INSTRUCTION SHEET

COMAR 26.12.01.01

Title: Regulations for the Control of Ionizing Radiation (1994)

SUPPLEMENT No. 25

Instructions: Supplement 25 to the document "Regulations for the Control of Ionizing Radiation (1994)" includes the following pages (all pages are inclusive):

Remove Pages	Insert Pages (future)
Cover Sheet	Cover Sheet
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Verify to make certain that you have the pages listed above.

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Code of Maryland Regulations 26.12.01.01

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REGULATIONS FOR THE CONTROL OF IONIZING RADIATION (1994)

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CONTENTS

PART D – STANDARDS FOR PROTECTION AGAINST RADIATION

(7) “External dose” means that portion of the dose equivalent received from any source of radiation outside the body.

(8) "Lens dose equivalent (LDE)" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

(9) "Shallow dose equivalent" (H_s), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

(10) "Total effective dose equivalent" (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

(11) "Total organ dose equivalent" (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in D.1107(a)(~~6~~vi) of this regulation.

"Dose equivalent" [see "Dose"]

"Dose Limits" means the permissible upper bounds of radiation doses established in accordance with this regulation. For purposes of this regulation, "limits" is an equivalent term.

"Effective dose equivalent" [See "Dose"]

"Embryo/fetus" means the developing human organism from conception until the time of birth.

"Entrance or access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

"Explosive material" means any chemical compound, mixture, or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

"Exposure" means being exposed to ionizing radiation or to radioactive material.

"Exposure" means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The special unit of exposure is the roentgen (R). See A.13 "Units of Exposure and Dose" for SI equivalent.[2]

"Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

"External dose" [See "Dose"]

"Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

"Eye dose equivalent" [See "Dose"]

"Facility" means the location at which one or more sources of radiation are installed or located within one building, vehicle, or under one roof and are under the same administrative control.

"Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

[2] When not underlined as above, the term 'Exposure' has a more general meaning in this regulation.

"General applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

"Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

"Hazardous waste" means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

"Healing arts" means a system of rules or methods of performing particular actions including the systematic application of knowledge or skill in effecting a desired result acquired by experience, study, or observation relating to the science of medical diagnosis, treatment, or surgery.

"High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

"Human use" means the internal or external administration of radiation or radioactive material to human beings.

"Individual" means any human being.

"Individual monitoring" means the assessment of:

(1) Dose equivalent (a) by the use of individual monitoring devices or (b) by the use of survey data; or

(2) Committed effective dose equivalent (a) by bioassay or (b) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. [See definition of DAC-hours in Part D.]

"Individual monitoring devices" (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal (“lapel”) air sampling devices.

"Inspection" means an official examination or observation including but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Agency.

(b) Complete application forms for registration furnished by the Agency that contain all the information required by the forms and accompanying instructions;

(c) Designate on the application form the individual to be responsible for radiation protection.

(d) Include full payment of all fees in the application for registration, as specified in COMAR 26.12.03 for the type(s) of radiation machine(s).

(e) Prohibit any person from furnishing radiation machine servicing or services as described in B.6(d) to a radiation machine facility until such person provides evidence to the registrant that they are currently registered with the Agency as a service provider in accordance with B.6.

(f) Apply for certification of the radiation machine(s) to be located in such facility if the radiation machines will be classified in Groups 1, 2, 3, 4, or 5, as described in COMAR 26.12.02.02B. Application for certification of radiation machines shall be made in accordance with COMAR 26.12.02.02D(2).

Sec. B.6 Application for Registration of Servicing and Services.

(a) Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this State shall apply for registration of such services with the Agency prior to furnishing or offering to furnish any such services.

(b) Application for registration shall be completed on forms furnished by the Agency and shall contain all information required by the Agency as indicated on the forms and accompanying instructions.

(c) Each person applying for registration under this part shall specify:

(1) A knowledge and understanding of the requirements of these regulations;

(2) A list of services to be provided under the registration;

(3) The training and experience provided to all repair staff as required in Section B.6(j)(3) and (4); ~~needed to perform the services;~~

(4) The type of measurement instrument(s) to be used, frequency of calibration, and source of calibration; and

(5) The type of personnel dosimeters used, frequency of reading, and replacement or exchange schedule for the exposure monitoring required in B.6(g).

(d) For the purposes of B.6, services may include but shall not be limited to:

(1) Installation and/or servicing of radiation machines and associated radiation machine components,

(2) Calibration of radiation machines or radiation measurement instruments or devices,

(3) ~~Radiation protection or health physics consultations or surveys~~Performance of radiation machine preventive maintenance tests and measurements,

(4) Radiation protection or health physics consultations or surveys, and

(5) Personnel dosimetry services.

(e) In performance of radiation machine preventive maintenance services, each registered service provider shall provide the radiation machine facility with a complete preventive maintenance report for each radiation machine for which preventive maintenance has been provided.

(1) Each Preventive Maintenance Report shall be completed on the specific preventive maintenance form made available by the Agency applicable to the type of machine tested. One form is required for each machine for which preventive maintenance has been performed. Each form shall be signed and dated by both the registrant and the service provider.

(2) If the Agency has not published a specific Preventive Maintenance Report form for the type of radiation machine tested, a registered service provider shall use its own preventive maintenance report format containing at minimum the following information:

(i) Signature and date of signature of both registered service provider and authorized facility representative;

(ii) Registered service provider's name and registration number;

(iii) Facility name and facility registration number;

(iv) Tested machine's MDE Machine Number if available and tube serial number;

(v) Room number or room name in which tested machine is located;

(vi) Date of preventive maintenance service;

(vii) Written values of every test taken and measurement made including average value as required, and results of all tests and measurements performed. If calibrations or adjustments are made, the report must include the values measured before and after any calibration or adjustment. Tests performed must comprise at minimum every maintenance service or calibration recommended by the machine's manufacturer; and

(viii) Written documentation that machine passes or fails preventive maintenance tests;

(f) The documentation listed in subsection (e) above shall be provided to the facility within one week after completion of the preventive maintenance service. If preventive maintenance includes installation, assembly, disablement, or disposal of a radiation machine, the 15 day Agency notification requirement in Section B.12(a) shall apply.

(g) Personnel Monitoring. Each person registered by the Agency to provide services to radiation machine facilities including installation, assembly, calibration, repair, maintenance, disablement, or removal of radiation machines shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Part D of this regulation. Such monitoring of exposures must be performed during all work with or involving radiation machines by means of each service provider and the provider's employees wearing individual monitoring devices to include at minimum film badges.

Comment [MDK1]: Last sentence is former (g)(1).

(1) Film badge reports shall be reviewed by each registered service provider to assure compliance with the occupational dose limits. Such reports shall be required from the film badge supplier on either a monthly or quarterly basis.

Comment [MDK2]: Former (g)(2).

(2) Application for registration or renewal of registration to provide services, as listed in this section, to radiation machine facilities must also specify the dosimetry information required in B.6(c)(5).

(h) No individual shall perform services which are not specifically stated for that individual on the notice of registration issued by the Agency.

(i) Duration of Registration. A service provider registration shall remain in effect for 3 years from date of issuance. Application for renewal of registration shall be made to the Department at least 30 days prior to the expiration date of the registration.

