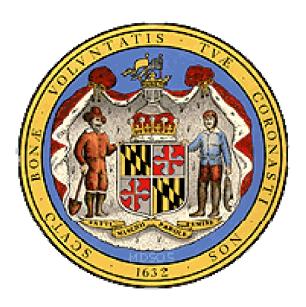
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REGULATIONS FOR THE CONTROL OF IONIZING RADIATION (1994)



RADIOLOGICAL HEALTH PROGRAM AIR AND RADIATION MANAGEMENT ADMINISTRATION MARYLAND DEPARTMENT OF THE ENVIRONMENT 1800 WASHINGTON BOULEVARD BALTIMORE, MARYLAND 21230

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- (a) Relative orientation of the high energy radiation machine;
- (b) A scale (0.25 inch = 1 foot is typical);
- (c) Direction of North;
- (d) Thickness and minimum density of shielding material(s);
- (e) Normal location of the high energy radiation machine's radiation port(s);
- (f) The port's travel and traverse limits;
- (g) General direction(s) of the useful beam;
- (h) Locations and sizes of all windows, doors and penetrations;
- (<u>i</u>) Location of the high energy radiation machine control panel; and
- (j) Details of the door(s) and maze.
- (iv) The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floors, and ceilings of the room(s) concerned;
- (v) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present;
- (vi) Description of all assumptions included in shielding calculations including, but not limited to, design energy [i.e.: room may be designed for 6 MV unit although only a 4 MV unit is currently proposed], workload, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier, such as walls, floor, and ceiling, and allowed radiation exposure in both restricted and unrestricted areas; and
- (vii) At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition; for example, primary and secondary/leakage barriers, restricted and unrestricted areas, entry door(s), and shielding material in the facility:
 - (<u>a</u>) If commercial software is used to generate shielding requirements, identify the software and version/revision date; and
 - (<u>b</u>) If the software used to generate shielding requirements is discussed in open literature, submit quality control sample calculations to verify the result obtained with the software.

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- (2) <u>Neutron Shielding</u>. In addition to the requirements in Section B.4(b)(1), any person owning or operating a facility that utilizes therapeutic, non-human use, or industrial radiation machines that produce photons and/or electrons with a maximum energy in excess of 10 MeV shall submit shielding plans which contain, as a minimum, the following additional information:
 - (i) The structural composition, thickness, minimum density and location of all neutron shielding material;
 - (ii) Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluence rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas;
 - (iii) At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition [i.e.: restricted and unrestricted areas, entry door(s) and maze] and neutron shielding material utilized in the facility:
 - (<u>a</u>) If commercial software is used to generate shielding requirements, identify the software and version/revision date; and
 - (b) If the software used to generate shielding requirements is discussed in open literature, submit quality control sample calculations to verify the result obtained with the software.
 - (iv) The method(s) and instrumentation that will be used to verify the adequacy of all neutron shielding installed.
- (3) All high energy facilities shall maintain for inspection by the Agency copies of the submittals required in Section B.4(b), as well as all Agency approvals.

Sec. B.5 Registration of Radiation Machine Facilities.

Each person owning or operating a radiation machine facility shall:

- (a) Apply for registration of such facility with the Agency prior to the following, whichever is earliest:
 - (1) The completion of the installation or the use of a radiation machine in the facility;
 - (2) The receipt of a radiation machine by a facility, if installation is not required by a service provider as described in Section B.6;
 - (3) The relocation of a radiation machine to a new facility location; or
 - (4) The purchase of the facility or radiation machine in the facility.

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- (c) Except as provided under B.6, no registrant shall possess, use, or store a radiation machine which:
 - (1) Does not meet the requirements of COMAR 26.12 "Radiation Management",
 - (2) Is located in a radiation machine facility that is not registered as required by B.5,
 - (3) Has been installed or serviced by any person who is not registered with the Agency as a service provider in accordance with B.6, or
 - (4) Has been modified as described in B.14(a) above.
- (d) A radiation machine that does not meet the requirements of B.14(a), B.14(b), and B.14(c) must, within 20 days, be
 - (1) Rendered internally inoperable, in a manner approved by the Department, by a service provider registered under B.6; or
 - (2) Removed from the facility by a service provider registered under B.6.

PART B

<u>APPENDIX</u> 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 than 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

- (ix) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of byproduct material, provided that:
 - (a) Each source contains no more than one exempt quantity set forth in Appendix B of this part, and
 - (b) Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Appendix B of this part, provided that the sum of such fractions shall not exceed unity.
 - (c) For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under Appendix B.

(x) [Reserved]

(2) Self-Luminous Products Containing Radioactive Material.

(i) <u>Tritium, Krypton-85</u>, or <u>Promethium-147</u>.

- (a) Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, or produced under an Agency specific license issued under Section C.28 and imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Section 32.22 that authorizes the transfer of the product to persons who are exempt from regulatory requirements.
- (b) Any person who desires to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147 for use under Section C.4(c)(2)(i)(a) should apply for a license under Section C.28. Any person who desires to initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under Section C.4(c)(2)(i)(a) should apply to the NRC for a license under 10 CFR Section 32.22 and for a certificate of registration in accordance with 10 CFR Section 32.210.
- (\underline{c}) The exemption in C.4(c)(2) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.
- (ii) <u>Radium-226</u>. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium-226 which were acquired prior to December 6, 1982.

(3) Gas and Aerosol Detectors Containing Byproduct Material.

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

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

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

- (i) Except as provided in paragraphs (b) and (c) of this section, any person is exempt from the requirements for a license and from these regulations provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 μ Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.
- (ii) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Section C.
- (iii) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to 10 CFR §32.21.
- (iv) Nothing in this section relieves persons from complying with applicable FDA, Federal, and State requirements governing receipt, administration, and use of drugs.

(5) Certain Industrial Devices.

