

INSTRUCTION SHEET

COMAR 26.12.01.01

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

SUPPLEMENT No. 23

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Instructions: Supplement 23 to the document "Regulations for the Control of Ionizing Radiation (1994)" includes the following pages (all pages are inclusive):

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Verify to make certain that you have the pages listed above.

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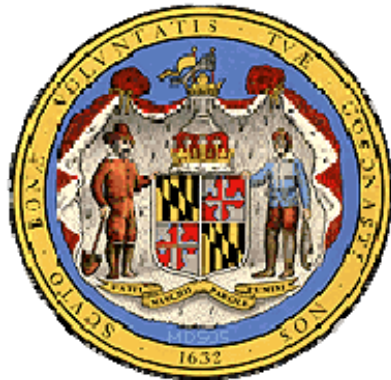


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## **REGULATIONS FOR THE CONTROL OF IONIZING RADIATION (1994)**



RADIOLOGICAL HEALTH PROGRAM  
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**Comment [mdk1]:** This is NRC Appendix A. RATS 2011-1

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- (ii) Any material that—
  - (a) Has been made radioactive by use of a particle accelerator; and
  - (b) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and
- (4) Any discrete source of naturally occurring radioactive material, other than source material, that—
  - (i) The NRC, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and
  - (ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

"Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him of determining calendar quarters for purposes of these regulations except at the beginning of a calendar year.

"Calibration" means the determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (2) the strength of a source of radiation relative to a standard.

"CFR" means Code of Federal Regulations.

"Chelating agent" means amine polycarboxylic acids, hydroxy-carboxylic acids, gluconic acid, and polycarboxylic acids.

"Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

"COMAR" means Code of Maryland Regulations

"Commencement of construction" means taking any action defined as "construction" or any other activity at the site of a facility or licensee subject to these regulations that has a connection to radiological health and safety;

Comment [mdk5]: RATS 2011-2; §§30.4 & 36.2

"Committed dose equivalent" [See "Dose"]

"Committed effective dose equivalent" [See "Dose"]

"Consortium" means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

"Construction" means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to these regulations that are related to radiological health and safety. The term "construction" does not include:

Comment [mdk6]: RATS 2011-2; §§30.4 & 36.2

- (i) Changes for temporary use of the land for public recreational purposes;
- (ii) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;
- (iii) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

- (iv) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to these regulations;
- (v) Excavation;
- (vi) Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;
- (vii) Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);
- (viii) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or
- (ix) Taking any other action that has no connection to radiological health and safety.

“Critical group” means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

“Curie” means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of  $3.7 \times 10^{10}$  transformations per second (tps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) = 0.001 curie =  $3.7 \times 10^7$  tps. One microcurie ( $\mu$ Ci) = 0.000001 curie =  $3.7 \times 10^4$  tps (see A.12 for SI equivalent becquerel).

“Decommission” means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:

- (1) Release of the property for unrestricted use and termination of the license; or
- (2) Release of the property under restricted conditions and termination of the license.

“Deep dose equivalent” [see “Dose”]

“Depleted uranium” means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

“Discrete source” means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

“Distinguishable from background” means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

“Dose” is a generic term that means absorbed dose, committed dose equivalent, committed effective dose equivalent, deep dose equivalent, dose equivalent, effective dose equivalent, external dose, eye dose equivalent, shallow dose equivalent, total effective dose equivalent, or total organ dose equivalent. For purposes of these regulations, “radiation dose” is an equivalent term.

- (1) “Absorbed dose” means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.
- (2) “Committed dose equivalent” ( $H_{T,50}$ ) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.
- (3) “Committed effective dose equivalent” ( $H_{E,50}$ ) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ( $H_{E,50} = \sum w_T H_{T,50}$ ).
- (4) “Deep dose equivalent” ( $H_d$ ), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter ( $1000 \text{ mg/cm}^2$ ).
- (5) “Dose equivalent ( $H_T$ )” means the product of the absorbed dose in tissue, quality factor and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.
- (6) “Effective dose equivalent ( $H_E$ )” means the sum of the products of the dose equivalent to each organ or tissue ( $H_T$ ) and the weighting factor ( $w_T$ ) applicable to each of the body organs or tissues that are irradiated ( $H_E = \sum w_T H_T$ ).



- (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<sup>2</sup>).
- (9) "Shallow dose equivalent" (H<sub>s</sub>), 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<sup>2</sup>).
- (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) of these regulations.

"Dose equivalent" [see "Dose"]

"Dose Limits" means the permissible upper bounds of radiation doses established in accordance with these regulations. For purposes of these regulations, "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.<sup>2</sup>

"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.

<sup>2</sup>When not underlined as above, the term 'Exposure' has a more general meaning in these regulations.

"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.

"Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

"Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

"License" means a license to possess or use radioactive material, including a license amendment, issued by the Agency.

"Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the Agency.

"Licensed Practitioner of the healing arts" means a person duly licensed to practice medicine and surgery, osteopathic medicine and surgery, chiropractic, dentistry, podiatry, or veterinary medicine and surgery approved by a health regulatory board of Maryland for the ascertainment, cure, relief, palliation, adjustment, or correction of any human/animal disease, ailment, deformity, or injury.

"Licensee" means any person who is licensed by the Agency in accordance with these regulations.

"Licensing State" means any State with regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

"Limits" [See "Dose Limits"]

"Lost or missing licensed material" means licensed material whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

"Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding 4 times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in Section 71.4 of 10 CFR Part 71.

"Medical use" means the intentional internal or external administration of radioactive material, or the radiation therefrom, to patients or human research subjects in the practice of the healing arts.

"Member of the public" means any individual except when that individual is receiving an occupational dose.

"Minor" means an individual less than 18 years of age.

"Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these regulations, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

"NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.

"Natural radioactivity" means radioactivity of naturally occurring nuclides.

“Normal form radioactive material” means radioactive material that has not been demonstrated to qualify as “special form radioactive material.”

"Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

"Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involved exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. This includes exposure to radiation from registered and unregistered radiation machines or exposure to radioactive material from licensed and unlicensed sources of radiation. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Sec. G.75, from voluntary participation in medical research programs, or as a member of the public.

"Package" means the packaging together with its radioactive contents as presented for transport.

"Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV.

"Person" means an individual, receiver, trustee, guardian, personal representative, fiduciary, or representative of any kind and any partnership, firm, association, corporation, or other entity. "Person" includes any public or municipal corporation and any agency, bureau, department, or instrumentality of State or local government and, to the extent authorized by federal law, federal government.

"Personnel monitoring equipment" [See "Individual monitoring devices"]

"Pharmacist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

"Physician" means an individual who is authorized under the Maryland Medical Practice Act to practice medicine in this State.

“Positron emission tomography (PET) radionuclide production facility” means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

“Prescribed dose” means:

- (1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
- (2) For teletherapy, the total dose and dose per fraction as documented in the written directive;
- (3) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or
- (4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

- (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 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 supplied, frequency of reading, and replacement or exchange schedule.
- (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, and
  - (4) 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) No individual shall perform services which are not specifically stated for that individual on the notice of registration issued by the Agency.