(j) Additional Requirements for Service Provider Registration. For a service provider registration to be approved, an applicant for service provider registration:

(1) Shall demonstrate compliance with the State Workers' Compensation Laws as required by Environment Article §1-202, Annotated Code of Maryland;

(2) Shall not have a financial arrangement with individual licensed private inspectors or any business entity offering licensed private inspections of radiation machines if such arrangement is or could be a conflict of interest as provided in State Government Article, Title 15, Subtitle 5, Annotated Code of Maryland;

(3) Shall ensure that all repair staff have been trained in radiation safety and in protective measures to reduce potentially hazardous conditions; and

(4) Shall ensure that all repair staff have a level of training and applied radiation machine experience equal to or greater than one of the following sets of criteria:

(a) Completion of applicable radiation equipment manufacturer's service school; or

(b) One year of applied radiation machine experience acceptable to the Department; or

(c) Advanced tradesman training in the service and repair of radiation emitting equipment including radiation safety and complex systems skill sets.

(k) Cancellation of Service Provider Registration.

(1) A registered service provider may request cancellation of its registration by submitting a request for cancellation to the Department.

(2) The Department may cancel a service provider registration if the service provider is found by the Department to have:

(a) a financial arrangement with individual licensed private inspectors or any business entity offering licensed private inspections of radiation machines if such arrangement is or could be a conflict of interest as provided in State Government Article, Title 15, Subtitle 5, Annotated Code of Maryland;

(b) falsified data on a report;

(c) performed work or services outside the provider's scope of practice as identified to the Department in the provider's application; or

(d) permitted employees who do not have the required level of training and applied radiation machine experience as identified in (j)(3) and (4) to perform service or repair work at a Maryland radiation machine facility.

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Agency Issues

Sec B.7 Issuance and Posting of Notice of Registration.

(a) Upon a determination that an applicant meets the requirements of the regulations, the agency shall issue a notice of registration. For a radiation machine facility, this will be issued in the form of a certificate of registration. Each certificate of registration shall be publicly posted by the radiation machine facility.

(b) The Agency may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use, transfer, or servicing of radiation machines as it deems appropriate or necessary.

Sec. B.8 Expiration of Notice of Registration.

Except as provided by B.9(c), each notice of registration shall expire at the end of the specified day in the month and year stated therein.

Sec. B.9 Renewal of Notice of Registration.

(a) The Agency will grant an application for renewal of registration upon receipt of all documentation and fees required by the Agency.

(b) Each application for renewal of registration of a radiation machine facility must be received by the Agency at least 14 days prior to expiration of the facility's existing registration. Such application shall be made in accordance with the provisions of Section B.5. The Agency shall not grant re-registration unless all previously invoiced radiation machine fees are paid in full.

(c) If a registrant has filed a complete application, not less than 14 days prior to the expiration of the existing notice of registration, including payment of all fees and submission of required inspections or certifications with all violations corrected, the existing notice of registration shall not expire until the application status has been determined by the Agency.

Sec. B.10 Report of Changes.

The registrant shall notify the Agency in writing before making any change which would render the information contained in the application for registration and/or the notice of registration no longer accurate. This includes, but is not limited to, requests for registration cancellation, changes of location and ownership, or changes to radiation machines or tubes. The registrant shall notify the Agency of installation, disposal or disablement of radiation machines within 30 days following such action by providing the Agency with a copy of a completed Form MDE RX 24 signed and dated by a State registered service provider.

Sec. B.10A Compliance with Regulations.

All owners, operators, or possessors of a radiation machine(s) shall comply with all applicable requirements of COMAR 26.12.01, .02, and .03. Any Agency Form RX-2 or RX-2a citing a regulation violation(s) which is presented to a radiation machine facility during or following an inspection by an Agency or State-licensed private inspector constitutes a notice to the facility that a violation(s) has been observed by the inspector. An as-found violation(s):

(5) No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by this exemption so that the aggregate quantity exceeds the limits set forth in Appendix B of this part, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this part.

(c) Exempt Items.

(1) Certain Items Containing Radioactive Material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from these regulations to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products: 2/

(i) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:

(a) 25 millicuries (925 MBq) of tritium per timepiece.

(b) 5 millicuries (185 MBq) of tritium per hand.

(c) 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial).

(d) 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece.

(e) 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand.

(f) 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial).

(g) The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(1) For wrist watches, 0.1 millirad (1 μGy) per hour at 10 centimeters from any surface.

(2) For pocket watches, 0.1 millirad (1 μGy) per hour at 1 centimeter from any surface.

(3) For any other timepiece, 0.2 millirad (2 μGy) per hour at 10 centimeters from any surface.

(h) One microcurie (0.037 MBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

(ii) ~~[Reserved]~~Static Elimination Devices and Ion Generating Tubes.

Comment [MDK3]: 30.15(a)(2)

(a) Static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 µCi) of polonium-210 per device.

(b) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 µCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

(c) Such devices authorized before October 23, 2012 for use under the general license then provided in Section C.22 and equivalent regulations of Agreement States and the NRC and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Agency.

(iii) Precision balances containing not more than 1 millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part manufactured before December 17, 2007.

(iv) [Reserved]

(v) Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas manufactured before December 17, 2007.

(vi) [Reserved]

(vii) Ionization chamber smoke detectors containing not more than 1 microcurie (0.037 MBq) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(viii) Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of byproduct material:

(a) 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube.

(b) 1 microcurie (37 kBq) of cobalt-60.

(c) 5 microcuries (185 kBq) of nickel-63.

(d) 30 microcuries (1.11 MBq) of krypton-85.

(e) 5 microcuries (185 kBq) of cesium-137.

(f) 30 microcuries (1.11 MBq) of promethium-147.

And provided further, that the radiation dose rate from each electron tube containing byproduct material will not exceed 1 millirad (10 µGy) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber. 3/

3/ For purposes of C.4(c)(1)(viii), "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

(ix) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of byproduct material, provided that:

(a) Each source contains no more than one exempt quantity set forth in Appendix B of this part, and

(b) Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Appendix B of this part, provided that the sum of such fractions shall not exceed unity.

(c) For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under Appendix B.

(x) [Reserved]

(2) Self-Luminous Products Containing Radioactive Material.

(i) Tritium, Krypton-85, or Promethium-147.

(a) Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, or produced under an Agency specific license issued under Section C.28 and~~,~~ imported~~,~~ or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Section 32.22 ~~of 10 CFR Part 32, which license~~ that authorizes the transfer of the product to persons who are exempt from regulatory requirements.

(b) Any person who desires to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147 for use under Section C.4(c)(2)(i)(a) should apply for a license under Section C.28. Any person who desires to initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under Section C.4(c)(2)(i)(a) should apply to the NRC for a license under 10 CFR Section 32.22 and for a certificate of registration in accordance with 10 CFR Section 32.210.

(c) The exemption in C.4(c)(2) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

(ii) Radium-226. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium-226 which were acquired prior to December 6, 1982.

(3) Gas and Aerosol Detectors Containing Byproduct Material.

(i) Except for persons who manufacture, process, produce or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in Parts A, C through E, G, J, W, and X of this regulation to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect ~~life or~~ health, safety, or property~~, from fires and airborne hazards provided that detectors containing byproduct material shall have been~~ and manufactured, processed, or produced under an Agency specific license issued under Section C.28 and imported~~,~~ or initially transferred in accordance with a specific license issued by the NRC ~~2/~~ pursuant to 10 CFR Section 32.26 that~~, or an Agreement State pursuant to C.25, which~~ authorizes the initial transfer of the ~~detectors~~product to persons who are exempt from regulatory requirements. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by ~~an Agreement State~~the Agency under Section C.28 or under comparable NRC or Agreement State regulations ~~provisions to 10 CFR 32.26~~ authorizing distribution to persons exempt from regulatory requirements.

