



MARYLAND DEPARTMENT OF THE ENVIRONMENT

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Duncan White, State Agreements Program Officer
U.S. Nuclear Regulatory Commission (NRC) Region-I
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Mr. White:

Enclosed please find proposed amendment (Supplement 7) to the Maryland State Regulations for the Control of Ionizing Radiation (1994). This proposal is being submitted for NRC review and comment. Maryland is pursuing accelerated promulgation of our license termination rule, so your expedient review would be greatly appreciated. Those highlighted portions of the document represent areas of proposed change. This amendment includes consideration of the following subjects:

- a) Radiological Criteria for Licensee Termination (62 FR 39057; August 20, 1997).
- b) Criteria for the Release of Individuals Administered Radioactive Material (62 FR 4120; May 29, 1997).
- c) (Appendix A only) for Licenses for Industrial Radiography and Radiation Safety-Requirements for Industrial Radiography Operations (62 FR 28948; June 27, 1997).

If you have any comments on this proposed amendment, please feel free to contact Carl E. Trump, Jr., Raymond E. Manley or me at (410) 631-3301.

Sincerely,

Roland G. Fletcher, Manager
Radiological Health Program

Enclosure: Supplement 7

could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC hours.

"Annually" means either (1) at intervals not to exceed 1 year or (2) once per year, at about the same time per year (plus or minus 1 month).

"As low as reasonably achievable (ALARA)" means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

"Authorized nuclear pharmacist" means a pharmacist who is:

- (1) Board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties;
- (2) Identified as an authorized nuclear pharmacist on a license issued by the Agency, the NRC, or any other Agreement State that authorizes the use of radioactive material in the practice of nuclear pharmacy; or
- (3) Identified as an authorized nuclear pharmacist on a permit issued by the Agency, NRC, or any other Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive material in the practice of nuclear pharmacy.

"Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include sources of radiation from radioactive materials or radiation producing machines regulated by the Agency.

"Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration or transformation per second (S-1).

"Bioassay" means the determination of kinds, quantities or concentrations and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these regulations, "radiobioassay" is an equivalent term.

"Byproduct material" means:

- (1) Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and
- (2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

"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

"Committed dose equivalent" [See "Dose"]

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

"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 3.7×10^{10} transformations per second (tps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) = 0.001 curie = 3.7×10^7 tps. One microcurie (μ Ci) = 0.000001 curie = 3.7×10^4 tps (See A.12 for SI equivalent becquerel).

"Decommissioning" means to remove nuclear facilities safely from Service and to reduce residual radioactivity to a level that permits release of the property for unrestricted use 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.

"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

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 be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance 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.

(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 unrestricted release levels 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).

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) 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.

(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 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

(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.

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

(a) Except as provided in Md. Code Ann., State Gov't Sec. 10-226 (1996), and provided that the licensee is applying for the same activities as allowed in the current license, each specific license expires at the end of the day, in the month and year stated in the license.

(b) No less than 30 days before expiration of a license, the licensee shall notify the Agency promptly, in writing, and request termination of the license when the licensee decides to terminate all activities involving materials authorized under the license.

(c) Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the Agency in writing, as specified in subsections (d) and (1)(i)-(iv) or by license conditions, of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Agency requirements, or submit within 12 months of notification a decommissioning plan, if required by subsection (1) of this section, and begin decommissioning upon approval of that plan if:

- (1) The license has expired pursuant to subsection (a) of this section; or
- (2) The licensee has decided to permanently cease principal activities, as defined in this part, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements; or
- (3) No principal activities under the license have been conducted for a period of 24 months; or
- (4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements.

~~(5) The licensee's right to operate has been terminated either by court action or by action of law or regulation.~~

(d) Coincident with the notification required by paragraph (c) of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to C.29 in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to paragraph (f)(4)(v) of this section.

(1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so on or before the effective date of this regulation.

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

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

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release ~~for unrestricted use in accordance with the criteria for decommissioning in §§ D 1401-1406~~. The licensee shall, as appropriate--

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

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

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

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

(1) Radioactive material has been properly disposed of;

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

(3) (i) A radiation survey has been performed which demonstrates that the premises are suitable for release ~~for unrestricted use in accordance with the criteria for decommissioning in §§ D 1401-1406~~, or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release ~~for unrestricted use in accordance with the criteria for decommissioning in §§ D 1401-1406~~.

Sec. C.33 Application for Renewal of Licenses. Subject to C.32(a), an application for renewal of a specific license must be filed on a form prescribed by the Agency, in accordance with C.24.

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

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

- ii. The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.
- d. If by the time the woman declares pregnancy to the licensee or registrant, the dose to the embryo/fetus has exceeded 4.5 mSv (0.45 rem), the licensee or registrant shall be deemed to be in compliance with D.208a. if the additional dose to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

Sec. D.301 Dose Limits for Individual Members of the Public.

- a. Each licensee or registrant shall conduct operations so that:
 - i. The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with G.25, from voluntary participation in medical research programs, and the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with D.1003, and
 - ii. The dose in any unrestricted area from external sources ~~exclusive of the dose contributions from patients administered radioactive material and released in accordance with Sec. G.25~~ does not exceed 0.02 mSv (0.002 rem) in any one hour.
- b. The Agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.
- c. If the licensee or registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

Sec. D.302 Compliance with Dose Limits for Individual Members of the Public.

- a. The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in D.301.