- (i) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in Part C and from the regulations in all parts of COMAR 26.12.01.01 to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, or produced in accordance with a specific license under Section C.28(d), or initially transferred in accordance with a specific license issued by the NRC pursuant to 10 CFR Section 32.30 that authorizes the initial transfer of the device to persons who are exempt from regulatory requirements. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.
- (ii) Any person who desires to manufacture, process, or produce industrial devices containing byproduct material for use under Section C.5(i) should apply to the Agency for a specific license under Section C.28(d). Any person who desires to initially transfer for sale or distribution industrial devices containing byproduct material for use under Section C.5(i) should apply to the NRC for a license in accordance with 10 CFR Section 32.30 and for a certificate of registration in accordance with 10 CFR Section 32.210.
- (d) Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from the regulations in this Part and Parts E, G, V, W, and X of this regulation and the requirements for a license set forth in Section 81 of the Atomic Energy Act of 1954, as Amended, to the extent that they transport or store byproduct material in the regular course of carriage for another or storage incident thereto.

Sec. C.5 - C.19 Reserved.

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 RX-37 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 RX-37, 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 RX-37 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 RX-37 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 intakes of radionuclides assessed pursuant to the regulations in Part D in effect before October 9, 1995. Further, occupational exposure histories obtained and recorded on Agency Form RX-37 or equivalent before October 9, 1995, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

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- e. If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:
 - i. In establishing administrative controls pursuant to D.201f. for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and
 - ii. That the individual is not available for planned special exposures.
- f. The licensee or registrant shall retain the records on Agency Form RX-37 or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Agency Form RX-37 or equivalent for 3 years after the record is made.

<u>Sec. D.206 Planned Special Exposures</u>. A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in D.201 provided that each of the following conditions is satisfied:

- a. The licensee or registrant has secured written permission from the Agency prior to the planned special exposure.
- b. The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.
- c. The licensee or registrant and employer (if the employer is not the licensee or registrant) specifically authorizes the planned special exposure, in writing, before the exposure occurs.
- d. Before a planned special exposure, the licensee or registrant ensures that each individual involved is:
 - i. Informed of the purpose of the planned operation; and
 - ii. Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and
 - iii. Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

- e. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by D.205b. during the lifetime of the individual for each individual involved.
- f. Subject to D.201b., the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:
 - i. The numerical values of any of the dose limits in D.201a. in any year; and
 - ii. Five times the annual dose limits in D.201a. during the individual's lifetime.
- g. The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with D.1106 and submits a written report in accordance with D.1204.
- h. The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to D.201a. but shall be included in evaluations required by D.206d. and e.

<u>Sec. D.207 Occupational Dose Limits for Minors</u>. The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in D.201.

Sec. D.208 Dose to an Embryo/Fetus.

- a. The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem). See D.1107 for recordkeeping requirements.
- b. The licensee or registrant shall make efforts to avoid substantial variation¹ above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in D.208a.
- c. The dose equivalent to the embryo/fetus is the sum of:
 - i. The deep dose equivalent to the declared pregnant woman; and

¹ The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.5 mSv (0.05 rem) to the embryo/fetus be received in any one month.

- d. Containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation; or
- e. Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to those individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or
- f. Installed manufacturing or process equipment, such as chemical process equipment, piping and tanks.

Sec. D.906 Procedures for Receiving and Opening Packages.

- a. Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in T.2 and Appendix A of Part T of these regulations, shall make arrangements to receive:
 - i. The package when the carrier offers it for delivery; or
 - ii. The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

b. Each licensee shall:

i. Monitor the external surfaces of a labeled³ package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in A.2 of these regulations; and

ii. Monitor the external surfaces of a labeled³ package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in T.2 and Appendix A to Part T of these regulations.

² Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by the U.S. Dept. of Transportation regulations 49 CFR 173.403 (m) and (w) and 173.421-424.

³ Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 and 172.436-440.

- iii. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of package degradation, such as packages that are crushed, wet, or damaged.
- c. The licensee shall perform the monitoring required by D.906b. as soon as practicable after receipt of the package, but not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.
- d. The licensee shall immediately notify the final delivery carrier and the Agency by telephone and telegram, mailgram, or facsimile, when:
 - i. Removable radioactive surface contamination exceeds the limits of T.87(i) of these regulations; or
 - ii. External radiation levels and surface temperatures exceed the limits of T.87(j) and (k) of these regulations.

e. Each licensee shall:

- i. Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and
- ii. Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.
- f. Licensees transferring special form sources in vehicles owned or operated by the licensee to and from a work site are exempt from the contamination monitoring requirements of D.906b., but are not exempt from the monitoring requirement in D.906b. for measuring radiation levels that ensures that the source is still properly lodged in its shield.

PART V

PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

General Provisions

Sec. V.1 Purpose. This Part has been established to provide the requirements for the physical protection program for any licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material listed in Appendix A to this Part. These requirements provide reasonable assurance of the security of category 1 or category 2 quantities of radioactive material by protecting these materials from theft or diversion. Specific requirements for access to material, use of material, transfer of material, and transport of material are included. No provision of this Part authorizes possession of licensed material.

Sec. V.2 [Reserved].

Sec. V.3 Scope.

- a. This Part applies to any person who, under Sections V.21 through V.57, possesses or uses at any site, an aggregated category 1 or category 2 quantity of radioactive material.
- b. This Part applies to any person who, under Sections V.71 through V.81:
 - i. Transports or delivers to a carrier for transport in a single shipment, a category 1 or category 2 quantity of radioactive material; or
 - ii. Imports or exports a category 1 or category 2 quantity of radioactive material; the provisions only apply to the domestic portion of the transport.

Sec. V.4 [Reserved].

Sec. V.5 Definitions. As used in this Part:

"Access control" means a system for allowing only approved individuals to have unescorted access to the security zone and for ensuring that all other individuals are subject to escorted access.

"Aggregated" means accessible by the breach of a single physical barrier that would allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a category 2 quantity of radioactive material.

"Approved individual" means an individual whom the licensee has determined to be trustworthy and reliable for unescorted access in accordance with Sections V.21 through V.33 and who has completed the training required by V.43(c).