Comment [MDK4]: DELETED SENTENCE: The exemption in C.4(c)(2) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

Comment [MDK5]: 30.19(b)

Comment [MDK6]: 30.20

(ii) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material under C.4(c)(3) should apply to the Agency for a license under Section C.28. Any person who desires to initially transfer and distribute such products for use under Section C.4(c)(3) should apply to the NRC for a license under 10 CFR Section 32.26 and for a certificate of registration in accordance with 10 CFR Section 32.210.

(4) Radioactive Drug: Capsules Containing Carbon-14 Urea for "In vivo" Diagnostic Use for Humans.

(i) Except as provided in paragraphs (b) and (c) of this section, any person is exempt from the requirements for a license and from these regulations provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 µCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

(ii) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Section C.

(iii) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to 10 CFR §32.21.

(iv) Nothing in this section relieves persons from complying with applicable FDA, Federal, and State requirements governing receipt, administration, and use of drugs.

(5) Certain Industrial Devices.

(i) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in Part C and from the regulations in all parts of COMAR 26.12.01.01 to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, or produced in accordance with a specific license under Section C.28(d), and initially imported or transferred in accordance with a specific license issued by the NRC pursuant to 10 CFR Section 32.30 that authorizes the initial transfer of the device to persons who are exempt from regulatory requirements. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(ii) Any person who desires to manufacture, process, or produce industrial devices containing byproduct material for use under Section C.5(i) should apply to the Agency for a specific license under Section C.28(d). Any person who desires to initially transfer for sale or distribution industrial devices containing byproduct material for use under Section C.5(i) should apply to the NRC for a license in accordance with 10 CFR Section 32.30 and for a certificate of registration in accordance with 10 CFR Section 32.210.

Sec. C.5 - C.19 Reserved.

Comment [MDK7]: DELETED EXISTING SUBPARAGRAPHS (ii) AND (iii):
(ii) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State shall be considered exempt under C.4(c)(3)(i), provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of C.25.
(iii) Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under C.4(c)(3)(i), provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of C.25.

Comment [mdk8]: 30.22(a)

Comment [mdk9]: 30.22(b)

Comment [MDK10]: DELETED NOTE: 2/ Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(iv) within 30 days of any transfer, shall report in writing to the Agency the name and address of the person receiving the depleted uranium pursuant to such transfer; and

(v) shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by C.21(e)(1) is exempt from the requirements of Parts D and J of these regulations with respect to the depleted uranium covered by that general license.

Sec. C.22 Reserved.~~General Licenses* - Radioactive Material Other Than Source Material~~.

Comment [MDK11]: 31.3 is now Reserved.

(a) [Reserved]~~Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of A.4 through A.9, C.4(a)(2), C.31, C.40, C.50 and Parts D [4/], J, and T of these regulations.~~

~~(1) Static Elimination Device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device.~~

~~(2) Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device or a total of not more than 50 millicuries (1.85 GBq) of hydrogen-3 (tritium) per device.~~

(b) General License to Install Devices Generally Licensed in Sec. C.22

Any person who holds a specific license issued by an Agreement State or the U.S. Nuclear Regulatory Commission authorizing the holder to manufacture, install, or service a device described in C.22 within such Agreement State is hereby granted a general license to install and service such device in the State of Maryland as defined in C.90 provided that:

(1) [Reserved]

(2) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or Agreement State.

(3) Such person assures that any labels required to be affixed to the device under regulations of the U.S. Nuclear Regulatory Commission or Agreement State that licensed manufacture of the device bear a statement that removal of the label is prohibited.

(c) Reserved.

~~*Note: Different general licenses are issued in this section, each of which has its own specific conditions and requirements.~~

~~[4/] Attention is directed particularly to the provisions of Part D of these regulations which relate to the labeling of containers~~.

(d) Certain Measuring, Gauging or Controlling Devices.

(1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and State or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of C.22(d)(2), (3), and (4), radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2) The general license in C.22(d)(1) applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the Agency pursuant to C.28(d) or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State and the device has been manufactured and installed so that:

(i) The dose rate in the radiation beam of the device at 18 inches (0.46 meters) from the radiation source with the device shutter in the open position does not exceed 125 millirem (1.25 mSv) per hour; and

(ii) There is not an accessible airgap of 18 inches (0.46 meters) or greater between the radiation source and detector which would allow insertion of a 12 inch (0.30 meters) diameter sphere into the radiation beam [5/].

(3) The devices must have been received from one of the specific licensees described in C.22(d)(2) or through a transfer made under C.22(d)(4)(vii).

(4) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in C.22(d)(1):

(i) shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(ii) shall assure that the device is tested for leakage of radioactive material and proper operation of the "on-off" mechanism and indicator, if any, at no longer than 6-month intervals or at such other intervals as are specified in the label, however,

(a) devices containing only krypton need not be tested for leakage of radioactive material, and

[5/] Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.

(11) Safe Shutdown

A brief description of restoring the facility to a safe condition after an accident.

(12) Exercises

Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

(d) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the Agency. The licensee shall provide any comments received within the 60 days to the Agency with the emergency plan.

Specific Licenses

Sec. C.24 Filing Application for Specific Licenses.

(a) Applications for specific licenses shall be filed on a form prescribed by the Agency.

(b) The Agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(d) An application for a license may include a request for a license authorizing one or more activities.

(e) In his application, the applicant may not incorporate by reference information contained in previous applications, statements, or reports filed with the Agency, but must resubmit the above information after the review, and updating as necessary, as part of the current application.

(f) Applications and other documents are subject to public inspection and copying as provided at State Government Article, §10-611 et seq. Annotated Code of Maryland.

(g) Application for a Specific License to use Byproduct Material in the Form of a Sealed Source or in a Device that Contains the Sealed Source.

(1) Except as provided in Sections C.24(g)(2),(3), and (4), an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either:

(i) Identify the source or device by manufacturer and model number as registered with the Agency under Section C.37 or comparable regulations of an Agreement State or the NRC, or for a source or a device containing radium-226 or accelerator-produced radioactive material with an Agreement State or the NRC under provisions comparable to Section C.37; or

(ii) Contain the information identified in Section C.37(b).

(2) For sources or devices manufactured before October 23, 2012 that are not registered with the Agency under Section C.37 or with the NRC or an Agreement State in accordance with provisions comparable to Section C.37, and for which the applicant is unable to provide all categories of information specified in Section C.37(b), the application must include:

(i) All available information identified in Section C.37(b) concerning the source, and, if applicable, the device; and

(ii) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

(3) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with Section C.37(f), the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

(4) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

~~Sec. C.25 General Requirements for the Issuance of Specific Licenses.~~

Comment [MDK12]: DELETED: An application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must identify the source or device by manufacturer and model number as registered with the NRC and must meet the requirements of Section C.37.

Comment [MDK13]: 30.32(g)

Comment [MDK14]: Moved to Page C24-1.

Sec. C.25 General Requirements for the Issuance of Specific Licenses.

(a) A license application will be approved if the Agency determines that:

(1) the applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these regulations in such a manner as to minimize danger to public health and safety or property;

(2) the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

(3) the issuance of the license will not be inimical to the health and safety of the public;

(4) the applicant satisfies any applicable special requirements in C.26, C.27, C.28, Part E, Part G, or Part W of these regulations;

(5) the applicant maintains an office in Maryland

(i) which is open for business during normal business hours,

(ii) where records are immediately available for inspection,

(iii) and where the radioactive material equipment or device will be available for inspection

(a) at either the office location, or

(b) at a temporary job site convenient to the inspector;

(6) the applicant has met the requirements for financial assurance and recordkeeping for decommission specified in C.29;

Comment [MDK15]: All text above moved from Page C24.