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Supp. 23

## **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(b), 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) 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):



(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) 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.

### 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, ~~and~~;
  - (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, ~~and~~;

- (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.

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."

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Sec. C.29 Financial Assurance and Recordkeeping for Decommissioning:

- (a) (1) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material in quantities exceeding the amounts specified in Table 1 or as required by (c)(5) of this section shall submit to the Agency for review and approval a decommissioning funding plan as described in paragraph (d) of this section. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by  $10^5$  is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix E.

TABLE 1

TYPE	EXCEEDING
SPECIAL NUCLEAR MATERIAL	$10^5$ times Appendix E. (Also, when R divided by $10^5$ is greater than 1.)
SOURCE MATERIAL	100 mCi in readily dispersible form.
BYPRODUCT MATERIAL	Half-life greater than 120 days and $10^5$ times Appendix E. (Also, when R divided by $10^5$ is greater than 1.)

\* For a combination of radionuclides, R is the sum of the fractions of the radionuclide divided by the Appendix E value for that radionuclide.

(2) Each holder of, or applicant for, any specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding  $10^{12}$  times the applicable quantities set forth in Appendix E (or when a combination of isotopes is involved if R, as defined in paragraph (a)(1) of this section, divided by  $10^{12}$  is greater than 1), shall submit a decommissioning funding plan as described in paragraph (d) of this section. The decommissioning funding plan must be submitted to the Agency no later than two years after the effective date of this regulation.

- (b) Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in Table 2 of this section shall either:

(1) Submit a decommissioning funding plan as described in paragraph (d) of this section; or

(2) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by Table 2 of this section using one of the methods described in paragraph (e) of this section. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section must be submitted to the Agency before receipt of the licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Agency, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section.

- (c) (1) Each holder of a specific license issued on or after October 15, 1998 which is of a type described in paragraph (a) or (b) of this section, shall provide a decommissioning funding plan in accordance with the criteria set forth in this section.

(2) Each holder of a specific license issued before October 15, 1998 and of a type described in paragraph (a) of this section shall submit, on or before October 15, 1998, a decommissioning funding plan as described in paragraph (d) of this section or a certification of financial assurance for decommissioning in an amount at least equal to \$1,125,000 in accordance with the criteria set forth in this section. If the licensee submits the certification of financial assurance instead of a decommissioning funding plan, the licensee shall provide a decommissioning funding plan on or before October 15, 2000.

(3) Each holder of a specific license issued before October 15, 1998, and of a type described in paragraph (b) of this section shall submit, on or before October 15, 1998, a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this section.

(4) Any licensee who has submitted an application before October 15, 1998, for renewal of license in accordance with C.33 shall provide financial assurance for decommissioning in accordance with paragraph (a) and (b) of this section. This assurance must be submitted on or before October 15, 2000.

(5) Waste collectors and waste processors, as defined in Section C.2 of this part, must provide financial assurance in an amount based on a decommissioning funding plan as described in paragraph (d) of this section. The decommissioning funding plan must include the cost of disposal of the maximum amount (curies) of radioactive material permitted by license, and the cost of disposal of the maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of Part D of this regulation. The decommissioning funding plan must be submitted no later than two years after the effective date of this regulation.

TABLE 2

TYPE OF RADIOACTIVE MATERIAL	EXCEEDING	ASSURANCE AMOUNT
SPECIAL NUCLEAR MATERIAL	Greater than $10^4$ but less than or equal to $10^5$ times the applicable quantities of Appendix E. (For a combination of radionuclides, if R divided by $10^4$ is greater than 1 but R divided by $10^5$ is less than or equal to 1.)*	\$1,125,000
	Greater than $10^3$ but less than or equal to $10^4$ times the applicable quantities of Appendix E. (For a combination of radionuclides, if R divided by $10^3$ is greater than 1 but R divided by $10^4$ is less than or equal to 1.)*	\$225,000
SOURCE MATERIAL	Greater than 10 mCi but less than or equal to 100 mCi in readily dispersible form.	\$225,000
BYPRODUCT MATERIAL	Half-Life greater than 120 days and in quantities:	
	Greater than $10^4$ but less than or equal to $10^5$ times the applicable quantities of Appendix E in unsealed form. (For a combination of radionuclides, if R divided by $10^4$ is greater than 1 but R divided by $10^5$ is less than or equal to 1.)*	\$1,125,000
	Greater than $10^3$ but less than or equal to $10^4$ times the applicable quantities of Appendix E in unsealed form. (For a combination of radionuclides, if R divided by $10^3$ is greater than 1 but R divided by $10^4$ is less than or equal to 1.)*	\$225,000
	Greater than $10^{10}$ but less than or equal to $10^{12}$ times the applicable quantities of Appendix E in sealed sources or plated foils. (For a combination of radionuclides, if R divided by $10^{10}$ is greater than 1, but R divided by $10^{12}$ is less than or equal to 1.)*	\$113,000

\* For a combination of radionuclides, R is the sum of the fractions of the radionuclide divided by the Appendix E value for the radionuclide.

(6) If, in surveys made under Section D.501(a) of these regulations, residual radioactivity in the facility and environment, including the subsurface, is detected at levels that would, if left uncorrected, prevent the site from meeting the D.1402 criteria for unrestricted use, the licensee must submit a decommissioning funding plan within one year of survey completion.

Comment [mdk7]: RATS 2011-1 §30.35(c)(6)

~~(d) Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from paragraph (e) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility. Cost estimates must be adjusted at intervals not to exceed 3 years. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section. Licensees required to submit the \$1,125,000 amount in Table 2 of this section must do so by one year after the effective date of this regulation. Licensees required to submit the \$113,000 or \$225,000 amount in Table 2 of this section must do so by 18 months after the effective date of this regulation. Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan. Licensees having possession limits exceeding the upper bounds of Table 2 or as required by (c)(5) or (6) of this section must base financial assurance on a decommissioning funding plan.~~

**Comment [mdk8]:** RATS 2011-1 §30.35(d)

~~(1) Each decommissioning funding plan must be submitted for review and approval and must contain:~~

**Comment [mdk9]:** RATS 2011-1 §30.35(e)

~~(i) A detailed cost estimate for decommissioning, in an amount reflecting:~~

- ~~(a) The cost of an independent contractor to perform all decommissioning activities;~~
- ~~(b) The cost of meeting the Section D.1402 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of Section D.1403 Criteria for License Termination Under Restricted Conditions, the cost estimate may be based on meeting the Section D.1403 criteria;~~
- ~~(c) The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and~~
- ~~(d) An adequate contingency factor.~~

~~(ii) Identification of and justification for using the key assumptions contained in the Decommissioning Cost Estimate;~~

~~(iii) A description of the method of assuring funds for decommissioning from paragraph (e) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;~~

~~(iv) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and~~

~~(v) A signed original of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).~~

