TO: J. C. Combs
DATE: 6/29/2000

MARYLAND DEPARTMENT OF THE ENVIRONMENT
2500 Broening Highway • Baltimore Maryland 21224
410-631-3000 • 1-800-633-6101 • http:// www. mde. state. md. us

Parris N. Glendening
Governor

Jane Nishida
Secretary

MEMORANDUM

TO: Holders of the Maryland State Regulations for Control of Ionizing Radiation (1994)

FROM: Roland G. Fletcher, Manager
Radiological Health Program

DATE: July 1, 1999

SUBJECT: Radiation Regulations Update – SUPPLEMENT 5

Agency records indicate that you have purchased a copy of the Maryland State Regulations for Control of Ionizing Radiation (1994). The attached package of amendments is furnished at no cost to you, so that you may keep the original current. You are advised that the inclusion of these amendments should be accomplished as soon as possible.

If you have any questions, please contact our office at (410) 631-3300. You may also reach our office toll-free by dialing 1-800-633-6101 and requesting extension 3300.

RGF:dk

Attachment

INSTRUCTION SHEET

COMAR 26.12.01.01

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

ADOPTED SUPPLEMENT No. 5

TO: HOLDERS OF COMAR 26.12.01.01 "MARYLAND STATE REGULATIONS FOR CONTROL OF IONIZING RADIATION (1994)."

Supplement 5 to the document COMAR 26.12.01.01 "Regulations for the Control of Ionizing Radiation (1994)" has been adopted and became effective on June 14, 1999. The pages that are necessary to update your copy of the regulations are enclosed and ready for insertion in your permanent regulations binder. Please follow these instructions carefully.

Instructions:

A. Locate the permanent regulations binder in your possession.

B. Change the permanent binder now as follows:

Carefully follow the "remove/insert" instructions appearing below. Remove the obsolete pages listed under the column "Remove Pages" from the permanent binder. From the package of pages enclosed, insert the new or replacement pages listed under the column "Insert Pages" in the permanent binder. Each of these pages has at least one of the two faces of the page printed with the words "Supp.5" in a lower corner. The obsolete pages removed from the permanent binder may be retained in a separate place for legal research.

Remove Pages From Permanent Binder	Insert Pages Into Permanent Binder
Cover	Cover
iii through xiii	iii through xiv
A7 through A10	A7 through A10
A15 and A16	A15 and A16
B3 and B4	B3 and B4
C25 and C26	C25 and C26
C43 through C51-1	C43 through C51-1
D1 and D2	D1 and D2
D9 and D10	D9 and D10
D13 and D14	D13 and D14
D25 and D26	D25 and D26
D37 through D42-2	D37 through D42-4
E1 through E15	E1 through E25
J1 through J4	J1 through J4

C. You will be sent further instructions about upcoming supplements when later action affects these regulations.

INQUIRIES TO: Radiological Health Program
Maryland Department of The Environment
2500 Broening Highway
Baltimore, MD 21224
(410) 631-3300

Code of Maryland Regulation 26.12.01.01

Adopted: September 9, 1995
Effective: October 9, 1995

Supplement 1 Effective: December 6, 1996
Supplement 2 Effective: November 3, 1997
Supplement 3 Effective: June 29, 1998
Supplement 4 Effective: December 28, 1998
Supplement 5 Effective: June 14, 1999

REGULATIONS FOR THE CONTROL OF IONIZING RADIATION (1994)

RADIOLOGICAL HEALTH PROGRAM
AIR AND RADIATION MANAGEMENT ADMINISTRATION
MARYLAND DEPARTMENT OF THE ENVIRONMENT

2500 BROENING HIGHWAY
BALTIMORE, MARYLAND 21224

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"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 all or any part of permission that:

(1) is required by law to be obtained from an agency;

(2) is not required only for revenue purposes; and

(3) is in any form, including:
(i) an approval;
(ii) a certificate;
(iii) a charter;
(iv) a permit; or
(v) a registration.

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

"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 that 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.

"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. 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 G.25, 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.

"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; or

(3) For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

"Public dose" means the dose received by a member of the public from exposure to radiation and/or to radioactive material released by a licensee or registrant, or to any other source of radiation under the control of the licensee or registrant. Public dose does not include occupational dose, dose received from background radiation, dose from any medical administration the individual has received, dose from exposure to individuals administered radioactive material and released in accordance with G.25, or dose from voluntary participation in medical research programs.

"Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below 130 F (54.4 C). A pyrophoric solid is any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

"Quality factor" (Q) means the modifying factor, listed in Tables 1 and 2 of A.13, that is used to derive dose equivalent from absorbed dose.

"Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg/gram or 0.01 joule/kilogram (0.01 gray).

"Radiation" means alpha particles, beta particles, gamma rays, x rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these regulations, ionizing radiation is an equivalent term. Radiation, as used in these regulations, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

"Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

"Radiation machine" means any assemblage of components capable of producing radiation except those devices with radioactive material as the only source of radiation. This assemblage may include, as determined by the Agency:

(1) Not more that one control panel;

(2) The necessary supporting structures; and

(3) Any additional components or auxiliary equipment that function with the assemblage to produce the result desired by using the machine.

"Radiation safety officer" means an individual, authorized by the agency under a specific license or a registration, who has the knowledge and responsibility to apply appropriate radiation protection regulations.

.Radioactive material" means any solid, liquid, or gas which emits radiation spontaneously.

"Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

"Registrant" means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to these regulations and Act.

"Registration" means registration with the Agency in accordance with the regulations adopted by the Agency.

"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.

"Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

"Research and development" means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

"Restricted area" means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

"Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs/kilogram of air (see "Exposure").

"Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

"Shallow dose equivalent" [See "Dose"]

"SI" means the abbreviation the International System of Units.

"Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 sv = 100 rem).

"Site Boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

"Source material" means:

(1) Uranium or thorium, or any combination thereof, in any physical or chemical form; or

(2) Ores that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material.

(b) U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors. Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this State is exempt from these regulations to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

(1) prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or -controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(2) prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

(3) prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and

(4) any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the State and the U.S. Nuclear Regulatory Commission jointly determine:

(i) that the exemption of the prime contractor or subcontractor is authorized by law; and

(ii) that under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

General Regulatory Requirements

Sec. A.4 Records.

(a) Each person who is a licensee for the use of radioactive materials shall maintain records required by these regulations at the licensee's office in Maryland. If a licensee maintains more than one office in Maryland, he shall inform the Agency of the location of the office where required records will be maintained.

(b) Each person responsible for a radiation machine facility shall maintain such records as required by these regulations at the facility where the radiation machine is located or stored.

(c) Each licensee or registrant shall maintain records showing the receipt, inventory, transfer, and disposal of all sources of radiation

(d) Additional record requirements are specified elsewhere in these regulations.

Sec. A.5 Inspections.

(a) Each licensee and registrant shall afford the Agency at all reasonable times opportunity to inspect sources of radiation,the premises and facilities wherein such sources of radiation are used or stored.

(b) Each licensee and registrant shall make available, upon inspection by the Agency, records maintained pursuant to these regulations.

Sec. A.6 Tests. Each licensee and registrant shall perform upon instructions from the Agency, or shall permit the Agency to perform, such reasonable tests as the Agency deems appropriate or necessary including, but not limited to, tests of:

(a) sources of radiation;

(b) facilities wherein sources of radiation are used or stored;

(c) radiation detection and monitoring instruments; and

(d) other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

Additional Regulatory Requirements

Sec. A.7 Additional Requirements. The Agency may, by rule, regulation, order, license amendment or registrant condition, impose such requirements upon any licensee/registrant above and beyond those established in these regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

Enforcement Requirements

Sec. A.8 Violations. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any regulation or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a misdemeanor and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

Sec. A.9 Impounding. Sources of radiation shall be subject to impounding pursuant to the Act.

Sec. A.10 Prohibited Uses.

(a) A hand-held fluoroscopic screen using X-ray equipment shall not be used unless it has been listed in the Registry of Sealed Source and Devices or accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health.

(b) A shoe-fitting fluoroscopic device shall not be used.

(c) No person shall possess or store a radiation machine which does not meet the requirements of these regulations or COMAR 26.12.02 unless such radiation machine has been internally rendered inoperable, in a manner approved by the Department, by a service provider registered under COMAR 26.12.01.01B.6.

(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:

(i) that he has read and understands the requirements of these regulations;

(ii) the services for which he is applying for registration;

(iii) the training and experience that qualify him to discharge the services for which he is applying for registration;

(iv) the type of measurement instrument to be used, frequency of calibration, and source of calibration; and

(v) the type of personnel dosimeters supplied, frequency of reading, and replacement or exchange schedule.

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

(i) installation and/or servicing of radiation machines and associated radiation machine components,

(ii) calibration of radiation machines or radiation measurement instruments or devices,

(iii) radiation protection or health physics consultations or surveys, and

(iv) personnel dosimetry services.

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

(f) A license granted by the State under COMAR 26.12.02.03 shall constitute registration under this Part.

Sec. B.7 Issuance 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.

(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) Application for renewal of registration shall be filed in accordance with B.5 or B.6.

(b) In any case in which a registrant has filed an application, not less than 14 days prior to the expiration of his existing notice of registration, in proper form for renewal, such existing notice of registration shall not expire until the application status has been finally 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.

Disclaimer

Sec. B.11 Approval Not Implied. No person, in any advertisement, shall refer to the fact that he or his facility is registered with the Agency pursuant to the provisions of B.5 or B.6, and no person shall state or imply that any activity under such registration has been approved by the Agency.

Assembler and Transferor Obligations

Sec. B.12 Assembler and/or Transfer or Service Obligation.

(a) Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines in this State shall notify the Agency within 15 days on forms provided by the Agency of the following:

(i) The present and previous machine location; and

(ii) The manufacturer, model, date of manufacture and other general information required by the form.

(b) No person shall make, sell, lease, transfer, lend, assemble, install, or service radiation machines or the supplies used in connection with such machines unless such machines and supplies, when properly placed in operation and used, meet the requirements of these regulations.

Sec. B.13 Out-of-State Radiation Machines.

(a) Whenever any radiation machine is to be brought into the State, for any temporary use, the person proposing to bring such machine into the State shall give written notice to the Agency at least 3 working days before such machine is to be used in the State. The notice shall include:

(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.

(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)-(d) Reserved.

(e) Specific License for Industrial Radiography. 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 of this chapter for byproduct material, as appropriate, and any special requirements contained in this part.

(2) The applicant submits an adequate program for training radiographers and radiographers' assistants that meets the requirements of Sec. E.43.

(i) After May 28, 1999, a license applicant need not describe its initial training and examination program for radiographers in the subjects outlined in Sec. E.43(g).

(ii) From the effective date of this regulation to May 28, 1999 a license applicant may affirm that all individuals acting as industrial radiographers will be certified in radiation safety by a certifying entity before commencing duty as radiographers. This affirmation substitutes for a description of its initial training and examination program for radiographers in the subjects outlined in Sec. E.43(g).

(3) The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

(4) The applicant submits written operating and emergency procedures as described in Sec. E.45.

(5) The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographers' assistant at intervals not to exceed 3 months as described in Sec. E.43(e)

(6) The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility.

(7) The applicant identifies and lists the qualifications of the individual(s) designated as the RSO (Sec. E.42) and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

(8) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application must include a description of the procedures to be followed. 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.

(9) If the applicant intends to perform "in-house" calibrations of survey instruments the applicant must describe methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in Sec. E.25.

(10) The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.

(11) The applicant identifies the locations where all records required by this part and other parts of this chapter will be maintained.

(f) Specific Licenses for Irradiators.

(1) The applicant shall satisfy the general requirements specified in Section C.25 and the requirements contained in this part.

(2) The application must describe the training provided to irradiator operators including:

(i) Classroom training;

(ii) On-the-job or simulator training;

(iii) Safety reviews;

(iv) Means employed by the applicant to test each operator's understanding of these regulations and licensing requirements and the irradiator operating and emergency procedures; and

(v) Minimum training and experience of personnel who may provide training.

(3) The application must include an outline of the written operating and emergency procedures listed in Section X.53 that describes the radiation safety aspects of the procedures.

sufficient information to complete a sealed source and device registration.

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

(a) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material in quantities exceeding the amounts specified in Table 1 shall submit 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.

(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 C.29(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 C.29(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 or a certification of financial assurance for decommissioning in an amount at least equal to $750,000 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 assurrance must be submitted on or before October 15, 2000.

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.)*	$750,000
	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.)*	$150,000
SOURCE MATERIAL	Greater than 10 mCi but less than or equal to 100 mCi in readily dispersible form.	$150,000
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.)*	$750,000
	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.)*	$150,000
	Greater than 10^{10} 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.)*	$75,000

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

(d) Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assurring 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. The decommissioning funding plan must also contain a certification by the licensee that financial assurrance 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.

(e) Financial assurance for decommissioning must be provided by one or more of the following methods:

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

(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, 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. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. A guarantee of funds by the applicant or licensee for the 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 guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or 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:

(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 or insurance, the value of which may decrease by the amount being acccumulated 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 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 safe and effective decommissioning of the facility in an identified location until the license is terminated by the Agency. 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 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.

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 (e)(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 (e)(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.

(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.

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

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

(f) (1) A decommissioning plan must be submitted if required by license condition or if the procedures andactivities necessary to carry out the decommissioning of the site or separate building or outdoor area have not been previously approved by the Agency and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

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

(iii) Procedures could result in significantly greater airborn concentrations of radioactive materials than are present during operation; or

(iv) Procedures could result in significantly greater releases of radioactive material to the environment that those associated with operation.

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

(3) Procedures such as those listed in paragraph (f)(1) of this section with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

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

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

(ii) A description of planned decommissioning activities;

(iii) A description of methods used to protect workers and the environment against radiation hazards during decommissioning;

(iv) A description of the planned final radiation survey;

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

(vi) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, tha plan shall include a justification for the delay based on the criteria in paragraph (i) of this section.

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

(g) (1) Except as provided in paragraph (h) of this section, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(2) Except as provided in paragraph (h) of this section, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later that 24 months collowing the initiation of decommissioning.

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

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

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

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

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

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

(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. 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.

(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; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release for unrestricted use.

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.

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

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

(a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific or general license may submit a request to the Agency for evaluation of radiation safety information about its product and for it's registration.

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

(c) The Agency normally evaluates a sealed source or a device using radiation safety criteria in accordance with accepted industry standards. If these standards and criteria do not readily apply to a particular case, the agency formulates reasonable standards and criteria with the help of the manufacturer or distributor. The Agency shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.

(d) After completion of the evaluation, the Agency may issue a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.

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

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

(2) The provisions of the registration certificate.

Sec. C.38 - C.39 Reserved.

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PART D

STANDARDS FOR PROTECTION AGAINST RADIATION

GENERAL PROVISIONS

Sec. D.1 Purpose. The requirements of Part D are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in Part D. However, nothing in Part D shall be construed as limiting actions that may be necessary to protect health and safety.

Sec. D.2 Scope. Part D applies to persons licensed or registered by the Agency to receive, possess, use, transfer, or dispose of sources of radiation. The limits in Part D do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with G.25, or to voluntary participation in medical research programs.

Sec. D.3 Definitions. As used in Part D:

"Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B.

"Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days , and for Class Y, Years, of greater than 100 days. For purposes of these regulations, "lung class" and "inhalation class" are equivalent terms.

"Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

"Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B.

"Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

"Dosimetry processor" means a person that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

"Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these regulations, "deterministic effect" is an equivalent term.

"Planned special exposure" means an infrequent exposure to radiation in an exceptional situation when alternatives that might avoid the higher exposures are unavailable or impractical. A planned special exposure shall be separate from and in addition to the annual occupational dose limits.

"Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

"Reference Man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the Reference Man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."

"Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

"Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

"Self-Shielded Irradiator" means a source of radiation that is used to irradiate materials where the source of radiation is both stored and operated within the same radiation shielding barrier and, in the designed configuration of the irradiator, does not allow exposure of any part of an individual to an exposure rate of 5 Gy (500 rads) per hour or greater.

mixture.

f. If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

g. When a mixture of radionuclides in air exists, a licensee may disregard certain radionuclides in the mixture if:

i. The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in D.201 and in complying with the monitoring requirements in D.502b., and

ii. The concentration of any radionuclide disregarded is less than 10 percent of its DAC, and

iii. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

h. When determining the committed effective dose equivalent, the following information may be considered:

i. In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

ii. For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.5 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B. The licensee may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALI, the licensee shall also demonstrate that the limit in D.201a.i.(2) is met.

Sec. D.205 Determination of Prior Occupational Dose.

a. For each individual who may receive, in a year, an occupational dose requiring monitoring pursuant to D.502, the licensee or registrant shall:

i. Determine the occupational radiation dose received during the current year; and

ii. Attempt to obtain the records of lifetime cumulative occupational radiation dose.

b. Prior to permitting an individual to participate in a planned special

exposure, the licensee or registrant shall determine:

i. The internal and external doses from all previous planned special exposures;

ii. All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

iii. The cumulative occupational radiation dose of the individual.

c. In complying with the requirements of D.205a., a licensee or registrant may:

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

ii. Accept, as the record of lifetime cumulative radiation dose, an up-to-date Agency Form ND 216 or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

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

d. i. The licensee or registrant shall record the exposure history, as required by D.205a., on Agency Form ND216, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing Agency Form ND216 or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on Agency Form ND216 or equivalent indicating the periods of time for which data are not available.

ii. Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or

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 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.

b. A licensee or registrant shall show compliance with the annual dose limit in D.301 a.i. by:

i. Demonstrating compliance with D.101 a; and

ii. (1) Demonstrating by measurement, or calculation, or appropriate simulation model that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered source of radiation does not exceed the annual dose limit of D.301; or

(2) Demonstrating that:

(a) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B; and

(b) If an individual were continually present in an unrestricted area,at the point of highest potential exposure from the licensed or registered source of radiation, the dose to that individual would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in any year.

TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

Sec. D.401 Testing for Leakage or Contamination of Sealed Sources.

a. Each sealed source, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas, shall be tested for leakage or contamination prior to initial use and, unless otherwise authorized by the Agency, at intervals not to exceed 6 months. If, at any other time, there is reason to suspect that a sealed source might have been damaged or might be leaking, it shall be tested for leakage before further use. In the absence of a certificate from a transferor indicating that a test for leakage has been made within 6 months prior to the transfer, the sealed source shall not be put into use until tested and the results received.

i. Tests for leakage for all sealed sources, except those manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005 μCi) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate.

Sec. D.902 Posting Requirements.

a. Posting of Radiation Areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

b. Posting of High Radiation Areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

c. Posting of Very High Radiation Areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

d. Posting of Airborne Radioactivity Areas. The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

e. Posting of Areas or Rooms in which Licensed Radioactive Material is Used or Stored. The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in Appendix C with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

Sec. D.903 Exceptions to Posting Requirements.

a. A licensee is not required to post caution signs in areas or rooms containing radioactive material for periods of less than 8 hours, if each of the following conditions is met:

   i. The radioactive material is constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to radiation or radioactive materials in excess of the limits established in Part D; and

   ii. The area or room is subject to the licensee's control.

b. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to D.902 provided that the patient could be released from license control pursuant to G.25.

c. Rooms or other areas which contain only therapeutic x-ray machines, or diagnostic x-ray machines, are not required to be posted with caution signs pursuant to D.902.

Sec. D.904 Labeling Containers and Radiation Machines.

a. The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

b. Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

c. Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

Sec. D.905 Exemptions to Labeling Requirements. A licensee is not required to label:

a. Containers holding licensed material in quantities less than the quantities listed in Appendix C; or

b. Containers holding licensed material in concentrations less than those specified in Table III of Appendix B; or

c. Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by Part D; or

i. An individual to receive, in a period of 24 hours:

(1) A total effective dose equivalent exceeding 0.05 Sv (5 rem); or

(2) An eye dose equivalent exceeding 0.15 Sv (15 rem); or

(3) A shallow dose equivalent to the skin or extremities exceeding 0.5 Sv (50 rem); or

ii. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

c. The licensee or registrant shall prepare each report filed with the Agency pursuant to D.1202 so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

d. The provisions of D.1202 do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to D.206a and D.1204.

Sec. D.1203 Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits.

a. Reportable Events. In addition to the notification required by D.1202, each licensee or registrant shall submit a written report to the Agency within 30 days after learning of any of the following occurrences:

i. Incidents for which notification is required by D.1202; or

ii. Doses in excess of any of the following:

(1) The occupational dose limits for adults in D.201; or

(2) The occupational dose limits for a minor in D.207; or

(3) The limits for an embryo/fetus of a declared pregnant woman in D.208; or

(4) The limits for an individual member of the public in D.301; or

(5) Any applicable limit in the license or registration; or

iii. Levels of radiation or concentrations of radioactive material in a restricted or unrestricted area in excess of the applicable limits set

forth in Part D or in any license or registration condition.

b. Contents of Reports.

i. Each report required by D.1203a. shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(1) Estimates of each individual's dose; and

(2) The levels of radiation and concentrations of radioactive material involved; and

(3) The cause of the elevated exposures, dose rates, or concentrations; and

(4) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, generally applicable environmental standards, and associated license or registration conditions.

ii. Each report filed pursuant to D.1203a. shall include for each individual exposed: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in D.208, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

Sec. D.1204 Reports of Planned Special Exposures.

The licensee or registrant shall submit a written report to the Agency within 30 days following any planned special exposure conducted in accordance with D.206, informing the Agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by Sec. D.1106.

Sec D.1205 Reports to Individuals of Exceeding Dose Limits.

When a licensee or registrant is required pursuant to D.1203 to report to the Agency any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee or registrant shall also provide a copy of the report submitted to the Agency to the individual. This report shall be transmitted at a time not later than the transmittal to the Agency, and shall comply with the provisions of J.13a of these regulations.

Sec. D.1206 Reports of Leaking or Contaminated Sealed Sources.

If the test for leakage or contamination required pursuant to D.401 indicates a sealed source is leaking or contaminated, a written report of the test shall be filed within 5 days with the Agency describing the equipment involved, the test results and the corrective action taken.

Sec. D.1207 Annual Reports from General Licensees

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

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

   ii. The form of the radioactive material;

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

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

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

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

Sec. D.1208 Misadministration Misadministration means:

a. A radiopharmaceutical dosage greater than 30 microcuries of either sodium sodium iodide I-125 or I-131:

   i. Involving the wrong individual or wrong radiopharmaceutical, or

   ii. When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries.

b. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

   i. Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or

   ii. When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

c. A gamma stereotactic radiosurgery radiation dose:

i. Involving the wrong individual or wrong treatment site; or

ii. When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.

d. A teletherapy radiation dose or dose from a radiation machine:

i. Involving the wrong individual, wrong mode of treatment, or wrong treatment site , or of a type other than the one intended ;

ii. When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent on the total prescribed dose;

iii. When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or

iv. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

e. A brachytherapy radiation dose:

i. Involving the wrong individual, wrong radioisotope, or wrong treatment site (excluding for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

ii. Involving a sealed source that is leaking;

iii. When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

iv. When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

f. A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, both:

i. Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

ii. When the dose of the individual exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.

Sec. D.1209 Notifications, Records and Reports of Misadministrations.

a. For a misadministration:

i. The licensee or registrant shall notify by telephone the Agency[4] no later than the next calendar day after the discovery of the misadministration.

ii. The licensee or registrant shall submit a written report to the Agency within 15 days after discovery of the misadministration. The written report must include the licensee's or registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual; what improvements are needed to prevent recurrence; whether the licensee or registrant notified the individual, or the individual's responsible relative or guardian (this person will be subsequently referred to as "the individual" in this section), and if not, why not, and if the individual was notified, what information was provided to the individual; and actions taken to prevent recurrence. The report must not include the individual's name or other information that could lead to identification of the individual. To meet the requirements of this section, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.

iii. The licensee or registrant shall notify the referring physician and also notify the individual of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee or registrant either that he will inform the individual or that, based on medical judgement, telling the individual would be harmful. The licensee or registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or individual cannot be reached within 24 hours, the licensee or registrant shall notify the individual as soon as possible thereafter. The licensee or registrant may not delay appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

iv. If the individual was notified, the licensee or registrant shall also furnish, within 15 days after discovery of the misadministration, a written report to the individual by sending either:

1. A copy of the report that was submitted to the Agency; or

2. A brief description of both the event and the consequence as they may affect the individual, provided a statement is included that the report submitted to the Agency can be obtained from

4 The after hours telephone number of the Agency Emergency Operations Unit is (410) 243-8700

the licensee or registrant.

b. Each licensee or registrant shall retain a record of each misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and that individual's referring physician , if applicable), the individual's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the individual, what improvements are needed to prevent recurrence, and the actions taken to prevent reoccurrence.

c. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees or registrants and physicians in relation to each other, to individuals receiving misadministrations, or to that individual's responsible relatives or guardians.

Sec. D.1210 Additional Reporting Requirements for Radioactive Materials.

a. Immediate report. Each licensee shall notify the Agency as soon as possible but no later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or release of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

b. Twenty-four hour report. Each licensee shall notify the Agency within 24 hours after the discovery of any of the following events involving licensed material:

1. An unplanned contamination event that:

i. Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

ii. Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of Part D; and

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

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

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

ii. The equipment is required to be available and operable when it is disabled

or fails to function; and

iii. No redundant equipment is available and operable to perform the required safety function.

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

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

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

ii. The damage affects the integrity of the licensed material or its container.

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

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

i. The caller's name and call back number;

ii. A description of the event, including date and time;

iii. The exact location of the event;

iv. The isotopes, quantities, and chemical and physical form of the licensed material involved; and

v. Any personnel radiation exposure data available.

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

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

ii. The exact location of the event;

iii. The isotopes, quantities, and chemical and physical form of the licensed material involved;

iv. Date and time of event;

v. Corrective actions taken or planned and the results of any evaluations or assessments; and

vi. The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

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

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

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

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

(3) Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in Sec. D.1220(a)(1) or Sec. D.1220(a)(2) if the construction or operation of a facility or activity, or a basic component supplied for such facility or activity--

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

(ii) Contains a defect.

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

or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to Sec. D.1220(a).

(c) A dedicating entity is responsible for--

(1) Identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and

(2) Maintaining auditable records for the dedication process.

(d) (1) A director or responsible officer subject to the regulations of this part or a person designated under Sec. D.1220(c)(5) must notify the Department when he or she obtains information reasonably indicating a failure to comply or a defect affecting--

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

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

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

(3) Notification required by paragraph (c)(1) of this section must be made as follows--

(i) Initial notification by facsimile, which is the preferred method of notification, to the Department at (410) 631-3198 or by telephone at (410) 631-3300 within two days following receipt of information by the director or responsible corporate officer under paragraph (a)(1) of this section, on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the Department. This paragraph does not apply to interim reports described in Sec. D.1220(a)(2).

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

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

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

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

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

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

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

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

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

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

(5) The director or responsible officer may authorize an individual to provide the notification required by this paragraph, provided that, this shall not relieve the director or responsible officer of his or her responsibility under this paragraph.

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

ADDITIONAL REQUIREMENTS

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

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

PART E

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Subpart A - General Provisions

Sec. E.1 Purpose. The regulations in this part establish radiation safety requirements for using sources of radiation for industrial radiography. The requirements of this part are in addition to, and not in substitution for, other applicable requirements of these regulations.

Sec. E.2 Scope. The regulations in this part apply to all licensees or registrants who use sources of radiation for industrial radiography. Except for those regulations of this part clearly applicable only to sealed sources of radiation, both radiation machines and sealed sources of radiation are covered by this part.

Sec. E.3 Definitions.

"Annual refresher safety training" means a review conducted or provided by the licensee for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

"Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, (e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator when it is used as an exposure head.

"Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet shielded so that radiation levels at every location on the exterior meet the limitations specified in D.301 of these regulations.

"Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet x-ray system is intended to contain at least that portion of a material being radiated, provide radiation attenuation, and exclude personnel from its interior during generation of the radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system.

"Certified cabinet x-ray system" means an x-ray system which has been certified in accordance with 21CFR 1010.2 as being being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

"Certifying Entity" means an independent certifying organization meeting the requirements in 10 CFR 34 Appendix A or the equivalent regulations of an Agreement State.

"Collimator" means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

"Control (drive) cable" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

"Control drive mechanism" means a device that enables the source assembly to be moved to and from the exposure device.

"Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

"Exposure head" means a device that locates the gamma radiography sealed source in the selected working position. (An exposure head is also known as a source stop.)

"Field station" means a facility where licensed material may be stored or used and from which equipment is dispatched.

"Guide tube (Projection sheath)" means a flexible or rigid tube (i.e., "J" tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

"Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process.

"Independent certifying organization" means an independent organization that meets all of the criteria of 10 CFR 34 Appendix A or the equivalent regulations of an Agreement State.

"Industrial radiography (radiography)" means an examination of the structure of materials by nondestructive methods, utilizing ionizing radiation to make radiographic images.

"Lay-barge radiography" means industrial radiography performed on any water vessel used for laying pipe.

"Lixiscope" means a portable light intensified imaging device using a sealed source.

"Offshore platform radiography" means industrial radiography conducted from a platform over a body of water.

"Permanent radiographic installation" means an enclosed shielded room, cell, or vault, not located at a temporary job site, in which radiography is performed.

"Practical Examination" means a demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.

"Radiation Safety Officer (RSO)" for industrial radiography means an individual with the responsibility for the overall radiation safety program on behalf of the licensee and who meets the requirements of Sec. E.42.

"Radiographer" means any individual who performs or who, in attendance at the site where the sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee for assuring compliance with the requirements of the Department's regulations and the conditions of the license.

"Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

"Radiographer's assistant" means any individual who under the direct supervision of a radiographer, uses a radiation machine, radiographic exposure devices, sealed sources or related handling tools, or radiation survey instruments in industrial radiography.

"Radiographic exposure device (also called a camera, or a projector)" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

"Radiographic operations" means all activities associated with the use of a radiation machine, or with the presence of radioactive sources in a radiographic exposure device during use of the device or transport (except when being transported by a common or contract transport), to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

"S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

"Sealed source" means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

"Shielded position" means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

"Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.

"Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those also used for transporting and storage of sealed sources.

"Storage area" means any location, facility, or vehicle which is used to store or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

"Storage container" means a container in which sealed sources are secured and stored.

"Underwater radiography" means industrial radiography performed when the radiographic exposure device and/or related equipment are beneath the surface of the water.

Subpart B - Exemptions and Cabinet Radiography

Sec. E.4 Exemptions.

(a) Except for the requirements of E.5, certified cabinet x-ray systems designed to exclude individuals from the interior of the cabinet are exempt from the requirements of this part.

(b) Industrial uses of lixiscopes are exempt from the requirements of this part.

Sec. E.5 Special Requirements for Cabinet Radiography.

(a) Systems for cabinet radiography designed to allow admittance of individuals shall:

(1) Comply with all applicable requirements of this part and D.301 of these regulations. If such a system is a certified cabinet x-ray system, it shall comply with all applicable requirements of this part and 21 CFR 1020.40.

(2) Be evaluated at intervals not to exceed 1 year to assure compliance with the applicable requirements of Part E. Records of these evaluations shall be maintained for inspection by the Agency for a period of 3 years after the evaluation.

(b) Certified cabinet x-ray systems designed to exclude individuals from the interior of the cabinet are exempt from the requirements of this part except that:

(1) Operating personnel must be provided with and required to wear either film badges or thermoluminescent dosimeters, and reports of the results of such monitoring shall be maintained for inspection by the Agency.

(2) No registrant shall permit any individual to operate a cabinet x-ray

system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this subparagraph shall be maintained for inspection by the Agency until disposition is authorized by the Agency.

(3) The registrant shall perform an evaluation, at intervals not to exceed 1 year, to determine conformance with D.301 of these regulations. If such a system is a certified cabinet x-ray system, it shall be evaluated at intervals not to exceed 1 year to determine conformance with 21 CFR 1020.40. Records of these evaluations shall be maintained for inspection by the Agency for a period of 3 years after the evaluation.

(c) Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the Agency pursuant to Part A.3(a) of these regulations.

Subpart C - Equipment

Sec. E.20 Performance Requirements for Industrial Radiography Equipment Using Sealed Sources of Radiation.

Equipment used in industrial radiographic operations must meet the following minimum criteria:

(a) (1) Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standards Institute, N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981).

(2) Notwithstanding the provisions of paragraph E.308(a)(1), engineering analyses may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography components. Upon review, the Agency may find this an acceptable alternative to actual testing of the component pursuant to the referenced standard.

(b) In addition to the requirements specified in paragraph (a) of this section, the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources:

(1) The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the--

(i) Chemical symbol and mass number of the radionuclide in the device;

(ii) Activity and the date on which this activity was last measured;

(iii) Model (or product code) and serial number of the sealed source;

(iv) Manufacturer's identity of the sealed source; and

(v) Licensee's name, address, and telephone number.

(2) Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of 10 CFR part 71.

(3) Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

(c) In addition to the requirements specified in paragraphs (a) and (b) of this section, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers:

(1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(2) The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

(3) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

(4) (i) Each sealed source or source assembly must have attached to it or engraved on it, a durable, legible, visible label with the words:

"DANGER--RADIOACTIVE."

(ii) The label may not interfere with the safe operation of the exposure device or associated equipment.

(5) The guide tube must be able to withstand a crushing test that closely

approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.

(6) Guide tubes must be used when moving the source out of the device.

(7) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during industrial radiography operations.

(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.

(9) Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(d) All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of this section.

(e) Notwithstanding paragraph (a)(1) of this section, equipment used in industrial radiographic operations need not comply with Sec. 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

Sec. E.21 Limits on External Radiation Levels from Storage Containers and Source Changers.

The maximum exposure rate limits for storage containers and source changers are 2 millisieverts (200 millirem) per hour at any exterior surface, and 0.1 millisieverts (10 millirem) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

Sec. E.23 Locking of Radiation Machines, Radiographic Exposure Devices, Storage Containers and Source Changers.

(a) Each radiation machine and radiographic exposure device must have a lock to prevent unauthorized use, or have an outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The radiation machine or exposure device and/or its container must be kept locked (and if a keyed-lock, with the key removed at all times) when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in Sec. E.51. In addition, during radiographic operations the sealed source assembly must be secured in the shielded position each

time the source is returned to that position.

(b) Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked (and if a keyed-lock, with the key removed at all times) when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

Sec. E.25 Radiation Survey Instruments.

(a) The licensee shall keep sufficient calibrated and operable radiation survey instruments at each location where a radiation machine or radioactive material is present to make the radiation surveys required by this part and by Part D of this regulation. Instrumentation required by this section must be capable of measuring a range from 0.02 millisieverts (2 millirems) per hour through 0.01 sievert (1 rem) per hour.

(b) The licensee shall have each radiation survey instrument required under paragraph (a) of this section calibrated--

(1) At intervals not to exceed 3 months and after instrument servicing, except for battery changes;

(2) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 millirems) per hour; and

(3) So that an accuracy within plus or minus 20 percent of the calibration source can be demonstrated at each point checked.

(c) The licensee shall maintain records of the results of the instrument calibrations in accordance with Sec. E.65.

Sec. E.27 Leak Testing and Replacement of Sealed Sources.

(a) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source must be performed by persons authorized to do so by the Agency, the NRC or an Agreement State.

(b) The opening, repair, or modification of any sealed source must be performed by persons specifically authorized to do so by the Agency, the NRC or an Agreement State.

(c) Testing and recordkeeping requirements.

(1) Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed 6 months. The leak testing of the source must be performed using a method approved by the Agency, the NRC or an Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 Bq (0.005 microcurie) of radioactive material on the test sample and must be performed by a person specifically authorized by the Agency, the NRC or an Agreement State to perform the analysis.

(2) The licensee shall maintain records of the leak tests in accordance with Sec. E.67.

(3) Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within 6 months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds 6 months.