(7) the environmental report, if required by the Agency under C.25(b), is acceptable;

(8) the radioactive material being licensed is not an isotope of Cesium for the use or storage in a liquid or water environment; and

(9) the applicant has adequately described in the application how facility design and procedures for operation will, in accordance with Section D.1406, minimize, to the extent practicable, the introduction of residual radioactivity into the site, including the subsurface, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

(b) In the case of an application for a license or amendment to an existing license to receive and possess radioactive material for the conduct of any activity which the Agency determines will significantly affect the quality of the environment, the applicant shall prepare an environmental report. The report shall address the environmental, economic, technical and other benefits against environmental costs considering available alternatives, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would 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.

(c) Each specific license application shall contain a provision for an emergency plan as specified in C.23.

Comment [MDK16]: All text above moved from Page C25.

(d) A specific licensee may not possess devices containing sealed sources, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas, that have not been used for a period longer than 3 years. When devices containing a shutter are not being used, the shutter must be locked in the closed position. The reporting requirements in Sec. D.1211(f) shall apply.

(The remainder of this page is blank.)

Comment [MDK17]: (d) is new text

~~(7) the environmental report, if required by the Agency under C.25(b), is acceptable;~~

~~(8) the radioactive material being licensed is not an isotope of Cesium for the use or storage in a liquid or water environment; and~~

~~(9) the applicant has adequately described in the application how facility design and procedures for operation will, in accordance with Section D.1406, minimize, to the extent practicable, the introduction of residual radioactivity into the site, including the subsurface, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.~~

~~(b) In the case of an application for a license or amendment to an existing license to receive and possess radioactive material for the conduct of any activity which the Agency determines will significantly affect the quality of the environment, the applicant shall prepare an environmental report. The report shall address the environmental, economic, technical and other benefits against environmental costs considering available alternatives, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would 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.~~

~~(c) Each specific license application shall contain a provision for an emergency plan as specified in C.23.~~

Comment [MDK18]: Text above moved to C24-1.

Sec. C.26 Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material.

(a) - (b) Reserved.

(c) Specific License for Certain Measurement and Control Devices.

Effective October 1, 2013, a specific license shall be obtained from the Agency in accordance with Sections C.24 and C.25 for the possession and use of sealed source devices containing radioactive material which contain at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, 3.7 MBq (0.1 mCi) of radium-226, or 37 MBq (1 mCi) of americium-241 or any other transuranic element (i.e., element with atomic number greater than uranium (92), based on the activity indicated on the label).

(d) Specific License for Well Logging. An application for a specific license for the use of licensed material in industrial radiography will be approved if the applicant meets the following requirements:

(1) The applicant satisfies the general requirements specified in Sec. C.25 for radioactive material, as appropriate, and any special requirements contained in this part.

(2) The applicant shall develop a program for training logging supervisors and logging assistants and submit to the Agency a description of this program which specifies the:

(i) Initial training;

(ii) On-the-job training;

(iii) Annual safety reviews provided by the licensee;

(iv) Means the applicant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the Agency's regulations and licensing requirements and the applicant's operating and emergency procedures; and

(v) Means the applicant will use to demonstrate the logging assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures.

(3) The applicant shall submit to the Agency written operating and emergency procedures as described in Sec.W.202 or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.

(4) The applicant shall establish and submit to the Agency its program for annual inspections of the job performance of each logging supervisor to ensure that the Agency's regulations, license requirements, and the applicant's operating and emergency procedures are followed. Inspection records must be retained for 3 years after each annual internal inspection.

(5) The applicant shall submit a description of its overall organizational structure as it applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility.

(6) If an applicant wants to perform leak testing of sealed sources, the applicant shall identify the manufacturers and the model numbers of the leak test kits to be used. If the applicant wants to analyze its own wipe samples, the applicant shall establish procedures to be followed and submit a description of these procedures to the Agency. The description must include the:

(i) Instruments to be used;

(ii) Methods of performing the analysis; and

(iii) Pertinent experience of the person who will analyze the wipe samples.

(7) A licensee may perform well logging with a sealed source only after the licensee has a written agreement with the employing well owner or operator. This written agreement must identify who will meet the following requirements:

(i) If a sealed source becomes lodged in the well, a reasonable effort will be made to recover it;

(ii) A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture;

(iii) The radiation monitoring required in Sec.W.202(n) will be performed;

(iv) If the environment, any equipment, or personnel are contaminated with licensed material, they must be decontaminated before release from the site or release for unrestricted use; and

(v) If the sealed source is classified as irretrievable after reasonable efforts at recovery have been expended, the following requirements must be implemented within 30 days:

(a) Each irretrievable well logging source must be immobilized and sealed in place with a cement plug;

(b) A means to prevent inadvertent intrusion on the source, unless the source is not accessible to any subsequent drilling operations; and

(c) A permanent identification plaque, constructed of long lasting material such as stainless steel, brass, bronze, or monel, must be mounted at the surface of the well, unless the mounting of the plaque is not practical. The size of the plaque must be at least 17 cm [7 inches] square and 3 mm [$^{1}/_{8}$-inch] thick. The plaque must contain:

(i) The word "CAUTION";

(ii) The radiation symbol (the color requirement in Sec. D.901(a) need not be met);

(iii) The date the source was abandoned;

(iv) The name of the well owner or well operator, as appropriate;

(v) The well name and well identification number(s) or other designation;

(vi) An identification of the sealed source(s) by radionuclide and quantity;

(vii) The depth of the source and depth to the top of the plug; and

(viii) An appropriate warning, such as, "DO NOT RE-ENTER THIS WELL."

(c) [Reserved]

(d) Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under C.22(d).

(1) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under C.22(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State will be approved if:

(i) the applicant satisfies the general requirements of C.25;

(ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(a) the device can be safely operated by persons not having training in radiological protection,

(b) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of 1 calendar quarter a dose in excess of 10 percent of the limits specified in the table in D.201(a) of these regulations, and

(c) under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye . . . . . 15 rems (150 mSv)

Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter . . . . . 200 rems (2 Sv)

Other organs . . . . . 50 rems (500 mSv); and

(d) the device has been manufactured so that:

(1) The dose rate in the radiation beam of the device at 18 inches (0.46 meters) from the radiation source with the device shutter in the open position does not exceed 125 millirem (1.25 mSv) per hour; and

(2) There is not an accessible air gap of 18 inches (0.46 meters) or greater between the radiation source and detector which would allow insertion of a 12 inch (0.30 meter) diameter sphere into the radiation beam.

(iii) each device bears a durable, legible, clearly visible label or labels approved by the Agency, which contain in a clearly identified and separate statement:

(a) instructions and precautions necessary to assure safe installation, operation, and servicing of the device; documents such as operating and service manuals may be identified in the label and used to provide this information,

(b) the requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity, and

(c) the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(1) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____ 9/, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

Name of manufacturer or distributor

(2) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____ 9/, are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

Name of manufacturer or distributor

Comment [MDK19]: Above text moved from Page C33.

(iv) The device has been registered in the Sealed Source and Device Registry.

Comment [MDK20]: 32.51(a)(6)

9/ The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

Comment [MDK21]: Note moved from Page C33.

~~Name of manufacturer or distributor~~

~~(2) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____[9], are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.~~

~~CAUTION - RADIOACTIVE MATERIAL~~

~~Name of manufacturer or distributor~~

Comment [MDK22]: Above text moved to Page C32.

(2) In the event the applicant desires that the device be required to be tested at intervals longer than 6 months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Agency will consider information which includes, but is not limited to:

(i) primary containment or source capsule;

(ii) protection of primary containment;

(iii) method of sealing containment;

(iv) containment construction materials;

(v) form of contained radioactive material;

(vi) maximum temperature withstood during prototype tests;

(vii) maximum pressure withstood during prototype tests;

(viii) maximum quantity of contained radioactive material;

(ix) radiotoxicity of contained radioactive material; and

(x) operating experience with identical devices or similarly designed and constructed devices.