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"Background investigation" means the investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

"Category 1 quantity of radioactive material" means a quantity of radioactive material meeting or exceeding the category 1 threshold in Table 1 of Appendix A to this Part. This is determined by calculating the ratio of the total activity of each radionuclide to the category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

"Category 2 quantity of radioactive material" means a quantity of radioactive material meeting or exceeding the category 2 threshold but less than the category 1 threshold in Table 1 of Appendix A to this Part. This is determined by calculating the ratio of the total activity of each radionuclide to the category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 2 quantity. Category 2 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

"Diversion" means the unauthorized movement of radioactive material subject to this Part to a location different from the material's authorized destination inside or outside of the site at which the material is used or stored.

"Escorted access" means accompaniment while in a security zone by an approved individual who maintains continuous direct visual surveillance at all times over an individual who is not approved for unescorted access.

"Fingerprint orders" means the orders issued by the U.S. Nuclear Regulatory Commission or the legally binding requirements issued by Agreement States that require fingerprints and criminal history records checks for individuals with unescorted access to category 1 and category 2 quantities of radioactive material or safeguards information-modified handling.

"License issuing authority" means the license agency that issues the license, i.e., the U.S. Nuclear Regulatory Commission or the appropriate agency of an Agreement State.

"Local law enforcement agency (LLEA)" means a public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests, and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed category 1 or category 2 quantity of radioactive material is used, stored, or transported.

"Mobile device" means a piece of equipment containing licensed radioactive material that is either mounted on wheels or casters, or otherwise equipped for moving without a need for disassembly or dismounting; or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location.

"Movement control center" means an operations center that is remote from transport activity and that maintains position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting these and other problems to appropriate agencies and can request and coordinate appropriate aid.

"No-later-than arrival time" means the date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than arrival time may not be more than 6 hours after the estimated arrival time for shipments of category 2 quantities of radioactive material.

"Reviewing official" means the individual who shall make the trustworthiness and reliability determination of an individual to determine whether the individual may have, or continue to have, unescorted access to the category 1 or category 2 quantities of radioactive materials that are possessed by the licensee.

"Sabotage" means deliberate damage, with malevolent intent, to a category 1 or category 2 quantity of radioactive material, a device that contains a category 1 or category 2 quantity of radioactive material, or the components of the security system.

"Safe haven" means a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law enforcement authorities.

"Security zone" means any temporary or permanent area determined and established by the licensee for the physical protection of category 1 or category 2 quantities of radioactive material.

"Telemetric position monitoring system" means a data transfer system that captures information by instrumentation and/or measuring devices about the location and status of a transport vehicle or package between the departure and destination locations.

"Trustworthiness and reliability" are characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to category 1 or category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

"Unescorted access" means solitary access to an aggregated category 1 or category 2 quantity of radioactive material or the devices that contain the material.

<u>Sec. V.6 – V.10 [Reserved]</u>.

Sec. V.11 Specific Exemptions.

[a. - b. Reserved].

- c. A licensee that possesses radioactive waste that contains category 1 or category 2 quantities of radioactive material is exempt from the requirements of Sections V.21 through V.81; except that any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs) is not exempt from the requirements of this Part. The licensee shall implement the following requirements to secure the radioactive waste:
 - i. Use continuous physical barriers that allow access to the radioactive waste only through established access control points;
 - ii. Use a locked door or gate with monitored alarm at the access control point;
 - iii. Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and
 - iv. Immediately notify the LLEA and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains category 1 or category 2 quantities of radioactive material.

<u>Sec. V.12 – V.20 [Reserved]</u>.

Background Investigations and Access Authorization Program

Sec. V.21 Personnel Access Authorization Requirements for Category 1 or Category 2 Quantities of Radioactive Material.

a. General.

- i. Each licensee that possesses an aggregated quantity of radioactive material at or above the category 2 threshold shall establish, implement, and maintain its access authorization program in accordance with the requirements of Sections V.21 V.33.
- ii. An applicant for a new license and each licensee that would become newly subject to the requirements of Sections V.21-V.33 upon application for modification of its license shall implement the requirements of Sections V.21-V.33, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.
- iii. Any licensee that has not previously implemented the Security Orders or been subject to the provisions of Sections V.21 through V.33 shall implement the provisions of Sections V.21 through V.33 before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

b. <u>General Performance Objective</u>. The licensee's access authorization program must ensure that the individuals specified in V.21(c)(i) are trustworthy and reliable.

c. <u>Applicability</u>.

- i. Licensees shall subject the following individuals to an access authorization program in accordance with V.23:
 - (1) Any individual whose assigned duties require unescorted access to category 1 or category 2 quantities of radioactive material or to any device that contains the radioactive material; and
 - (2) Reviewing officials.
- ii. Licensees need not subject the categories of individuals listed in Subsections V.29(a)(i) (xiii) to the investigation elements of the access authorization program.
- iii. Licensees shall approve for unescorted access to category 1 or category 2 quantities of radioactive material only those individuals with job duties that require unescorted access to category 1 or category 2 quantities of radioactive material.
- iv. Licensees may include individuals needing access to safeguards information-modified handling under 10 CFR Part 73 in the access authorization program under Sections V21 V33.

Sec. V.22 [Reserved].

Sec. V.23 Access Authorization Program Requirements.

a. Granting Unescorted Access Authorization.

- i. Licensees shall implement the requirements of Sections V.21 V.33 for granting initial or reinstated unescorted access authorization.
- ii. Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by V.43(c) before being allowed unescorted access to category 1 or category 2 quantities of radioactive material.

b. <u>Reviewing Officials.</u>

i. Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 quantities of radioactive materials possessed by the licensee.

- ii. Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. The fingerprints of the named reviewing official must be taken by a law enforcement agency, Federal or State agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a State to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every 10 years in accordance with Section V.25(b).
- iii. Reviewing officials must be permitted to have unescorted access to category 1 or category 2 quantities of radioactive materials or access to safeguards information or safeguards information-modified handling, if the licensee possesses safeguards information or safeguards information-modified handling.
- iv. Reviewing officials cannot approve other individuals to act as reviewing officials.
- v. A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:
 - (1) The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or
 - (2) The individual is subject to a category listed in Section V.29(a).

c. Informed Consent.

