

## **2011-1 for Parts 20.140, 20.1404, and 20.1406**

### **333-102-0310**

#### **Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas**

(1)(a) Except as provided in subsection (1)(b) of this rule, each specific license must expire at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under OAR 333-102-0315 before the expiration date stated in the existing license (or, for those licenses subject to subsection (1)(b) of this rule, before the deemed expiration date in that section). If an application for renewal has been filed before the expiration date stated in the existing license (or, for those licenses subject to subsection (2)(a) of this rule, before the deemed expiration date in that section), the existing license expires at the end of the day on which the Authority makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(b) Each specific license that has an expiration date after July 1, 1995, and is not one of the licenses described in subsection (1)(c) of this rule, shall be deemed to have an expiration date that is five years after the expiration date stated in the current license.

(c) The following specific licenses are not subject to, or otherwise affected by, the provisions of subsection (1)(b) of this rule:

(A) Specific licenses for which, on February 15, 1996, an evaluation or an emergency plan is required in accordance with OAR 333-102-0190(10);

(B) Specific licenses whose holders are subject to the financial assurance requirements specified in OAR 333-102-0200(6), and on February 15, 1996, the holders either:

(i) Have not submitted a decommissioning funding plan or certification of financial assurance for decommissioning; or

(ii) Have not received written notice that the decommissioning funding plan or certification of financial assurance for decommissioning is acceptable;

(C) Specific licenses who need an environmental assessment or environmental impact statement pursuant to OAR 333-102-0200(5);

(D) Specific licenses whose holders have not had at least one Authority inspection of licensed activities before February 15, 1996;

(E) Specific licenses whose holders, as the result of the most recent Authority inspection of licensed activities conducted before February 15, 1996, have been:

(i) Cited for a serious health and safety noncompliance;

(ii) Subject to an Order issued by the Authority; or

(iii) Subject to a Confirmatory Action Letter issued by the Authority.

(F) Specific licenses with expiration dates before July 1, 1995, for which the holders have submitted applications for renewal under OAR 333-102-0315.

(2) Each specific license revoked by the Authority expires at the end of the day on the date of the Commission's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Authority Order.

(3) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material or source material until the Authority notifies the licensee in writing that the license is terminated. During this time, the licensee must:

(a) Limit actions involving material to those related to decommissioning; and

(b) Continue to control entry to restricted areas until they are suitable for release in accordance with Authority requirements.

(4) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in OAR 333-100-0045, each licensee must provide notification to the Authority in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Authority requirements, or submit within 12 months of notification a decommissioning plan, if required by subsection (7)(a) of this rule, and begin decommissioning upon approval of that plan if:

(a) The license has expired pursuant to sections (1) or (2) of this rule; or

(b) The licensee has decided to permanently cease principal activities, as defined in OAR 333-102-0203, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Authority requirements; or

(c) No principal activities under the license have been conducted for a period of 24 months; or

(d) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Authority requirements.

(5) Coincident with the notification required by section (4) of this rule, the licensee must maintain in effect all decommissioning financial assurances established by the licensee pursuant to OAR 333-102-0200(6) in conjunction with a license issuance or renewal or as required by this rule. The amount of the financial assurance must be increased, or may be decreased, as

appropriate, to cover the detailed cost estimate for decommissioning established pursuant to paragraph (7)(d)(E) of this rule.

(a) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan must do so when this rule becomes effective November 24, 1995.

(b) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Authority.

(6) The Authority may grant a request to extend the time periods established in section (4) of this rule if the Authority determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to section (4) of this rule. The schedule for decommissioning set forth in section (4) of this rule may not commence until the Authority has made a determination on the request.

(7)(a) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Authority and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(A) Procedures may involve techniques not applied routinely during cleanup or maintenance operations;

(B) Workers that may be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(C) Procedures could result in significantly greater airborne concentrations of radioactive material or source material than are present during operation; or

(D) Procedures could result in significantly greater releases of radioactive material or source material to the environment than those associated with operation.

(b) The Authority may approve an alternate schedule for submittal of a decommissioning plan required pursuant to section (4) of this rule if the Authority determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(c) Procedures such as those listed in subsection (7)(a) of this rule with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(d) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(A) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(B) A description of planned decommissioning activities;

(C) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(D) A description of the planned final radiation survey; and

(E) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(F) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan must include a justification for the delay based on the criteria in section (9) of this rule.