~~[9] The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.~~

Comment [MDK23]: Note moved to Page C32.

(3) In the event the applicant desires that the general licensee under C.22(d), or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10 percent of the limits specified in the table in D.201(a) of these regulations.

(4) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution – Radioactive Material", the radiation symbol described in D.901 and the name of the manufacturer or initial distributor.

(5) Each device meeting the criteria of C.26(c) bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution – Radioactive Material", and, if practicable, the radiation symbol described in D.901.

(6) If a device containing byproduct material is to be transferred for use under the general license contained in C.22, each person that is licensed under C.28(d) shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(i) A copy of the general license contained in C.22; if requirements in C.22(d)(3)(ii-iv) or C.26(c) do not apply to the particular device, those requirements may be omitted;

(ii) A copy of Sections C.20(a), C.22(d), C.38, D.1201 and D.1202;

(iii) A list of the services that can only be performed by a specific licensee;

(iv) Information on acceptable disposal options including estimated costs of disposal; and

(v) An indication that the U.S. Nuclear Regulatory Commission's policy is to issue high civil penalties for improper disposal.

(7) If byproduct material is to be transferred in a device for use under an equivalent general license of an Agreement State, each person that is licensed under C.28(d) shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(c) For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(d) If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(e) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(f) The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

(g) If no transfers have been made to or from the U.S. Nuclear Regulatory Commission or other Agreement States during the reporting period, this information shall be reported to the responsible U.S. Nuclear Regulatory Commission or Agreement State agency upon request of that agency.

(iii) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this paragraph must be maintained for a period of 3 years following the date of the recorded event.

(e) Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under C.22(e) will be approved if:

(1) the applicant satisfies the general requirements specified in C.25; and

(2) the applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, and 32.56~~, and 32.101~~ of 10 CFR Part 32, or their equivalent.

Comment [MDK24]: 32.53(b)(5),(d)(4),(e),(f), 32.55, 32.56

(f) Calibration or Reference Sources Containing Americium-241 or Radium-226: Requirements for License to Manufacture or Initially Transfer. An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226, for distribution to persons generally licensed under Section C.22(g), will be approved if:

(1) The applicant satisfies the general requirements of Section C.25;

(2) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(i) Chemical and physical form and maximum quantity of americium-241 or radium-226 in the source;

(ii) Details of construction and design;

(iii) Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;

(iv) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

(v) Details of quality control procedures to be followed in manufacture of the source;

(vi) Description of labeling to be affixed to the source or the storage container for the source;

(vii) Any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the source.

(3) Each source will contain no more than 5 microcuries of americium-241 or radium-226.

(4) The Agency determines, with respect to any type of source containing more than 0.005 microcurie of americium-241 or radium-226, that:

(i) The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

(ii) The source has been subjected to and has satisfactorily passed ~~the prototype tests prescribed by Appendix I of this section~~ appropriate tests required by C.28(f)(5).

Comment [MDK25]: 32.57(d)(2)

(5) The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 to tests as follows:

Comment [MDK26]: 32.57(e)

(i) The initial quantity of radioactive material deposited on each source is measured by direct counting of the source.

(ii) The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion.

(iii) The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in subparagraph (iv) of this section.

(iv) Source designs are rejected for which the following has been detected for any unit: Removal of more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 from the source or any other evidence of physical damage.

~~(g) Calibration or Reference Sources Containing Americium-241 or Radium-226: Labeling of Devices in Section C.28(f).~~

~~Each person licensed under Section C.28(f) shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:~~

Comment [MDK27]: Stricken text moved to Page C35-2.

~~(This page intentionally blank.)~~

(g) Calibration or Reference Sources Containing Americium-241 or Radium-226: Labeling of Devices in Section C.28(f).

Each person licensed under Section C.28(f) shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:

> The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.
>
> CAUTION – RADIOACTIVE MATERIAL
> THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226)
> DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE
>
> _____
> (Name of Manufacturer or Initial Transferor)

(h) Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of C.22(i) will be approved if:

Comment [MDK28]: This text moved from Page C35-1.

(1) the applicant satisfies the general requirements specified in C.25.

(2) the radioactive material is to be prepared for distribution in prepackaged units of:

(i) carbon-14 in units not exceeding 10 microcuries (370 kBq) each.

(ii) cobalt-57 in units not exceeding 10 microcuries (370 kBq) each.

(iii) hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.

(iv) iodine-125 in units not exceeding 10 microcuries (370 kBq) each.

(v) Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.

(vi) iodine-131 in units not exceeding 10 microcuries (370 kBq) each.

(vii) iron-59 in units not exceeding 20 microcuries (740 kBq) each.

(viii) selenium-75 in units not exceeding 10 microcuries (370 kBq) each.

(3) each prepackaged unit bears a durable, clearly visible label:

(i) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; and

(ii) displaying the radiation caution symbol described in D.901(a)(1) and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals."

(4) one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(i) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

(ii) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a Licensing State.

Name of manufacturer

(5) the label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in D.1001 of these regulations.

(i) Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under C.22(j) will be approved if:

(1) the applicant satisfies the general requirements of C.25; and

(2) the criteria of Sections 32.61 and~~,~~ 32.62~~, and 32.103~~ of 10 CFR Part 32 are met.

Comment [MDK29]: 32.61(e)(4)

(j) Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Radioactive Material for Medical Use Under Part G.

(1) An application for a specific license to manufacture, prepare or transfer for commercial distribution radioactive drugs containing radioactive material for persons authorized pursuant to Part G of this regulation will be approved if:

(i) The applicant satisfies the general requirements specified in C.25;

(ii) 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.

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

(iv) 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 radioactive 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 radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive 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 radioactive 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 in C.28(j)(1)(ii)(c) or (d):

(i) May prepare radioactive drugs for medical use, as defined in Sec. A.2, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in C.28(j)(2)(ii) and (iv), or an individual under the supervision of an authorized nuclear pharmacist as specified in Sec. G.27.

(ii) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(a) This individual qualifies as an authorized nuclear pharmacist as defined in Sec. A.2;

(b) This individual meets the requirements specified in Secs. G.55(b) and G.59 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(c) This individual is designated as an authorized nuclear pharmacist in accordance with C.28(j)(2)(iv).

(iii) The actions authorized in C.28(j)(2)(i) and (ii) are permitted in spite of more restrictive language in license conditions.

(iv) May designate a pharmacist (as defined in Sec. A.2) as an authorized nuclear pharmacist if:

(a) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

(b) The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the Agency.

(v) Shall provide to the Agency:

(a) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Agency, NRC, or an Agreement State as specified in Section G.55(a) of this regulation with the written attestation signed by a preceptor as required by Section G.55(b)(2) of this regulation; or

(b) The Agreement State or NRC license; or

(c) The NRC master materials licensee permit; or

(d) The permit issued by a licensee or NRC master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

(e) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the Agency; and

(f) A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under Sections C.28(j)(2)(ii)(a) and C.28(j)(2)(ii)(c), the individual to work as an authorized nuclear pharmacist.

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(i) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(ii) Check each instrument for constancy and proper operation at the beginning of each day of use.

(4) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(k) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material.10/ An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to this part for the uses listed in G.200 of these regulations will be approved if:

(1) the applicant satisfies the general requirements specified in C.25;

(2) the applicant submits evidence that:

(i) the generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or

(ii) the manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(3) the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(4) the label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

(5) the label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

(i) adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

(ii) a statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the Agency pursuant to G.200 of these regulations or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The labels, leaflets, or brochures required by C.28(k) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

10/ Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the Agency for use by persons licensed pursuant to G.200 of these regulations may submit the pertinent information specified in C.28(k).