- i. Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals that meet the requirements of Section V.25(b). A signed consent must be obtained prior to any reinvestigation.
- ii. The subject individual may withdraw his or her consent at any time. Licensees shall inform the individual that:
 - (1) If an individual withdraws his or her consent, the licensee may not initiate any elements of the background investigation that were not in progress at the time the individual withdrew his or her consent; and
 - (2) The withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

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d. <u>Personal History Disclosure</u>. Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information required by this Part is sufficient cause for denial or termination of unescorted access.

e. <u>Determination Basis</u>.

- i. The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all of the information collected to meet the requirements of this Part.
- ii. The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all of the information collected to meet the requirements of this Part and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on information obtained at any time during the background investigation.
- iii. The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.
- iv. The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual granted unescorted access authorization.
- v. Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or meets the access authorization requirement, the licensee shall remove the person from the approved list as soon as possible, but no later than 7 working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.
- f. <u>Procedures</u>. Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures must include provisions for the notification of individuals who are denied unescorted access. The procedures must include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization. The procedures must contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

g. <u>Right to Correct and Complete Information</u>.

- i. Prior to any final adverse determination, licensees shall provide each individual subject to this Part with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification must be maintained by the licensee for a period of 1 year from the date of the notification.
- If, after reviewing his or her criminal history record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures. These procedures include direct application by the individual challenging the record to the law enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D-2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in 28 CFR 16.30 through 16.34. In the latter case, the Federal Bureau of Investigation (FBI) will forward the challenge to the agency that submitted the data, and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency. Licensees must provide at least 10 days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his or her review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

h. Records.

- i. The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.
- ii. The licensee shall retain a copy of the current access authorization program procedures as a record for 3 years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee shall retain the superseded material for 3 years after the record is superseded.
- iii. The licensee shall retain the list of persons approved for unescorted access authorization for 3 years after the list is superseded or replaced.

Sec. V.24 [Reserved].

Sec. V.25 Background Investigations.

- a. <u>Initial Investigation</u>. Before allowing an individual unescorted access to category 1 or category 2 quantities of radioactive material or to the devices that contain the material, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation must encompass at least the 7 years preceding the date of the background investigation or since the individual's eighteenth birthday, whichever is shorter. The background investigation must include at a minimum:
 - i. Fingerprinting and an FBI identification and criminal history records check in accordance with Section V.27;
 - ii. <u>Verification of True Identity</u>. Licensees shall verify the true identity of the individual who is applying for unescorted access authorization to ensure that the applicant is who he or she claims to be. A licensee shall review official identification documents (e.g., driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth) and compare the documents to personal information data provided by the individual to identify any discrepancy in the information. Licensees shall document the type, expiration, and identification number of the identification document, or maintain a photocopy of identifying documents on file in accordance with Section V.31. Licensees shall certify in writing that the identification was properly reviewed, and shall maintain the certification and all related documents for review upon inspection;
 - iii. <u>Employment History Verification</u>. Licensees shall complete an employment history verification, including military history. Licensees shall verify the individual's employment with each previous employer for the most recent 7 years before the date of application;
 - iv. <u>Verification of Education</u>. Licensees shall verify that the individual Participated in the education process during the claimed period;
 - v. <u>Character and Reputation Determination</u>. Licensees shall complete reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under this Part must be limited to whether the individual has been and continues to be trustworthy and reliable;
 - vi. The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the individual (e.g., seek references not supplied by the individual); and

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vii. If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide information or indicates an inability or unwillingness to provide information within a time frame deemed appropriate by the licensee but at least after 10 business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the record of investigation; and attempt to obtain the information from an alternate source.

b. <u>Grandfathering</u>.

- i. Individuals who have been determined to be trustworthy and reliable for unescorted access to category 1 or category 2 quantities of radioactive material under the Fingerprint Orders may continue to have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. These individuals shall be subject to the reinvestigation requirement.
- ii. Individuals who have been determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or the security orders for access to safeguards information, safeguards information-modified handling, or risk-significant material may have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. The licensee shall document that the individual was determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or a security order. Security order, in this context, refers to any order that was issued by the NRC that required fingerprints and an FBI criminal history records check for access to safeguards information, safeguards information-modified handling, or risk significant material such as special nuclear material or large quantities of uranium hexafluoride. These individuals shall be subject to the reinvestigation requirement.
- c. <u>Reinvestigations</u>. Licensees shall conduct a reinvestigation every 10 years for any individual with unescorted access to category 1 or category 2 quantities of radioactive material. The reinvestigation shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with Section V.27. The reinvestigations must be completed within 10 years of the date on which these elements were last completed.

V.26 [Reserved].

Sec. V.27 Requirements for Criminal History Records Checks of Individuals Granted Unescorted Access to Category 1 or Category 2 Quantities of Radioactive Material.

- a. <u>General Performance Objective and Requirements.</u>
 - i. Except for those individuals listed in Section V.29 and those individuals grandfathered under Section V.25(b), each licensee subject to the provisions of this Part shall fingerprint each individual who is to be permitted unescorted access to category 1 or category 2 quantities of radioactive material. Licensees shall transmit all collected fingerprints to the NRC for transmission to the FBI. The licensee shall use the information received from the FBI as Part of the required background investigation to determine whether to grant or deny further unescorted access to category 1 or category 2 quantities of radioactive materials for that individual.
 - ii. The licensee shall notify each affected individual that his or her fingerprints will be used to secure a review of his or her criminal history record, and shall inform him or her of the procedures for revising the record or adding explanations to the record.
 - iii. Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to category 1 or category 2 quantities of radioactive materials if:
 - (1) The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his or her unescorted access authorization; and
 - (2) The previous access was terminated under favorable conditions.
 - iv. Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to category 1 or category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee, based upon a background investigation conducted under this Part, the Fingerprint Orders, or 10 CFR Part 73. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the provisions of V.31(c).
 - v. Licensees shall use the information obtained as Part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to category 1 or category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

b. Prohibitions.

i. Licensees may not base a final determination to deny an individual unescorted access authorization to category 1 or category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:

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- (1) An arrest more than 1 year old for which there is no information of the disposition of the case; or
- (2) An arrest that resulted in dismissal of the charge or an acquittal.
- ii. Licensees may not use information received from a criminal history records check obtained under this Part in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

c. <u>Procedures for Processing of Fingerprint Checks.</u>

- i. For the purpose of complying with this Part, licensees shall submit to the U.S. Nuclear Regulatory Commission, Director, Division of Facilities and Security, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop T-03B46M, Rockville, Maryland 20852-2738, one completed, legible standard fingerprint card (Form FD–258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by calling 1–301–415–7513, or by e-mail to FORMS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at http://www.nrc.gov/site-help/e-submittals.html.
- ii. Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." (For guidance on making electronic payments, contact the Security Branch, Division of Facilities and Security at 301–415–7513.) Combined payment for multiple applications is acceptable. The U.S. Nuclear Regulatory Commission publishes the amount of the fingerprint check application fee on the NRC's public Web site. (To find the current fee amount, go to the Electronic Submittals page at http://www.nrc.gov/site-help/e-submittals.html and see the link for the Criminal History Program under Electronic Submission Systems.)
- iii. The NRC will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

Sec. V.28 [Reserved].

Sec. V.29 Relief from Fingerprinting, Identification, and Criminal History Records Checks and Other Elements of Background Investigations for Designated Categories of Individuals Permitted Unescorted Access to Certain Radioactive Materials.

- a. Fingerprinting, and the identification and criminal history records checks required by Section 149 of the Atomic Energy Act of 1954, as amended, and other elements of the background investigation are not required for the following individuals prior to granting unescorted access to category 1 or category 2 quantities of radioactive materials:
 - i. An employee of the NRC or of the Executive Branch of the U.S. Government who has undergone fingerprinting for a prior U.S. Government criminal history records check;
 - ii. A Member of Congress;
 - iii. An employee of a member of Congress or Congressional committee who has undergone fingerprinting for a prior U.S. Government criminal history records check;
 - iv. The Governor of a State or his or her designated State employee representative;
 - v. Federal, State, or local law enforcement personnel;
 - vi. State Radiation Control Program Directors and State Homeland Security Advisors or their designated State employee representatives;
 - vii. Agreement State employees conducting security inspections on behalf of the NRC under an agreement executed under Section 274.i. of the Atomic Energy Act;
 - viii. Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC;
 - ix. Emergency response personnel who are responding to an emergency;
 - x. Commercial vehicle drivers for road shipments of category 2 quantities of radioactive material;
 - xi. Package handlers at transportation facilities such as freight terminals and railroad yards;
 - xii. Any individual who has an active Federal security clearance, provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that granted the Federal security clearance or reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material; and

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- xiii. Any individual employed by a service provider licensee for which the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to category 1 or category 2 quantities of radioactive material. Written verification from the service provider must be provided to the licensee. The licensee shall retain the documentation for a period of 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.
- b. Fingerprinting, and the identification and criminal history records checks required by Section 149 of the Atomic Energy Act of 1954, as amended, are not required for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the last 5 years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material. These programs include, but are not limited to:
 - i. National Agency Check;
 - ii. Transportation Worker Identification Credentials (TWIC) under 49 CFR part 1572;
 - iii. Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR part 555;
 - iv. Health and Human Services security risk assessments for possession and use of select agents and toxins under 42 CFR part 73;
 - v. Hazardous Material security threat assessment for hazardous material endorsement to commercial driver's license under 49 CFR part 1572; and
 - vi. Customs and Border Protection's Free and Secure Trade (FAST) Program.

Sec. V30 [Reserved].

Sec. V.31 Protection of Information.

a. Each licensee who obtains background information on an individual under this Part shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

- b. The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his or her representative, or to those who have a need to have access to the information in performing assigned duties in the process of granting or denying unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling. No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.
- c. The personal information obtained on an individual from a background investigation may be provided to another licensee:
 - i. Upon the individual's written request to the licensee holding the data to disseminate the information contained in his or her file; and
 - ii. The recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.
- d. The licensee shall make background investigation records obtained under this Part available for examination by an authorized representative of the Agency to determine compliance with the regulations and laws.
- e. The licensee shall retain all fingerprint and criminal history records (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred, on an individual for 3 years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

Sec. V.32 [Reserved].

Sec. V.33 Access Authorization Program Review.

- a. Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements of this Part and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements. Each licensee shall periodically (at least annually) review the access program content and implementation.
- b. The results of the reviews, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the access authorization program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.
- c. Review records must be maintained for 3 years.

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Sec. V.34 – V.40 [Reserved].

Physical Protection Requirements During Use

Sec. V.41 Security Program.

a. <u>Applicability</u>.

- i. Each licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of this Part.
- ii. An applicant for a new license and each licensee that would become newly subject to the requirements of this Part upon application for modification of its license shall implement the requirements of this Part, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.
- iii. Any licensee that has not previously implemented the Security Orders or been subject to the provisions of Sections V.41 through V.57 shall provide written notification to the Agency as specified in Section A.12 at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold
- b. <u>General Performance Objective</u>. Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive material.
- c. <u>Program Features</u>. Each licensee's security program must include the program features, as appropriate, described in Sections V.43 through V.55.

Sec. V.42 [Reserved].

Sec. V.43 General Security Program Requirements.

a. <u>Security Plan</u>.

- i. Each licensee identified in Section V.41(a) shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by this Part. The security plan must, at a minimum:
 - (1) Describe the measures and strategies used to implement the requirements of this Part; and

- (2) Identify the security resources, equipment, and technology used to satisfy the requirements of this Part.
- ii. The security plan must be reviewed and approved by the individual with overall responsibility for the security program.
- iii. A licensee shall revise its security plan as necessary to ensure the effective implementation of Agency requirements. The licensee shall ensure that:
 - (1) The revision has been reviewed and approved by the individual with overall responsibility for the security program; and
 - (2) The affected individuals are instructed on the revised plan before the changes are implemented.
- iv. The licensee shall retain a copy of the current security plan as a record for 3 years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for 3 years after the record is superseded.

b. <u>Implementing Procedures</u>.