(e) The proposed decommissioning plan will be approved by the Authority if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(8)(a) Except as provided in section (9) of this rule, licensees must complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(b) Except as provided in section (9) of this rule, when decommissioning involves the entire site, the licensee must request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(9) The Authority may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Authority determines that the alternative is warranted by consideration of the following:

(a) Whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(b) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(c) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(d) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(e) Other site-specific factors which the Authority may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(10) As the final step in decommissioning, the licensee must:

(a) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and

(b) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E. The licensee must, as appropriate:

(A) Report levels of gamma radiation in units of millisieverts (microrentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters — removable and fixed — for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(B) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(11) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Authority determines that:

(a) Radioactive material or source material has been properly disposed;

(b) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(c)(A) A radiation survey has been performed that demonstrates that the premises are suitable for release or establishes the level of residual activity in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E; or

(B) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

(i) Funds placed into an account separate from the licensee's assets and outside of the licensee's control before the start of decommissioning operations; or

(ii) A statement of intent containing a cost estimate for decommissioning or an amount based on the table in paragraph (d) of 10 CFR section 30.35(d), and indicating that funds for decommissioning will be obtained when necessary; or

(iii) An arrangement deemed acceptable by the governmental entity that is assuming custody and ownership of a site.

(C) Alternate criteria for license termination. The Authority will terminate a license using alternate criteria greater than the dose criterion of OAR 333-102-0310, if the licensee:

(i) Provides assurance that public health and safety shall continue to be protected and that it is unlikely that the total effective dose equivalent from all combined man-made sources other than medical sources shall be more than 100 millirem per year (1 millisievert per year) by submitting an analysis of possible sources of exposure;

(ii) Has employed restrictions on site use in minimizing exposures at the site;

(iii) Reduces doses to ALARA levels considering any detriments such as traffic accidents potentially expected to result from decontamination and waste disposal; and

(D) Has submitted a decommissioning or license termination plan to the Authority indicating the licensee's intent to decommission as specified in OAR 333-102-0310, and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the license termination or decommissioning plan how the advice of individuals and institutions in the community who could be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice in:

(i) Participation by representatives of a broad cross section of community interests who could be affected by the decommissioning;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement on the issues.

(E) The use of alternate criteria to terminate a license requires the approval of the Authority after consideration of any comments provided by the U. S. Environmental Protection Agency and any public comments submitted.

(F) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E.

(d) The licensee has kept records of receipt, transfer, and disposal of radioactive material or source material, pursuant to OAR 333-100-0055 that meet the following criteria:

(A) The licensee must retain each record of receipt of radioactive material or source material as long as the material is possessed and for three years following transfer or disposal of the material.

(B) The licensee who transferred the material must retain each record of transfer for three years after each transfer unless a specific requirement in another part of the rules in this chapter dictates otherwise.

(C) The licensee who disposed of the material must retain each record of disposal of byproduct material until the Authority terminates each license that authorizes disposal of the material.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

## **RATS 2011-1 for Parts 20.1501, 30.35, 40.36, and 70.25**

### **333-102-0200**

#### **General Requirements for the Issuance of Specific Licenses**

An application for a specific license, will be approved if:

- (1) The application is for a purpose authorized by the Act;
- (2) The applicant is qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property;
- (3) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property;
- (4) The applicant satisfies any applicable special requirements contained in divisions 102, 105, 113, 115, 116, 117, or 121 of this chapter; and
- (5) In the case of an application for a license to receive and possess radioactive material for the conduct of any activity which the Authority determines will significantly affect the quality of the environment, the Authority Manager or designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to Subpart A of Part 51 of 10 CFR, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of

construction prior to such conclusion must be grounds for denial of a license to receive and possess byproduct material in such plant or facility. As used in this rule, the term "commencement of construction" means any clearing of land, excavation, or other substantial action that can adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values. Upon a determination that an application meets the requirements of the Act, and the rules of the Authority, the Authority will issue a specific license authorizing the possession and use of radioactive material ("Radioactive Materials License").

(6) Financial assurance and recordkeeping for decommissioning following the specific requirements listed below:

- (a) 10 CFR 30.35 and 30.36 for radioactive material that is not source or special nuclear material; or
- (b) 10 CFR 40.36 for source material; or
- (c) 10 CFR 70.25 for special nuclear material.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

## **RATS ID 2011-1 for Parts 30.34, 40.46, and 70.36**

**333-102-0305**

### **Specific Terms and Conditions of License**

(1) Each license issued pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120, 121 and 124 of this chapter are subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations and orders of the Authority.

(2) No license issued or granted pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter nor any right may be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Authority, after securing full information, shall find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.



