that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by OAR 333-120-0640.

(2) The following licensees must have available for inspection by the Authority ~~submit~~ a written report ~~to~~ the Authority ~~on or before~~ April 30 ~~of each year,~~ documenting results of individual monitoring carried out by the licensee for each individual for whom monitoring was required pursuant to OAR 333-120-0210 during that year.

333-123-0005, Definitions

(18) "Electronic brachytherapy" means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.

(19) "Electronic brachytherapy device" means the system used to produce and deliver therapeutic radiation including the x-ray tube, the control mechanism, the cooling system, and the power source.

(20) "Electronic brachytherapy source" means the x-ray tube component used in an electronic brachytherapy device.

333-123-0055,Electronic Brachytherarpy

(1) Electronic brachytherapy devices shall be exempt from the requirements in OAR 333-123-0025.

(a) An electronic brachytherapy device that does not meet the requirements of this rule shall not be used for irradiation of patients; and

(b) An electronic brachytherapy device shall only be utilized for human use applications specifically approved by the U.S. Food and Drug Administration (FDA) unless participating in a research study approved by the Agency.

(2) Each facility location authorized to use an electronic brachytherapy device shall possess calibrated portable radiation measurement survey instrument capable of measuring dose rates over the range 10 µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with OAR 333-123-0100 for the applicable electronic brachytherapy source energy.

333-123-0060, Facility Design Requirements for Electronic Brachytherapy Devices

(1) In addition to shielding adequate to meet the requirements of division 120 of this chapter, the treatment room shall meet the following design requirements:

(a) If applicable, provision shall be made to prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room; and

(b) Access to the treatment room shall be controlled by a door at each entrance; and

(c) Each treatment room shall have provisions to permit communication and visual observation of the patient from the treatment control panel during the irradiation from an electronic brachytherapy device.

(2) Electronic brachytherapy devices capable of operating at or below 50 kV, radiation, shielding for the staff in the treatment room shall be available, either as a portable shield or as localized shielded material around the treatment site.

(3) For electronic brachytherapy devices capable of operating at greater than 150 kV,

(a) The control panel shall be located outside the treatment room; and

(b) Electrical interlocks shall be provided for all doors providing entrance into the treatment room that will:

(A) Prevent the operator from initiating the treatment cycle if a door remains open.

(B) Cause the source to be shielded when an entrance door is opened.

(C) Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.

333-123-0065, Electrical Safety for electronic Brachytherapy Devices

(1) The high voltage transformer shall be electrically isolated to prevent electrical and magnetic interference with the surrounding environment and ancillary equipment.

(2) The high voltage transformer shall be isolated from personnel (e.g., operator) and the environment by a protective housing that can only be accessed through a cover requiring a tool for access or with electrical interlocks to prevent operation while open.

(3) The high voltage transformer shall have appropriate safety labels warning personnel of potential electrical shock and/or heat related injuries.

(4) Equipment manufactured shall be in compliance with the most current revision of the following International Electrotechnical Commission (IEC) Documents.

(a) IEC 60601-1:1998+A1+A2:1995;
(b) IEC 60601-1-2:2001;
(c) IEC 60601-2-8:1999; and
(d) IEC 60601-2-17:2004.

333-123-0070, Control Panel Functions

(1) The control panel must be designed to provide:

(a) An indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible; and

(b) An indication of whether x-rays are being produced; and

(c) A means for indicating electronic brachytherapy source potential and current; and

(d) The means for terminating an exposure at any time; and

(e) An access locking control device that will prevent unauthorized use of the electronic brachytherapy device.

333-123-0075

Timer

1. An irradiation control device timer shall be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor.

(a) A timer shall be provided at the treatment control panel. The timer shall indicate planned setting and the time elapsed or remaining; and

(b) The timer shall not permit an exposure if set at zero; and

(c) The timer shall be a cumulative device that activates with an indication of "BEAM-ON" 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; and

(d) The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation; and

(e) The timer shall permit setting of exposure times as short as 0.1 second; and

(f) The timer shall be accurate to within one (1) percent of the selected value or 0.1 second, whichever is greater.

333-123-0080, Medical Physicist

(1) A Qualified Medical Physicist that meets the requirements of OAR 333-123-0015 is required in facilities having electronic brachtherapy devices. The Medical Physicist is responsible for:

(a) Evaluation of the output from the electronic brachtherapy source;

(b) Generation of the necessary dosimetric information;

(c) Supervision and review of treatment calculations prior to initial treatment of any treatment site;

(d) Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in sections (1)(a) through (1)(f) of this rule and OAR 333-123-0100;

(e) Consultation with the Radiation Therapy Physician in treatment planning as needed; and

(f) Performing calculations and assessments regarding patient treatments that may constitute a misadministration.