(d) Any test conducted pursuant to paragraphs (b) and (c) of this section which reveals the presence of 185 Bq (0.005 microcurie) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall have it decontaminated and repaired or disposed of in accordance with Commission regulations. A report must be filed in accordance with D.1206.

(e) Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 185 Bq (0.005 microcuries) of radioactive material on the test sample and must be performed by a person specifically authorized by the Agency, the NRC or an Agreement State to perform the analysis. Should such testing reveal the presence of DU contamination, the exposure device must be removed from use until an evaluation of the wear of the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device however the device must be tested for DU contamination, if the interval of storage exceeds 12 months. A record of the DU leak-test must be made in accordance with Sec. E.67.

Sec. E.29 Quarterly Inventory.

(a) Each licensee shall conduct a quarterly physical inventory to account for all radiation machines, sealed sources and for devices containing depleted uranium received and possessed under this license.

(b) The licensee shall maintain records of the quarterly inventory in accordance with Sec. E.69.

Sec. E.31 Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.

(a) The licensee shall perform visual and operability checks on survey meters, radiation machines, radiographic exposure devices, transport and storage containers, associated equipment and source changers before use on each day the equipment is to be used to ensure that the equipment is in good working condition, that the sources are adequately shielded, and that required labeling is present. Survey instrument operability must be performed using check sources or other appropriate means. If equipment problems are found, the equipment must be removed from service until repaired.

(b) Each licensee shall have written procedures for:

(1) Inspection and routine maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed 3 months or before the first use thereafter to ensure the proper functioning of components important to safety. Replacement components shall meet design specifications. If equipment problems are found, the equipment must be removed from service until repaired.

(2) Inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials. The inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

(c) Records of equipment problems and of any maintenance performed under paragraphs (a) and (b) of this section must be made in accordance with Sec. E.73.

Sec. E.33 Permanent Radiographic Installations.

(a) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

(1) An entrance control of the type described in Sec. D.601 of these regulations that reduces the radiation level upon entry into the area, or

(2) Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the source is exposed or the radiation machine is on. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed or the radiation machine is on.

(b) The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry (designated in paragraph (a)(1) of this section) must be tested monthly. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within 7 calendar days. The facility may continue to be used during this 7-day period, provided the licensee implements the continuous surveillance requirements of Sec. E.51 and uses an alarming ratemeter. Test records for entrance controls and audible and visual alarm must be maintained in accordance with Sec. E.75.

Sec. E.35 Labeling, Storage, and Transportation.

(a) The licensee may not use a source changer or a container to store licensed material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording

CAUTION[1]
RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES (or "NAME OF COMPANY")

(b) The licensee may not transport licensed material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in Part T of these regulations.

(c) Locked radiation machines, radiographic exposure devices and storage containers must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store licensed material in a manner which will minimize danger from explosion or fire.

(d) The licensee shall lock and physically secure the transport package containing licensed material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed material from the vehicle.

[1] The Licensee may use the word "DANGER"

Subpart D - Radiation Safety Requirements

Sec. E.41 Conducting Industrial Radiographic Operations.

(a) Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of Sec. E.43(c). The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

(b) All radiographic operations conducted at locations of use authorized on the license must be conducted in a permanent radiographic installation, unless specifically authorized by the Agency.

(c) A licensee may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the Agency, the NRC or by an Agreement State.

(d) Each licensee or registrant shall provide as a minimum two radiographic personnel when sealed sources of radiation are used at temporary jobsites. If one of the personnel is a radiographer assistant, the other person shall be a raadiographer

Sec. E.42 Radiation Safety Officer for Industrial Radiography.

The RSO shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's program.

(a) The minimum qualifications, training, and experience for RSOs for industrial radiography are as follows:

(1) Completion of the training and testing requirements of Sec. E.43(a);

(2) 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

(3) Formal training in the establishment and maintenance of a radiation protection program.

(b) The Department will consider alternatives when the RSO has appropriate training and/or experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

(c) The specific duties and authorities of the RSO include, but are not limited to:

(1) Establishing and overseeing all operating, emergency, and ALARA procedures as required by Part D of this chapter, and reviewing them regularly to ensure that the procedures in use conform to current Part D procedures, conform to other Agency regulations and to the license conditions.

(2) Overseeing and approving all phases of the training program for radiographic personnel, ensuring that appropriate and effective radiation protection practices are taught;

(3) Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the regulations, including any corrective measures when levels of radiation exceed established limits;

(4) Ensuring that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by Sec. D.1203 of this chapter; and

(5) Ensuring that operations are conducted safely and to assume control for instituting corrective actions including stopping of operations when necessary.

(d) Licensees will have until May 28, 2000 to meet the requirements of paragraph (a) or (b) of this section.

Sec. E.43 Training.

(a) The licensee may not permit any individual to act as a radiographer until the individual--

(1) Has received training in the subjects in paragraph (g) of this section, in addition to a minimum of 2 months of on-the-job training, and is certified through a radiographer certification program by a certifying entity that has been approved by the NRC or an agreement state (An independent organization that would like to be recognized as a certifying entity shall submit its request to the Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC. 20555-0001), or

(2) The licensee may, until May 28, 2000, allow an individual who has not met the requirement of paragraph (a)(1) of this section, to act as a radiographer after the individual has received training in the subjects

outlined in paragraph (g) of this section and demonstrated an understanding of these subjects by successful completion of a written examination that was previously submitted to and approved by the Department.

(b) In addition, the licensee may not permit any individual to act as a radiographer until the individual--

(1) Has received copies of and instruction in:

(a) The regulations governing industrial radiography contained in Part E of this chapter, or the equivalent regulations of an Agreement State or the NRC;

(b) The regulations governing radiation protection standards and notices, instructions, and reports to workers contained in Parts D and J of this chapter, or the equivalent regulations of the NRC or an Agreement State;

(c) Applicable DOT regulations as referenced in 10 CFR part 71;

(d) The Agency, NRC or Agreement State license(s) under which the radiographer will perform industrial radiography; and

(e) The licensee's operating and emergency procedures.

(2) Has demonstrated understanding of the licensee's license and operating and emergency procedures by successful completion of a written or oral examination covering this material.

(3) Has received training in the use of the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments.

(4) Has demonstrated understanding of the use of radiographic exposure devices, sources, survey instruments and associated equipment described in paragraphs (b)(1) and (b)(3) of this section by successful completion of a practical examination covering this material.

(c) The licensee may not permit any individual to act as a radiographer's assistant until the individual--

(1) Has received copies of and instruction in:

(a) The regulations governing industrial radiography contained in Part E of this chapter, or the equivalent regulations of an Agreement State or the NRC;

(b) The regulations governing radiation protection standards and notices, instructions, and reports to workers contained in Parts D and J of this chapter, or the equivalent regulations of the NRC or an Agreement State;

(c) Applicable DOT regulations as referenced in 10 CFR part 71;

(d) The Agency, NRC or Agreement State license(s) under which the radiographer's assistant will perform industrial radiography; and

(e) The licensee's operating and emergency procedures.

(2) Has developed competence to use, under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, associated equipment, and radiation survey instruments that the assistant will use; and

(3) Has demonstrated understanding of the instructions provided under (c)(1) of this section by successfully completing a written test on the subjects covered and has demonstrated competence in the use of hardware described in (c)(2) of this section by successful completion of a practical examination on the use of such hardware.

(d) The licensee shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

(e) Except as provided in paragraph (e)(4), the RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the regulations governing industrial radiography contained in Part E of this chapter, or the equivalent regulations of the NRC or an Agreement State, the license requirements, and the applicant's operating and emergency procedures are followed. The inspection program must:

(1) Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed 3 months; and

(2) Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than 3 months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of Sec. E.43(b)(3) and the radiographer's assistant must re-demonstrate knowledge of the training requirements of Sec. E.43(c)(2) by a practical examination before these individuals can next participate in a radiographic operation.

(3) The Department may consider alternatives in those situations where the

individual serves as both radiographer and RSO.

(4) In those operations where a single individual serves as both radiographer and RSO, and performs all radiography operations, an inspection program is not required.

(f) The licensee shall maintain records of the above training to include certification documents, written and practical examinations, refresher safety training and inspections of job performance in accordance with Sec. E.79.

(g) The licensee shall include the following subjects required in paragraph (a) of this section:

(1) Fundamentals of radiation safety including--

(i) Characteristics of x-ray and gamma radiation;

(ii) Units of radiation dose and quantity of radioactivity;

(iii) Hazards of exposure to radiation;

(iv) Levels of radiation from radiation machines and licensed material; and

(v) Methods of controlling radiation dose (time, distance, and shielding);

(2) Radiation detection instruments including--

(i) Use, operation, calibration, and limitations of radiation survey instruments;

(ii) Survey techniques; and

(iii) Use of personnel monitoring equipment;

(3) Equipment to be used including--

(i) Operation and control of radiation machines, radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails).

(ii) Storage, control, and disposal of licensed material and radiation machines; and

(iii) Inspection and maintenance of equipment.

(4) The requirements of pertinent Agency regulations; and

(5) Case histories of accidents in radiography.

(h) Licensees will have until May 28, 2000 to comply with the additional training requirements specified in paragraphs (b)(1) and (c)(1) of this section.

Sec. E.45 Operating and Emergency Procedures.

(a) Operating and emergency procedures must include, as a minimum, instructions in the following:

(1) Appropriate handling and use of radiation machines, licensed sealed sources and radiographic exposure devices so that no person is likely to be exposed to radiation doses in excess of the limits established in Part D of this chapter "Standards for Protection Against Radiation";

(2) Methods and occasions for conducting radiation surveys;

(3) Methods for controlling access to radiographic areas;

(4) Methods and occasions for locking and securing radiographic exposure devices, transport and storage containers and sealed sources;

(5) Personnel monitoring and the use of personnel monitoring equipment;

(6) Transporting sealed sources to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when needed, and control of the sealed sources during transportation (refer to Part T of these regulations);

(7) The inspection, maintenance, and operability checks of radiographic exposure devices, survey instruments, transport containers, and storage containers;

(8) Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarm ratemeter alarms unexpectedly.

(9) The procedure(s) for identifying and reporting defects and noncompliance, as required by COMAR 26.12.01.01D.1220 of this chapter;

(10) The procedure for notifying proper persons in the event of an accident;

(11) Minimizing exposure of persons in the event of an accident;

(12) Source recovery procedure if licensee will perform source recovery;

(13) Maintenance of records.

(b) The licensee shall maintain copies of current operating and emergency procedures in accordance with Secs. E.81 and E.89.

Sec. E.46 Supervision of Radiographers' Assistants.

Whenever a radiographer's assistant uses radiation machines, radiographic exposure devices, associated equipment or sealed sources or conducts radiation surveys required by Sec. E.49(b) to determine that the sealed source has returned to the shielded position or the radiation machine has turned off after an exposure, the assistant shall be under the personal supervision of a radiographer. The personal supervision must include:

(a) The radiographer's physical presence at the site where the radiation machines or sealed sources are being used;

(b) The availability of the radiographer to give immediate assistance if required; and

(c) The radiographer's direct observation of the assistant's performance of the operations referred to in this section.

Sec. E.47 Personnel Monitoring.

(a) The licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of direct reading dosimeter, an operating alarm ratemeter, and either a film badge or a TLD. At permanent radiography installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required.

(1) Pocket dosimeters must have a range from zero to 2 millisieverts (200 millirems) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

(2) Each film badge and TLD must be assigned to and worn by only one individual.

(3) Film badges and TLD must be replaced at periods not to exceed one month.

(4) After replacement, each film badge or TLD must be processed as soon as possible.

(b) Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with Sec. E.82.

(c) Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with Sec. E.82. Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure.

(d) If an individual's pocket dosimeter is found to be off-scale, or if his or her electronic personal dosimeter reads greater than 2 millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's film badge or TLD must be sent for processing within 24 hours. In addition, the individual may not resume work associated with licensed material use or radiation machines until a determination of the individual's radiation exposure has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in the records maintained in accordance with Sec. E.82.

(e) If a film badge or TLD is lost or damaged, the worker shall cease work immediately until a replacement film badge or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge or TLD. The results of the calculated exposure and the time period for which the film badge or TLD was lost or damaged must be included in the records maintained in accordance with Sec. E.82.

(f) Reports received from the film badge or TLD processor must be retained in accordance with Sec. E.82.

(g) Each alarm ratemeter must--

(1) Be checked to ensure that the alarm functions properly (sounds) before using at the start of each shift;

(2) Be set to give an alarm signal at a preset dose rate of 5 mSv/hr (500 mrem/hr); with an accuracy of plus or minus 20 percent of the true radiation dose rate;

(3) Require special means to change the preset alarm function; and

(4) Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee shall maintain records of alarm ratemeter calibrations in accordance with Sec. E.83.

Sec. E.49 Radiation Surveys.

The licensee shall:

(a) Not conduct a radiographic operation unless at least one calibrated and operable radiation survey instrument, as described in E.25, is available and used by each radiographic person at the site of each exposure.

(b) Survey with a radiation survey instrument after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall also include the entire length of the guide tube. If using a radiation machine, a similar survey shall be performed to determine if the machine has turned off.

(c) Conduct a survey of the radiographic exposure device with a calibrated radiation survey instrument any time the source is exchanged and whenever a radiographic exposure device is placed in a storage area (as defined in Sec. E.3), to ensure that the sealed source is in its shielded position.

(d) Maintain records in accordance with Sec. E.85.

Sec. E.51 Surveillance.

During each radiographic operation the radiographer, or the other individual present, as required by Sec. E.41, shall maintain continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Part D of this chapter except at permanent radiographic installations where all entryways are locked and the requirements of Sec. E.33 are met.

Sec. E.53 Posting.

All areas in which industrial radiography is being performed must be conspicuously posted as required by Sec. D.902 of this chapter. Exceptions listed in Sec. D.903 of this chapter do not apply to industrial radiographic operations.

Subpart E - Recordkeeping Requirements

Sec. E.61 Records of the Specific License for Industrial Radiography.

Each licensee shall maintain a copy of its license, license conditions, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Agency, or until the Agency terminates the license.

Sec. E.63 Records of Receipt and Transfer of Sealed Sources.

(a) Each licensee shall maintain records showing the receipts and transfers of sealed sources and devices using depleted uranium for shielding and retain each record for 3 years after it is made.

(b) These records must include the date, the name of the individual making the record, radionuclide, number of becquerels (curies) or mass (for depleted uranium), and manufacturer, model, and serial number of each sealed source and/or device, as appropriate.

Sec. E.65 Records of Radiation Survey Instruments.

Each licensee shall maintain records of the calibrations of its radiation survey instruments that are required under Sec. E.25 and retain each record for 3 years after it is made.

Sec. E.67 Records of Leak Testing of Sealed Sources and Devices Containing Depleted Uranium.

Each licensee shall maintain records of leak test results for sealed sources and for devices containing depleted uranium. The results must be stated in units of becquerels (microcuries). The licensee shall retain each record for 3 years after it is made or until the source in storage is removed.

Sec. E.69 Records of Quarterly Inventory.

(a) Each licensee shall maintain records of the quarterly inventory of sealed sources and of devices containing depleted uranium as required by Sec. E.29 and retain each record for 3 years after it is made.

(b) The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sealed source and/or devices, and manufacturer, model, and serial number of each sealed source and/or device, as appropriate.

Sec. E.71 Utilization Logs.

(a) Each licensee shall maintain utilization logs showing for each radiation machine or sealed source the following information:

(1) A description, including the make, model, and serial number of the radiation machine, radiographic exposure device or transport or storage container in which the sealed source is located;

(2) The identity and signature of the radiographer to whom assigned; and

(3) The plant or site where used and dates of use, including the dates removed and returned to storage.

(b) The licensee shall retain the logs required by paragraph (a) of this section for 3 years after the log is made.

Sec. E.73 Records of Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.

(a) Each licensee shall maintain records specified in Sec. E.31 of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments; and retain each record for 3 years after it is made.

(b) The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was done.

Sec. E.75 Records of Alarm System and Entrance Control Checks at Permanent Radiographic Installations.

Each licensee shall maintain records of alarm system and entrance control device tests required under Sec. E.33 and retain each record for 3 years after it is made.

Sec. E.79 Records of Training and Certification.

Each licensee shall maintain the following records (of training and certification) for 3 years after the record is made:

(a) Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, and names of individuals conducting and receiving the oral and practical examinations; and

(b) Records of annual refresher safety training and quarterly inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliances observed by the Radiation Safety Officer.

Sec. E.81 Copies of Operating and Emergency Procedures.

Each licensee shall maintain a copy of current operating and emergency procedures until the Department terminates the license. Superceded material must be retained for 3 years after the change is made.

Sec. E.82 Records of Personnel Monitoring Procedures.

Each licensee shall maintain the following exposure records specified in Sec. E.47:

(a) Direct reading dosimeter readings and yearly operability checks required by Sec. E.47(b) and (c) for 3 years after the record is made.

(b) Records of alarm ratemeter calibrations for 3 years after the record is made.

(c) Reports received from the film badge or TLD processor until the Department terminates the license.

(d) Records of estimates of exposures as a result of: off-scale personal direct reading dosimeters, or lost or damaged film badges or TLDs, until the Department terminates the license.

Sec. E.85 Records of Radiation Surveys.

Each licensee shall maintain a record of each exposure device survey conducted before the device is placed in storage as specified in Sec. E.49(c), if that survey is the last one performed in the workday. Each record must be maintained for 3 years after it is made.

Sec. E.87 Form of Records.

Each record required by this part must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

Sec. E.89 Location of Documents and Records.

(a) Each licensee or registrant subject to Part E shall maintain copies of records required by this part and other applicable parts of this chapter at the location specified in the person's license or registration.