(l) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part G for use as a calibration, transmission, or reference source, or for diagnostic, brachytherapy or teletherapy sources for the uses listed in G.400, G.500, G.600, and G.1000 of these regulations, will be approved if:

(1) the applicant satisfies the general requirements in C.25 of this part;

(2) the applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) the radioactive material contained, its chemical and physical form, and amount,

(ii) details of design and construction of the source or device,

(iii) procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

(iv) for devices containing radioactive material, the radiation profile of a prototype device,

(v) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

(vi) procedures and standards for calibrating sources and devices,

(vii) legend and methods for labeling sources and devices as to their radioactive content, and

(viii) instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(3) the label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the source or device is licensed by the Agency for distribution to persons licensed pursuant to G.400, G.500, G.600, and G.1000 of these regulations or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, provided that such labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;

(4) the source or device has been registered in the Sealed Source and Device Registry;

Comment [MDK30]: 32.59

(45) in the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than 6 months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

(~~5~~6) in determining the acceptable interval for test of leakage of radioactive material, the Agency will consider information that includes, but is not limited to:

(i) primary containment or source capsule,

(ii) protection of primary containment,

(iii) method of sealing containment,

(iv) containment construction materials,

(v) form of contained radioactive material,

(vi) maximum temperature withstood during prototype tests,

(vii) maximum pressure withstood during prototype tests,

(viii) maximum quantity of contained radioactive material,

(ix) radiotoxicity of contained radioactive material, and

(x) operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(m) Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications.

(1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to C.21(e) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

(i) the applicant satisfies the general requirements specified in C.25;

(ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of 1 calendar quarter a radiation dose in excess of 10 percent of the limits specified in D.201 of these regulations; and

(iii) the applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the Agency will approve an application for a specific license under C.28(m) only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The Agency may deny any application for a specific license under C.28(m) if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to C.28(m)(1) shall:

(i) maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

(ii) label or mark each unit to:

(a) identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(b) state that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an Agreement State;

(iii) assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

(iv) (a) furnish a copy of the general license contained in C.21(e) to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in C.21(e), or

(b) furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to C.21(e) and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in C.21(e) to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in C.21(e);

(v) report to the Agency all transfers of industrial products or devices to persons for use under the general license in C.21(e). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under C.21(e) during the reporting period, the report shall so indicate;

(vi) (a) report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40,

(b) report to the responsible State agency all transfers of devices manufactured and distributed pursuant to C.28(m) for use under a general license in that State's regulations equivalent to C.21(e),

(c) such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person,

(d) if no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission, and

(e) if no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon the request of that agency; and

(vii) keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in C.21(e) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of 2 years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

(n) Requirement for Sealed Source and Device Sheets. Any applicant or specific licensee who wishes to manufacture and distribute a sealed source or a device containing a sealed source shall provide sufficient information to complete a sealed source and device registration.

(o) Calibration or Reference Sources Containing Americium-241 or Radium-226: Leak Testing of Each Source Under Section C.28(f). Each person licensed under Section C.28(f) shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under Section C.22(g) or under equivalent regulations of NRC or an Agreement State. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper shall be measured by using methods capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 by the methods described in this section, the source shall be rejected and shall not be transferred to a general licensee under Section C.22(g) or equivalent NRC or Agreement State regulations ~~or NRC regulations~~.

Comment [MDK31]: Delete "radiation detection instrumentation"

Comment [MDK32]: Delete "this test discloses"

Comment [MDK33]: Delete "radioactive material"

Comment [MDK34]: Delete "shall be deemed to be leaking or losing americium-241 or radium-226"

(i) As the final step in decommissioning, the licensee shall—

(1) Certify to the Agency in writing the disposition of all licensed material, including accumulated wastes; and

(2) 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 Sections D.1401-1406. The licensee shall, as appropriate—

(i) Report levels of gamma radiation in units of millisieverts (microroentgens) 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

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

(3) Forward all records required by Sec. C.38 to the Agency.

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

(1) Radioactive material has been properly disposed of;

(2) Reasonable effort (as determined by the Agency) has been made to eliminate residual radioactive contamination if present; and

(3) (i) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in Sections D.1401-1406; or

(ii) 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 Sections D.1401-1406.

Sec. C.33 Application for Renewal of Licenses.

(a) Subject to C.32(a), an application for renewal of a specific license must be filed on a form prescribed by the Agency, in accordance with C.24.

(b) All applications for the renewal of a specific license shall be submitted to the Agency for review and approval seven (7) months prior to the expiration date of the license.

Sec. C.34 Amendment of Licenses at Request of Licensee. Applications for amendment of a license shall be filed in accordance with C.24 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

Sec. C.35 Agency Action on Applications to Renew or Amend. In considering an application by a licensee to renew or amend the license, the Agency will apply the criteria set forth in C.25, C.26, C.27, and C.28 and in Parts E, G, or W of these regulations, as applicable.

Sec. C. 36 Person Possessing a License for Medical Use of Radioactive Material on Effective Date of These Regulations. Any person or institution possessing a specific license for the medical use of radioactive material issued prior to October 9, 1995 when the licensee was authorized according to Groups I through VI of Schedule C, Part C, shall be deemed to possess a license issued under the revised regulations, according to Part G. The existing license will be valid until its stated expiration date and the renewal will be issued in accordance with the regulations dated October 9, 1995.

Sec. C.37 Registration of Sources or Devices Containing Radioactive Materials.

(a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the Agency in a form acceptable to the Agency for evaluation of radiation safety information about its product and for its registration.

Comment [MDK35]: DELETED: "whose product is intended for use under a specific or general license"

Comment [MDK36]: 32.210(a) and (b)

(b) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

(c) The Agency normally evaluates a sealed source or device using radiation safety criteria in accordance with accepted industry standards. If these standards and criteria do not readily apply to a particular case, the agency formulates reasonable standards and criteria with the help of the manufacturer or distributor. The Agency shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property. Section C.4 includes specific criteria that apply to certain exempt products and Section C.22 includes specific criteria applicable to certain generally licensed devices. Section C.28 includes specific provisions that apply to certain specifically licensed items.

Comment [MDK37]: 32.210(d)

(d) After completion of the evaluation, the Agency may issue a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.

Comment [MDK38]: 32-210(e)

(e) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:

(1) The statements and representations, including quality control program, contained in the request; and

(2) The provisions of the registration certificate.

(f) Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:

Comment [MDK39]: 32.210(g)

(1) Calibration and reference sources containing no more than:

(i) 37 MBq (1 mCi), for beta and/or gamma emitting radionuclides; or

(ii) 0.37 MBq (10 µCi), for alpha emitting radionuclides; or

(2) The intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses; and

(i) The intended recipients are licensed under Part C of this regulation or comparable provisions of NRC or an Agreement State; or

(ii) The recipients are authorized for research and development; or

(iii) The sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide.

(g) After the certificate is issued, the Agency may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the Agency will complete its evaluation in accordance with criteria specified in Section C.37. The Agency may request such additional information as it considers necessary to conduct its review and the certificate holder shall provide the information as requested.

Comment [MDK40]: 32.210(h)

(~~f~~h) For sources or devices containing naturally occurring or accelerator produced radioactive material manufactured prior to November 30, 2007 that are not registered with the Agency under Section C.37, with the NRC under 10 CFR 32.210, or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in Section C.37, the applicant shall provide:

Comment [MDK41]: Moved from Page C51-1.

