Part XIII. Transportation of Radioactive Material

Article 1. Purpose and Scope

12VAC5-481-2950. Purpose and scope.

The regulations in this part apply to any licensee authorized by specific or general license issued by the agency to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the agency license, or transports that material on public highways. No provision of this part authorizes possession of licensed material.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes


12VAC5-481-2960. Requirement for license.

No person shall transport radioactive material or deliver radioactive material to a carrier for transport except as authorized in a general or specific license issued by the agency or as exempted in 12VAC5-481-2970.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes

12VAC5-481-2970. Exemptions.

A. Common and contract carriers, freight forwarders, and warehouse workers that are subject to the requirements of the United States Department of Transportation (DOT) in 49 CFR Part 170 through 49 Part CFR 189 or the United States Postal Service in the Postal Service Domestic Mail Manual (DMM), Section C-023.9.0, and the United States Postal Service, are exempt from the requirements of this part to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers that are not subject to the requirements of the DOT or United States Postal Service are subject to 12VAC5-481-2960 and other applicable requirements of these regulations.

B. A licensee is exempt from all the requirements of this part with respect to shipment or carriage of the following low-level materials:

1. Natural material and ores containing naturally occurring radionuclides that are either in their natural state, or have only been processed for purposes other than the extraction of the radionuclides, and that are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed 10 times the values specified in Table 2 or Table 3 of 12VAC5-481-3770.
2. Materials for which the activity concentration is not greater than the activity concentration values specified in Table 2 or Table 3 of 12VAC5-481-3770, or for which the consignment activity is not greater than the limit for an exempt consignment found in Table 2 or Table 3 of 12VAC5-481-3770.

3. Nonradioactive solid objects with radioactive substances present on any surfaces in quantities not in excess of the levels cited in the definition of "contamination" in 12VAC5-481-10.

C. Fissile material meeting one of the following requirements are exempt from classification as fissile material and from the fissile material package standards of 10 CFR 71.55 and 10 CFR 71.59, but are subject to all other requirements of 10 CFR 71, except as noted.

1. Individual package containing two grams or less fissile material.

2. Individual or bulk packaging containing 15 grams or less of fissile material provided the package has at least 200 grams of solid nonfissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass for solid nonfissile material.

3. Low concentrations of solid fissile material commingled with solid nonfissile material, provided that there is at least 2,000 grams of solid nonfissile material for every gram of fissile material, and there is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass of solid nonfissile material.

4. Uranium enriched in uranium-235 to a maximum of 1.0% by weight, and with total plutonium and uranium-233 content of up to 1.0% of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5.0% of the uranium mass, and that the fissile material is distributed homogeneously and does not form a lattice arrangement within the package.

5. Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of 2.0% by mass, with a total plutonium and uranium-233 content not exceeding 0.002% of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of 2. The material must be contained in at least a DOT Type A package.

6. Packages containing, individually, a total plutonium mass of not more than 1,000 grams, of which not more than 20% by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

D. Any physician licensed by the Commonwealth of Virginia to dispense drugs in the practice of medicine is exempt from this section with respect to transport by the physician of radioactive material for use in the practice of medicine provided the physician is an authorized user under Part VII (12VAC5-481-1660 et seq.).

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes

12VAC5-481-2980. Transportation of licensed material.

A. Each licensee who transports licensed material outside the site of usage, as specified in the agency license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall:

1. Comply with the applicable requirements, appropriate to the mode of transport, of the regulations of the DOT; particularly the regulations of the DOT in the following areas:


e. Shipping papers and emergency information – 49 CFR Part 172: Subpart C and Subpart G.
g. Hazardous material shipper/carrier registration – 49 CFR Part 107: Subpart G.

2. The licensee shall also comply with applicable DOT regulations pertaining to the following modes of transportation:
c. Vessel – 49 CFR Part 176: Subparts A through F and M.

3. Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee in accordance with 12VAC5-481-900.

B. If, for any reason, the regulations of the DOT are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of 49 CFR Parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport to the same extent as if the shipment was subject to the regulations.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes

Article 3. General Licenses

12VAC5-481-2900. General licenses for carriers.

A. A general license is hereby issued to any common or contract carrier not exempt under 12VAC5-481-2970 to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the United States Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Notification of an incident shall be filed with, or made to, the agency as prescribed in 49 CFR, regardless of or in addition to notification made to the United States Department of Transportation or other agencies.

B. A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the United States Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Notification of an incident shall be filed with, or made to, the agency as prescribed in 49 CFR, regardless of or in addition to notification made to the United States Department of Transportation or other agencies.