(b) Each licensee or registrant subject to Part E shall also maintain copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary job site;

(1) The license or registration authorizing the use of sources of radiation;

(2) A copy of COMAR 26.12.01.01 Regulations for Control of Ionizing Radiation (1994);

(3) Utilization records for each radiation machine or radiographic exposure device dispatched from that location as required by Sec. E.71;

(4) Records of equipment problems identified in daily checks of equipment as required by Sec. E.73(a);

(5) Records of alarm system and entrance control checks required by Sec. E.75, if applicable;

(6) Records of direct reading dosimeters such as pocket dosimeter and/or electronic personal dosimeters readings as required by Sec. E.82;

(7) Operating and emergency procedures required by Sec. E.81;

(8) Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by Sec. E.65;

(9) Evidence of the latest calibrations of alarm ratemeters and operability checks of pocket dosimeters and/or electronic personal dosimeters as required by Sec. E.82;

(10) Latest survey records required by Sec. E.85;

(11) The shipping papers for the transportation of radioactive materials required by Sec. T.5 of this chapter; and

(12) When operating under reciprocity pursuant to Sec. C.90, a copy of the NRC or Agreement State license authorizing the use of licensed materials.

Subpart F - Notifications

Sec. E.101 Notifications.

(a) In addition to the reporting requirements specified in Sec. D.1201 through D.1206, D.1210, and D.1220 of these regulations, each licensee or registrant shall immediately notify the Department and shall provide a written report to the Maryland Department of the Environment, Radiological Health Program, 2500 Broening Highway,

Baltimore, MD 21224 within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

(1) Unintentional disconnection of the source assembly from the control cable;

(2) Inability to retract the source assembly to its fully shielded position and secure it in this position; or

(3) Failure of any component (critical to safe operation of the device) to properly perform its intended function;

(b) The licensee shall include the following information in each report submitted under paragraph (a) of this section, and in each report of overexposure submitted under D.1203 which involves failure of safety components of radiography equipment:

(1) A description of the equipment problem;

(2) Cause of each incident, if known;

(3) Name of the manufacturer and model number of equipment involved in the incident;

(4) Place, date, and time of the incident;

(5) Actions taken to establish normal operations;

(6) Corrective actions taken or planned to prevent recurrence; and

(7) Qualifications of personnel involved in the incident.

(c) Any person conducting radiographic operations or storing radiation machines or radioactive material at any location not listed on the registration or license for a period in excess of 180 days in a calendar year, shall notify the Agency prior to exceeding the 180 days.

PART J

NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

Sec. J.1 Purpose and Scope. This part establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in activities under a license or registration and options available to such individuals in connection with Agency inspections of licensees or registrants to ascertain compliance with the provisions of the Act and regulations, orders, and licenses issued thereunder regarding radiological working conditions. The regulations in this part apply to all persons who receive, possess, use, own, or transfer sources of radiation registered with or licensed by the Agency pursuant to Parts B and C of these regulations.

General Regulatory Provisions and Specific Requirements

Sec. J.11 Posting of Notices to Workers.

(a) Each licensee or registrant shall post current copies of the following documents:

(1) The regulations in this part and in Part D of these regulations;

(2) The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;

(3) The operating procedures applicable to activities under the license or registration; and

(4) Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Part A of these regulations, and any response from the licensee or registrant.

(b) If posting of a document specified in J.11(a)(1), (2), (3) or (4) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(c) Agency MDE 279 "Notice to Employees" shall be posted by each licensee or registrant as required by these regulations.

(d) Agency documents posted pursuant to J.11(a)(4) shall be posted within 5 working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within 5 working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

(e) Documents, notices, or forms posted pursuant to J.11 shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

Sec. J.12 Instructions to Workers.

(a) All individuals who in the course of employment potentially may receive in a year an occupational dose in excess of 100 mrem (1 mSv):

(1) Shall be kept informed of the storage, transfer, or use of radiation or radioactive materials;

(2) Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material, in the precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

(3) Shall be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of these regulations and licenses for the protection of personnel from exposures to radiation or radioactive material;

(4) Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of the Act, these regulations, and licenses or unnecessary exposure to radiation or radioactive material;

(5) Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

(6) Shall be advised as to the radiation exposure reports which workers may request pursuant to J.13.

(b) In determining those individuals subject to the requirements of paragraph (a) of this section, licensees or registrants must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed or registered facility. The extent of these instructions shall be commensurate with potential radiological health protection problems in the work place.

Sec. J.13 Notifications and Reports to Individuals.

(a) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in J.13. The information reported shall include data and results obtained pursuant to these regulations, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to D.1107 of these regulations. Each notification and report shall:

(1) Be in writing;

(2) Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number;

(3) Include the individual's exposure information; and

(4) Contain the following statement:

"This report is furnished to you under the provisions of COMAR 26.12.01.01 Part J. You should preserve this report for further reference."

(b) Each licensee or registrant shall furnish a report to each worker annually, and within 90 days following termination, of the worker's dose as shown in records maintained by the licensee or registrant pursuant to D.1107 of these regulations.

(c) Each licensee or registrant shall furnish a report of the worker's exposure to sources of radiation at the request of a worker formerly or presently engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to D.502 of these regulations. Such report shall be furnished within 30 days from date the request was made, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever

is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

(d) When a licensee or registrant is required pursuant to D.1203 or D.1204 of these regulations to report to the Agency any exposure of an individual to sources of radiation, the licensee or the registrant shall also provide the individual a report on the exposure data included therein. Such report shall be transmitted at a time not later than the transmittal to the Agency.

(e) A licensee or registrant shall furnish to each worker who is terminating employment in work involving exposure to sources of radiation, a written report during the current year to each such worker, or to a worker's designee, regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

Sec. J.14 Presence of Representatives of Licensees or Registrants and Workers During Inspection.

(a) Each licensee or registrant shall afford to the Agency, or an agent of the Agency licensed under COMAR 26.12.02.03, at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these regulations.

(b) During an inspection, Agency inspectors, or agents of the Agency licensed under COMAR 26.12.02.03, may consult privately with workers as specified in J.15. The licensee or registrant may accompany Agency inspectors or agents etc. during other phases of an inspection.

(c) If, at the time of inspection, an individual has been authorized by the workers to represent them during Agency inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(d) Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in J.12.

(e) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(f) With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany Agency inspectors or agents of the Agency etc. during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of J.14, Agency inspectors or agents of the Agency etc. are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. [Subsection J.14(g) continued next page]

With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

Sec. J.15 Consultation with Workers During Inspections.

(a) Agency inspectors or agents etc. or a State-licensed inspector performing an inspection under the authority of COMAR 26.12.01.02 may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these regulations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(b) During the course of an inspection, any worker may bring privately to the attention of the Agency inspector or agents etc., either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Act, these regulations, or license condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of J.16(a).

(c) The provisions of J.15(b) shall not be interpreted as authorization to disregard instructions pursuant to J.12.

Sec. J.16 Requests by Workers for Inspections.

(a) Any worker or representative of workers believing that a violation of the Act, these regulations, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the Agency. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the Agency no later than at the time of inspection except that, upon the request of the worker giving such notice, such worker's name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Agency, except for good cause shown.

(b) If, upon receipt of such notice, the Agency determines that the complaint meets the requirements set forth in J.16(a), and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to J.16 need not be limited to matters referred to in the complaint.

(c) No licensee, registrant, or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these regulations or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of such worker or others of any option afforded by this part.

Sec. J.17 Inspections Not Warranted; Informal Review.

(a) (1) If the Agency determines, with respect to a complaint under J.16, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Agency shall notify the complainant in writing of such determination. The

MDE

MARYLAND DEPARTMENT OF THE ENVIRONMENT
2500 Broening Highway • Baltimore Maryland 21224
410-631-3000 • 1-800-633-6101 • http:// www. mde. state. md. us

Parris N. Glendening
Governor

Jane Nishida
Secretary

MEMORANDUM

TO: Holders of the Maryland State Regulations for the Control of Ionizing Radiation (1994)

FROM: Roland G. Fletcher, Manager
Radiological Health Program

DATE: April 13, 2000

SUBJECT: Radiation Regulations Update - - SUPPLEMENT 6

Agency records indicate that you have purchased a copy of the Maryland State Regulations for the Control of Ionizing Radiation (1994). The attached package of amendments is furnished at no cost to you, so that you may keep the original current. You are advised that the inclusion of these amendments should be accomplished as soon as possible.

If you have any questions, please contact Mr. Ray Manley or me at (410) 631-3300. You may also reach our office toll-free by calling 1-800-633-6101.

RGF/rem

Attachment

COMAR 26.12.01.01

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

ADOPTED SUPPLEMENT No. 6

TO: HOLDERS OF COMAR 26.12.01.01 "MARYLAND STATE REGULATIONS FOR CONTROL OF IONIZING RADIATION (1994)."

Supplement 6 to the document COMAR 26.12.01.01 "Regulations for the Control of Ionizing Radiation (1994)" has been adopted and became effective on February 7, 2000. The pages that are necessary to update your copy of the regulations are enclosed and ready for insertion in your permanent regulations binder. Please follow these instructions carefully.

Instructions:

A. Locate the permanent regulations binder in your possession.

B. Change the permanent binder now as follows:

Carefully follow the "remove/insert" instructions appearing below. Remove the obsolete pages listed under the column "Remove Pages" from the permanent binder. From the package of pages enclosed, insert the new or replacement pages listed under the column "Insert Pages" in the permanent binder. Each of these pages has at least one of the two faces of the page printed with the words "Supp.6" in a lower corner. The obsolete pages removed from the permanent binder may be retained in a separate place for legal research.

Remove Pages From Permanent Binder	Insert Pages Into Permanent Binder
Cover Page	Cover Page
i through iv	i through iv
xi through xiv	xi through xv
B5 and B6	B5 and B6
C45 and C46	C45 and C46
C51, C51-1 and C-52	C51, C51-1, C51-2 and C52
D36 and D36	D35 and D36
D42-3 and D42-4	D42-3 and D42-4
F13and F14	F13 and F14
T1 through T31	T1 through T40

C. You will be sent further instructions about upcoming supplements when later action affects these regulations.

INQUIRIES TO: Radiological Health Program
Maryland Department of The Environment
2500 Broening Highway
Baltimore, MD 21224
(410) 631-3301

Code of Maryland Regulation 26.12.01.01

Adopted: September 9, 1995
Effective: October 9, 1995

Supplement 1 Effective: December 6, 1996
Supplement 2 Effective: November 3, 1997
Supplement 3 Effective: June 29, 1998
Supplement 4 Effective: November 28, 1998
Supplement 5 Effective: June 1, 1999
Supplement 6 Effective: February 7, 2000

REGULATIONS FOR THE CONTROL OF IONIZING RADIATION (1994)

RADIOLOGICAL HEALTH PROGRAM
AIR AND RADIATION MANAGEMENT ADMINISTRATION
MARYLAND DEPARTMENT OF THE ENVIRONMENT

2500 BROENING HIGHWAY
BALTIMORE, MARYLAND 21224

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(i) The type of radiation machine;

(ii) The nature, duration, and scope of use;

(iii) The exact location(s) where the radiation machine is to be used; and

(iv) The State of Maryland facility registration number, the State machine number and the date last certified.

(b) If, for a specific case, the three-day period would impose an undue hardship on the person, upon application to the Agency, permission to proceed sooner may be granted.

(c) The person referred to in B.13(a) shall:

(i) Comply with all applicable regulations of the Agency;

(ii) Supply the Agency with such other information as the Agency may reasonably request; and

(iii) Not operate within the State on a temporary basis in excess of 180 calendar days per year.

Sec. B.14 Service, Possession or Storage of Radiation Machines

(a) No person shall modify a radiation machine, or any other auxiliary equipment that functions with the radiation machine to produce the result desired by use of the machine, in such a manner that the machine or auxiliary equipment fails to operate properly or otherwise does not meet any provision of these regulations.

(b) No person shall possess or store for more than 30 days a radiation machine which does not meet the requirements of COMAR 26.12 "Radiation Management" unless such radiation machine has been internally rendered inoperable, in a manner approved by the Department.

PART B

APPENDIX A

DESIGN GUIDELINES FOR AN OPERATOR'S BOOTH

1. Space Requirements:

(a) The operator should be allotted not less than 0.7 m2 (7.5 square feet) of unobstructed floor space in the booth.

(b) The operator's booth may be any geometric configuration with no dimension of less that 0.6 m (2 feet).

(c) The space should be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments.

(d) The booth should be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette holder will not reach the operator's position in the booth.

2. Structural Requirements:

(a) The booth walls should be permanently fixed barriers of at least 2.1 m (7 feet) high.

(b) When a door or movable panel is used as an integral part of the booth structure, it should have an interlock which will prevent an exposure when the door or panel is not closed.

(c) Shielding should be provided to meet the requirements of Part D of these regulations.

3. X-Ray Exposure Control Placement: The x-ray exposure control for the system should be fixed within the booth and:

(a) Should be at least 0.08 m (30 inches) from any point subject to direct scatter, leakage or primary beam radiation.

(b) Should allow the operator to use the majority of the available viewing windows.

4. Viewing System Requirements:

(a) Each booth should have at least one viewing device which will:

(i) Be so placed that the operator can view the patient during any exposure, and

(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. 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.

(e) Financial assurance for decommissioning must be provided by one or more of the following methods:

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

(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, 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. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. A guarantee of funds by the applicant or licensee for the 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 guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or 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:

(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 or insurance, 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 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 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.

(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. 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; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release for unrestricted use.

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.

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

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

(a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific or general license may submit a request to the Agency for evaluation of radiation safety information about its product and for it's registration.

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

(c) The Agency normally evaluates a sealed source or a device using radiation safety criteria in accordance with accepted industry standards. If these standards and criteria do not readily apply to a particular case, the agency formulates reasonable standards and criteria with the help of the manufacturer or distributor. The Agency shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.

(d) After completion of the evaluation, the Agency may issue a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.

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

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

(2) The provisions of the registration certificate.

Sec.C.38 Records.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Transfer of Material

Sec. C.40 Transfer of Material.

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

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

(1) to the Agency; [11]

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

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

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

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

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

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

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

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

(3) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or

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

b. The licensee shall retain the records required by D.1109 until the Department terminates each pertinent license requiring the record. Requirements for disposition of these records, prior to license termination, are located in § C.38 for activities licensed under this part.

Sec. D.1110 Records of Testing Entry Control Devices for Very High Radiation Areas.

a. Each licensee or registrant shall maintain records of tests made pursuant to D.602 on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

b. The licensee or registrant shall retain the records required by D.1110a. for 3 years after the record is made or for such time as the Agency shall determine.

Sec. D.1111 Form of Records.

Each record required by Part D shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

REPORTS

Sec. D.1201 Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.

a. Immediate Report. Each licensee or registrant shall report by telephone immediately and in writing within 24 hours to the Agency the theft or loss of any source of radiation immediately after such occurrence becomes known.

b. Following Report. Each licensee or registrant required to make a report pursuant to D.1201a. shall, within 30 days after making the telephone report, make a written report to the Agency setting forth the following information:

i. A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted; and

ii. A description of the circumstances under which the loss or theft occurred; and

iii. A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

iv. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

v. Actions that have been taken, or will be taken, to recover the source of radiation; and

vi. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

c. Subsequent to filing the written report required in D.1201(b), the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

d. The licensee or registrant shall prepare any report filed with the Agency pursuant to D.1201 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

Sec. D.1202 Notification of Incidents.

a. Immediate Notification. In addition to other requirements for notification, each licensee or registrant shall immediately report by telephone each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

i. An individual to receive:

(1) A total effective dose equivalent of 0.25 Sv (25 rem) or more; or

(2) An eye dose equivalent of 0.75 Sv (75 rem) or more; or

(3) A shallow dose equivalent to the skin or extremities 2.5 Gy (250 rad) or more; or

ii. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

b. Twenty-Four Hour Notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Agency in writing by telegram, mailgram or facsimile, each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to Sec. D.1220(a).

(c) A dedicating entity is responsible for--

(1) Identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and

(2) Maintaining auditable records for the dedication process.

(d) (1) A director or responsible officer subject to the regulations of this part or a person designated under Sec. D.1220(c)(5) must notify the Department when he or she obtains information reasonably indicating a failure to comply or a defect affecting--

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

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

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

(3) Notification required by paragraph (c)(1) of this section must be made as follows--

(i) Initial notification by facsimile, which is the preferred method of notification, to the Department at (410) 631-3198 or by telephone at (410) 631-3300 within two days following receipt of information by the director or responsible corporate officer under paragraph (a)(1) of this section, on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the Department. This paragraph does not apply to interim reports described in Sec. D.1220(a)(2).

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

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

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

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

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

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

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

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

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

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

(5) The director or responsible officer may authorize an individual to provide the notification required by this paragraph, provided that, this shall not relieve the director or responsible officer of his or her responsibility under this paragraph.

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

ADDITIONAL REQUIREMENTS

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

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

(3) X-Ray Log. Each facility shall maintain an x-ray log containing the patient's name, the type of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

(b) Processing of film.

(1) All film shall be processed in such a fashion as to achieve adequate sensitometric performance. "Adequate sensitometric performance" means:

(i) A measured processing speed of greater than or equal to 80; and

(ii) that the base plus fog of the facility's film shall not exceed 0.3 OD;

as measured by the Sensitometric Technique for the Evaluation of Processing (STEP) test 1/.

(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), and

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

(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 (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.

1/This test is described by Suleiman, O.H. et al. in the article "Automatic Film Processing: Analysis of 9 Years of Observations." Radiology 1992 Vol. 185, pp. 25-28.

(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.

(c) Quality Assurance.

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

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

(2) That film processing systems will be maintained at the highest quality level;

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

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

PART T

PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

GENERAL PROVISIONS

Sec. T.1 Purpose and Scope. The regulations in this part establish requirements for packaging, preparation for shipment, and transportation of radioactive material and apply to any person who transports radioactive material or delivers radioactive material to a carrier for transport.

Sec. T2 Requirement for License. Except as authorized in a general license or a specific license issued by the Department, or as exempted in this Part, no licensee may –

(a) Deliver licensed material to a carrier for transport; or

(b) Transport licensed material.