(1) All available information identified in Section C.37 concerning the source, and, if applicable, the device; and

(2) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information shall include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

(i) Inactivation of Certificates.

(1) A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the Agency shall request inactivation of the registration certificate. Such a request must be made to the Agency by an appropriate method approved by the Agency and must normally be made no later than two years after initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the certificate holder shall request inactivation of the certificate within 90 days of this determination and briefly describe the circumstances of the delay.

Comment [MDK42]: 32.211

(2) If a distribution license is to be terminated in accordance with Part C of this regulation, the licensee shall request inactivation of its registration certificates associated with that distribution license before the Agency will terminate the license. Such a request for inactivation of certificate(s) must indicate that the license is being terminated and include the associated specific license number.

(3) A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.

Sec. C.38 Records.

(a) Each person who receives radioactive material through a license issued pursuant to the regulations in this part shall keep records showing the receipt, transfer, and disposal of the radioactive material as follows:

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

Comment [MDK43]: C.38 moved from Page C51-1.

(2) The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a specific requirement in another part of these regulations dictates otherwise.

(3) The licensee who disposed of the material shall retain each record of disposal of radioactive material until the Department terminates each license that authorizes disposal of the material.

(b) The license~~e~~ shall retain each record that is required by the regulations in this Part and Part D or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(c) (1) Records which must be maintained pursuant to this Part and Part D may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Department regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(2) If there is a conflict between the Department's regulations in this Part and Part D, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this Part and Part D for such records shall apply unless the Department, pursuant to Sec. A(3)(a), has granted a specific exemption from the record retention requirements specified in the regulations in this Part or Part D.

(d) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the Agency:

(1) Records of disposal of licensed material made under Secs. D.1002 (including burials authorized before September 21, 1986), D.1003, D.1005, D.1006; and

(2) Records required by Sec. D.1103(b)(iv).

(e) If licensed activities are transferred or assigned in accordance with Sec. C.31(b), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material made under D.1002 (including burials authorized before January 28, 1981), D.1103, D.1105, D.1106; and

(2) Records required by D.1103(b)(iv).

(f) Prior to license termination, each licensee shall forward the records required by C.29(f) to the Agency.

Comment [MDK44]: This text moved from C51-2.

Comment [MDK45]: End of text moved from Page C51-2.

Transfer of Material

Sec. C.40 Transfer of Material.

(a) No licensee shall transfer radioactive material except as authorized pursuant to C.40.

(b) Except as otherwise provided in his license and subject to the provisions of C.40(c) and (d), any licensee may transfer radioactive material:

(1) to the Agency;[11]

(2) to the U.S. Department of Energy;

(3) to any person exempt from these regulations to the extent permitted under such exemption;

(4) to any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Agency, the U.S. Nuclear Regulatory Commission, any Agreement State or any Licensing State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Agency, an Agreement State, or a Licensing State; or

(5) as otherwise authorized by the Agency in writing.

[11] A licensee may transfer material to the Agency only after receiving prior written approval from the Agency.

(c) Before transferring radioactive material to a specific licensee of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a general licensee who is required to register with the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

Comment [MDK46]: Moved from Page C52.

(d) Any of the following methods for the verification required by C.40(c) is acceptable:

(1) The transferor may possess and read a current copy of the transferee's specific license or registration certificate.

(2) The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date.

(3) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within 10 days.

Comment [MDK47]: End of text moved from Page C52.

(4) The transferor may obtain other information compiled by a reporting service from official records of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State regarding the identity of licensees and the scope and expiration dates of licenses and registration.

(5) When none of the methods of verification described in C.40(d)(1) through (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State, or a Licensing State that the transferee is licensed to receive the radioactive material.

(e) Shipment and transport of radioactive material shall be in accordance with the provisions of Part T of these regulations.

National Source Tracking System

C.41 Nationally Tracked Source Thresholds.

Nationally tracked source thresholds are specified in Appendix H of this Part.

C.42 Serialization of Nationally Tracked Sources.

Each licensee who manufactures a nationally tracked source shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alphanumeric characters.

C.43 Reports of Transactions Involving Nationally Tracked Sources. Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in (a) through (e) of this section for each type of transaction.

(a) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of the source;

(4) The radioactive material in the source;

(5) The initial source strength in becquerels (curies) at the time of manufacture; and

(6) The manufacture date of the source.

Comment [MDK48]: (5) and (6) moved from C53.

(b) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The name and license number of the recipient facility and the shipping address;

(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The shipping date;

(9) The estimated arrival date; and

(10) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the identification of the container with the nationally tracked source.

(c) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The name, address, and license number of the person that provided the source;

(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The date of receipt; and

(9) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container information with the nationally tracked source.

Part C

Appendix H

Nationally Tracked Source Thresholds

Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1600	0.6	16
Americium-241/Be	60	1600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1400	0.5	14
Cesium-137	100	2700	1	27
Gadolinium-153	1000	27000	10	270
Iridium-192	80	2200	0.8	22
Plutonium-238	60	1600	0.6	16
Plutonium-239/Be	60	1600	0.6	16
Polonium-210	60	1600	0.6	16
Promethium-147	40000	1100000	400	11000
Radium-226	40	1100	0.4	11
Selenium-75	200	5400	2	54
Strontium-90	1000	27000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20000	540000	200	5400
Ytterbium-169	300	8100	3	81

Appendix I [Reserved]

~~Prototype Tests for Calibration or Reference Sources Containing Americium-241 or Radium-226~~

~~An applicant for a license under Section C.28(f) shall, for any type of source which is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, conduct prototype tests, in the order listed, on each of five prototypes of the source, which contains more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, as follows:~~

~~(a) *Initial measurement*. The quantity of radioactive material deposited on the source shall be measured by direct counting of the source.~~

~~(b) *Dry wipe test*. The entire radioactive surface of the source shall be wiped with filter paper with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper or by direct measurement of the radioactivity on the source following the dry wipe.~~

~~(c) *Wet wipe test*. The entire radioactive surface of the source shall be wiped with filter paper, moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper after it has dried or by direct measurement of the radioactivity on the source following the wet wipe.~~

~~(d) *Water soak test*. The source shall be immersed in water at room temperature for a period of 24 consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall be determined by direct measurement of the radioactivity on the source after it has dried or by measuring the radioactivity in the residue obtained by evaporation of the water in which the source was immersed.~~

~~(e) *Dry wipe test*. On completion of the preceding test in this section, the dry wipe test described in paragraph (b) of this section shall be repeated.~~

~~(f) *Observations*. Removal of more than 0.005 microcurie of radioactivity in any test prescribed by this section shall be cause for rejection of the source design. Results of prototype tests submitted to the Agency shall be given in terms of radioactivity in microcuries and percent of removal from the total amount of radioactive material deposited on the source.~~

Sec. D.1207 Annual Reports from General Licensees.

a. A licensee granted a general license under Section C.22(e), (g), (i), or (j) shall report annually, the following information on a form provided by the Agency:

   i. The amount and kind of radioactive material received during the previous year;

   ii. The form of the radioactive material;

   iii. The amount possessed by the licensee at the time of the report; and

   iv. The pathways and amounts of radioactive material disposed of by that person during the previous year.

b. The information required by D.1207a.iv. shall be estimated using a technique that is acceptable to the Department.

c. The report required by D.1207a. shall cover the calendar year from January 1 to December 31 and shall be forwarded to the Department not later than March 1 of the following year.