(3) An application for transfer of license must include:

(a) The identity, technical and financial qualification of the proposed transferee; and

(b) Financial assurance for decommissioning as required by 10 CFR Part 30.35.

(4) Each person licensed by the Authority pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter must confine the use and possession of the radioactive material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter shall carry with it the right to receive, acquire, own, and possess radioactive material. Preparation for shipment and transport of radioactive material must be in accordance with the provisions of division 118 of this chapter.

(5) Each license issued pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter shall be deemed to contain the provisions set forth in section 183b.-d., inclusive, of the Atomic Energy Act of 1954, as amended, whether or not these provisions are expressly set forth in the license.

(6) The Authority may incorporate, in any license issued pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter, at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material as it deems appropriate or necessary in order to:

(a) Promote the common defense and security;

(b) Protect health or to minimize danger to life or property;

(c) Protect restricted data; and

(d) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

(7) Licensees required to submit emergency plans by OAR 333-102-0190(10) must follow the emergency plan approved by the Authority. The licensee may change the approved plan without Authority approval only if the changes do not decrease the effectiveness of the plan. The licensee must furnish the change to the Authority and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the Authority.

(8) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators must test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85,

respectively, in accordance with OAR 333-116-0330. The licensee must record the results of each test and retain each record for three years after the record is made.

(9)(a) Each general licensee subject to the registration requirement in OAR 333-101-0007 and each specific licensee must notify the Authority in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(A) The licensee;

(B) An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

(C) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(b) This notification must indicate:

(A) The bankruptcy court in which the petition for bankruptcy was filed; and

(B) The date of the filing of the petition.

(10) Sealed sources or detector cells containing licensed material must not be opened or sources removed from source holders or detector cells by the licensee.

(11) No licensee may acquire licensed radioactive material in a sealed source or in a device that contains a sealed source unless the source or device has been registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

(12) Any sealed source fabricated by a licensee must be registered, inspected, and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source in accordance with requirements in 10 CFR 32.210.

(13) Each licensee must conduct a physical inventory at intervals not to exceed six months to account for all radioactive material received and possessed by licensee. Inventories must include the types and quantities of radioactive material, location of materials, date of receipt, and the date of the inventory; and for sealed sources, the inventory must include the types and quantities of sealed sources, sealed source manufacturer, model number, serial number, date of receipt, condition of sealed sources, and the date of the inventory. Records of the inventories required by this section must be kept until inspection by the Authority.

(14) Each licensee must transport radioactive material or deliver radioactive material to a carrier for transport in accordance with the provisions of Parts 170 through 189 of Title 49, Code of Federal Regulations and in accordance with division 118 of this chapter, "Transportation of Radioactive Material."

(15) Each licensee possessing a device licensed pursuant to OAR 333-103-0010(2)(h) must perform an inspection of all devices at intervals not to exceed six months. Inspections must include condition of labeling and posting of each radiation device, and corrective actions taken if any; condition of shutter operation, if applicable, of each device, and corrective actions taken if any; and location of each device. Records of the inspections required by this section must be kept until inspection by the Authority.

(16) No licensee may open or remove radioactive material from sealed sources or detector cells containing licensed radiation sources.

(17) No person may repair, modify, dismantle, or effect any change in licensed devices or radiation sources, nor modify nor alter labels affixed to licensed devices by the manufacturer

(18) Installation, initial radiation survey, relocation, removal from service, maintenance, and repair of fixed gauging devices containing radioactive sealed sources, and installation, replacement, and disposal of sealed sources must be performed only by persons specifically authorized by the Authority, the U.S. Nuclear Regulatory Commission, or another Agreement state to perform such services. Records of all surveys must be maintained for inspection by the Radiation Protection Services section.

(19) If the licensee has previously determined that monitoring for internal exposure pursuant to OAR 333-120-0130, 333-120-0210, or 333-120-0320 is required, the data and results of this evaluation must be placed in the worker's exposure records and included the worker's Oregon Form Z report.

(20) Testing for leakage or contamination of sealed sources must be in accordance with requirements in OAR 333-120-0460. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source or detector cell received from another person must not be put into use until tested.

(21) Detector cells must be used only in conjunction with a properly operating temperature control mechanism that prevents foil temperatures from exceeding manufacturer's specifications. Exhaust from detector cells must be vented to keep exposures to personnel and the public as low as reasonably achievable pursuant to OAR 333-120-0180.