Sec. T.3 Definitions. To ensure compatibility with international transportation standards, all limits in this part are given in terms of dual units: The International System of Units (SI) followed or preceded by U.S. standard or customary units. The U.S. customary units are not exact equivalents, but are rounded to a convenient value, providing a functionally equivalent unit. For the purpose of this part, either unit may be used. As used in this part, the following definitions apply:

"A1" means the maximum activity of special form radioactive material permitted in a Type A package. "A2" means the maximum activity of radioactive material, other than special form, LSA and SCO material, permitted in a Type A package. These values are either listed in Appendix A of this part, Table A-1, or may be derived in accordance with the procedure prescribed in Appendix A of this part.

"Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

"Certificate holder" means a person who has been issued a certificate of compliance or other package approval by the U.S. Nuclear Regulatory Commission.

"Close reflection by water" means immediate contact by water of sufficient thickness for maximum reflection of neutrons.

"Containment system" means the assembly of components of the packaging intended to retain the radioactive material during transport.

"Conveyance" means:

(1) "For transport by public highway or rail" any transport vehicle or large freight container;

(2) "For transport by water" any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and

(3) "For transport by aircraft" any aircraft.

"Exclusive use" means the sole use by a single consignor of a conveyance for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.

"Fissile material" means plutonium-238, plutonium-239, plutonium-241, uranium-233, uranium-235, or any combination of these radionuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only, are not included in this definition. Certain exclusions from fissile material controls are provided in 10 CFR 71.53.

"Licensed material" means by-product, source, or special nuclear material received, possessed, used, or transferred under a general or specific license issued by the Department pursuant to the regulations in this chapter.

"Low Specific Activity (LSA) material" means radioactive material with limited specific activity that satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups:

(1) LSA-I.

(i) Ores containing only naturally occurring radionuclides (e.g., uranium, thorium) and uranium or thorium concentrates of such ores; or

(ii) Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures; or

(iii) Radioactive material, other than fissile material, for which the A2 value is unlimited; or

(iv) Mill tailings, contaminated earth, concrete, rubble, other debris, and activated material in which the radioactive material is essentially uniformly distributed, and the average specific activity does not exceed 10^{-6} A2/g.

(2). LSA-II.

(i) Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or

(ii) Material in which the radioactive material is distributed throughout, and the average specific activity does not exceed 10^{-4} A2/g for solids and gases, and 10^{-5} A2/g for liquids.

(3) LSA-III. Solids (e.g., consolidated wastes, activated materials) in which:

(i) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.); and

(ii) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for 7 days, would not exceed 0.1 A2; and

(iii) The average specific activity of the solid does not exceed 2×10^{-3} A2/g.

"Low toxicity alpha emitters" means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than 10 days.

"Maximum normal operating pressure" means the maximum gauge pressure that would develop in the containment system in a period of 1 year under the heat condition specified in 10 CFR 71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport.

"Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

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

"Optimum interspersed hydrogenous moderation" means the presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results.

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

(1) "Fissile material package" means a fissile material packaging together with its fissile material contents.

(2) "Type B package" means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by the Department as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lb/in^2) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 10 CFR 71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in Sec. T.13.

"Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of this part. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaing.
"Special form radioactive material" means radioactive material that satisfies the following conditions:

(1) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(2) The piece or capsule has at least one dimension not less than 5 mm (0.2 in); and

(3) It satisfies the requirements of 10 CFR 71.75. A special form encapsulation designed in accordance with the requirements of 10 CFR part 71, revised as of January 1, 1983, and constructed before July 1, 1985, and a special form encapsulation designed in accordance with the requirements of 10 CFR part 71, revised as of January 1, 1983, and constructed before April 1, 1998, may continue to be used. Any other special form encapsulation must meet the specifications of this definition.

"Specific activity of a radionuclide" means the radioactivity of the radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

"State" means a State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

"Surface Contaminated Object (SCO)" means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the following limits:

(1) SCO-I: A solid object on which:

(i) The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 4 Bq/cm^2 (10^{-4} microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or 0.4 Bq/cm^2 (10^{-5} microcurie/cm^2) for all other alpha emitters;

(ii) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $4x10^4$ Bq/cm^2 (1.0 microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or $4x10^3$ Bq/cm^2 (0.1 microcurie/cm^2) for all other alpha emitters; and

(iii) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 4×10^4

Bq/cm^2 (1 microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or 4 x 10^3 Bq/cm^2 (0.1 microcurie/cm^2) for all other alpha emitters.

(2) SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:

(i) The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 400 Bq/cm^2 (10^{-2} microcurie/cm^2) for beta and gamma and low toxicity alpha emitters or 40 Bq/cm^2 (10^{-3} microcurie/cm^2) for all other alpha emitters;

(ii) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 8 x 10^5 Bq/cm^2 (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or 8 x 10^4 Bq/cm^2 (2 microcuries/cm^2) for all other alpha emitters; and

(iii) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 8 x 105 Bq/cm^2 (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or 8 x 104 Bq/cm^2 (2 microcuries/cm^2) for all other alpha emitters.

"Transport index" means the dimensionless number (rounded up to the next tenth) placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. The transport index is determined as follows:

(1) For non-fissile material packages, the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one meter (3.3 ft)); or

(2) For fissile material packages, the number determined by multiplying the maximum radiation level in millisievert per hour at one meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one meter (3.3 ft)), or, for criticality control purposes, the number obtained as described in Sec. T.59, whichever is larger.

"Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A1 for special form radioactive material, or A2, for normal form radioactive material, where A1 and A2 are given in Table A-1 of this part, or may be determined by procedures described in Appendix A of this part.

"Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

"Uranium-natural, depleted, enriched"

(1) "Natural uranium" means uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).

(2) "Depleted uranium" means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(3) "Enriched uranium" means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

Sec. T.5 Transportation of Licensed Material.

(a) Each licensee who transports licensed material outside the site of usage, as specified in the Department license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the DOT regulations in 49 CFR parts 170 through 189 appropriate to the mode of transport.

(1) The licensee shall particularly note DOT regulations in the following areas:

(i) Packaging--49 CFR part 173: Subparts A and B and I.

(ii) Marking and labeling--49 CFR part 172: Subpart D, Secs. 172.400 through 172.407, Secs. 172.436 through 172.440, and subpart E.

(iii) Placarding--49 CFR part 172: Subpart F, especially Secs. 172.500 through 172.519, 172.556, and appendices B and C.

(iv) Accident reporting--49 CFR part 171: Secs. 171.15 and 171.16.

(v) Shipping papers and emergency information--49 CFR part 172: Subparts C and G.

(vi) Hazardous material employee training--49 CFR part 172: Subpart H.

(vii) Hazardous material shipper/carrier registration--49 CFR part 107: Subpart G.

(2) The licensee shall also note DOT regulations pertaining to the following modes of transportation:

(i) Rail--49 CFR part 174: Subparts A through D and K.

(ii) Air--49 CFR part 175.

(iii) Vessel--49 CFR part 176: Subparts A through F and M.

(iv) Public Highway--49 CFR part 177 and parts 390 through 397.

(b) If DOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the DOT specified in paragraph (a) of this section to the same extent as if the shipment or transportation were subject to DOT regulations. A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Administrator, Radiological Health Program, 2500 Broening Highway, Baltimore Maryland 21224.

EXEMPTIONS

Sec. T.10 Exemption for Low-Level Materials.

(a) A licensee is exempt from all requirements of this part with respect to shipment or carriage of a package containing radioactive material having a specific activity not greater than 70 Bq/g (0.002 μCi/g).

(b) A licensee is exempt from all requirements of this part, other than Sec. T.5 and Sec. T.88, with respect to shipment or carriage of the following packages, provided the packages contain no fissile material, or the fissile material exemption standards of Sec. T.53 are satisfied:

(1) A package containing no more than a Type A quantity of radioactive material;

(2) A package in which the only radioactive material is low specific activity (LSA) material or surface contaminated objects (SCO), provided the external radiation level at 3 m from the unshielded material or objects does not exceed 10 mSv/h (1 rem/h); or

(3) A package transported within locations within the United States which contains only americium or plutonium in special form with an aggregate radioactivity not to exceed 20 curies.

(c) A licensee is exempt from all requirements of this part, other than Secs. 71.5 and 71.88, with respect to shipment or carriage of low-specific-activity (LSA) material in group LSA-I, or surface contaminated objects (SCOs) in group SCO-I.

GENERAL LICENSES

Sec. T.12 General License: Department-Approved Package.

(a) A general license is hereby issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by the Department.

(b) This general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the provisions of T.101 through T.137 of this part.

(c) This general license applies only to a licensee who-

(1) Has a copy of the certificate of compliance, or other approval of the package, and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment;

(2) Complies with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of this part; and

(3) Submits in writing to the Administrator, Radiological Health Program, Maryland Department of the Environment, 2500 Broening Highway, Baltimore, Maryland, 21224, before the licensee's first use of the package, the licensee's name and license number and the package identification number specified in the package approval.

(d) This general license applies only when the package approval authorizes use of the package under this general license.

(e) For a Type B or fissile material package, the design of which was approved by the NRC before April 1, 1996, the general license is subject to the additional restrictions of Sec. T.13.

Sec. T.13 Previously Approved Package.

(a) A Type B package previously approved by the NRC but not designated as B(U) or B(M) in the identification number of the Department Certificate of Compliance, may be used under the general license of Sec. T.12 with the following additional conditions:

(1) Fabrication of the packaging was satisfactorily completed by August 31, 1986, as demonstrated by application of its model number in accordance with Sec. T.85(c);

(2) A package used for a shipment to a location outside the United States is subject to multilateral approval, as defined in DOT regulations at 49 CFR 173.403; and

(3) A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.

(b) A Type B(U) package, a Type B(M) package, a low specific activity (LSA) material package or a fissile material package, previously approved by the Department but without the designation "-85" in the identification number of the Department Certificate of Compliance, may be used under the general license of Sec. T.12 with the following additional conditions:

(1) Fabrication of the package is satisfactorily completed by April 1, 1999 as demonstrated by application of its model number in accordance with Sec. T.85(c);

(2) A package used for a shipment to a location outside the United States is subject to multilateral approval as defined in DOT regulations at 49 CFR 173.403; and

(3) A serial number which uniquely identifies each packaging which conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging.

Sec. T.14 General License: DOT Specification Container.

(a) A general license is issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in DOT regulations at 49 CFR parts 173 and 178.

(b) This general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the provisions of Sections 101 - 137 of this part.

(c) This general license applies only to a licensee who-

(1) Has a copy of the specification; and

(2) Complies with the terms and conditions of the specification and the applicable requirements of Sections 2, 5, 81 – 97, and 101 - 137 of this Part.

(d) This general license is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States, except by multilateral approval, as defined in DOT regulations at 49 CFR 173.403.

Sec. T.16 General License: Use of Foreign Approved Package.

(a) A general license is issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate that has been revalidated by DOT as meeting the applicable requirements of 49 CFR 171.12.

(b) Except as otherwise provided in this section, the general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the applicable provisions of Sections 101 -- 137 of this part.

(c) This general license applies only to shipments made to or from locations outside the United States.

(d) This general license applies only to a licensee who-

(1) Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate, relating to the use and maintenance of the packaging and to the actions to be taken before shipment; and

(2) Complies with the terms and conditions of the certificate and revalidation, and with the applicable requirements of Sections 2, 5, 81 – 97, and 101 - 137 of this Part. With respect to the quality assurance provisions of Sections 101 - 137 of this Part, the licensee is exempt from design, construction, and fabrication considerations.

OPERATING CONTROLS AND PROCEDURES

Sec. T.81 Applicability of Operating Controls and Procedures.

A licensee subject to this part, who, under a general or specific license, transports licensed material or delivers licensed material to a carrier for transport, shall comply with the requirements of Sections 81 – 100 of this Part, with the quality assurance requirements of Sections 101 - 137 of this Part, and with the general provisions of Sections 1 - 5 of this Part.

Sec. T.85 Preliminary Determinations.

Before the first use of any packaging for the shipment of licensed material-

(a) The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging;

(b) Where the maximum normal operating pressure will exceed 35 kPa (5 lbf/in^2) gauge, the licensee shall test the containment system at an internal pressure at least 50 percent higher than the maximum normal operating pressure, to verify the capability of that system to maintain its structural integrity at that pressure; and

(c) The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by the Department. Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the Department.

Sec. T.87 Routine Determinations.

Before each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this part and of the license. The licensee shall determine that-

(a) The package is proper for the contents to be shipped;

(b) The package is in unimpaired physical condition except for superficial defects such as marks or dents;

(c) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

(d) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

(e) Any pressure relief device is operable and set in accordance with written procedures;

(f) The package has been loaded and closed in accordance with written procedures;

(g) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

(h) Any structural part of the package that could be used to lift or tie down the package during transport is rendered inoperable for that purpose, unless it satisfies the design requirements of 10 CFR 71.45;

(i) The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable, and within the limits specified in DOT regulations in 49 CFR 173.443;

(j) External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in 10 CFR 71.47 at any time during transportation; and

(k) Accessible package surface temperatures will not exceed the limits specified in 10 CFR 71.43(g) at any time during transportation.

Sec. T.88 Air Transport of Plutonium.

(a) Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this part or included indirectly by citation of 49 CFR chapter I, as may be applicable, the licensee shall assure that plutonium in any form, whether for import, export, or domestic shipment, is not transported by air or delivered to a carrier for air transport unless:

(1) The plutonium is contained in a medical device designed for individual human application; or

(2) The plutonium is contained in a material in which the specific activity is not greater than 0.002 (Ci/g (70 Bq/g) of material and in which the radioactivity is essentially uniformly distributed; or

(3) The plutonium is shipped in a single package containing no more than an A2 quantity of plutonium in any isotope or form, and is shipped in accordance with Sec. T.5; or

(4) The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the Department.

(b) Nothing in paragraph (a) of this section is to be interpreted as removing or diminishing the requirements of 10 CFR 73.24.

(c) For a shipment of plutonium by air which is subject to paragraph (a)(4) of this section, the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, U.S. Department of Transportation regulations applicable to the air transport of plutonium.

Sec. T.89 Opening Instructions.

Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with Section D.906(e).

Sec. T.91 Records.

(a) Each licensee shall maintain, for a period of 3 years after shipment, a record of each shipment of licensed material not exempt under Sec. T.10, showing where applicable-

(1) Identification of the packaging by model number and serial number;

(2) Verification that there are no significant defects in the packaging, as shipped;

(3) Volume and identification of coolant;

(4) Type and quantity of licensed material in each package, and the total quantity of each shipment;

(5) For each item of irradiated fissile material-

(i) Identification by model number and serial number;

(ii) Irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and

(iii) Any abnormal or unusual condition relevant to radiation safety;

(6) Date of the shipment;

(7) For fissile packages and for Type B packages, any special controls exercised;

(8) Name and address of the transferee;

(9) Address to which the shipment was made; and

(10) Results of the determinations required by Sec. T.87 and by the conditions of the package approval.

(b) The licensee shall make available to the Department for inspection, upon reasonable notice, all records required by this part. Records are only valid if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.

(c) The licensee shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include results of the determinations required by Sec. T.85; design, fabrication, and assembly records, results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability and the action taken in connection with any deficiencies noted. The records must be retained for three years after the life of the packaging to which they apply.

Sec. T.93 Inspection and Tests.

(a) The licensee or certificate holder shall permit the Department, at all reasonable times, to inspect the licensed material, packaging, premises, and facilities in which the licensed material or packaging is used, provided, constructed, fabricated, tested, stored, or shipped.

(b) The licensee shall perform, and permit the Department to perform, any tests the Department deems necessary or appropriate for the administration of these regulations.

(c) The licensee shall notify the Administrator of the Agency, at least 45 days before fabrication of a package to be used for the shipment of licensed material having a decay heat load in excess of 5 kW or with a maximum normal operating pressure in excess of 103 kPa (15 lbf/in^2) gauge.

Sec. T.95 Reports. The licensee shall report to the Administrator, Radiological Health Program, Maryland Department of the Environment, 2500 Broening Highway, Baltimore, Maryland 21224 within 30 days-

(a) Any instance in which there is significant reduction in the effectiveness of any approved Type B, or fissile, packaging during use;

(b) Details of any defects with safety significance in Type B, or fissile, packaging after first use, with the means employed to repair the defects and prevent their recurrence; or

(c) Instances in which the conditions of approval in the certificate of compliance were not observed in making a shipment.

Sec. T.97 Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste.

(a) As specified in paragraphs (b), (c) and (d) of this section, each licensee shall provide advance notification to the governor of a State, or the governor's designee, of the shipment of licensed material, through, or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(b) Advance notification is required under this section for shipments of irradiated reactor fuel in quantities less than that subject to advance notification requirements of 10 CFR 71.37(f). Advance notification is also required under this section for shipment of licensed material, other than irradiated fuel, meeting the following three conditions:

(1) The licensed material is required by this part to be in Type B packaging for transportation;

(2) The licensed material is being transported to or across a State boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and

(3) The quantity of licensed material in a single package exceeds the least of the following:

(i) 3000 times the A1 value of the radionuclides as specified in Appendix A, Table A-1 for special form radioactive material;

(ii) 3000 times the A2 value of the radionuclides as specified in Appendix A, Table A-1 for normal form radioactive material; or

(iii) 1000 TBq (27,000 Ci).

(c) Procedures for submitting advance notification.

(1) The notification must be made in writing to the office of each appropriate governor or governor's designee and to the Administrator of the appropriate NRC Regional Office listed in Appendix A to 10 CFR 73.

(2) A notification delivered by mail must be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

(3) A notification delivered by messenger must reach the office of the governor or of the governor's designee at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

(i) A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30, 1995 (60 FR 34306).

(ii) The list will be published annually in the Federal Register on or about June 30 to reflect any changes in information.

(iii) A list of the names and mailing addresses of the governors' designees is available on request from the Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(4) The licensee shall retain a copy of the notification as a record for 3 years.