Sec. D.1208 Report and Notification of a Misadministration.

a. Licensees and registrants shall establish appropriate procedures, through compliance with the written directive, to prevent the occurrence of a misadministration.

b. A licensee or registrant shall report any misadministration in which the administration of byproduct material, or radiation from byproduct material or a radiation machine results in:

   i. A dose from byproduct material that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; and

      (1) The total dose delivered differs from the prescribed dose by 20 percent or more;

      (2) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

      (3) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

   ii. A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:

      (1) An administration of a wrong radioactive drug containing byproduct material;

      (2) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

      (3) An administration of a byproduct material dose or dosage to the wrong individual or human research subject;

      (4) An administration of a byproduct material dose or dosage delivered by the wrong mode of treatment; or

      (5) A leaking sealed source.

iii. A byproduct material dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

iv. A radiation ~~tele~~therapy ~~radiation~~ dose or dose from a radiation machine:

(1) Involving the wrong individual, wrong mode of treatment, or wrong treatment site, or of a type other than the one intended; or

(2) When the treatment consists of three or fewer fractions, a difference of the calculated total administered dose from the total prescribed dose by more than 10 percent of the total prescribed dose; or

(3) A calculated weekly administered dose that is 30 percent greater than the weekly prescribed dose; or

(4) A calculated total administered dose that differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

c. The licensee or registrant shall notify by telephone the Agency no later than the next calendar day after discovery of the misadministration.

d. The licensee or registrant shall submit a written report to the Agency within 15 days after discovery of the misadministration.

i. The written report must include:

(1) The licensee's or registrant's name;

(2) The name of the prescribing physician;

(3) A brief description of the misadministration;

(4) Why the misadministration occurred;

(5) The effect, if any, on the individual(s) who received the administration;

(6) What actions, if any, have been taken or are planned to prevent recurrence; and

(7) A certification signed by the appropriate authorized user or registrant that the licensee or registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not.

ii. The report may not contain the individual's name or any other information that could lead to identification of the individual.

e. The licensee or registrant shall provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee or registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee or registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee or registrant shall notify the individual as soon as possible thereafter. The licensee or registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee or registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the misadministration can be obtained from the licensee or registrant upon request. The licensee or registrant shall provide such a written description if requested.

(3) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

ii. An event in which equipment is disabled or fails to function as designed when:

(1) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(2) The equipment is required to be available and operable when it is disabled or fails to function; and

(3) No redundant equipment is available and operable to perform the required safety function.

iii. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

iv. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(1) The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of Part D; and

(2) The damage affects the integrity of the licensed material or its container.

c. Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

i. Licensees shall make reports required by paragraphs a. and b. of this section by telephone to the Agency. To the extent that the information is available at the time of notification, the information provided in these reports must include:

(1) The caller's name and call back number;

(2) A description of the event, including date and time;

(3) The exact location of the event;

(4) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(5) Any personnel radiation exposure data available.

ii. Written report. Each licensee who makes a report required by paragraph a. or b. of this section shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These reports must be sent to the Agency. The reports must include the following:

(1) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(2) The exact location of the event;

(3) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(4) Date and time of event;

(5) Corrective actions taken or planned and the results of any evaluations or assessments; and

(6) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

d. Each specific licensee shall notify the Agency 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:

i. The licensee;

ii. An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

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

e. The notification specified in D.1211d. shall indicate the bankruptcy court in which the petition for bankruptcy was filed, a copy of the bankruptcy petition, and the date of the filing of the petition.

f. A specific licensee shall notify the Agency in writing of the possession of a device containing a sealed source, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas, that has not been used for a period longer than 3 years.

Sec. D.1220 Notification of Failure To Comply or Existence of a Defect and Its Evaluation.

Comment [MDK49]: 10 CFR 21.21 – fix numbering

a. Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to--

~~1~~i. Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(~~2~~ii) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected;

~~2~~ii. Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Department through a director or responsible officer or designated person as discussed in Sec. D.1220(~~e~~d)(v~~5~~). The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply; and

~~3~~iii. Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in Sec. D.1220(a)(~~i1~~) or Sec. D.1220(a)(ii~~2~~) if the construction or operation of a facility or activity, or a basic component supplied for such facility or activity--

~~i.~~(1) Fails to comply with COMAR 26.12.01.01 Regulations for the Control of Ionizing Radiation (1994), or any applicable rule, order, or license of the Department relating to a substantial safety hazard, or

~~ii.~~(2) Contains a defect.

~~b. If the deviation or failure to comply is discovered by a supplier of basic components, or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers~~

b. If the deviation or failure to comply is discovered by a supplier of basic components, or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to Sec. D.1220(a).

Comment [MDK50]: First part of b. moved from Page D42-2.

c. A dedicating entity is responsible for--

~~1~~i. Identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and

ii~~2~~. Maintaining auditable records for the dedication process.

d. i~~1~~. A director or responsible officer subject to the regulations of this part or a person designated under Sec. D.1220(d~~e~~)(v~~s~~) must notify the Department when he or she obtains information reasonably indicating a failure to comply or a defect affecting--

(1)~~i.~~ The construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under Part C of these regulations, or the equivalent regulations of the NRC or another Agreement State, and that is within his or her organization's responsibility; or

(2)~~ii.~~ A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing requirements under Part C of these regulations, or the equivalent regulations of the NRC or another Agreement State.

ii~~2~~. The notification to the Department of a failure to comply or of a defect under paragraph (d~~e~~)(i~~1~~) of this section and the evaluation of a failure to comply or a defect under paragraphs (a)(i~~1~~) and (a)(ii~~2~~) of this section, are not required if the director or responsible officer has actual knowledge that the Department has been notified in writing of the defect or the failure to comply.

iii~~3~~. Notification required by paragraph (~~e~~d)(i~~1~~) of this section must be made as follows--

(1)~~i.~~ Initial notification by facsimile, which is the preferred method of notification, to the Department at (410) 537-3198 or by telephone at (410) 537-3300 within two days following receipt of information by the director or responsible corporate officer under paragraph (a)(i~~1~~) of this section, on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the Department. This paragraph does not apply to interim reports described in Sec. D.1220(a)(ii~~2~~).

(2)~~ii.~~ Written notification to the Department at the address specified in Sec. A.12 within 30 days following receipt of information by the director or responsible corporate officer under paragraph (a)(iii~~3~~) of this section, on the identification of a defect or a failure to comply.

iv~~4~~. The written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:

(1)~~i.~~ Name and address of the individual or individuals informing the Department.

(2)~~ii.~~ Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.

(3)~~iii.~~ Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.

(4)~~iv.~~ Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

~~v~~(5). The date on which the information of such defect or failure to comply was obtained.

(6)~~vi.~~ In the case of a basic component which contains a defect or fails to comply, the number and location of all such components in use at, supplied for, or being supplied for one or more facilities or activities subject to the regulations in this part.

(7)~~vii.~~ The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(8)~~viii.~~ Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.

~~v~~5. The director or responsible officer may authorize an individual to provide the notification required by this paragraph. However, such authorization does not relieve the director or responsible officer of his or her responsibility under this paragraph.

e. Individuals subject to this part may be required by the Department to supply additional information related to a defect or failure to comply. Department action to obtain additional information may be based on reports of defects from other reporting entities.

ADDITIONAL REQUIREMENTS

Sec. D.1301 Vacating Premises. (See also C.32, "Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas")

Each specific licensee shall, no less than 30 days before vacating or relinquishing possession or control of premises or other authorized use location which may have been contaminated with radioactive material as a result of his activities, notify in writing of intent to vacate and submit a written decontamination survey to the Agency. Records required by COMAR 26.12.01.01C.38 shall be forwarded to the Agency. When deemed necessary by the Agency, the licensee shall decontaminate the premises in such a manner as the Agency may specify.