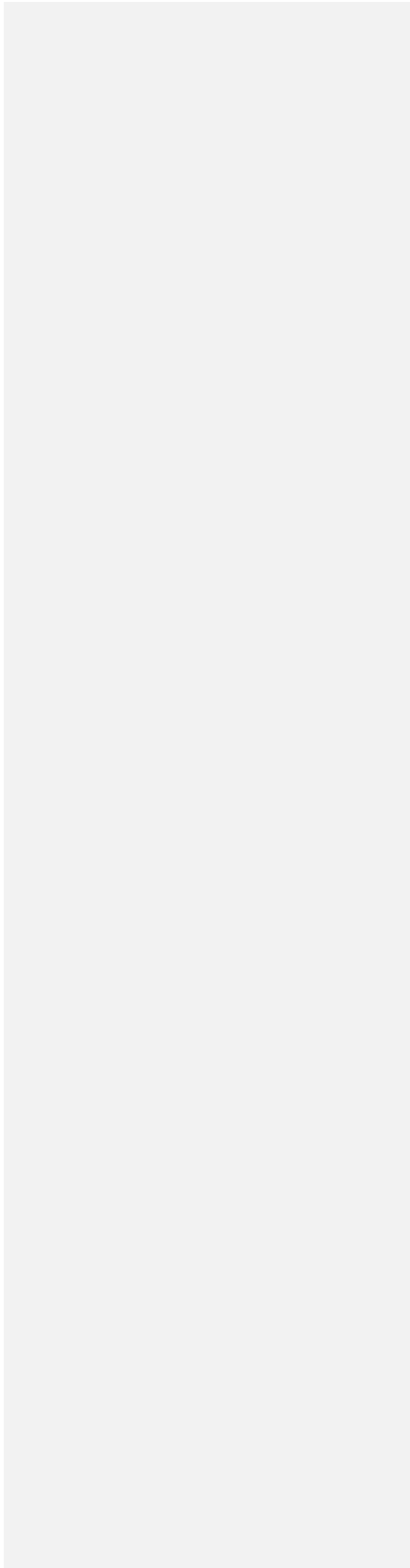
~~(2) At the time of license renewal and at intervals not to exceed 42 months, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this can not be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:~~

- ~~(i) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;~~
- ~~(ii) Waste inventory increasing above the amount previously estimated;~~
- ~~(iii) Waste disposal costs increasing above the amount previously estimated;~~

- (iv) Facility modifications;
- (v) Changes in authorized possession limits;
- (vi) Actual remediation costs that exceed the previous cost estimate;
- (vii) Onsite disposal; and
- (viii) Use of a settling pond.

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(e) The financial instrument must include the licensee's name, license number, and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. The financial instrument submitted must be a signed original or signed original duplicate, except where a copy of the signed original is specifically permitted. Financial assurance for decommissioning must be provided by one or more of the following methods:

Comment [mdk10]: RATS 2011 §30.35(f)

(1) *Prepayment.* Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment ~~may~~ must be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities, made into a trust account, and the trustee and the trust must be acceptable to the Agency.

(2) *A surety method, insurance, or other guarantee method.* These methods guarantee that decommissioning costs will be paid ~~should the licensee default.~~ A surety method may be in the form of a surety bond, or letter of credit, ~~or line of credit.~~ A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix F of this part. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix G of this part. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in Appendix J of this part. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in Appendix K of this part. Except for an external sinking fund, a parent company guarantee or a guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of this section. A guarantee by the applicant or licensee may not be used in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

Comment [mdk11]: NRC Appendix A

Comment [mdk12]: NRC Appendix C

Comment [mdk13]: NRC Appendix D

Comment [mdk14]: NRC Appendix E

(i) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Agency, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Agency within 30 days after receipt of notification of cancellation.

(ii) The surety method or insurance must be payable to a trust established for decommissioning cost. The trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate State and federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or State agency.

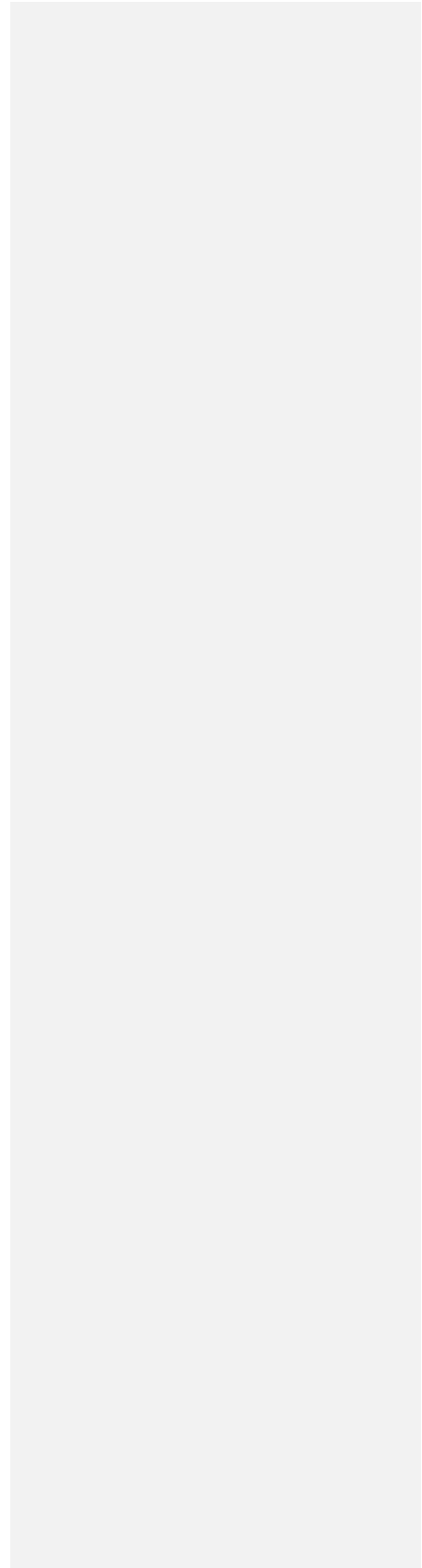
(iii) The surety method or insurance must remain in effect until the Agency has terminated the license.

(3) *An external sinking fund* in which deposits are made at least annually, coupled with a surety method, insurance, or other guarantee method, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund ~~may~~ must be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. If the other guarantee method is used, no surety or insurance may be combined with the external sinking fund. The surety, insurance, or other guarantee provisions must be as stated in paragraph (e)(2) of this section.

(4) In the case of federal, State, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on Table 2 of this section, and indicating that funds for decommissioning will be obtained when necessary.