(d) Information to be furnished in advance notification of shipment. Each advance notification of shipment of irradiated reactor fuel or nuclear waste must contain the following information:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste shipment;

(2) A description of the irradiated reactor fuel or nuclear waste contained in the shipment, as specified in the regulations of DOT in 49 CFR 172.202 and 172.203(d);

(3) The point of origin of the shipment and the 7-day period during which departure of the shipment is estimated to occur;

(4) The 7-day period during which arrival of the shipment at State boundaries is estimated to occur;

(5) The destination of the shipment, and the 7-day period during which arrival of the shipment is estimated to occur; and

(6) A point of contact, with a telephone number, for current shipment information.

(e) Revision notice. A licensee who finds that schedule information previously furnished to a governor or governor's designee, in accordance with this section, will not be met, shall telephone a responsible individual in the office of the governor of the State or of the governor's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for 3 years.

(f) Cancellation notice.

(1) Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified, and to the Administrator of the appropriate NRC Regional Office listed in appendix A of part 73 of this chapter.

(2) The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for 3 years.

QUALITY ASSURANCE

Sec. T.101 Quality Assurance Requirements.

(a) Purpose. This subpart describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this subpart, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.

(b) Establishment of program. Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of Secs. T.101 through T.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee shall apply each of the applicable criteria in a graded approach, i.e., to an extent that is consistent with its importance to safety.

(c) Approval of program. Before the use of any package for the shipment of licensed material subject to this subpart, each licensee shall obtain Department approval of its quality assurance program. Each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied, with the Administrator, Radiological Health Program, Maryland Department of the Environment, 2500 Broening Highway, Baltimore, Maryland 21224.

(d) Existing package designs. The provisions of this paragraph deal with packages that have been approved for use in accordance with this part before January 1, 1979, and which have been designed in accordance with the provisions of this part in effect at the time of application for package approval. Those packages will be accepted as having been designed in accordance with a quality assurance program that satisfies the provisions of paragraph (b) of this section.

(e) Existing packages. The provisions of this paragraph deal with packages that have been approved for use in accordance with this part before January 1, 1979; have been at least partially fabricated prior to that date; and for which the fabrication is in accordance with the provisions of this part in effect at the time of application for approval of package design. These packages will be accepted as having been fabricated and assembled in accordance with a quality assurance program that satisfies the provisions of paragraph (b) of this section.

(f) Previously approved programs. A Department-approved quality assurance program that satisfies the applicable criteria of 10 CFR 50 Appendix B, and that is established, maintained, and executed with regard to transport packages, will be accepted as satisfying the requirements of paragraph (b) of this section. Before first use, the licensee shall notify the Administrator, Radiological Health Program, Maryland Department of the Environment, 2500 Broening Highway, Baltimore, Maryland 21224, of its intent to apply its previously approved Appendix B program to transportation activities. The licensee shall identify the program by date of submittal to the U.S. Nuclear Regulatory Commission, Docket Number, and date of NRC approval.

(g) Radiography containers. A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of Sec. E.31(b) or equivalent NRC or Agreement State requirement, is deemed to satisfy the requirements of Sec. T.12(b) and T.101(b) of this chapter.

Sec. T.103 Quality Assurance Organization.

(a) The licensee/[1] shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. The licensee shall clearly establish and delineate, in writing, the authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(b) The quality assurance functions are-

(1) Assuring that an appropriate quality assurance program is established and effectively executed; and

[1] While the term "licensee" is used in these criteria, the requirements are applicable to whatever design, fabrication, assembly, and testing of the package is accomplished with respect to a package prior to the time a package approval is issued.

(2) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the safety-related functions have been performed correctly.

(c) The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom to-

(1) Identify quality problems;

(2) Initiate, recommend, or provide solutions; and

(3) Verify implementation of solutions.

(d) The persons and organizations performing quality assurance functions shall report to a management level that assures that the required authority and organizational freedom, including sufficient independence from cost and schedule, when opposed to safety considerations, are provided.

(e) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom.

(f) Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform this function.

Sec. T.105 Quality Assurance Program.

(a) The licensee shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of Secs. T.101 through T.137. The licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

(b) The licensee, through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee shall take into account the need for special controls,

processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

(c) The licensee shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:

(1) The impact of malfunction or failure of the item to safety;

(2) The design and fabrication complexity or uniqueness of the item;

(3) The need for special controls and surveillance over processes and equipment;

(4) The degree to which functional compliance can be demonstrated by inspection or test; and

(5) The quality history and degree of standardization of the item.

(d) The licensee shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program which they are executing.

Sec. T.107 Package Design Control.

(a) The licensee shall establish measures to assure that applicable regulatory requirements and the package design, as specified in the license for those materials and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the materials, parts, and components of the packaging.

(b) The licensee shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures, among participating design organizations, for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design, by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, the licensee shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. The licensee shall apply design control measures to items such as the following:

(1) Criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses;

(2) Compatibility of materials;

(3) Accessibility for inservice inspection, maintenance, and repair;

(4) Features to facilitate decontamination; and

(5) Delineation of acceptance criteria for inspections and tests.

(c) The licensee shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the package approval require NRC approval.

Sec. T.109 Procurement Document Control. The licensee shall establish measures to assure that adequate quality is required in the documents for procurement of material, equipment, and services, whether purchased by the licensee or by its contractors or subcontractors. To the extent necessary, the licensee shall require contractors or subcontractors to provide a quality assurance program consistent with the applicable provisions of this part.

Sec. T.111 Instructions, Procedures, and Drawings. The licensee shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

Sec. T.113 Document Control. The licensee shall establish measures to control the issuance of documents such as instructions, procedures, and drawings, including changes, which prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed. These measures must assure that changes to documents are reviewed and approved.

Sec. T.115 Control of Purchased Material, Equipment, and Services.

(a) The licensee shall establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products on delivery.

(b) The licensee shall have available documentary evidence that material and equipment conform to the procurement specifications before installation or use of the material and equipment. The licensee shall retain, or have available, this documentary evidence for the life of the package to

which it applies. The licensee shall assure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment.

(c) The licensee shall assess the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or services.

Sec. T.117 Identification and Control of Materials, Parts, and Components. The licensee shall establish measures for the identification and control of materials, parts, and components. These measures must assure that identification of the item is maintained by heat number, part number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, installation, and use of the item. These identification and control measures must be designed to prevent the use of incorrect or defective materials, parts, and components.

Sec. T.119 Control of Special Processes. The licensee shall establish measures to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

Sec. T.121 Internal Inspection. The licensee shall establish and execute a program for inspection of activities affecting quality by or for the organization performing the activity, to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. The inspection must be performed by individuals other than those who performed the activity being inspected. Examination, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If direct inspection of processed material or products is not carried out, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when quality control is inadequate without both. If mandatory inspection hold points, which require witnessing or inspecting by the licensee's designated representative and beyond which work should not proceed without the consent of its designated representative, are required, the specific hold points must be indicated in appropriate documents.

Sec. T.123 Test Control. The licensee shall establish a test program to assure that all testing required to demonstrate that the packaging components will perform satisfactorily in service is identified and performed in accordance with written test procedures that incorporate the requirements of this part and the requirements and acceptance limits contained in the package approval. The test procedures must include provisions for assuring that all prerequisites for the given test are met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. The licensee shall document and evaluate the test results to assure that test requirements have been satisfied.

Sec. T.125 Control of Measuring and Test Equipment. The licensee shall establish measures to assure that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified times to maintain accuracy within necessary limits.

Sec. T.127 Handling, Storage, and Shipping Control. The licensee shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.

Sec. T.129 Inspection, Test, and Operating Status.

(a) The licensee shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of the inspections and tests.

(b) The licensee shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

Sec. T.131 Nonconforming Materials, Parts, or Components. The licensee shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

Sec. T.133 Corrective Action. The licensee shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

Sec. T.135 Quality Assurance Records. The licensee shall maintain sufficient written records to describe the activities affecting quality. The records must include the instructions, procedures, and drawings required by Sec. T.111 to prescribe quality assurance activities and must include closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures which establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee shall retain these records for 3 years beyond the date when the licensee last engages in the activity for which the quality assurance program was developed. If any portion of the written procedures or instructions is superseded, the licensee shall retain the superseded material for 3 years after it is superseded.

Sec. T.137 Audits. The licensee shall carry out a comprehensive system of planned and periodic audits, to verify compliance with all aspects of the quality assurance program, and to determine the effectiveness of the program. The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being

audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Follow-up action, including reaudit of deficient areas, must be taken where indicated.

Part T
Appendix A
Determination of A1 and A2

I. Values of A1 and A2 for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations are given in Table A-1. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) figure. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is one tenth of one percent or less. Where values of A1 or A2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

II. For individual radionuclides whose identities are known, but which are not listed in Table A-1, the determination of the values of A1 and A2 requires Commission approval, except that the values of A1 and A2 in Table A-2 may be used without obtaining Commission approval.

III. In the calculations of A1 and A2 for a radionuclide not in Table A-1, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter nuclide has a half-life either longer than 10 days, or longer than that of the parent nuclide, shall be considered as a single radionuclide, and the activity to be taken into account, and the A1 or A2 value to be applied shall be those corresponding to the parent nuclide of that chain. In the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than 10 days, or greater than that of the parent nuclide, the parent and those daughter nuclides shall be considered as mixtures of different nuclides.

IV. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:

(a) For special form radioactive material, the maximum quantity transported in a Type A package:

$$\sum_{I} \frac{B(i)}{A1(i)} \text{ less than or equal to } 1$$

(b) For normal form radioactive material, the maximum quantity transported in a Type A package:

$$\sum_{I} \frac{B(i)}{A2(i)} \text{ less than or equal to } 1$$

Where B(i) is the activity of radionuclide I and A1(i) and A2(i) are the A1 and A2 values for radionuclide I, respectively.

Alternatively, an A1 value for mixtures of special form material may be determined as follows:

$$\text{A1 for mixture} = \frac{1}{\sum_{I} \frac{f(i)}{A1(i)}}$$

Where f(i) is the fraction of activity of nuclide I in the mixture and $A_1(i)$ is the appropriate A1 value for nuclide I.

An A2 value for mixtures of normal form material may be determined as follows:

$$\text{A2 for mixture} = \frac{1}{\sum_{I} \frac{f(i)}{A2(i)}}$$

Where f(i) is the fraction of activity of nuclide I in the mixture and A2(i) is the appropriate A2 value for nuclide I.

V. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest A1 or A2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A1 or A2 values for the alpha emitters and beta/gamma emitters.

Table A-1. -- A_1 and A_2 Values For Radionuclides

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Ac-225	Actinium(89)	0.6	16.2	$1x10^{-2}$	0.270	$2.1x10^{3}$	$5.8x10^{4}$
Ac-227		40	1080		$5.41x10^{-4}$	2.7	$7.2x10^{1}$
Ac-228		0.6	16.2	0.4	10.8	$8.4x10^{4}$	$2.2x10^{6}$
Ag-105	Silver(47)	2	54.1	2	54.1	$1.1x10^{3}$	$3.0x10^{4}$
Ag-108m		0.6	16.2	0.6	16.2	$9.7x10^{-1}$	$2.6x10^{1}$
Ag-110m		0.4	10.8	0.4	10.8	$1.8x10^{2}$	$4.7x10^{3}$
Ag-111		0.6	16.2	0.5	13.5	$5.8x10^{3}$	$1.6x10^{5}$
Al-26	Aluminum(13)	0.4	10.8	0.4	10.8	$7.0x10^{-4}$	$1.9x10^{-2}$
Am-241	Americium(95)	2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$1.3x10^{-1}$	3.4
Am-242m		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$3.6x10^{-1}$	$1.0x10^{1}$
Am-243		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$7.4x10^{-3}$	$2.0x10^{-1}$
Ar-37	Argon(18)	40	1080	40	1080	$3.7x10^{3}$	$9.9x10^{4}$
Ar-39		20	541	20	541	1.3	$3.4x10^{1}$
Ar-41		0.6	16.2	0.6	16.2	$1.5x10^{6}$	$4.2x10^{7}$
Ar-42		0.2	5.41	0.2	5.41	9.6	$2.6x10^{2}$
As-72	Arsenic(33)	0.2	5.41	0.2	5.41	$6.2x10^{4}$	$1.7x10^{6}$
As-73		40	1080	40	1080	$8.2x10^{2}$	$2.2x10^{4}$
As-74		1	27.0	0.5	13.5	$3.7x10^{3}$	$9.9x10^{4}$
As-76		0.2	5.41	0.2	5.41	$5.8x10^{4}$	$1.6x10^{6}$
As-77		20	541	0.5	13.5	$3.9x10^{4}$	$1.0x10^{6}$
At-211	Astatine(85)	30	811	2	54.1	$7.6x10^{4}$	$2.1x10^{6}$
Au-193	Gold(79)	6	162	6	162	$3.4x10^{4}$	$9.2x10^{5}$
Au-194		1	27.0	1	27.0	$1.5x10^{4}$	$4.1x10^{5}$
Au-195		10	270	10	270	$1.4x10^{2}$	$3.7x10^{3}$
Au-196		2	54.1	2	54.1	$4.0x10^{3}$	$1.1x10^{5}$
Au-198		3	81.1	0.5	13.5	$9.0x10^{3}$	$2.4x10^{5}$
Au-199		10	270	0.9	24.3	$7.7x10^{3}$	$2.1x10^{5}$
Ba-131	Barium(56)	2	54.1	2	54.1	$3.1x10^{3}$	$8.4x10^{4}$

Table A-1. -- A_1 and A_2 Values For Radionuclides

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Ba-133m		10	270	0.9	24.3	$2.2x10^4$	$6.1x10^5$
Ba-133		3	81.1	3	81.1	9.4	$2.6x10^4$
Ba-140		0.4	10.8	0.4	10.8	$2.7x10^3$	$7.3x10^4$
Be-7	Beryllium(4)	20	541	20	541	$1.3x10^4$	$3.5x10^5$
Be-10		20	541	0.5	13.5	$8.3x10^{-4}$	$2.2x10^{-2}$
Bi-205	Bismuth(83)	0.6	16.2	0.6	16.2	$1.5x10^{-3}$	$4.2x10^4$
Bi-206		0.3	8.11	0.3	8.11	$3.8x10^3$	$1.0x10^5$
Bi-207		0.7	18.9	0.7	18.9	1.9	$5.2x10^1$
Bi-210m		0.3	8.11	$3x10^{-2}$	0.811	$2.1x10^{-5}$	$5.7x10^{-4}$
Bi-210		0.6	16.2	0.5	13.5	$4.6x10^3$	$1.2x10^5$
Bi-212		0.3	8.11	0.3	8.11	$5.4x10^5$	$1.5x10^7$
Bk-247	Berkelium(97)	2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$3.8x10^{-2}$	1.0
Bk-249		40	1080	$8x10^{-2}$	2.16	$6.1x10^1$	$1.6x10^3$
Br-76	Bromine(35)	0.3	8.11	0.3	8.11	$9.4x10^4$	$2.5x10^6$
Br-77		3	81.1	3	81.1	$2.6x10^4$	$7.1x10^5$
Br-82		0.4	10.8	0.4	10.8	$4.0x10^4$	$1.1x10^6$
C-11	Carbon(6)	1	27	0.5	13.5	$3.1x10^7$	$8.4x10^8$
C-14		40	1080	2	54.1	$1.6x10^{-1}$	4.5
Ca-41	Calcium(20)	40	1080	40	1080	$3.1x10^{-3}$	$8.5x10^{-2}$
Ca-45		40	1080	0.9	24.3	$6.6x10^2$	$1.8x10^4$
Ca-47		0.9	24.3	0.5	13.5	$2.3x10^4$	$6.1x10^5$
Cd-109	Cadmium(48)	40	1080	1	27.0	$9.6x10^1$	$2.6x10^3$
Cd-113m		20	541	$9x10^{-2}$	2.43	8.3	$2.2x10^2$
Cd-115m		0.3	8.11	0.3	8.11	$9.4x10^2$	$2.5x10^4$
Cd-115		4	108	0.5	13.5	$1.9x10^4$	$5.1x10^5$
Ce-139	Cerium(58)	6	162	6	162	$2.5x10^2$	$6.8x10^3$
Ce-141		10	270	0.5	13.5	$1.1x10^3$	$2.8x10^4$
Ce-143		0.6	16.2	0.5	13.5	$2.5x10^4$	$6.6x10^5$

Table A-1. -- A_1 and A_2 Values For Radionuclides

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Ce-144		0.2	5.41	0.2	5.41	$1.2x10^{2}$	$3.2x10^{3}$
Cf-248	Californium(98)	30	811	$3x10^{-3}$	$8.11x10^{-2}$	$5.8x10^{1}$	$1.6x10^{3}$
Cf-249		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$1.5x10^{-1}$	4.1
Cf-250		5	135	$5x10^{-4}$	$1.35x10^{-2}$	4.0	$1.1x10^{2}$
Cf-251		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$5.9x10^{-2}$	1.6
Cf-252		0.1	2.70	$1x10^{-3}$	$2.70x10^{-2}$	$2.0x10^{1}$	$5.4x10^{2}$
Cf-253		40	1080	$6x10^{-2}$	1.62	$1.1x10^{3}$	$2.9x10^{4}$
Cf-254		$3x10^{-3}$	$8.11x10^{-2}$	$6x10^{-4}$	$1.62x10^{-2}$	$3.1x10^{2}$	$8.5x10^{3}$
Cl-36	Chlorine(17)	20	541	0.5	13.5	$1.2x10^{-3}$	$3.3x10^{-2}$
Cl-38		0.2	5.41	0.2	5.41	$4.9x10^{6}$	$1.3x10^{8}$
Cm-240	Curium(96)	40	1080	$2x10^{-2}$	0.541	$7.5x10^{2}$	$2.0x10^{4}$
Cm-241		2	54.1	0.9	24.3	$6.1x10^{2}$	$1.7x10^{4}$
Cm-242		40	1080	$1x10^{-2}$	0.270	$1.2x10^{2}$	$3.3x10^{3}$
Cm-243		3	81.1	$3x10^{-4}$	$8.11x10^{-3}$	1.9	$5.2x10^{1}$
Cm-244		4	108	$4x10^{-4}$	$1.08x10^{-2}$	3.0	$8.1x10^{1}$
Cm-245		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$6.4x10^{-3}$	$1.7x10^{-1}$
Cm-246		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$1.1x10^{-2}$	$3.1x10^{-1}$
Cm-247		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$3.4x10^{-6}$	$9.3x10^{-5}$
Cm-248		$4x10^{-2}$	1.08	$5x10^{-5}$	$1.35x10^{-3}$	$1.6x10^{-4}$	$4.2x10^{-3}$
Co-55	Cobalt(27)	0.5	13.5	0.5	13.5	$1.1x10^{5}$	$3.1x10^{6}$
Co-56		0.3	8.11	0.3	8.11	$1.1x10^{3}$	$3.0x10^{4}$
Co-57		8	216	8	216	$3.1x10^{2}$	$8.4x10^{3}$
Co-58m		40	1080	40	1080	$2.2x10^{5}$	$5.9x10^{6}$
Co-58		1	27.0	1	27.0	$1.2x10^{3}$	$3.2x10^{4}$
Co-60		0.4	10.8	0.4	10.8	$4.2x10^{1}$	$1.1x10^{3}$
Cr-51	Chromium(24)	30	811	30	811	$3.4x10^{3}$	$9.2x10^{4}$
Cs-129	Cesium(55)	4	108	4	108	$2.8x10^{4}$	$7.6x10^{5}$
Cs-131		40	1080	40	1080	$3.8x10^{3}$	$1.0x10^{5}$