C. Persons who transport radioactive material pursuant to the general licenses in subsection A or B of this section are exempt from the requirements of Parts IV (12VAC5-481-600 et seq.) and X (12VAC5-481-2250 et seq.) of this chapter to the extent that they transport radioactive material.
12VAC5-481-3000. General license: NRC-approved packages.

A. A general license is hereby issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance (CoC), or other approval has been issued by the NRC. This general license applies only to a licensee who has a quality assurance program approved by the agency as satisfying the provisions of 12VAC5-481-3130.

B. This general license applies only to a licensee who:

1. Has a copy of the license, CoC, or other approval by the NRC of the package and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

2. Complies with the terms and conditions of the license, certificate, or other approval by the NRC, as applicable, and the applicable requirements of Part XIII (12VAC5-481-2950 et seq.) of this chapter;

3. Prior to the licensee's first use of the package, submits in writing to the NRC: ATTN: Document Control Desk, Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 CFR 71.1(a), the licensee's name and license number and the package identification number specified in the package approval; and

4. Has a quality assurance program that complies with 12VAC5-481-3130.

C. The general license in subsection A of this section applies only when the package approval authorizes use of the package under this general license.

D. For a Type B or fissile material package, the design of which was approved by the NRC before April 1, 1996, the general license is subject to the additional restrictions of 12VAC5-481-3010.

12VAC5-481-3010. Previously approved packages.

A Type B(U) package, a Type B(M) package or a fissile material package, previously approved by the NRC but without the designation "-85" in the identification number of the NRC CoC, may be used under the general license of 12VAC5-481-3000 with the following additional conditions:

1. Fabrication of the package is satisfactorily completed by April 1, 1999, as demonstrated by application of its model number in accordance with 10 CFR 71.85(c);

2. A package used for a shipment to a location outside the United States is subject to multilateral approval except approved under special arrangement in accordance with United States Department of Transportation regulations at 49 CFR 173.403; and

3. A serial number that uniquely identifies each packaging that conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging.
12VAC5-481-3020. General License: United States Department of Transportation specification container.
A. A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in 49 CFR Parts 173 and 178.

B. This general license applies only to a licensee who:

1. Has a copy of the specification;

2. Complies with the terms and conditions of the specification and the applicable requirements of this part; and

3. Has a quality assurance program that complies with 12VAC5-481-3130.

C. The general license in subsection A of this section is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States except by multilateral approval as defined in 49 CFR 173.403.

A. A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate that has been revalidated by the DOT as meeting the applicable requirements of 49 CFR 171.23.

B. This general license applies only to shipments made to or from locations outside the United States.

C. This general license applies only to a licensee who:

1. Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

2. Complies with the terms and conditions of the certificate and revalidation, and with the applicable requirements of this part; and

3. The licensee has a quality assurance program approved by the agency that complies with 12VAC5-481-3130.

12VAC5-481-3040. General license: fissile material.
A. A general license is issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section. The fissile material need not be contained in a package that meets the standards of 10 CFR Part 71, Subparts E and F; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

B. The general license applies only to a licensee who has a quality assurance program that complies with 12VAC5-481-3130.

C. The general license applies only when a package's contents:

1. Contain no more than a Type A quantity of radioactive material; and

2. Contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

D. The general license applies only to packages containing fissile material that are labeled with a CSI that:

1. Has been determined in accordance with subsection E of this section;

2. Has a value less than or equal to 10; and

3. For a shipment of multiple packages containing fissile material, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

E. The value for the CSI must be greater than or equal to the number calculated by the following equation:

\[
CSI = 10 \left[ \frac{\text{grams of } ^{235}\text{U}}{X} + \frac{\text{gram of } ^{233}\text{U}}{Y} + \frac{\text{grams of Pu}}{Z} \right]
\]

1. The calculated CSI must be rounded up to the first decimal place;

2. The values of X, Y, and Z used in the CSI equation must be taken from Tables 5 or 6, as appropriate;

3. If Table 5 is used to obtain the value of X, then the values for the terms in the equation for uranium-233 and plutonium must be assumed to be zero; and

4. Table 4 values for X, Y, and Z must be used to determine the CSI if:

a. Uranium-233 is present in the package;

b. The mass of plutonium exceeds one percent of the mass of uranium-235;

c. The uranium is of unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or

d. Substances having a moderating effectiveness (i.e., an average hydrogen density greater than \( \text{H}_2\text{O} \)) (e.g., certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

<table>
<thead>
<tr>
<th>Fissile material mass mixed with moderating substances having an average hydrogen density less than or equal to ( \text{H}_2\text{O} ) (grams)</th>
<th>Fissile material mass mixed with moderating substances having an average hydrogen density greater than ( \text{H}_2\text{O} ) (grams)</th>
</tr>
</thead>
<tbody>
<tr>
<td>U-235 (X)</td>
<td>60</td>
</tr>
</tbody>
</table>
aWhen mixtures of moderating substances are present, the lower mass limits shall be used if more than 15 percent of the moderating substance has an average hydrogen density greater than H₂O.