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 segregated from the licensee's assets and outside the licensee's administrative control as described in Sec. C.29(e)(1) of this chapter;

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

(3) 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

(4) 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.

(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; and

(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.32(d) of this chapter, and 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; 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.

(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, or whenever the Department deems such notice to be in the public interest, the Department shall:

(a) Notify and solicit comments from:

(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.

Appendix A to Part 34--Radiographer Certification

I. Requirements for an Independent Certifying Organization

An independent certifying organization shall:

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

for providing an appropriate examination environment.

II. Requirements for Certification Programs

All certification programs must:

1. Require applicants for certification to (a) receive training in the topics set forth in Sec. E.43(g) or equivalent Agreement State regulations, and (b) satisfactorily complete a written examination covering these topics;
2. Require applicants for certification to provide documentation that demonstrates that the applicant has:
 - (a) received training in the topics set forth in Sec. E.43(g) or equivalent Agreement State regulations;
 - (b) satisfactorily completed a minimum period of on-the-job training, and
 - (c) has received verification by an Agreement State or a NRC licensee that the applicant has demonstrated the capability of independently working as a radiographer;
3. Include procedures to ensure that all examination questions are protected from disclosure;
4. Include procedures for denying an application, revoking, suspending, and reinstating a certificate;
5. Provide a certification period of not less than 3 years nor more than 5 years;
6. Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training.
7. Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

III. Requirements for Written Examinations

All examinations must be:

1. Designed to test an individual's knowledge and understanding of the topics listed in Sec. E.43(g) or equivalent Agreement State requirements;
2. Written in a multiple-choice format;
3. Have test items drawn from a question bank containing psychometrically valid questions based on the material in Sec. E.43(g).

material for check, calibration and reference use:

- (a) Sealed sources manufactured and distributed by persons specifically licensed pursuant to Part C of these regulations or equivalent provisions of the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State and that do not exceed 3 millicuries (555 MBq) each;
- (b) Any radioactive material listed in G.29 or G.31 with a half-life of 100 days or less in individual amounts not to exceed 15 millicuries (555 MBq);
- (c) Any radioactive material listed in G.29 or G.31 with a half life greater than 100 days in individual amounts not to exceed 200 microcuries (7.4 MBq) each; and
- (d) Technetium-99m in individual amounts not to exceed 50 millicuries (1.85 GBq).

Sec. G.19 Requirements for Possession of Sealed Sources and Brachytherapy Sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Agency and shall maintain the instructions for the duration of source use in a legible form convenient to users.

(b) A licensee in possession of a sealed source shall assure that:

(1) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(2) The source is tested for leakage at intervals not to exceed 6 months or at intervals approved by the Agency, another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission.

(c) To satisfy the leak test requirements of G.19(b), the licensee shall assure that:

(1) Leak tests are capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 Bq) per 24 hours;

(2) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

(3) Test samples are taken when the source is in the "off" position.

(d) A licensee shall retain leak test records for 5 years. The records shall

(d) A licensee shall establish dose rate action levels for the surveys required by G.24(a) and (b) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

(e) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.

(f) A licensee shall conduct the surveys required by G.24(e) so as to be able to detect contamination on each wipe sample of 200 disintegrations per minute (33.3 Bq).

(g) A licensee shall establish removable contamination action levels for the surveys required by G.24(e) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

(h) A licensee shall retain a record of each survey required by G.24 (a), (b), and (e) for 2 years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

Sec. G.25 Release of Individuals Containing Radiopharmaceuticals or Permanent Implants.

~~(a) A licensee shall not authorize release from confinement for medical care any patient or human research subject administered a radiopharmaceutical until either:~~

~~(1) The measured dose rate from the patient or human research subject is less than 5 millirems (50 (Sv) per hour at a distance of 1 meter; or~~

~~(2) The activity in the patient or human research subject is less than 30 millicuries (1.11 GBq).~~

~~(b) A licensee shall not authorize release from confinement for medical care any patient or human research subject administered a permanent implant until the measured dose rate from the patient or human research subject is less than 5 millirems (50 (Sv) per hour at a distance of 1 meter.~~

(a) The licensee may authorize release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).³

(b) The licensee shall provide the released individual with written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

(1) Guidance on the interruption or discontinuation of breast-feeding; and

³ NRC Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 millisieverts (0.5 rem).

(2) Information on the consequences of failure to follow the guidance.

(c) The licensee shall maintain a record of the basis for authorizing the release of an individual, for 3 years after the date of release, if the total effective dose equivalent is calculated by:

(1) Using the retained activity rather than the activity administered;

(2) Using an occupancy factor less than 0.25 at one meter;

(3) Using the biological or effective half-life, or

(4) Considering the shielding by tissue.

(d) The licensee shall maintain a record, for 3 years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem).

Sec. G.26 Mobile Nuclear Medicine Service Technical Requirements. A licensee providing mobile nuclear medicine service shall:

(a) Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

(b) Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

(c) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use;

(d) Check survey instruments and dose calibrators as required in G.15(b)(1), G.15(d), G.15(e) and G.16(d), and check all other transported equipment for proper function before medical use at each location of use;

(e) Carry two calibrated survey meters in each vehicle that is being used to transport radioactive material, and, before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed; and

(f) Retain a record of each survey required by G.26(e) for 2 years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirems (microsieverts) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.

Sec. G.27 Storage of Volatiles and Gases.

(a) A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.

(b) A licensee shall store and use a multidose container in a properly functioning fume hood.

Sect. G.28 Reserved.