Table A-1. -- A_1 and A_2 Values For Radionuclides

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Cs-132		1	27.0	1	27.0	$5.7x10^3$	$1.5x10^5$
Cs-134m		40	1080	9	243	$3.0x10^5$	$8.0x10^6$
Cs-134		0.6	16.2	0.5	13.5	$4.8x10^1$	$1.3x10^3$
Cs-135		40	1080	0.9	24.3	$4.3x10^{-5}$	$1.2x10^{-3}$
Cs-136		0.5	13.5	0.5	13.5	$2.7x10^3$	$7.3x10^4$
Cs-137		2	54.1	0.5	13.5	3.2	$8.7x10^1$
Cu-64	Copper(29)	5	135	0.9	24.3	$1.4x10^5$	$3.9x10^6$
Cu-67		9	243	0.9	24.3	$2.8x10^4$	$7.6x10^5$
Dy-159	Dysprosium(66)	20	541	20	541	$2.1x10^2$	$5.7x10^3$
Dy-165		0.6	16.2	0.5	13.5	$3.0x10^5$	$8.2x10^6$
Dy-166		0.3	8.11	0.3	8.11	$8.6x10^3$	$2.3x10^5$
Er-169	Erbium(68)	40	1080	0.9	24.3	$3.1x10^3$	$8.3x10^4$
Er-171		0.6	16.2	0.5	13.5	$9.0x10^4$	$2.4x10^6$
Es-253	Einsteinium(99)[a]	200	5400	$2x10^{-2}$	$5.41x10^{-1}$		
Es-254		30	811	$3x10^{-3}$	$8.11x10^{-2}$		
Es-254m		0.6	16.2	0.4	10.8		
Es-255							
Eu-147	Europium(63)	2	54.1	2	54.1	$1.4x10^3$	$3.7x10^4$
Eu-148		0.5	13.5	0.5	13.5	$6.0x10^2$	$1.6x10^4$
Eu-149		20	541	20	541	$3.5x10^2$	$9.4x10^3$
Eu-150		0.7	18.9	0.7	18.9	$6.1x10^4$	$1.6x10^6$
Eu-152m		0.6	16.2	0.5	13.5	$8.2x10^4$	$2.2x10^6$
Eu-152		0.9	24.3	0.9	24.3	6.5	$1.8x10^2$
Eu-154		0.8	21.6	0.5	13.5	9.8	$2.6x10^2$
Eu-155		20	541	2	54.1	$1.8x10^1$	$4.9x10^2$
Eu-156		0.6	16.2	0.5	13.5	$2.0x10^3$	$5.5x10^4$
F-18	Flourine(9)	1	27.0	0.5	13.5	$3.5x10^6$	$9.5x10^7$
Fe-52	Iron(26)	0.2	5.41	0.2	5.41	$2.7x10^5$	$7.3x10^6$

Table A-1. -- A_1 and A_2 Values For Radionuclides

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Fe-55		40	1080	40	1080	$8.8x10^{1}$	$2.4x10^{3}$
Fe-59		0.8	21.6	0.8	21.6	$1.8x10^{3}$	$5.0x10^{4}$
Fe-60		40	1080	0.2	5.41	$7.4x10^{-4}$	$2.0x10^{-2}$
Fm-225	Fermium(100)[a]	40	1080	0.8	21.6		
Fm-257		10	270	$8x10^{-3}$	$2.16x10^{-1}$		
Ga-67	Gallium(31)	6	162	6	162	$2.2x10^{4}$	$6.0x10^{5}$
Ga-68		0.3	8.11	0.3	8.11	$1.5x10^{6}$	$4.1x10^{7}$
Ga-72		0.4	10.8	0.4	10.8	$1.1x10^{5}$	$3.1x10^{6}$
Gd-146	Gadolinium(64)	0.4	10.8	0.4	10.8	$6.9x10^{2}$	$1.9x10^{4}$
Gd-148		3	81.1	$3x10^{-4}$	$8.11x10^{-3}$	1.2	$3.2x10^{1}$
Gd-153		10	270	5	135	$1.3x10^{2}$	$3.5x10^{3}$
Gd-159		4	108	0.5	13.5	$3.9x10^{4}$	$1.1x10^{6}$
Ge-68	Germanium(32)	0.3	8.11	0.3	8.11	$2.6x10^{2}$	$7.1x10^{3}$
Ge-71		40	1080	40	1080	$5.8x10^{3}$	$1.6x10^{5}$
Ge-77		0.3	8.11	0.3	8.11	$1.3x10^{5}$	$3.6x10^{6}$
H-3	Hydrogen(1)	See T-tritium					
Hf-172	Halfnium(72)	0.5	13.5	0.3	8.11	$4.1x10^{1}$	$1.1x10^{3}$
Hf-175		3	81.1	3	81.1	$3.9x10^{2}$	$1.1x10^{4}$
Hf-181		2	54.1	0.9	24.3	$6.3x10^{2}$	$1.7x10^{4}$
Hf-182		4	108	$3x10^{-2}$	0.811	$8.1x10^{-6}$	$2.2x10^{-4}$
Hg-194	Mercury(80)	1	27.0	1	27.0	$1.3x10^{-1}$	3.5
Hg-195m		5	135	5	135	$1.5x10^{4}$	$4.0x10^{5}$
Hg-197m		10	270	0.9	24.3	$2.5x10^{4}$	$6.7x10^{5}$
Hg-197		10	270	10	270	$9.2x10^{3}$	$2.5x10^{5}$
Hg-203		4	108	0.9	24.3	$5.1x10^{2}$	$1.4x10^{4}$
Ho-163	Holmium(67)	40	1080	40	1080	2.7	$7.6x10^{1}$
Ho-166m		0.6	16.2	0.3	8.11	$6.6x10^{-2}$	1.8
Ho-166		0.3	8.11	0.3	8.11	$2.6x10^{4}$	$7.0x10^{5}$

Table A-1. -- A_1 and A_2 Values For Radionuclides

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
I-123	Iodine(53)	6	162	6	162	$7.1x10^4$	$1.9x10^6$
I-124		0.9	24.3	0.9	24.3	$9.3x10^3$	$2.5x10^5$
I-125		20	541	2	54.1	$6.4x10^2$	$1.7x10^4$
I-126		2	54.1	0.9	24.3	$2.9x10^3$	$8.0x10^4$
I-129		Unlimited	Unlimited	Unlimited	Unlimited	$6.5x10^{-6}$	$1.8x10^{-4}$
I-131		3	81.1	0.5	13.5	$4.6x10^3$	$1.2x10^5$
I-132		0.4	10.8	0.4	10.8	$3.8x10^5$	$1.0x10^7$
I-133		0.6	16.2	0.5	13.5	$4.2x10^4$	$1.1x10^6$
I-134		0.3	8.11	0.3	8.11	$9.9x10^5$	$2.7x10^7$
I-135		.6	16.2	0.5	13.5	$1.3x10^5$	$3.5x10^6$
In-111	Indium(49)	2	54.1	2	54.1	$1.5x10^4$	$4.2x10^5$
In-113m		4	108	4	108	$6.2x10^5$	$1.7x10^7$
In-114m		0.3	8.11	0.3	8.11	$8.6x10^2$	$2.3x10^4$
In-115m		6	162	0.9	24.3	$2.2x10^5$	$6.1x10^6$
Ir-189	Iridium(77)	10	270	10	270	$1.9x10^3$	$5.2x10^4$
Ir-190		0.7	18.9	0.7	18.9	$2.3x10^3$	$6.2x10^4$
Ir-192		1	27	0.5	13.5	$3.4x10^2$	$9.2x10^3$
Ir-193m		10	270	10	270	$2.4x10^3$	$6.4x10^4$
Ir-194		0.2	5.41	0.2	5.41	$3.1x10^4$	$8.4x10^5$
K-40	Potassium(19)	0.6	16.2	0.6	16.2	$2.7x10^{-7}$	$6.4x10^{-6}$
K-42		0.2	5.41	0.2	5.41	$2.2x10^5$	$6.0x10^6$
K-43		1.0	27.0	0.5	13.5	$1.2x10^5$	$3.3x10^6$
Kr-81	Krypton(36)	40	1080	40	1080	$7.8x10^{-4}$	$2.1x10^{-2}$
Kr-85m		6	162	6	162	$3.0x10^5$	$8.2x10^6$
Kr-85		20	541	10	270	$1.5x10^1$	$3.9x10^2$
Kr-87		0.2	5.41	0.2	5.41	$1.0x10^6$	$2.8x10^7$
La-137	Lanthanum(57)	40	1080	2	54.1	$1.6x10^{-3}$	$4.4x10^{-2}$
La-140		0.4	10.8	0.4	10.8	$2.1x10^4$	$5.6x10^5$

Table A-1. -- A_1 and A_2 Values For Radionuclides

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Lu-172	Lutetium(71)	0.5	13.5	0.5	13.5	4.2×10^{3}	1.1×10^{5}
Lu-173		8	216	8	216	5.6×10^{1}	1.5×10^{3}
Lu-174m		20	541	8	216	2.0×10^{2}	5.3×10^{3}
Lu-174		8	216	4	108	2.3×10^{1}	6.2×10^{2}
Lu-177		30	811	0.9	24.3	4.1×10^{3}	1.1×10^{5}
MFP	For mixed fission products, use the formula for mixtures or Table A-2						
Mg-28	Magnesium(12)	0.2	5.41	0.2	5.41	2.0×10^{5}	5.4×10^{6}
Mn-52	Manganese(25)	0.3	8.11	0.3	8.11	1.6×10^{4}	1.8×10^{-3}
Mn-53		Unlimited	Unlimited	Unlimited	Unlimited	6.8×10^{-5}	1.8×10^{-3}
Mn-54		1	27.0	1	27.0	2.9×10^{2}	7.7×10^{3}
Mn-56		0.2	5.41	0.2	5.41	8.0×10^{5}	2.2×10^{7}
Mo-93	Molybdenum(42)	40	1080	7	189	4.1×10^{-2}	1.1
Mo-99		0.6	16.2	0.5	13.5[c]	1.8×10^{4}	4.8×10^{5}
N-13	Nitrogen(7)	0.6	16.2	0.5	13.5	5.4×10^{7}	1.5×10^{9}
Na-22	Sodium(11)	0.5	13.5	0.5	13.5	2.3×10^{2}	6.3×10^{3}
Na-24		0.2	5.41	0.2	5.41	3.2×10^{5}	8.7×10^{6}
Nb-92m	Niobium(41)	0.7	18.9	0.7	18.9	5.2×10^{3}	1.4×10^{5}
Nb-93m		40	1080	6	162	8.8	2.4×10^{2}
Nb-94		0.6	16.2	0.6	16.2	6.9×10^{-3}	1.9×10^{-1}
Nb-95		1	27.0	1	27.0	1.5×10^{3}	3.9×10^{4}
Nb-97		0.6	16.2	0.5	13.5	9.9×10^{5}	2.7×10^{7}
Nd-147	Neodymium(60)	4	108	0.5	13.5	3.0×10^{3}	8.1×10^{4}
Nd-149		0.6	16.2	0.5	13.5	4.5×10^{5}	1.2×10^{7}
Ni-59	Nickel(28)	40	1080	40	1080	3.0×10^{-3}	8.0×10^{-2}
Ni-63		40	1080	30	811	2.1	5.7×10^{1}
Ni-65		0.3	8.11	0.3	8.11	7.1×10^{5}	1.9×10^{7}
Np-235	Neptunium(93)	40	1080	40	1080	5.2×10^{1}	1.4×10^{3}
Np-236		7	189	1×10^{-3}	2.70×10^{-2}	4.7×10^{-4}	1.3×10^{-2}

Table A-1. -- A_1 and A_2 Values For Radionuclides

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Np-237		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$2.6x10^{-5}$	$7.1x10^{-4}$
Np-239		6	162	0.5	13.5	$8.6x10^{3}$	$2.3x10^{5}$
Os-185	Osmium(76)	1	27.0	1	27.0	$2.8x10^{2}$	$7.5x10^{3}$
Os-191m		40	1080	40	1080	$4.6x10^{4}$	$1.3x10^{6}$
Os-191		10	270	0.9	24.3	$1.6x10^{3}$	$4.4x10^{4}$
Os-193		0.6	16.2	0.5	13.5	$2.0x10^{4}$	$5.3x10^{5}$
Os-194		0.2	5.41	0.2	5.41	$1.1x10^{1}$	$3.1x10^{2}$
P-32	Phosphorus(15)	0.3	8.11	0.3	8.11	$1.1x10^{4}$	$2.9x10^{5}$
P-33		40	1080	0.9	24.3	$5.8x10^{3}$	$1.6x10^{5}$
Pa-230	Proactinium(91)	2	54.1	0.1	2.70	$1.2x10^{3}$	$3.3x10^{4}$
Pa-231		0.6	16.2	$6x10^{-5}$	$1.62x10^{-3}$	$1.7x10^{-3}$	$4.7x10^{-2}$
Pa-233		5	135	0.9	24.3	$7.7x10^{2}$	$2.1x10^{4}$
Pb-201	Lead(82)	1	27.0	1	27.0	$6.2x10^{4}$	$1.7x10^{6}$
Pb-202		40	1080	2	54.1	$1.2x10^{-4}$	$3.4x10^{-3}$
Pb-203		3	81.1	3	81.1	$1.1x10^{4}$	$3.0x10^{5}$
Pb-205		Unlimited	Unlimited	Unlimited	Unlimited	$4.5x10^{-6}$	$1.2x10^{-4}$
Pb-210		0.6	16.2	$9x10^{-3}$	0.243	2.8	$7.6x10^{1}$
Pb-212		0.3	8.11	0.3	8.11	$5.1x10^{4}$	$1.4x10^{6}$
Pd-103	Palladium(46)	40	1080	40	1080	$2.8x10^{3}$	$7.5x10^{4}$
Pd-107		Unlimited	Unlimited	Unlimited	Unlimited	$1.9x10^{-5}$	$5.1x10^{-4}$
Pd-109		0.6	16.2	0.5	13.5	$7.9x10^{4}$	$2.1x10^{6}$
Pm-143	Promethium(61)	3	81.1	3	81.1	$1.3x10^{2}$	$3.4x10^{3}$
Pm-144		0.6	16.2	0.6	16.2	$9.2x10^{1}$	$2.5x10^{3}$
Pm-145		30	811	7	189	5.2	$1.4x10^{2}$
Pm-147		40	1080	0.9	24.3	$3.4x10^{1}$	$9.3x10^{2}$
Pm-148m		0.5	13.5	0.5	13.5	$7.9x10^{2}$	$2.1x10^{4}$
Pm-149		0.6	16.2	0.5	13.5	$1.5x10^{4}$	$4.0x10^{5}$
Pm-151		3	81.1	0.5	13.5	$2.7x10^{4}$	$7.3x10^{5}$

Table A-1. -- A_1 and A_2 Values For Radionuclides

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Po-208	Polonium(84)	40	1080	$2x10^{-2}$	0.541	$2.2x10^{1}$	$5.9x10^{2}$
Po-209		40	1080	$2x10^{-2}$	0.541	$6.2x10^{-1}$	$1.7x10^{1}$
Po-210		40	1080	$2x10^{-2}$	0.541	$1.7x10^{2}$	$4.5x10^{3}$
Pr-142	Praseodymium(59)	0.2	5.41	0.2	5.41	$4.3x10^{4}$	$1.2x10^{6}$
Pr-143		4	108	0.5	13.5	$2.5x10^{3}$	$6.7x10^{4}$
Pt-188	Platinum(78)	0.6	16.2	0.6	16.2	$2.5x10^{3}$	$6.8x10^{4}$
Pt-191		3	81.1	3	81.1	$8.7x10^{3}$	$2.4x10^{5}$
Pt-193m		40	1080	9	243	$5.8x10^{3}$	$1.6x10^{5}$
Pt-193		40	1080	40	1080	1.4	$3.7x10^{1}$
Pt-195m		10	270	2	54.1	$6.2x10^{3}$	$1.7x10^{5}$
Pt-197m		10	270	0.9	24.3	$3.7x10^{5}$	$1.0x10^{7}$
Pt-197		20	541	0.5	13.5	$3.2x10^{4}$	$8.7x10^{5}$
Pu-236	Plutonium(94)	7	189	$7x10^{-4}$	$1.89x10^{-2}$	$2.0x10^{1}$	$5.3x10^{2}$
Pu-237		20	541	20	541	$4.5x10^{2}$	$1.2x10^{4}$
Pu-238		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$6.3x10^{-1}$	$1.7x10^{1}$
Pu-239		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$2.3x10^{-3}$	$6.2x10^{-2}$
Pu-240		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$8.4x10^{-3}$	$2.3x10^{-1}$
Pu-241		40	1080	$1x10^{-2}$	0.270	3.8	$1.0x10^{2}$
Pu-242		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$1.5x10^{-4}$	$3.9x10^{-3}$
Pu-244		0.3	8.11	$2x10^{-4}$	$5.41x10^{-3}$	$6.7x10^{-7}$	$1.8x10^{-5}$
Ra-223	Radium(88)	0.6	16.2	$3x10^{-2}$	0.811	$1.9x10^{3}$	$5.1x10^{4}$
Ra-224		0.3	8.11	$6x10^{-2}$	1.62	$5.9x10^{3}$	$1.6x10^{5}$
Ra-225		0.6	16.2	$2x10^{-2}$	0.541	$1.5x10^{3}$	$3.9x10^{4}$
Ra-226		0.3	8.11	$2x10^{-2}$	0.541	$3.7x10^{-2}$	1.0
Ra-228		0.6	16.2	$4x10^{-2}$	1.08	$1.0x10^{1}$	$2.7x10^{2}$
Rb-81	Rubidium(37)	2	54.1	0.9	24.3	$3.1x10^{5}$	$8.4x10^{6}$
Rb-83		2	54.1	2	54.1	$6.8x10^{2}$	$1.8x10^{4}$
Rb-84		1	27.0	0.9	24.3	$1.8x10^{3}$	$4.7x10^{4}$