(22) Licensees who possess sealed sources used for testing at field sites must possess at such locations transport documents, a current copy of the specific radioactive materials license, specific license validation certificates, the current leak test certificate, and the licensee's operating and emergency procedures. Licensed materials stored in an unrestricted area must be secured from unauthorized removal from the place of storage in accordance with provisions of OAR 333-120-0250 and 333-120-0260.

(23) Any specific licensee is authorized to receive, possess, use, transfer, and import up to 999 kilograms of uranium contained as shielding for specific licensed radioactive material authorized by license.

(24) A licensee may store, pursuant to OAR 333-120-0500, radioactive waste for decay in storage before disposal in accordance with 333-116-0290.

(25) Licensed materials in an unrestricted area and not in storage must be tended under the constant surveillance and immediate control of the licensee.

(26) Except as otherwise specified in a radioactive materials license, the licensee must have available and follow the instructions contained in the manufacturer's instruction manual for the chromatography device.

(27) In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in OAR 333-120-0400(2), the licensee is hereby authorized to label detector cells and cell baths, containing licensed radioactive material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.

(28) If a radiography licensee plans to use, during normal industrial radiographic operations subject to division 105 of this chapter, two or more exposure devices at one jobsite, the licensee must require at least one Radiographer or Radiographer Instructor authorized user for each exposure device, and the total number of authorized personnel (radiographers and assistant radiographers) at the temporary jobsite must not be less than  $n+1$  where  $n$ =the number of cameras.

(29) Security requirements for portable devices containing licensed radioactive materials. Each portable device containing licensed radioactive materials must be secured using a minimum of two independent physical controls that form two separate tangible barriers to prevent unauthorized removal or use, whenever the portable device is not under the direct control and constant surveillance of the licensee.

(30) Authorization under OAR 333-102-0190(10)(c)(N) to produce Positron Emission Tomography (PET) radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other federal, and state requirements governing radiopharmaceutical drugs.

(31) Each licensee authorized under OAR 333-102-0190(10)(c)(N) to produce PET radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium shall:

(a) Satisfy the labeling requirements in OAR 333-102-0285(1)(d) for each PET radiopharmaceutical drug transport radiation shield and each syringe, vial, or other container used to hold a PET radiopharmaceutical drug intended for noncommercial distribution to members of its consortium.

(b) Possess and use instrumentation to measure the radioactivity of the PET radiopharmaceutical drugs intended for noncommercial distribution to members of its consortium and meet the

procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in OAR 333-102-0285(3).

(32) A licensee that is a pharmacy authorized under OAR 333-102-0190(10)(c)(N) to produce PET radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radiopharmaceutical drugs shall be:

(a) An authorized nuclear pharmacist who meets the requirements in OAR 333-116-0910; or

(b) An individual under the supervision of an authorized nuclear pharmacist as specified in OAR 333-116-0100.

(33) A pharmacy, authorized under OAR 333-102-0190(10)(c)(N) to produce PET radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of 333-116-0910.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

## **RATS 2011-1 for Parts 20.1401**

### **333-102-0310**

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(b) Each specific license that has an expiration date after July 1, 1995, and is not one of the licenses described in subsection (1)(c) of this rule, shall be deemed to have an expiration date that is five years after the expiration date stated in the current license.

(c) The following specific licenses are not subject to, or otherwise affected by, the provisions of subsection (1)(b) of this rule:

(A) Specific licenses for which, on February 15, 1996, an evaluation or an emergency plan is required in accordance with OAR 333-102-0190(10);

(B) Specific licenses whose holders are subject to the financial assurance requirements specified in OAR 333-102-0200(6), and on February 15, 1996, the holders either:

(i) Have not submitted a decommissioning funding plan or certification of financial assurance for decommissioning; or

(ii) Have not received written notice that the decommissioning funding plan or certification of financial assurance for decommissioning is acceptable;

(C) Specific licenses who need an environmental assessment or environmental impact statement pursuant to OAR 333-102-0200(5);

(D) Specific licenses whose holders have not had at least one Authority inspection of licensed activities before February 15, 1996;

(E) Specific licenses whose holders, as the result of the most recent Authority inspection of licensed activities conducted before February 15, 1996, have been:

(i) Cited for a serious health and safety noncompliance;

(ii) Subject to an Order issued by the Authority; or

(iii) Subject to a Confirmatory Action Letter issued by the Authority.

(F) Specific licenses with expiration dates before July 1, 1995, for which the holders have submitted applications for renewal under OAR 333-102-0315.

(2) Each specific license revoked by the Authority expires at the end of the day on the date of the Commission's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Authority Order.