- i. The licensee shall develop and maintain written procedures that document how the requirements of this Part and the security plan will be met.
- ii. The implementing procedures and revisions to these procedures must be approved in writing by the individual with overall responsibility for the security program.
- iii. The licensee shall retain a copy of the current procedure as a record for 3 years after the procedure is no longer needed. Superseded portions of the procedure must be retained for 3 years after the record is superseded.

c. Training.

- i. Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training must include instruction in:
 - (1) The licensee's security program and procedures to secure category 1 or category 2 quantities of radioactive material, and in the purposes and functions of the security measures employed;
 - (2) The responsibility to report promptly to the licensee any condition that causes or may cause a violation of Agency requirements;

- (3) The responsibility of the licensee to report promptly to the local law enforcement agency and licensee any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material; and
- (4) The appropriate response to security alarms.
- ii. In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of category 1 or category 2 quantities of radioactive material. The extent of the training must be commensurate with the individual's potential involvement in the security of category 1 or category 2 quantities of radioactive material.
- iii. Refresher training must be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training must include:
 - (1) Review of the training requirements of paragraph (c) of this section and any changes made to the security program since the last training;
 - (2) Reports on any relevant security issues, problems, and lessons learned;
 - (3) Relevant results of Agency inspections; and
 - (4) Relevant results of the licensee's program review and testing and maintenance.
- iv. The licensee shall maintain records of the initial and refresher training for 3 years from the date of the training. The training records must include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.

d. Protection of Information.

- i. Licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.
- ii. Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan and implementing procedures.

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- iii. Before granting an individual access to the security plan or implementing procedures, licensees shall:
 - (1) Evaluate an individual's need to know the security plan or implementing procedures; and
 - (2) If the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in V.25(a)(ii) through (a)(vii).
- iv. Licensees need not subject the following individuals to the background investigation elements for protection of information:
 - (1) The categories of individuals listed in V.29(a)(i) through (a)(xiii); or
 - (2) Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in V.25(a)(ii) though (a)(vii), has been provided by the security service provider.
- v. The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan or implementing procedures.
- vi. Licensees shall maintain a list of persons currently approved for access to the security plan or implementing procedures. When a licensee determines that a person no longer needs access to the security plan or implementing procedures or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than 7 working days, and take prompt measures to ensure that the individual is unable to obtain the security plan or implementing procedures.
- vii. When not in use, the licensee shall store its security plan and implementing procedures in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.
- viii. The licensee shall retain as a record for 3 years after the document is no longer needed:
 - (1) A copy of the information protection procedures; and

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(2) The list of individuals approved for access to the security plan or implementing procedures.

Sec. V.44 [Reserved].

Sec. V.45 LLEA Coordination.

- a. A licensee subject to this Part shall coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA must include:
 - i. A description of the facilities and the category 1 and category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with this Part; and
 - ii. A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of material.
- b. The licensee shall notify the Agency listed in A.12 within 3 business days if:
 - i. The LLEA has not responded to the request for coordination within 60 days of the coordination request; or
 - ii. The LLEA notifies the licensee that the LLEA does not plan to Participate in coordination activities.
- c. The licensee shall document its efforts to coordinate with the LLEA. The documentation must be kept for 3 years.
- d. The licensee shall coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

Sec. V.46 [Reserved].

Sec. V.47 Security Zones.

a. Licensees shall ensure that all aggregated category 1 and category 2 quantities of radioactive material are used or stored within licensee-established security zones. Security zones may be permanent or temporary.

- b. Temporary security zones must be established as necessary to meet the licensee's transitory or intermittent business activities, such as periods of maintenance, source delivery, and source replacement.
- c. Security zones must, at a minimum, allow unescorted access only to approved individuals through:
 - i. Isolation of category 1 and category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the category 1 or category 2 quantities of radioactive material within a security zone; or
 - ii. Direct control of the security zone by approved individuals at all times; or
 - iii. A combination of continuous physical barriers and direct control.
- d. For category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.
- e. Individuals not approved for unescorted access to category 1 or category 2 quantities of radioactive material must be escorted by an approved individual when in a security zone.

Sec. V.48 [Reserved].

Sec V.49 Monitoring, Detection, and Assessment.

- a. Monitoring and Detection.
 - i. Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones. Licensees shall provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary power source, or provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.
 - ii. Monitoring and detection must be performed by:
 - (1) A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility; or
 - (2) Electronic devices for intrusion detection alarms that will alert nearby facility personnel; or

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- (3) A monitored video surveillance system; or
- (4) Direct visual surveillance by approved individuals located within the security zone; or
- (5) Direct visual surveillance by a licensee designated individual located outside the security zone.
- iii. A licensee subject to this Part shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability must provide:
 - (1) For category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability must be provided by:
 - (a) Electronic sensors linked to an alarm; or
 - (b) Continuous monitored video surveillance; or
 - (c) Direct visual surveillance.
 - (2) For category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.
- b. <u>Assessment</u>. Licensees shall immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.
- c. <u>Personnel Communications and Data Transmission</u>. For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessment systems, licensees shall:
 - i. Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and
 - ii. Provide an alternative communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of communication or data transmission and processing. Alternative communications and data transmission systems may not be subject to the same failure modes as the primary systems.

d. <u>Response</u>. Licensees shall immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA.

Sec. V.50 [Reserved].

Sec. V.51 Maintenance and Testing.

- a. Each licensee subject to this Part shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of this Part must be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no manufacturer's suggested frequency, the testing must be performed at intervals not to exceed 12 months.
- b. The licensee shall maintain records on the maintenance and testing activities for 3 years.

Sec. V.52 [Reserved].

<u>Sec. V.53 Requirements for Mobile Devices</u>. Each licensee that possesses mobile devices containing category 1 or category 2 quantities of radioactive material must:

- a. Have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and
- b. For devices in or on a vehicle or trailer, unless the health and safety requirements for a site prohibit the disabling of the vehicle, the licensee shall utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.

Sec. V.54 [Reserved].

Sec. V.55 Security Program Review.

a. Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of this Part and that comprehensive actions are taken to correct any noncompliance that is identified. The review must include the radioactive material security program content and implementation. Each licensee shall periodically (at least every 12 months) review the security program content and implementation.