Table A-1. – A_1 and A_2 Values For Radionuclides

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Rb-86		0.3	8.11	0.3	8.11	$3.0x10^3$	$8.1x10^4$
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	$3.2x10^{-9}$	$8.6x10^{-8}$
Rb (nat)		Unlimited	Unlimited	Unlimited	Unlimited	$6.7x10^6$	$1.8x10^8$
Re-183	Rhenium(75)	5	135	5	135	$3.8x10^2$	$1.0x10^4$
Re-184m		3	81.1	3	81.1	$1.6x10^2$	$4.3x10^3$
Re-184		1	27.0	1	27.0	$6.9x10^2$	$1.9x10^4$
Re-186		4	108	0.5	13.5	$6.9x10^3$	$1.9x10^5$
Re-187		Unlimited	Unlimited	Unlimited	Unlimited	$1.4x10^{-9}$	$3.8x10^{-8}$
Re-188		0.2	5.41	0.2	5.41	$3.4x10^4$	$9.8x10^5$
Re-189		4	108	0.5	13.5	$2.5x10^4$	$6.8x10^5$
Re (nat)		Unlimited	Unlimited	Unlimited	Unlimited		$2.4x10^{-8}$
Rh-99	Rhodium(45)	2	54.1	2	54.1	$3.0x10^3$	$8.2x10^4$
Rh-101		4	108	4	108	$4.1x10^1$	$1.1x10^3$
Rh-102m		2	54.1	0.9	24.3	$2.3x10^2$	$6.2x10^3$
Rh-102		0.5	13.5	0.5	13.5	$4.5x10^1$	$1.2x10^3$
Rh-103m		40	1080	40	1080	$1.2x10^6$	$3.3x10^7$
Rh-105		10	270	0.9	24.3	$3.1x10^4$	$8.4x10^5$
Rn-222	Radon(86)	0.2	5.41	$4x10^{-3}$	0.108	$5.7x10^3$	$1.5x10^5$
Ru-97	Ruthenium(44)	4	108	4	108	$1.7x10^4$	$4.6x10^5$
Ru-103		2	54.1	0.9	24.3	$1.2x10^3$	$3.2x10^4$
Ru-105		0.6	16.2	0.5	13.5	$2.5x10^5$	$6.7x10^6$
Ru-106		0.2	5.41	0.2	5.41	$1.2x10^2$	$3.3x10^3$
S-35	Sulfur(16)	40	1080	2	54.1	$1.6x10^3$	$4.3x10^4$
Sb-122	Antimony(51)	0.3	8.11	0.3	8.11	$1.5x10^4$	$4.0x10^5$
Sb-124		0.6	16.2	0.5	13.5	$6.5x10^2$	$1.7x10^4$
Sb-125		2	54.1	0.9	24.3	$3.9x10^1$	$1.0x10^3$
Sb-126		0.4	10.8	0.4	10.8	$3.1x10^3$	$8.4x10^4$
Sc-44	Scandium(21)	0.5	13.5	0.5	13.5	$6.7x10^5$	$1.8x10^7$

Table A-1. -- A_1 and A_2 Values For Radionuclides

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Sc-46		0.5	13.5	0.5	13.5	$1.3x10^{3}$	$3.4x10^{4}$
Sc-47		9	243	0.9	24.3	$3.1x10^{4}$	$8.3x10^{5}$
Sc-48		0.3	8.11	0.3	8.11	$5.5x10^{4}$	$1.5x10^{6}$
Se-75	Selenium(34)	3	81.1	3	81.1	$5.5x10^{2}$	$1.5x10^{4}$
Se-79		40	1080	2	54.1	$2.6x10^{-3}$	$7.0x10^{-2}$
Si-31	Silicon(14)	0.6	16.2	0.5	13.5	$1.4x10^{6}$	$3.9x10^{7}$
Si-32		40	1080	0.2	5.41	3.9	$1.1x10^{2}$
Sm-145	Samarium(62)	20	541	20	541	$9.8x10^{1}$	$2.6x10^{3}$
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	$8.5x10^{-1}$	$2.3x10^{-8}$
Sm-151		40	1080	4	108	$9.7x10^{-1}$	$2.6x10^{1}$
Sm-153		4	108	0.5	13.5	$1.6x10^{4}$	$4.4x10^{5}$
Sn-133	Tin(50)	4	108	4	108	$3.7x10^{2}$	$1.0x10^{4}$
Sn-117m		6	162	2	54.1	$3.0x10^{3}$	$8.2x10^{4}$
Sn-119m		40	1080	40	1080	$1.4x10^{2}$	$3.7x10^{3}$
Sn-121m		40	1080	0.9	24.3	2.0	$5.4x10^{1}$
Sn-123		0.6	16.2	0.5	13.5	$3.0x10^{2}$	$8.2x10^{3}$
Sn-125		0.2	5.41	0.2	5.41	$4.0x10^{3}$	$1.1x10^{5}$
Sn-126		0.3	8.11	0.3	8.11	$1.0x10^{-3}$	$2.8x10^{-2}$
Sr-82	Strontium(38)	0.2	5.41	0.2	5.41	$2.3x10^{3}$	$6.2x10^{4}$
Sr-85m		5	135	5	1.35	$1.2x10^{6}$	$3.3x10^{7}$
Sr-85		2	54.1	2	54.1	$8.8x10^{2}$	$2.4x10^{4}$
Sr-87m		3	81.1	3	81.1	$4.8x10^{5}$	$1.3x10^{7}$
Sr-89		0.6	16.2	0.5	13.5	$1.1x10^{3}$	$2.9x10^{4}$
Sr-90		0.2	5.41	0.1	2.70	5.1	$1.4x10^{2}$
Sr-91		0.3	8.11	0.3	8.11	$1.3x10^{5}$	$3.6x10^{6}$
Sr-92		0.8	21.6	0.5	13.5	$4.7x10^{5}$	$1.3x10^{7}$
T	Tritium(1)	40	1080	40	1080	$3.6x10^{2}$	$9.7x10^{3}$
Ta-178	Tantalum(73)	1	27.0	1	27.0	$4.2x10^{6}$	$1.1x10^{8}$

Table A-1. -- A_1 and A_2 Values For Radionuclides

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Ta-179		30	811	30	811	$4.1x10^{1}$	$1.1x10^{3}$
Ta-182		0.8	21.6	0.5	13.5	$2.3x10^{2}$	$6.2x10^{3}$
Tb-157	Terbium(65)	40	1080	10	270	$5.6x10^{-1}$	$1.5x10^{1}$
Tb-158		1	27.0	0.7	18.9	$5.6x10^{-1}$	$1.5x10^{1}$
Tb-160		0.9	24.3	0.5	13.5	$4.2x10^{2}$	$1.1x10^{4}$
Tc-95m	Technetium(43)	2	54.1	2	54.1	$8.3x10^{2}$	$2.2x10^{4}$
Tc-96m		0.4	10.8	.04	10.8	$1.4x10^{6}$	$3.8x10^{7}$
Tc-96		0.4	10.8	0.4	10.8	$1.2x10^{4}$	$3.2x10^{5}$
Tc-97m		40	1080	40	1080	$5.6x10^{2}$	$1.5x10^{4}$
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	$5.2x10^{-5}$	$1.4x10^{-3}$
Tc-98		0.7	18.9	0.7	18.9	$3.2x10^{-5}$	$8.7x10^{-4}$
Tc-99m		8	216	8	216	$1.9x10^{5}$	$5.3x10^{6}$
Tc-99		40	1080	0.9	24.3	$6.3x10^{-4}$	$1.7x10^{-2}$
Te-118	Tellurium(52)	0.2	5.41	0.2	5.41	$6.8x10^{3}$	$1.8x10^{5}$
Te-121m		5	135	5	135	$2.6x10^{2}$	$7.0x10^{3}$
Te-121		2	54.1	2	54.1	$2.4x10^{3}$	$6.4x10^{4}$
Te-123m		7	189	7	189	$3.3x10^{2}$	$8.9x10^{3}$
Te-125m		30	811	9	243	$6.7x10^{2}$	$1.8x10^{4}$
Te-127m		20	541	0.5	13.5	$3.5x10^{2}$	$9.4x10^{3}$
Te-127		20	541	0.5	13.5	$9.8x10^{4}$	$2.6x10^{6}$
Te-129m		0.6	16.2	0.5	13.5	$1.1x10^{3}$	$3.0x10^{4}$
Te-129		0.6	16.2	0.5	13.5	$7.7x10^{5}$	$2.1x10^{7}$
Te-131m		0.7	18.9	0.5	13.5	$3.0x10^{4}$	$8.0x10^{5}$
Te-132		0.4	10.8	0.4	10.8	$1.1x10^{4}$	$3.0x10^{5}$
Th-227	Thorium(90)	9	243	$1x10^{-2}$	0.270	$1.1x10^{3}$	$3.1x10^{4}$
Th-228		0.3	8.11	$4x10^{-4}$	$1.08x10^{-2}$	$3.0x10^{1}$	$8.2x10^{2}$
Th-229		0.3	8.11	$3x10^{-5}$	$8.44x10^{-4}$	$7.9x10^{-3}$	$2.1x10^{-1}$
Th-230		2	54.1	2x10-4	$5.41x10^{-3}$	$7.6x10^{-4}$	$2.1x10^{-2}$

Table A-1. -- A_1 and A_2 Values For Radionuclides

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Th-231		40	1080	0.9	24.3	$2.0x10^4$	$5.3x10^5$
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	$4.0x10^{-9}$	$1.1x10^{-7}$
Th-234		0.2	5.41	0.2	5.41	$8.6x10^2$	$2.3x10^4$
Th (nat)		Unlimited	Unlimited	Unlimited	Unlimited	$8.1x10^{-9}$	$2.2x10^{-7}$
Ti-44	Titanium(22)	0.5	13.5	0.2	5.41	6.4	$1.7x10^2$
Tl-200	Thallium(81.1)	0.8	21.6	0.8	21.6	$2.2x10^4$	$6.0x10^5$
Tl-201		10	270	10	270	$7.9x10^3$	$2.1x10^5$
Tl-202		2	54.1	2	54.1	$2.0x10^3$	$5.3x10^4$
Tl-204		4	108	0.5	13.5	$1.7x10^1$	$4.6x10^2$
Tm-167	Thulium(69)	7	189	7	189	$3.1x10^3$	$8.5x10^4$
Tm-168		0.8	21.6	0.8	21.6	$3.1x10^2$	$8.3x10^3$
Tm-170		4	108	0.5	13.5	$2.2x10^2$	$6.0x10^3$
Tm-171		40	1080	10	270	$4.0x10^1$	$1.1x10^3$
U-230	Uranium(92)	40	1080	$1x10^{-2}$	0.270	$1.0x10^3$	$2.7x10^4$
U-232		3	81.1	$3x10^{-4}$	$8.11x10^{-3}$	$8.3x10^{-1}$	$2.2x10^1$
U-233		10	270	$1x10^{-3}$	$2.70x10^{-2}$	$3.6x10^{-4}$	$9.7x10^{-3}$
U-234		10	270	$1x10^{-3}$	$2.70x10^{-2}$	$2.3x10^{-4}$	$6.2x10^{-3}$
U-235		Unlimited	Unlimited	Unlimited	Unlimited	$8.0x10^{-8}$	$2.2x10^{-6}$
U-236		10	270	$1x10^{-3}$	$2.70x10^{-2}$	$2.4x10^{-6}$	$6.5x10^{-5}$
U-238		Unlimited	Unlimited	Unlimited	Unlimited	$1.2x10^{-8}$	$3.4x10^{-7}$
U (nat)		Unlimited	Unlimited	Unlimited	Unlimited	$2.6x10^{-8}$	$7.1x10^{-7}$
U ≤ 5% (enriched)		Unlimited	Unlimited	Unlimited	Unlimited		(See Table A-3)
U > 5% (enriched)		10	270	$2.70x10^{-2}$	$2.70x10^{-2}$		(See Table A-3)
U (depleted)		Unlimited	Unlimited	Unlimited	Unlimited		(See Table A-3)
V-48	Vanadium(23)	0.3	8.11	0.3	8.11	$6.3x10^3$	$1.7x10^5$
V-49		40	1080	40	1080	$3.0x10^2$	$8.1x10^3$
W-178	Tungsten(74)	1	27.0	1	27.0	$1.3x10^3$	$3.4x10^4$

Table A-1. -- A_1 and A_2 Values For Radionuclides

Symbol of radio-nuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
W-181		30	811	30	811	$2.2x10^2$	$6.0x10^3$
W-185		40	1080	0.9	24.3	$3.5x10^2$	$9.4x10^3$
W-197		2	54.1	0.5	13.5	$2.6x10^4$	$7.0x10^5$
W-188		0.2	5.41	0.2	5.41	$3.7x10^2$	$1.0x10^4$
Xe-122	Xenon(54)	0.2	5.41	0.2	5.41	$4.8x10^4$	$1.3x10^6$
Xe-123		0.2	5.41	0.2	5.41	$4.4x10^5$	$1.2x10^7$
Xe-127		4	108	4	108	$1.0x10^3$	$2.8x10^4$
Xe-131m		40	1080	40	1080	$3.1x10^3$	$8.4x10^4$
Xe-133		20	541	20	541	$6.9x10^3$	$1.9x10^5$
Xe-135		4	108	4	108	$9.5x10^4$	$2.6x10^6$
Y-87	Yttrium(39)	2	54.14	2	54.1	$1.7x10^4$	$4.5x10^5$
Y-88		0.4	10.8	0.4	10.8	$5.2x10^2$	$1.4x10^4$
Y-90		0.2	5.41	0.2	5.41	$2.0x10^4$	$5.4x10^5$
Y-91m		2	54.1	2	54.1	$1.5x10^6$	$4.2x10^7$
Y-91		0.3	8.11	0.3	8.11	$9.1x10^2$	$2.5x10^4$
Y-92		0.2	5.41	0.2	5.41	$3.6x10^5$	$9.6x10^6$
Y-93		0.2	5.41	0.2	5.41	$1.2x10^5$	$3.3x10^6$
Yb-169	Ytterbium(70)	3	81.1	3	81.1	$8.9x10^2$	$2.4x10^4$
Yb-175		30	811	0.9	24.3	$6.6x10^3$	$1.8x10^5$
Zn-65	Zinc(30)	2	54.1	2	54.1	$3.0x10^2$	$8.2x10^3$
Zn-69m		2	54.1	0.5	13.5	$1.2x10^5$	$3.3x10^6$
Zn-69		4	108	0.5	13.5	$1.8x10^6$	$4.9x10^7$
Zr-88	Zirconium(40)	3	81.1	3	81.1	$6.6x10^2$	$1.8x10^4$
Zr-93		40	1080	0.2	5.41	$9.3x10^{-5}$	$2.5x10^{-3}$
Zr-95		1	27.0	0.9	24.3	$7.9x10^2$	$2.1x10^4$
Zr-97		0.3	8.11	0.3	8.11	$7.1x10^4$	$1.9x10^6$

[a] International shipments of Einsteinium require multilateral approval of A_1 and A_2 values.
[b] International shipments of Fermium require multilateral approval of A_1 and A_2 values.

° 20 Ci for Mo99 for domestic use.

Table A-2. -- General Values for A_1 and A_2

Contents	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)
Only beta- or gamma-emitting nuclides are known to be present	0.2	5	0.02	0.5
Alpha-emitting nuclides are known to be present, or no relevant data are available	0.10	2.7	$2x10^{-5}$	$5.41x10^{-4}$

Table A-3. -- Activity - Mass Relationships for Uranium

Uranium Enrichment[1] wt% U-235 present	Specific Activity TBq/g	Ci/g
0.45	$1.8x10^{-8}$	$5.0x10^{-7}$
0.72	$2.6x10^{-8}$	$7.1x10^{-7}$
1.0	$2.8x10^{-8}$	$7.6x10^{-7}$
1.5	$3.7x10^{-8}$	$1.0x10^{-6}$
5.0	$1.0x10^{-7}$	$2.7x10^{-6}$
10.0	$1.8x10^{-7}$	$4.8x10^{-6}$
20.0	$3.7x10^{-7}$	$1.0x10^{-5}$
35.0	$7.4x10^{-7}$	$2.0x10^{-5}$
50.0	$9.3x10^{-7}$	$2.5x10^{-5}$
90.0	$2.2x10^{-6}$	$5.8x10^{-5}$
93.0	$2.6x10^{-6}$	$7.0x10^{-5}$
95.0	$3.4x10^{-6}$	$9.1x10^{-5}$

1 The figures for uranium include representative values for the activity of the uranium-234 that is concentrated during the enrichment process.