Table 5
Mass Limits for General License Packages Containing Uranium-235 of Known Enrichment

<table>
<thead>
<tr>
<th>Uranium enrichment in weight percent of U-235 not exceeding</th>
<th>Fissile material mass of U-235 (X) (grams)</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td>60</td>
</tr>
<tr>
<td>20</td>
<td>63</td>
</tr>
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<td>15</td>
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<td>11</td>
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<td>1.5</td>
<td>408</td>
</tr>
<tr>
<td>1.35</td>
<td>480</td>
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<td>1,020</td>
</tr>
<tr>
<td>0.92</td>
<td>1,800</td>
</tr>
</tbody>
</table>

Statutory Authority
§ 32.1-229 of the Code of Virginia.
12VAC5-481-3051. General license: plutonium-beryllium special form material.

A. A general license is issued to any licensee to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with this section. This material need not be contained in a package that meets the standards of Subparts E and F of 10 CFR Part 71; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

B. The general license applies only to a licensee who has a quality assurance program that complies with 12VAC5-481-3130.

C. The general license applies only when a package's contents:

1. Contain no more than a Type A quantity of radioactive material; and

2. Contain less than 1,000 grams of plutonium, provided that: plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 grams of the total quantity of plutonium in the package.

D. The general license applies only to packages labeled with a CSI that:

1. Has been determined in accordance with subsection E of this section;

2. Has a value less than or equal to 100; and

3. For a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

E. The value for the CSI must be greater than or equal to the number calculated by the following equation:

\[
\text{CSI} = 10 \left( \frac{\text{grams of Pu-239} + \text{grams of Pu-241}}{24} \right)
\]

The calculated CSI must be rounded up to the first decimal place.

Statutory Authority
§ 32.1-229 of the Code of Virginia.
When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes

12VAC5-481-3070. Preliminary determinations.

Prior to the first use of any packaging for the shipment of radioactive material, the licensee shall ascertain that the determinations made in 10 CFR 71.85(a) through (c) have been made.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes

12VAC5-481-3080. Routine determinations.

Prior to each shipment of licensed material, the licensee shall determine that:

1. The package is proper for the contents to be shipped;
2. The package is in unimpaired physical condition except for superficial defects such as marks or dents;
3. Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;
4. Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;
5. Any pressure relief device is operable and set in accordance with written procedures;
6. The package has been loaded and closed in accordance with written procedures;
7. For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;
8. Any structural part of the package that could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified in 10 CFR 71.45;
9. The level of nonfixed radioactive contamination on the external surfaces of each package offered for shipment is ALARA and within the limits specified in 49 CFR 173.443;
10. External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in 10 CFR 71.47 at any time during transportation; and
11. Accessible package surface temperatures will not exceed the limits specified in 10 CFR 71.43(g) at any time during transportation.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
12VAC5-481-3090. Air transport of plutonium.

Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this part or included indirectly by citation of the DOT regulations, as may be applicable, the licensee shall assure that plutonium in any form is not transported by air, or delivered to a carrier for air transport, unless:

1. The plutonium is contained in a medical device designed for individual human application;

2. The plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for plutonium specified in Table A-2 of 12VAC5-481-3770 and in which the radioactivity is essentially uniformly distributed;

3. The plutonium is shipped in a single package containing no more than an A₂ quantity of plutonium in any isotope or form and is shipped in accordance with 12VAC5-481-2980;

4. The plutonium is shipped in a package specifically authorized, in the CoC, issued by the NRC, for the shipment of plutonium by air and the licensee requires, through special arrangement with the carrier, compliance with 49 CFR 175.704, the DOT regulations applicable to the air transport of plutonium.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes

12VAC5-481-3091. Opening instructions.

Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with 12VAC5-481-900.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 24, Issue 18, eff. June 12, 2008.

12VAC5-481-3100. Shipment records.

A. Each licensee shall maintain for a period of three years after shipment a record of each shipment of licensed material not exempt under 12VAC5-481-2970, showing, where applicable:

1. Identification of the packaging by model number and serial number;

2. Verification that the packaging, as shipped, had no significant defect;

3. Volume and identification of coolant;

4. Type and quantity of licensed material in each package, and the total quantity of each shipment;

5. Date of the shipment;

6. Name and address of the transferee;

7. Address to which the shipment was made; and
8. Results of the determinations required by 12VAC5-481-3080 and by the conditions of the package approval.