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(f) Each person licensed under Part C shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with C31(b), licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for certifying that all the received records are complete and accurate and will be responsible for maintaining these records until the license is terminated. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the Agency considers important to decommissioning consists of:

- (1) Records of spills or other occurrences involving the spread of radioactive material in and around the facility, equipment, or site. These records may be limited to instances when radioactive material remains after any cleanup procedures or when there is reasonable likelihood that radioactive material may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations;
- (2) As built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of location of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations; and
- (3) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years, of the following:
  - (i) All areas designated and formerly designated restricted areas as defined in Part A, Section 2;
  - (ii) All areas outside of restricted areas that require documentation under D.1202;
  - (iii) All areas outside of restricted areas where current and previous wastes have been buried; and
  - (iv) All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in §§D.1401-1406 or apply for approval for disposal under D.1002.
- (4) Records of the cost estimate performed for the decommissioning funding plan or the amount certified for decommissioning, and records of funding method used for assuring funds if either a funding plan or certification is used.

(g) Approval of decommissioning funding plans and certifications.

- (1) Upon a determination that an application under this section meets the requirements of this section, the Agency shall approve such decommissioning funding plan or certification.
- (2) No person shall receive, possess, use, transfer, own or acquire radioactive material of a type described in paragraph (a) or (b) of this section for more than 180 days following the dates prescribed in this section for submittal of a decommissioning funding plan or certification, if that decommissioning funding plan or certification has not been approved by the Agency.

(h) Financial assurance for decommissioning pursuant to termination under restricted conditions as described in Section D.1403 of Part D shall not be considered a potential financial mechanism until such time as the licensee has submitted its intent to decommission in accordance with C.32 and has submitted a License Termination Plan (LTP) in accordance with Section D.1403(d).

(i) In providing financial assurance under this section, each licensee must use the financial assurance funds only for decommissioning activities and each licensee must monitor the balance of funds held to account for market variations. The licensee must replenish the funds, and report such actions to the Agency, as follows:

**Comment [mdk15]:** RATS 2011-1 §30.35(h)

(1) If, at the end of a calendar quarter, the fund balance is below the amount necessary to cover the cost of decommissioning, but is not below 75 percent of the cost, the licensee must increase the balance to cover the cost, and must do so within 30 days after the end of the calendar quarter.

(2) If, at any time, the fund balance falls below 75 percent of the amount necessary to cover the cost of decommissioning, the licensee must increase the balance to cover the cost, and must do so within 30 days of the occurrence.

(3) Within 30 days of taking the actions required by paragraph (i)(1) or (2) of this section, the licensee must provide a written report of such actions to the Program Manager, Radiological Health Program, Air and Radiation Management Administration, and state the new balance of the fund.

Sec. C.30 Issuance of Specific Licenses.

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

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

- (1) minimize danger to public health and safety or property;
- (2) require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and
- (3) prevent loss or theft of material subject to this part.

Sec. C.31 Specific Terms and Conditions of Licenses.

(a) Each license issued pursuant to this part shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

(b) ~~(1)~~ No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations, and orders of the Agency, and shall give its consent in writing.

~~(2) An application for transfer of license must include:~~

~~(i) The identity, technical and financial qualifications of the proposed transferee; and~~

~~(ii) Financial assurance for decommissioning information required by Section C.29.~~

(c) Each person licensed by the Agency pursuant to this part shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

(d) Each licensee shall notify the Agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

(e) 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:

- (1) the licensee;
- (2) 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

Comment [mdk16]: RATS 2011-1 §30.34(d)

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

(f) The notification specified in C.31(e) 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.

(g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Section G.204. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

(h) Production of PET Radioactive Drugs.

(1) Authorization under Section C.26(g) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(2) Each licensee authorized under Section C.26(g) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in Section C.28(j)(1)(iv) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in Section C.28(j)(3).

(3) A licensee that is a pharmacy authorized under Section C.26(g) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(i) an authorized nuclear pharmacist that meets the requirements in Section C.28(j)(2), or

(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in Section G.27.

(4) A pharmacy, authorized under Section C.26(g) to produce PET radioactive drugs for non-commercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirement of Section C.28(j)(2)(v).

Part C

**APPENDIX F**

**Comment [mdk17]:** NRC Appendix A.  
Substitute in entirety for prior Appendix F.

**CRITERIA RELATING TO USE OF FINANCIAL TESTS AND PARENT COMPANY GUARANTEES  
FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING**

*I. Introduction*

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

*II. Financial Test*

A. To pass the financial test, the parent company must meet the criteria of either paragraph A.1 or A.2 of this section. For purposes of applying the Appendix F criteria, tangible net worth must be calculated to exclude all intangible assets and the net book value of the facility and site, and total net worth, which may include intangible assets, must be calculated to exclude the net book value and goodwill of the facility and site.

1. The parent company must have:

(i) Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and

(ii) Net working capital and tangible net worth each at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all facilities or parts thereof (or prescribed amount if a certification is used); and

(iii) Tangible net worth of at least \$21 million; and

(iv) Assets located in the United States amounting to at least 90 percent of the total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used).

2. The parent company must have:

(i) A current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, A, or BBB (including adjustments of + and -) as issued by Standard and Poor's or Aaa, Aa, A, or Baa (including adjustment of 1, 2, or 3) as issued by Moody's; and

(ii) Total net worth at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all facilities or parts thereof (or prescribed amount if a certification is used); and

(iii) Tangible net worth of at least \$21 million; and

(iv) Assets located in the United States amounting to at least 90 percent of the total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used).

B. The parent company's independent certified public accountant must compare the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must evaluate the parent company's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the parent company's ability to pay for decommissioning costs. The accountant must verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements of paragraph A of this section. In connection with the auditing procedure, the licensee must inform the Agency within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

C. 1. After the initial financial test, the parent company must annually pass the test and provide documentation of its continued eligibility to use the parent company guarantee to the Agency within 90 days after the close of each succeeding fiscal year.

2. If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the Agency of intent to establish alternate financial assurance as specified in this appendix or Appendix G of this part. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

### III. Parent Company Guarantee

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Agency, as evidenced by the return receipts.

B. If the licensee fails to provide alternate financial assurance as specified in the Agency's regulations within 90 days after receipt by the licensee and the Agency of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide alternative financial assurance that meets the provisions of the Agency's regulations in the name of the licensee.

C. The parent company guarantee and the financial test provisions must remain in effect until the Agency has terminated the license, accepted in writing the parent company's alternate financial assurances, or accepted in writing the licensee's financial assurances.

D. A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the parent company guarantee agreement is submitted. The trustee and the trust must be acceptable to the Agency. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency. The Agency has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these regulations that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.



E. The guarantor must agree that it would be subject to Agency orders to make payments under the guarantee agreement.

F. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for the guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Agency may:

1. Declare that the financial assurance guaranteed by the parent company guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

2. Exercise any and all of its other rights under applicable law.

G. 1. The guarantor must agree to 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, or the occurrence of any other event listed in paragraph F of this appendix, by or against:

(i) The guarantor;

(ii) The licensee;

(iii) 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

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

2. This notification must include:

(i) A description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the parent company guarantee for decommissioning will be transferred to the standby trust as soon as possible;

(ii) If a petition of bankruptcy was filed, the identity of the bankruptcy court in which the petition for bankruptcy was filed; and

(iii) The date of filing of any petitions.