(3) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material or source material until the Authority notifies the licensee in writing that the license is terminated. During this time, the licensee must:

(a) Limit actions involving material to those related to decommissioning; and

(b) Continue to control entry to restricted areas until they are suitable for release in accordance with Authority requirements.

(4) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in OAR 333-100-0045, each licensee must provide notification to the Authority in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Authority requirements, or submit within 12 months of notification a decommissioning plan, if required by subsection (7)(a) of this rule, and begin decommissioning upon approval of that plan if:

(a) The license has expired pursuant to sections (1) or (2) of this rule; or

(b) The licensee has decided to permanently cease principal activities, as defined in OAR 333-102-0203, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Authority requirements; or

(c) No principal activities under the license have been conducted for a period of 24 months; or

(d) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Authority requirements.

(5) Coincident with the notification required by section (4) of this rule, the licensee must maintain in effect all decommissioning financial assurances established by the licensee pursuant to OAR 333-102-0200(6) in conjunction with a license issuance or renewal or as required by this rule. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to paragraph (7)(d)(E) of this rule.

(a) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan must do so when this rule becomes effective November 24, 1995.

(b) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Authority.

(6) The Authority may grant a request to extend the time periods established in section (4) of this rule if the Authority determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to section (4) of this rule. The schedule for decommissioning set forth in section (4) of this rule may not commence until the Authority has made a determination on the request.

(7)(a) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Authority and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(A) Procedures may involve techniques not applied routinely during cleanup or maintenance operations;

(B) Workers that may be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(C) Procedures could result in significantly greater airborne concentrations of radioactive material or source material than are present during operation; or

(D) Procedures could result in significantly greater releases of radioactive material or source material to the environment than those associated with operation.

(b) The Authority may approve an alternate schedule for submittal of a decommissioning plan required pursuant to section (4) of this rule if the Authority determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(c) Procedures such as those listed in subsection (7)(a) of this rule with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(d) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(A) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(B) A description of planned decommissioning activities;

(C) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(D) A description of the planned final radiation survey; and

(E) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(F) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan must include a justification for the delay based on the criteria in section (9) of this rule.



(e) The proposed decommissioning plan will be approved by the Authority if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(8)(a) Except as provided in section (9) of this rule, licensees must complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(b) Except as provided in section (9) of this rule, when decommissioning involves the entire site, the licensee must request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(9) The Authority may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Authority determines that the alternative is warranted by consideration of the following:

(a) Whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(b) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(c) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(d) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(e) Other site-specific factors which the Authority may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(10) As the final step in decommissioning, the licensee must:

(a) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and

(b) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E. The licensee must, as appropriate:

(A) Report levels of gamma radiation in units of millisieverts (microrentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of

megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters — removable and fixed — for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(B) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(11) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Authority determines that:

(a) Radioactive material or source material has been properly disposed;

(b) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(c)(A) A radiation survey has been performed that demonstrates that the premises are suitable for release or establishes the level of residual activity in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E; or

(B) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

(i) Funds placed into an account separate from the licensee's assets and outside of the licensee's control before the start of decommissioning operations; or

(ii) A statement of intent containing a cost estimate for decommissioning or an amount based on the table in paragraph (d) of 10 CFR section 30.35(d), and indicating that funds for decommissioning will be obtained when necessary; or

(iii) An arrangement deemed acceptable by the governmental entity that is assuming custody and ownership of a site.

(C) Alternate criteria for license termination. The Authority will terminate a license using alternate criteria greater than the dose criterion of OAR 333-102-0310, if the licensee:

(i) Provides assurance that public health and safety shall continue to be protected and that it is unlikely that the total effective dose equivalent from all combined man-made sources other than medical sources shall be more than 100 millirem per year (1 millisievert per year) by submitting an analysis of possible sources of exposure;

(ii) Has employed restrictions on site use in minimizing exposures at the site;

(iii) Reduces doses to ALARA levels considering any detriments such as traffic accidents potentially expected to result from decontamination and waste disposal; and

(D) Has submitted a decommissioning or license termination plan to the Authority indicating the licensee's intent to decommission as specified in OAR 333-102-0310, and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the license termination or decommissioning plan how the advice of individuals and institutions in the community who could be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice in:

(i) Participation by representatives of a broad cross section of community interests who could be affected by the decommissioning;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement on the issues.

(E) The use of alternate criteria to terminate a license requires the approval of the Authority after consideration of any comments provided by the U. S. Environmental Protection Agency and any public comments submitted.