(2) For the Qualified Medical Physicist not located at the facility, written procedures shall be established on how the Qualified Medical Physicist is to be contacted for problems or emergencies. The written procedures must address actions to be taken until the Qualified Medical Physicist can be contacted.

333-123-0085, Operating Procedures

(1) Only individuals approved by the Radiation Therapy Physician, Radiation Safety Officer, or Qualified Medical Physicist shall be present in the treatment room during treatment.

(2) Electronic brachytherapy devices shall not be made available for medical use unless the requirements of OAR 333-123-0010(4), 333-123-0090 and 333-123-0095 have been met.

(3) The electronic brachytherapy device shall be inoperable, either by hardware or password, when unattended by qualified staff or service personnel.

(4) During operation, the electronic brachytherapy device operator shall monitor the position of all persons in the treatment room, and all persons entering the treatment room, to prevent entering persons from unshielded exposure from the treatment beam.

(5) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

(6) Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation. These procedures shall include:

(a) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and

(b) The names and telephone numbers of the Radiation Therapy Physician, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.

(7) A copy of the current operating and emergency procedures shall be physically located at the electronic brachytherapy device control console.

(a) For control consoles that are integral to the electronic brachytherapy device, the required procedures shall be kept where the operator is located during electronic brachytherapy device operation.

(8) Instructions shall be posted at the electronic brachytherapy device control console[1] to inform the operator of the names and telephone numbers of the authorized users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.

(9) The Radiation Safety Officer, or designee, and a Radiation Therapy Physician shall be notified as soon as possible if the patient has a medical emergency, suffers injury or dies. The Radiation Safety Officer or the Qualified Medical Physicist shall inform the manufacturer of the event.

333-123-0090, Safety Precautions for Electronic Brachytherapy Devices

(1) A Qualified Medical Physicist shall determine which persons in the treatment room require monitoring when the beam is energized.

(2) A Radiation Therapy Physician and a Qualified Medical Physicist shall be physically present during the initiation of all patient treatments involving the electronic brachytherapy device.
(3) A Qualified Medical Physicist and either an authorized user or a Radiation Therapy Physician or electronic brachytherapy device operator, under the supervision of an authorized user, who has been trained in the operation and emergency response for the electronic brachytherapy device, shall be physically present during continuation of all patient treatments involving the electronic brachytherapy device.

(4) When shielding is required by OAR 333-123-0060, the electronic brachytherapy device operator shall use a survey meter to verify proper placement of the shielding immediately upon initiation of treatment. Alternatively, a Qualified Medical Physicist shall designate shield locations sufficient to meet the requirements of division 120 of this chapter for any individual, other than the patient, in the treatment room.

(5) All personnel in the treatment room are required to remain behind shielding during treatment. A Qualified Medical Physicist shall approve any deviation from this requirement and shall designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

333-123-0095, Electronic Brachytherapy Source Calibration Measurements

(1) Calibration of the electronic brachytherapy source output for an electronic brachytherapy device shall be performed by, or under the direct supervision of a Qualified Medical Physicist.

(2) Calibration of the electronic brachytherapy source output shall be made for each electronic brachytherapy source, or after any repair affecting the x-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks.

(3) Calibration of the electronic brachytherapy source output shall utilize a calibrated dosimetry system as described in OAR 333-123-0100(5). The dosimetry system shall have been calibrated at the applicable electronic brachytherapy source energy.

(4) Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:

(a) The output within two percent of the expected value, if applicable, or determination of the output if there is no expected value.

(b) Timer accuracy and linearity over the typical range of use.

(c) Proper operation of back-up exposure control devices.

(d) Evaluation that relative dose distribution about the source is within five percent of that expected????? (expected what).

(e) Source positioning accuracy to within 1 millimeter within the applicator.

(5) Calibration of the x-ray source output shall be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol shall be followed.

(6) The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include: the date of the calibration; the manufacturer's name, model number and serial number for the electronic brachytherapy device and a unique identifier for its electronic brachytherapy source; the model numbers and serial numbers of the instrument(s) used to calibrate the electronic brachytherapy device; and the name and signature of the Qualified Medical Physicist responsible for performing the calibration.

333-123-0100, Periodic and Day-of-Use Quality Assurance Checks for Electronic Brachytherapy Devices

(1) Quality assurance checks shall be performed on each electronic brachytherapy device subject to this rule.