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Part C

**APPENDIX G**

**CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING**

**Comment [mdk18]:** NRC Appendix C. Substitute in entirety for prior Appendix G.

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self guarantee.

II. Financial Test

A. To pass the financial test a company must meet all of the criteria set forth in this section. For purposes of applying the Appendix G criteria, tangible net worth must be calculated to exclude all intangible assets and the net book value of the facility and site, and total net worth, which may include intangible assets, must be calculated to exclude the net book value and goodwill of the facility and site. These criteria include:

- (1) Tangible net worth of at least \$21 million, and total net worth at least 10 times the amount of decommissioning funds being assured by a self-guarantee for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all facilities or parts thereof (or the current amount required if certification is used).
- (2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the amount of decommissioning funds being assured by a self-guarantee, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all facilities or parts thereof (or the current amount required if certification is used).
- (3) A current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + and -) as issued by Standard and Poor's, or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

B. To pass the financial test, a company must meet all of the following additional requirements:

- (1) The company must have a least one class of equity securities registered under the Securities Exchange Act of 1934.
- (2) The company's independent certified public accountant must compare the data used by the company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must evaluate the company's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the company's ability to pay for decommissioning costs. The accountant must verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements of Section II, paragraph A of this appendix. In connection with the auditing procedure, the licensee must inform the Agency within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the company must annually pass the test and provide documentation of its continued eligibility to use the self-guarantee to the Agency within 90 days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in this appendix within 120 days of such notice.

### III. Company Self Guarantee

The terms of a self guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Agency, as evidenced by the return receipt.

B. The licensee shall provide alternative financial assurance as specified in this appendix within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

D. The licensee will promptly forward to the Agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

E. (1) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A -" and above by Standard and Poor's or in any category of "A3" and above by Moody's, the licensee will notify the Agency in writing within 20 days after publication of the change by the rating service.

(2) If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor's and Moody's, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will fund the standby trust as described in paragraph G of this appendix in the amount guaranteed by the self-guarantee agreement.

G. (1) A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the self-guarantee agreement is submitted.

(2) The trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency. The Agency has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these regulations that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

H. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for the guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Agency may:

(1) Declare that the financial assurance guaranteed by the self-guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

(2) Exercise any and all of its other rights under applicable law.

I. The guarantor must notify the Agency, in writing, immediately following the occurrence of any event listed in paragraph H of this appendix, and must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible.

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Part C

**APPENDIX J**

Comment [mdk19]: NRC Appendix D.

**CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING BY COMMERCIAL COMPANIES THAT HAVE NO OUTSTANDING RATED BONDS**

*I. Introduction*

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

*II. Financial Test*

A. To pass the financial test a company must meet all of the criteria set forth in this section. For purposes of applying the Appendix J criteria, tangible net worth must be calculated to exclude all intangible assets and the net book value of the facility and site, and total net worth, which may include intangible assets, must be calculated to exclude the net book value and goodwill of the facility and site. These criteria include:

- (1) Tangible net worth of at least \$21 million, and total net worth of at least 10 times the amount of decommissioning funds being assured by a self-guarantee for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all facilities or parts thereof (or the current amount required if certification is used).
- (2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.
- (3) A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by total net worth less than 1.5.

B. In addition, to pass the financial test, a company must meet all of the following requirements:

(1) The company's independent certified public accountant must compare the data used by the company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must evaluate the company's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the company's ability to pay for decommissioning costs. In connection with the auditing procedure, the licensee must inform the Agency within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(2) After the initial financial test, the company must annually pass the test and provide documentation of its continued eligibility to use the self-guarantee to the Agency within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of paragraph II.A of this appendix, the licensee must send notice to the Agency of intent to establish alternative financial assurance as specified in Agency regulations. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

### III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the Agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the regulations within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

D. The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will fund the standby trust as described in paragraph E of this appendix in the amount of the current cost estimates for decommissioning.



E. A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the self-guarantee agreement is submitted. The trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency. The Agency will have the right to change the trustee. An acceptable trust will meet the regulatory criteria established in the part of these regulations that governs the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

F. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for the guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Agency may:

(1) Declare that the financial assurance guaranteed by the self-guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

(2) Exercise any and all of its other rights under applicable law.

G. The guarantor must notify the Agency, in writing, immediately following the occurrence of any event listed in paragraph F of this appendix, and must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible.

Part C

**APPENDIX K**

Comment [mdk20]: NRC Appendix E.

**CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING BY NONPROFIT COLLEGES, UNIVERSITIES, AND HOSPITALS**

*I. Introduction*

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

*II. Financial Test*

A. For colleges and universities, to pass the financial test a college or university must meet either the criteria in Paragraph II.A.(1) or the criteria in Paragraph II.A.(2) of this appendix.

(1) For applicants or licensees that issue bonds, a current rating for its most recent unsecured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + or -) as issued by Standard and Poor's or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

(2) For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least \$50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

B. For hospitals, to pass the financial test a hospital must meet either the criteria in Paragraph II.B.(1) or the criteria in Paragraph II.B.(2) of this appendix:

(1) For applicants or licensees that issue bonds, a current rating for its most recent unsecured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + or -) as issued by Standard and Poor's or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

(2) For applicants or licensees that do not issue bonds, all the following tests must be met:

(a) (Total revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

(b) Long term debt divided by net fixed assets must be less than or equal to 0.67.

(c) (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

(d) Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing licensee.

C. In addition, to pass the financial test, a licensee must meet all the following requirements:

(1) The licensee's independent certified public accountant must compare the data used by the licensee in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must evaluate the licensee's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the licensee's ability to pay for decommissioning costs. The accountant must verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements of Section II of this appendix. In connection with the auditing procedure, the licensee must inform the Agency within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.

(2) After the initial financial test, the licensee must repeat passage of the test and provide documentation of its continued eligibility to use the self-guarantee to the Agency within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of Section I of this appendix, the licensee must send notice to the Agency of its intent to establish alternative financial assurance as specified in Agency regulations. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

### III. Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that--

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the Agency. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the Agency's regulations within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

D. The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will fund the standby trust as described in paragraph F. of this section in the amount of the current cost estimates for decommissioning.

E. (1) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee shall notify the Agency in writing within 20 days after publication of the change by the rating service.

(2) If the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by Standard and Poor's or in any category of "A3" and above by Moody's, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. (1) A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the self-guarantee agreement is submitted.

(2) The trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency. The Agency has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in the part of these regulations that governs the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

G. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Agency may:

(1) Declare that the financial assurance guaranteed by the self-guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

(2) Exercise any and all of its other rights under applicable law.

H. The guarantor must notify the Agency, in writing, immediately following the occurrence of any event listed in paragraph G of this appendix, and must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible.