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- b. The results of the review, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the security program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and describe corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.
- c. The licensee shall retain the review documentation for 3 years.

Sec. V.56 [Reserved].

Sec. V.57 Reporting of Events.

- a. The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the Agency by telephone. In no case shall the notification to the Agency be later than 4 hours after the discovery of any attempted or actual theft, sabotage, or diversion.
- b. The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than 4 hours after notifying the LLEA, the licensee shall notify the Agency by telephone.
- c. The initial telephonic notification required by V.57(a) must be followed within a period of 30 days by a written report submitted to the Agency at the address specified in Section A.12 of this regulation. The report must include sufficient information for Agency analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

V.58 – V.70 [Reserved].

Physical Protection in Transit

Sec. V.71 Additional Requirements for Transfer of Category 1 and Category 2 Quantities of Radioactive Material. A licensee transferring a category 1 or category 2 quantity of radioactive material to a licensee of the Agency, NRC, or an Agreement State shall meet the license verification provisions listed below instead of those listed in Section C.40(d) of these regulations:

- a. Any licensee transferring category 1 quantities of radioactive material to a licensee of the Agency, NRC, or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.
- b. Any licensee transferring category 2 quantities of radioactive material to a licensee of the Agency, NRC, or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.
- c. In an emergency where the licensee cannot reach the license issuing authority and the license verification system is nonfunctional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred. The certification must include the license number, current revision number, issuing agency, expiration date, and for a category 1 shipment the authorized address. The licensee shall keep a copy of the certification. The certification must be confirmed by use of the NRC's license verification system or by contacting the license issuing authority by the end of the next business day.
- d. The transferor shall keep a copy of the verification documentation as a record for 3 years.

Sec. V.72 [Reserved].

Sec. V.73 Applicability of Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Transit.

- a. For shipments of category 1 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in V.75(a) and (e); V.77; V.79(a)(i), (b)(i) and (c); and V.81(a), (c), (e), (g), and (h).
- b. For shipments of category 2 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in V.75(b) through (e); V.79(a)(ii), (a)(iii), (b)(ii), and (c); and V.81(b), (d), (f), (g), and (h). For those shipments of category 2 quantities of radioactive material that meet the criteria of T.97(b), the shipping licensee shall also comply with the advance notification provisions of T.97.

- c. The shipping licensee shall be responsible for meeting the requirements of this Part unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under this Part.
- d. Each licensee that imports or exports category 1 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in V.75(a)(ii) and (e); V.77; V.79(a)(i), (b)(i), and (c); and V.81(a), (c), (e), (g), and (h) for the domestic portion of the shipment.
- e. Each licensee that imports or exports category 2 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in V.79(a)(ii), (a)(iii), and (b)(ii); and V.81(b), (d), (f), (g), and (h) for the domestic portion of the shipment.

Sec. V.74 [Reserved].

Sec. V.75 Preplanning and Coordination of Shipment of Category 1 or Category 2 Quantities of Radioactive Material.

- a. Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall:
 - i. Preplan and coordinate shipment arrival and departure times with the receiving licensee;
 - ii. Preplan and coordinate shipment information with the governor or the governor's designee of any State through which the shipment will pass to:
 - (1) Discuss the State's intention to provide law enforcement escorts; and
 - (2) Identify safe havens; and
 - iii. Document the preplanning and coordination activities.
- b. Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.
- c. Each licensee who receives a shipment of a category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

- d. Each licensee, who transports or plans to transport a shipment of a category 2 quantity of radioactive material, and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to V.75(b), shall promptly notify the receiving licensee of the new no-later-than arrival time.
- e. The licensee shall retain for 3 years a copy of the documentation for preplanning and coordination and any revision thereof.

Sec. V.76 [Reserved].

Sec. V.77 Advance Notification of Shipment of Category 1 Quantities of Radioactive Material. As specified in paragraphs (a) and (b) of this section, each licensee shall provide advance notification to the NRC and the governor of a State, or the governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the State, before the transport, or delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

a. Procedures for Submitting Advance Notification.

- i. The notification must be made to the NRC and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governors' designees, is available on the NRC's Web site at http://nrc-stp.ornl.gov/special/designee.pdf. A list of the contact information is also available upon request from the Director, Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Notifications to the NRC must be to the NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The notification to the NRC may be made by email to RAMQC_SHIPMENTS@nrc.gov or by fax to 301–816–5151.
- ii. A notification delivered by mail must be postmarked at least 7 days before transport of the shipment commences at the shipping facility.
- iii. A notification delivered by any means other than mail must reach NRC at least 4 days before the transport of the shipment commences and must reach the office of the governor or the governor's designee at least 4 days before transport of a shipment within or through the State.
- b. <u>Information To Be Furnished in Advance Notification of Shipment</u>. Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

- i. The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;
- ii. The license numbers of the shipper and receiver;
- iii. A description of the radioactive material contained in the shipment, including the radionuclides and quantity;
- iv. The point of origin of the shipment and the estimated time and date that shipment will commence;
- v. The estimated time and date that the shipment is expected to enter each State along the route;
- vi. The estimated time and date of arrival of the shipment at the destination; and
- vii. A point of contact, with a telephone number, for current shipment information.

c. <u>Revision Notice</u>.

- i. The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the governor of the State or the governor's designee and to the NRC's Director of Nuclear Security, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.
- ii. A licensee shall promptly notify the governor of the State or the governor's designee of any changes to the information provided in accordance with paragraphs (b) and (c)(1) of this section. The licensee shall also immediately notify the NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 of any such changes.
- d. <u>Cancellation Notice</u>. Each licensee who cancels a 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 NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.
- e. <u>Records</u>. The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for 3 years.

Sec. V.78 [Reserved].

Sec. V.79 Requirements for Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Shipment.

a. <u>Shipments by Road</u>.