(a) At the beginning of each day of use; and

(b) After each x-ray tube installation.

(2) The registrant shall perform periodic quality assurance checks required by this rule in accordance with procedures established by the Qualified Medical Physicist.

(3) To satisfy the requirements of this rule, radiation output quality assurance checks shall include as a minimum:

(a) Verification that output of the electronic brachytherapy source falls within three percent of expected values, as appropriate for the device, as determined by:

(A) Output as a function of time, or

(B) Output as a function of setting on a monitor chamber.

(b) Verification of the consistency of the dose distribution to within three percent (3%) of that found during calibration required by OAR 333-123-0095.

(c) Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within one (1) mm.

(4) The registrant shall use a dosimetry system that has been intercompared within the previous twelve (12) months with the dosimetry system described in OAR 333-123-0100(5) to make the quality assurance checks required in within this rule.

(5) The registrant shall review the results of each radiation output quality assurance check according to the following procedures:

(a) A Radiation Therapy Physician and a Qualified Medical Physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The electronic brachytherapy device shall not be made available for subsequent medical use until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances.

(b) If all radiation output quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either a Radiation Therapy Physician or Qualified Medical Physicist within two (2) days.

(c) The Qualified Medical Physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed thirty (30) days.

(6) To satisfy the requirements of this rule, safety device quality assurance checks shall, at a minimum, assure:

(a) Proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console; and
(b) Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable; and

(c) Proper operation of radiation monitors, if applicable; and

(d) The integrity of all cables, catheters or parts of the device that carry high voltages; and

(e) Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.

(7) If the results of the safety device quality assurance checks required in this rule indicate the malfunction of any system, a registrant shall secure the control console in the OFF position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.

(8) The registrant shall maintain a record of each quality assurance check required by sections (3) and (7) of this rule in an auditable form for three years.

(a) The record shall include the date of the quality assurance check; the manufacturer's name, model number and serial number for the electronic brachytherapy device; the name and signature of the individual who performed the periodic quality assurance check and the name and signature of the Qualified Medical Physicist who reviewed the quality assurance check; and

(b) For radiation output quality assurance checks required by this rule, the record shall also include the unique identifier for the electronic brachytherapy source and the manufacturer's name; model number and serial number for the instrument(s) used to measure the radiation output of the electronic brachytherapy device.

333-123-0105, Therapy Related Computer Systems

(1) The registrant shall perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol shall be followed.

(a) Acceptance testing shall be performed by, or under the direct supervision of, a Qualified Medical Physicist. At a minimum, the acceptance testing shall include, as applicable, verification of:

(A) The source-specific input parameters required by the dose calculation algorithm.
(B) The accuracy of dose, dwell time, and treatment time calculations at representative points.

(C) The accuracy of isodose plots and graphic displays.

(D) The accuracy of the software used to determine radiation source positions from radiographic images.
(E) If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(2) The position indicators in the applicator shall be compared to the actual position of the source or planned swell positions, as appropriate, at the time of commissioning.
(3) Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated and approved by the Radiation Therapy Physician and the Qualified Medical Physicist for correctness through means independent of that used for determination of the parameters.

333-123-0110, Training

(1) A registrant shall provide instruction, initially and at least annually, to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in OAR 333-123-0085. If the interval between patients exceeds one year, retraining of the individuals shall be provided.

(2) In addition to the requirements of OAR 333-123-0015(1) for Radiation Therapy Physicians and OAR 333-123-0015(2) for Qualified Medical Physicists, these individuals shall also receive device specific instruction initially from the manufacturer, and annually from either the manufacturer or other qualified trainer. The training shall be of a duration recommended by a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of any training protocol recommended by a national professional association, the manufacturer's training protocol shall be followed. The training shall include, but not be limited to:

(a) Device-specific radiation safety requirements.

(b) Device operations.

(c) Clinical use for the types of use approved by the FDA.

(d) Emergency procedures, including an emergency drill.

(e) The registrant's Quality Assurance Program.

(3) A registrant shall retain a record of individuals receiving instruction required by this rule for three (3) years. The record shall include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

333-123-0115, Mobile Electronic Brachytherapy Service

(1) A registrant providing mobile electronic brachtherapy service shall, as a minimum:

(a) Check all survey instruments before medical use at each address of use or on each day of use, whichever is more restrictive

(b) Account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address.

(c) Perform, at each location on each day of use, all of the required quality assurance checks specified in OAR 333-123-0100 to assure proper operation of the device.