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- ii. The test for leakage for sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001  $\mu$ Ci) of radon-222 in a 24 hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time.
  - iii. Test samples shall also be taken from the interior surfaces of the container in which sealed sources of radium are stored. This test shall be capable of detecting the presence of 185 Bq (0.005  $\mu$ Ci) of a radium daughter which has a half-life greater than 4 days.
  - iv. Notwithstanding the periodic test for leakage required, any sealed source is exempt from such tests for leakage when the sealed source contains 3.7 MBq (100  $\mu$ Ci) or less of beta or gamma emitting material or 370 KBq (10  $\mu$ Ci) or less of alpha emitting material.
- b. Tests for leakage or contamination shall be performed by persons specifically authorized by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.
- c. The following shall be considered evidence that the sealed source is leaking:
- i. The presence of 185 Bq (0.005  $\mu$ Ci) or more of removable contamination on any test sample. If the test of a sealed source, other than radium, reveals the presence of 185 Bq (0.005  $\mu$ Ci) or more of removable contamination, the licensee or registrant shall immediately withdraw the sealed source from use, take action to prevent the spread of contamination, and cause the sealed source to be decontaminated and repaired or to be disposed of in accordance with Part D.
  - ii. Leakage of 37 Bq (0.001  $\mu$ Ci) of radon-222 per 24 hours for sealed sources manufactured to contain radium. If the test of a sealed source manufactured to contain radium reveals the presence of removable contamination resulting from the decay of 185 Bq (0.005  $\mu$ Ci) or more of radium-226, the licensee or registrant shall immediately withdraw the sealed source from use, take action to prevent the spread of contamination, cause the sealed source to be decontaminated and repaired or to be disposed of in accordance with Part D.
- d. Test results shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency.
- e. Reports of test results for leaking or contaminated sealed sources shall be made pursuant to D.1206.

## SURVEYS AND MONITORING

### Sec. D.501 General.

- a. Each licensee or registrant shall make, or cause to be made, surveys of areas that:
- i. Are necessary for the licensee or registrant to comply with Part D; and
  - ii. Are reasonable under the circumstances to evaluate:
    - (1) The magnitude and extent of radiation levels; and
    - (2) Concentrations or quantities of residual radioactive ~~material-ity~~; and
    - (3) The potential radiological hazards of the radiation levels and residual radioactivity detected.

Comment [mdk21]: RATS 2011-1 §20-1501(a)

b. For radioactive materials licensees, surveys as described in D.501a. shall include surface and subsurface areas.

c. Notwithstanding the requirements of D.1103(a), records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with Section C.29(f).

Comment [mdk22]: RATS 2011 §20.1501(b)

- d. The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated for the radiation measured at intervals not to exceed 12 months.
- e. All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with D.201, with other applicable provisions of these regulations, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:
- i. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and
  - ii. Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.
- f. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

### Sec. D.502 Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Part D. As a minimum:

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- a. Each licensee or registrant shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee or registered and unregistered radiation machines under the control of the registrant and shall supply and require the use of individual monitoring devices by:
  - i. Adults who potentially may receive, in 1 year, from sources external to the body, a dose in excess of 10 percent of the limits in D.201a;
  - ii. Minors who potentially may receive, in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of .15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);
  - iii. Declared pregnant women who potentially may likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv);<sup>a</sup> and
  - iv. Individuals entering a high or very high radiation area.
- b. Each licensee shall monitor, to determine compliance with D.204, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:
  - i. Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B;
  - ii. Minors likely to receive, in one year, a committed effective dose equivalent in excess of 0.1 rem (1 mSv); and
  - iii. Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

Comment [mdk23]: § 20.1502

#### CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

##### Sec. D.601 Control of Access to High Radiation Areas.

- a. The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:
  - i. A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or
  - ii. A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or
  - iii. Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

<sup>a</sup> All the occupational doses in Section D.201 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.

- b. In the case of a high radiation area established for a period of 30 days or less, direct surveillance to prevent unauthorized entry may be substituted for the controls required by D.601a.
- c. The licensee or registrant may apply to the Agency for approval of alternative methods for controlling access to high radiation areas.
- d. The licensee or registrant shall establish the controls required by D.601a. and c. in a way that does not prevent individuals from leaving a high radiation area.
- e. The licensee is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation provided that:
  - i. The packages do not remain in the area longer than 3 days; and
  - ii. The dose rate at 1 meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.
- f. The licensee is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in Part D and to operate within the ALARA provisions of the licensee's radiation protection program.

Sec. D.602 Control of Access to Very High Radiation Areas.

- a. The provisions of D.602 do not apply to sources of radiation that are used in teletherapy, field radiography, diagnostic x-ray, or in self-shielded irradiators.
- b. In addition to the requirements in D.601, the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to very high radiation areas. This requirement includes, but is not limited to the following provisions:
  - i. Each entrance or access point that is large enough to admit a person shall be equipped with entry control devices which:
    - (1) Function automatically to prevent any individual from inadvertently entering a very high radiation area; and
    - (2) Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

## **RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION**

### Sec. D.1401 General Provisions and Scope.

(a) The criteria in this subpart apply to the decommissioning of facilities licensed under Part C of this regulation, as well as other facilities subject to the Department's jurisdiction. For low-level waste disposal facilities (COMAR 26.13.05 through .10), the criteria apply only to ancillary surface facilities that support radioactive waste disposal activities.

(b) The criteria in this subpart do not apply to sites which:

(1) Have been decommissioned prior to the effective date of this regulation in accordance with criteria identified in the Site Decommissioning Management Plan (SDMP) Action Plan of April 16, 1992 (57 FR 13389);

(2) Have previously submitted and received Agency approval on a license termination plan (LTP) or decommissioning plan that is compatible with the SDMP Action Plan criteria; or

(3) Submit a sufficient LTP or decommissioning plan prior to the [effective date of this regulation] and such LTP or decommissioning plan is approved by the Department before March 1, 2001 and in accordance with the criteria identified in the SDMP Action Plan, except that if an EIS is required in the submittal, there will be a provision for day-for-day extension.

(c) After a site has been decommissioned and the license terminated in accordance with the criteria in this subpart, the Department will require additional cleanup only if, based on new information, it determines that the criteria of this subpart were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

(d) When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

### Sec. D.1402 Radiological Criteria for Unrestricted Use.

A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

Sec. D.1403 Criteria for License Termination Under Restricted Conditions. A site will be considered acceptable for license termination under restricted conditions if:

(a) The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of C.1402 would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

(b) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) per year;

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

(1) Funds placed into ~~an account-a trust~~ segregated from the licensee's assets and outside the licensee's administrative control ~~as described in Sec. C.29(e)(1) of this chapter~~, and in which the adequacy of the trust funds is to be assessed based on an assumed annual 1 percent real rate of return on investment;

~~(2) Surety method, insurance, or other guarantee method as described in Sec. C.29(e)(2) of this chapter;~~

(2) A statement of intent in the case of Federal, State, or local Government licensees, as described in Sec. C.29(e)(4) of this chapter; or

(3) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(d) The licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the Department indicating the licensee's intent to decommission in accordance with Sec.C.32 and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

(1) Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning--

(i) Whether provisions for institutional controls proposed by the licensee --

(a) Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) TEDE per year;

(b) Will be enforceable; and

(c) Will not impose undue burdens on the local community or other affected parties.