- i. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:
 - (1) Ensure that movement control centers are established that maintain position information from a remote location. These control centers must monitor shipments 24 hours a day, 7 days a week, and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies.
 - (2) Ensure that redundant communications are established that allow the transport to contact the escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication.
 - (3) Ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center must provide positive confirmation of the location, status, and control over the shipment. The movement control center must be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.
 - (4) Provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver.
 - (5) Develop written normal and contingency procedures to address:
 - (a) Notifications to the communication center and law enforcement agencies;
 - (<u>b</u>) Communication protocols. Communication protocols must include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost;

- (c) Loss of communications; and
- (<u>d</u>) Responses to an actual or attempted theft or diversion of a shipment.
- (6) Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.
- ii. Each licensee that transports category 2 quantities of radioactive material shall maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.
- iii. Each licensee who delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:
 - (1) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.
 - (2) Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and
 - (3) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

b. <u>Shipments by Rail</u>.

- i. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:
 - (1) Ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-Party, or railroad communications center. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

- (2) Ensure that periodic reports to the communications center are made at preset intervals.
- ii. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:
 - (1) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.
 - (2) Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and
 - (3) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.
- c. <u>Investigations</u>. Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall immediately conduct an investigation upon the discovery that a category 1 shipment is lost or missing. Each licensee who makes arrangements for the shipment of category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

Sec. V.80 [Reserved].

Sec. V.81 Reporting of Events.

- a. The shipping licensee shall notify the appropriate LLEA and the NRC's Operations Center (301–816–5100) within 1 hour of its determination that a shipment of category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law enforcement agency in the area of the shipment's last confirmed location. During the investigation required by V.79(c), the shipping licensee will provide agreed upon updates to the Agency on the status of the investigation.
- b. The shipping licensee shall notify the Agency within 4 hours of its determination that a shipment of category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secured, the licensee shall immediately notify the Agency.

- c. The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the Agency upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment of category 1 radioactive material.
- d. The shipping licensee shall notify the Agency as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a category 2 quantity of radioactive material.
- e. The shipping licensee shall notify the Agency and the LLEA as soon as possible upon recovery of any lost or missing category 1 quantities of radioactive material.
- f. The shipping licensee shall notify the Agency as soon as possible upon recovery of any lost or missing category 2 quantities of radioactive material.
- g. The initial telephonic notification required by V.81(a) through (d) must be followed within a period of 30 days by a written report submitted to the Agency at the address specified in Section A.12 of this regulation. A written report is not required for notifications on suspicious activities required by V.81(c) and (d). In addition, the licensee shall provide one copy of the written report addressed to the Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The report must set forth the following information:
 - i. A description of the licensed material involved, including kind, quantity, and chemical and physical form;
 - ii. A description of the circumstances under which the loss or theft occurred;
 - iii. A statement of the disposition, or probable disposition, of the licensed material involved;
 - iv. Actions that have been taken, or will be taken, to recover the material; and
 - v. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.
- h. Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

Sec. V.82 – V.100 [Reserved].

Records

Sec. V.101 Form of Records. Each record required by this Part must be legible throughout the retention period specified by each Agency regulation. 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 producing 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. V.102 [Reserved].

<u>Sec. V.103 Record Retention</u>. Licensees shall maintain the records that are required by the regulations in this Part for the period specified by the appropriate regulation. If a retention period is not otherwise specified, these records must be retained until the Agency terminates the facility's license. All records related to this Part may be destroyed upon Agency termination of the facility license.

Sec. V.104 [Reserved].

Enforcement

Sec. V.105 Inspections.

- a. Each licensee shall afford to the Agency at all reasonable times opportunity to inspect category 1 or category 2 quantities of radioactive material and the premises and facilities wherein the nuclear material is used, produced, or stored.
- b. Each licensee shall make available to the Agency for inspection, upon reasonable notice, records kept by the licensee pertaining to its receipt, possession, use, acquisition, import, export, or transfer of category 1 or category 2 quantities of radioactive material.

Appendix A - Category 1 and Category 2 Radioactive Materials

Table 1—Category 1 and Category 2 Threshold

The terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only.

Radioactive material	Category 1	Category 1	Category 2	Category 2
	(TBq)	(Ci)	(TBq)	(Ci)
Americium-241	60	1,620	0.6	16.2
Americium-241/Be	60	1,620	0.6	16.2
Californium-252	20	540	0.2	5.40
Cobalt-60	30	810	0.3	8.10
Curium-244.	50	1,350	0.5	13.5
Cesium-137	100	2,700	1	27.0
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,160	0.8	21.6
Plutonium-238.	60	1,620	0.6	16.2
Plutonium-239/Be	60	1,620	0.6	16.2
Promethium-147	40,000	1,080,000	400	10,800
Radium-226.	40	1,080	0.4	10.8
Selenium-75	200	5,400	2	54.0
Strontium-90.	1,000	27,000	10	270
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169.	300	8,100	3	81.0

Note: Calculations Concerning Multiple Sources or Multiple Radionuclides The "sum of fractions" methodology for evaluating combinations of multiple sources or multiple radionuclides is to be used in determining whether a location meets or exceeds the threshold and is thus subject to the requirements of this Part.

I. If multiple sources of the same radionuclide and/or multiple radionuclides are aggregated at a location, the sum of the ratios of the total activity of each of the radionuclides must be determined to verify whether the activity at the location is less than the category 1 or category 2 thresholds of Table 1, as appropriate. If the calculated sum of the ratios, using the equation below, is greater than or equal to 1.0, then the applicable requirements of this Part apply.

II. First determine the total activity for each radionuclide from Table 1. This is done by adding the activity of each individual source, material in any device, and any loose or bulk material that contains the radionuclide. Then use the equation below to calculate the sum of the ratios by inserting the total activity of the applicable radionuclides from Table 1 in the numerator of the equation and the corresponding threshold activity from Table 1 in the denominator of the equation. Calculations must be performed in metric values (i.e., TBq) and the numerator and denominator values must be in the same units.

 R_1 = total activity for radionuclide 1

 R_2 = total activity for radionuclide 2

 R_N = total activity for radionuclide n

AR₁ = activity threshold for radionuclide 1

AR₂ = activity threshold for radionuclide 2

 $AR_N = activity threshold for radionuclide n$

$$\sum_{1}^{n} \left[\frac{R_{1}}{AR_{1}} + \frac{R_{2}}{AR_{2}} + \frac{R_{n}}{AR_{n}} \right] \ge 1.0$$