(F) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E.

(d) The licensee has kept records of receipt, transfer, and disposal of radioactive material or source material, pursuant to OAR 333-100-0055 that meet the following criteria:

(A) The licensee must retain each record of receipt of radioactive material or source material as long as the material is possessed and for three years following transfer or disposal of the material.

(B) The licensee who transferred the material must retain each record of transfer for three years after each transfer unless a specific requirement in another part of the rules in this chapter dictates otherwise.

(C) The licensee who disposed of the material must retain each record of disposal of byproduct material until the Authority terminates each license that authorizes disposal of the material.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

## **RATS 1995-2 for Parts 20.1703**

### **333-120-0320**

#### **Use of Individual Respiratory Protection Equipment**

(1) If the licensee uses respiratory protection equipment to limit intakes pursuant to OAR 333-120-0310:

(a) The licensee must use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health/Mine Safety and Health Administration (NIOSH/MSHA).

(b) The licensee may use equipment that has not been tested or certified by NIOSH/MSHA, has not had certification extended by NIOSH/MSHA, or for which there is no schedule for testing or certification, the licensee must submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

(c) The licensee must implement and maintain a respiratory protection program that includes:

(A) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures; and

(B) Surveys and bioassays, as appropriate, to evaluate actual intakes; and

(C) Testing of respirators for operability immediately prior to each use; and

(D) Written procedures regarding:

(i) Monitoring, including air sampling and bioassays;

(ii) Supervision and training of respirator users;

(iii) Fit testing;

(iv) Respirator selection;

(v) Breathing air quality;

(vi) Inventory and control;

(vii) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

(viii) Recordkeeping; and

(ix) Limitations on periods of respirator use and relief from respirator use; and

(E) Determination by a physician prior to initial fitting and use of respirators, and at least every 12 months thereafter, that the individual user is physically able to use the respiratory protection equipment.

(F) Fit testing, with fit factor > 10 times the APF for negative pressure devices, and a fit factor > 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed one year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

(d) The licensee must issue a written policy statement on respirator usage covering:

(A) The use of process or other engineering controls, instead of respirators; and

(B) The routine, nonroutine, and emergency use of respirators; and

(C) The periods of respirator use and relief from respirator use.

(e) The licensee must advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(f) The licensee must use equipment within limitations for type and mode of use and must provide proper visual, communication, low temperature work environments, the concurrent use of safety or radiological protection equipment and other special capabilities (such as adequate skin protection) when needed. The licensee must ensure equipment is used in such a way as not to interfere with the proper operation of the respirator.

(2) In estimating exposure of individuals to airborne radioactive materials, the licensee or registrant may make allowance for respiratory protection equipment used to limit intakes pursuant to OAR 333-120-0310, provided that the following conditions, in addition to those in section (1) of this rule, are satisfied:

(a) The licensee selects respiratory protection equipment that provides a protection factor (10 CFR Part 20 Appendix A to 20.1001 to 20.2401) greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in 10 CFR Part 20 Table 1, Column 3 of Appendix B to 20.1001 to 20.2401. If the selection of a respiratory protection device with a protection factor greater than the peak concentration is inconsistent with the goal specified in OAR 333-120-0310 of keeping the total effective dose equivalent ALARA, the licensee or registrant may select respiratory protection equipment with a lower protection factor only if such a selection would result in keeping the total

effective dose equivalent ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than estimated, the corrected value must be used; if the exposure is later found to be less than estimated, the corrected value may be used; and

(b) The licensee must obtain authorization from the Authority before assigning respiratory protection factors in excess of those specified in 10 CFR Part 20 Appendix A to 20.1001 to 20.2401. The Authority may authorize a licensee to use higher protection factors on receipt of an application that:

(A) Describes the situation for which a need exists for higher protection factors; and

(B) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use. Disposition

(3) The licensee must use as emergency devices only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by NIOSH/MSHA.

(4) The licensee must notify the Authority, in writing, at least 30 days before the date that respiratory protection equipment is first used under the provisions of either sections (1) or (2) of this rule. Disposition

(5) Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons must observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

(6) Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997. Grade D quality air criteria include:

(a) Oxygen content (v/v) of 19.5-23.5%;

(b) Hydrocarbon (condensed) content of five milligrams per cubic meter of air or less;

(c) Carbon monoxide (CO) content of 10 ppm or less;

(d) Carbon dioxide content of 1,000 ppm or less; and

(e) Lack of noticeable odor.

(7) The licensee must ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

(8) In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

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