Comment [mdk24]: RATS 2011-1 §20.1403(c)

(ii) Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site;

(2) In seeking advice on the issues identified in Sec. 20.1403(d)(1), the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning. The scope of participation and persons representing community interests must be pre-approved by the Agency;

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

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

(e) Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either--

(1) 100 mrem (1 mSv) per year; or

(2) 500 mrem (5 mSv) per year provided the licensee--

(i) Demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem/y (1 mSv/y) value of paragraph (e)(1) of this section are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(ii) Makes provisions for durable institutional controls;

(iii) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every 5 years to assure that the institutional controls remain in place as necessary to meet the criteria of Sec. D.1403(b) and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in paragraph (c) of this section.

Sec. D.1404 Alternate Criteria for License Termination.

(a) The Department may terminate a license using alternate criteria greater than the dose criterion of D.1402 if the licensee—

(1) Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 1 mSv/y (100 mrem/y) limit of subpart D, by submitting an analysis of possible sources of exposure;

(2) Has employed to the extent practical restrictions on site use according to the provisions of D.1403 in minimizing exposures at the site;

(3) Reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal;

(4) Has submitted a decommissioning plan or License Termination Plan (LTP) to the Department indicating the licensee's intent to decommission in accordance with Sec. ~~D.C.32(c)~~ of this chapter, specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning. The scope of participation and persons representing community interests must be pre-approved by the Agency;

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

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

(5) Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

(b) The use of alternate criteria to terminate a license requires the approval of the Department after consideration of the Agency staff's recommendations that will address any comments provided by the Environmental Protection Agency and any public comments submitted pursuant to Sec. D.1405.

Sec. D.1405 Public Notification and Public Participation.

Upon the receipt of an LTP or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to Sec. D.1404, D.1403 or whenever the Department deems such notice to be in the public interest, the Department shall:

(a) Notify and solicit comments from:

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Comment [mdk25]: (correction)

Comment [mdk26]: RATS 2011-1 §20.1404(a)

(1) Local and State governments in the vicinity of the site and any Indian Nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

(2) The Environmental Protection Agency for cases where the licensee proposes to release a site pursuant to Sec. D.1404.

(b) Publish a notice in the Maryland Register and in a forum, such as local newspapers, letters to State or local organizations, posting of the site or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

Sec. D.1406 Minimization of Contamination.

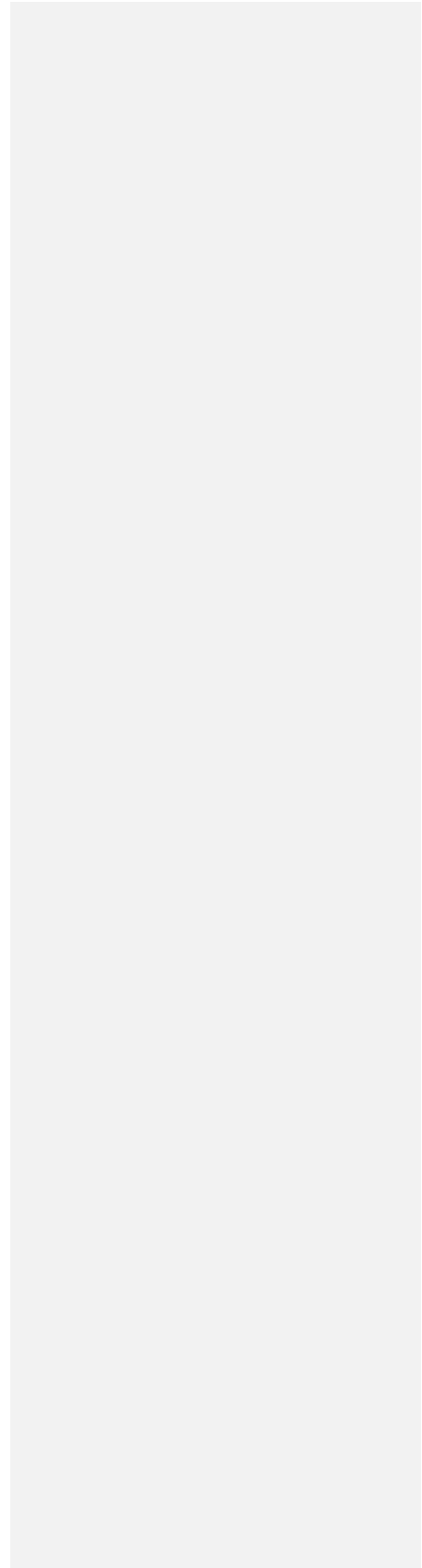
~~Applicants for licenses, other than renewals, after [the effective date of this regulation], shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.~~  
Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with existing radiation protection requirements in D.101 and radiological criteria for license termination in D.1401 through D.1406.

Comment [mdk27]: RATS 2011-1 §20.1406(c)

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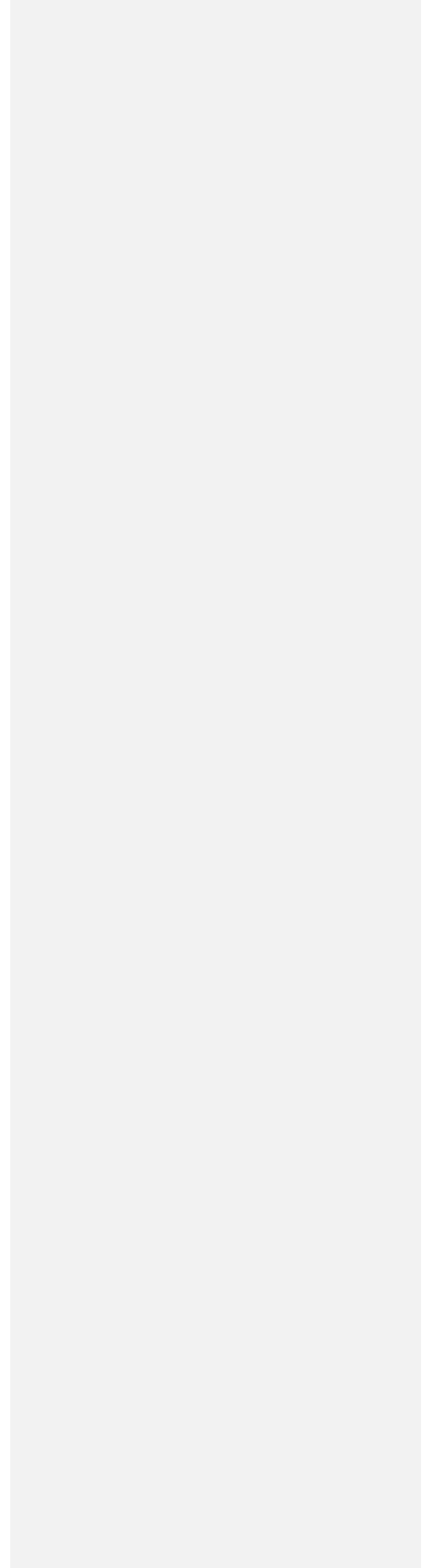




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(2) Manual Processing of Film.

(i) Where film is developed manually, a system shall be available which consists of at least one three-sectional tank made of mechanically rigid, corrosion resistant material (each section of which shall be constructed so as to retain its solution separate from the other two) and has the overall temperature controlling capability of maintaining each solution such that the temperature of each solution will always fall within the range of 60°F to 80°F (16-27°C).

(ii) Devices shall be available which will:

(a) Give the actual temperature of the developer, plus or minus 2°F (or 1°C if SI units are used),

(b) Give an audible or visible signal after a preset time, plus or minus 10% of the preset time, and

(iii) Film shall be developed in accordance with the appropriate time and temperature charts. Time and temperature charts matched to the film types in use in the facility shall be available and posted in the development work area.

(3) Chemical-Film Processing Control.

(i) Chemicals shall be mixed in accord with the chemical manufacturer's recommendations.

(ii) Replenishing of chemicals shall be sufficient to maintain the standards of Section F.3(b)(1) above.

(iii) All processing chemicals shall be completely replaced at least every 3 months.

(4) Automatic Processors and Other Closed Processing Systems. Preventive maintenance shall be performed on the unit, except for extended periods of non-use, on a frequency basis which is not less than that schedule recommended by the manufacturer. In the event that no schedule is available from the manufacturer, a maintenance schedule shall be established which will preserve good film quality.

(5) Film Fog Prevention.

(i) Film processing areas and devices shall be constructed so that film being processed, handled, or stored will be exposed only to light which has passed through a proper safelight filter.

(ii) That light which remains in a film processing area or device following compliance with F.3(b)(5)(i) shall, when exposed to film in a two minute fog test, produce an increase in fog of not more than 0.05 density units.

(iii) In determining compliance with F.3(b)(5)(ii), fog measurements are to be made at exposed film densities of 1.0 plus base plus fog.

(6) Soft Copy Image Production.

(i) Display monitors. The registrant shall use only appropriate display monitors that meet manufacturer's recommended specifications for diagnostic interpretation for image quality parameters.

(ii) Lasers. The registrant shall use only appropriate lasers that meet manufacturer's recommended specifications for image quality parameters.

(iii) Replacement devices for electronic image retrieval or duplication instrumentation shall meet manufacturer's recommended specifications.

(c) Quality Assurance.

The registrant shall be responsible for establishing and operating an effective program for radiographic or fluoroscopic imaging quality control. This program shall be designed to fulfill the following goals:

(1) That the diagnostic quality of radiographic or fluoroscopic images will be maintained at the highest level;

(2) That film processing systems, including electronic imaging collection systems, will be maintained at the highest quality level;

(3) That radiographic or fluoroscopic images will be produced using the minimum radiation doses to patients; and

(4) That the above three goals will be consistently met.

(d) Machine Maintenance.

(1) A registrant shall maintain each radiation machine in accordance with the manufacturer's recommended maintenance specifications.

(2) If documentation regarding the recommended maintenance schedule is not available from the manufacturer, maintenance shall be performed on at least an annual basis.

(3) A registrant shall maintain documentation that the machine manufacturer's recommended maintenance schedule has been met. Documentation to satisfy the requirements of this section shall include a detailed service report that includes the results of all tests performed by the registered service company. Such documentation shall clearly designate the registrant name and facility registration number, service date and provider of maintenance service, Department-assigned machine number, if present, and tube serial number, and room name or number in which the machine is located, for each machine for which preventive maintenance has been provided.

(4) Each registrant shall provide to the Agency written documentation as described in (d)(3) sufficient to demonstrate that the maintenance required under (d)(1) and (2) has been performed. Such documentation shall be provided to the Agency no later than thirty (30) days following performance of this maintenance.

(5) Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

(6) The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than +/- 35 percent over the range of 6 mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than 3 seconds.

(m) Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of Sections F.5(a), F.5(c), F.5(d), and F.5(g) provided that:

(1) Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and

(2) Systems which do not meet the requirements of Section F.5(g) are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

(n) Qualifications for Users who Energize Fluoroscopic System.

(1) By December 31, 2005 the registrant shall ensure that only a licensed practitioner of the healing arts or a radiological technologist be allowed to energize fluoroscopic x-ray systems. In addition, all persons energizing these systems shall have completed at least four hours of training as specified in Section F.5(n)(2) prior to clinical use of a fluoroscopic system, or provide documentation to demonstrate completion of four hours of training as specified in Section F.5(n)(2) prior to clinical use of a fluoroscopic system.

(2) Training to meet the requirements of Section F.5(n)(1) shall include, but is not limited to the following:

(i) Biological effects of x-ray;

(ii) Principles of radiation protection;

(iii) Factors affecting fluoroscopic outputs;

(iv) Dose reduction techniques;

(v) Principles and operation of the specific fluoroscopic x-ray system(s) to be used;

(vi) Fluoroscopic and fluorographic outputs of each mode of operation on the system(s) to be used; and

(vii) Applicable requirements of these regulations.

(3) The registrant shall maintain records to demonstrate a minimum of one hour of in-service training or continuing medical education training for all users who energize fluoroscopic equipment every twenty-four months in fluoroscopic radiation safety and patient dose management.

(4) The registrant shall maintain documentation pertaining to the requirements of Sections F.5(n)(1), F.5(n)(2) and F.5(n)(3) for review for three years.

(5) Documentation to meet the requirements of Sections F.5(n)(1), F.5(n)(2) and F.5(n)(3) are not registrant specific and should be transferable to other work areas if authorized between the users who energize fluoroscopic radiation machines and the registrant(s).

(6) The registrant may exempt from the requirements of Sections F.5(n)(1) through F.5(n)(4):

(i) Radiologists, if the registrant verifies initially, and biennially thereafter, via original documentation of continued certification by an accepted professional organization; or

(ii) Licensed practitioners of the healing arts and radiation therapy technologists exclusively energizing fluoroscopic radiation machines for the purpose of therapy simulation. The registrant shall maintain records verifying exempt status per user a minimum of every twenty-four months; ~~or.~~

~~(iii) — A user whose energizing of fluoroscopic equipment is limited to a C-arm type fluoroscope manufactured exclusively for imaging extremities. The registrant shall maintain records verifying exempt status per user a minimum of every twenty-four months.~~

(o) Equipment Operation.

(1) Fluoroscopy shall not be used as a positioning tool for radiographic examinations, except for therapy simulation.

(2) By the registrant's first certification date after December 31, 2005 and biennially thereafter, the registrant shall perform an evaluation that will span no less than three months of cumulative electrophysiological and interventional, including cardiac catheterization, fluoroscopic exposure times by procedure and by licensed practitioner. The report shall include the number of fluorographic images recorded for examination.