9. For each item of irradiated fissile material, in addition to the items listed in subdivisions 1 through 8 of this subsection, identification by model number and serial number; irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and any abnormal or unusual condition relevant to radiation safety.

10. For each fissile package and for Type B packages, in addition to the items listed in subdivisions 1 through 8 of this subsection, any special controls exercised.

B. Each licensee shall maintain, for a period of three years after the life of the packaging to which they apply, records identifying the packaging by model number, serial number, and date of manufacture.

C. The licensee shall make available to the agency for inspection, upon reasonable notice, all records required by this section. Records are valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.

D. The licensee shall maintain sufficient written records to furnish evidence of the quality of the packaging. The records to be maintained include results of the determinations made by 12VAC5-481-3000; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability, and the actions to be taken in connection with any deficiencies noted. These records must be retained for three years after the life of the packaging to which they apply.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes

12VAC5-481-3110. Reports.

The licensee shall report to the agency within 30 days:

1. Any instance in which there is significant reduction in the effectiveness of any packaging during use;

2. Details of any defects with safety significance in the packaging after first use, with the means employed to repair the defects and prevent their recurrence; or

3. Instances in which the conditions of approval in the CoC were not observed in making a shipment.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes

12VAC5-481-3120. Advance notification of transport of nuclear waste.

A. Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport.

B. Advance notification for transport of licensed material is required when:

1. The licensed material is required to be in Type B packaging for transportation;
2. The licensed material is being transported to or across state boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and

3. The quantity of licensed material in a single package exceeds:

a. 3000 times the $A_1$ value of the radionuclides as specified in 12VAC5-481-3770;

b. 3000 times the $A_2$ value of the radionuclides as specified in 12VAC5-481-3770; or

c. 1000 terabecquerel (27,000 curies).

C. Each advance notification required by subsections A and B of this section shall contain the following information:

1. The name, address, and telephone number of the shipper, carrier, and receiver of the shipment;

2. A description of the nuclear waste contained in the shipment as required by 49 CFR 172.202 and 172.203(d);

3. The point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;

4. The seven-day period during which arrival of the shipment at state boundaries or tribal reservation boundaries is estimated to occur;

5. The destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and

6. A point of contact with a telephone number for current shipment information.

D. The notification required by subsections A and B of this section shall be made in writing to each office of the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and to the agency. A notification delivered by mail shall be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A notification delivered by any other means than mail shall reach each office of the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and the agency, at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for three years.

1. A list of names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30, 1995 (60 FR 34306).

2. Contact information for each state, including telephone and mailing addresses of governors and governors' designees, and participating tribes, including telephone and mailing addresses of tribal officials and tribal officials' designees, is available on the NRC website at: https://scp.nrc.gov/special/designee.pdf.

3. A list of the names and mailing addresses of the governors' designees and tribal officials' designees of participating tribes is available on request from the Director, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

E. The licensee shall notify the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and the agency of any changes to schedule information provided pursuant to subsections A and B of this section. Such notification shall be by telephone to a responsible individual in the office of the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and the agency. The licensee shall maintain for three years a record of the name of the individual contacted.

F. Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice, identifying the advance notification that is being canceled, to the governor or governor's designee, the office of each appropriate tribal official or tribal official's designee, and to the agency. A copy of the notice shall be retained by the licensee for three years.
Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes

Article 5. Quality Assurance

12VAC5-481-3130. Quality assurance.

A. Quality assurance requirements apply to the design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. Quality assurance comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each licensee is responsible for the quality assurance provision that applies to its use of packaging for the shipment of licensed material subject to this chapter.

B. Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of this section, 10 CFR Part 71 Subpart H and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

C. Before the use of any package for the shipment of licensed material subject to this rule, each licensee shall obtain approval of its quality assurance program. Using an appropriate method, each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this section are applicable and how they will be satisfied by submitting the description to the agency.

D. A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of 12VAC5-481-1270 or equivalent NRC or agreement state requirement, is deemed to satisfy the requirements of 12VAC5-481-3000 and subsection B of this section.

E. The licensee shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. The licensee shall clearly establish and delineate, in writing, the authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions. While the term licensee is used in these criteria, the requirements are applicable to whatever design, fabrication, assembly, and testing of the package is accomplished with respect to a package before the time a package is issued.

F. The quality assurance functions are:

1. Assuring that an appropriate quality assurance program is established and effectively executed; and

2. Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the safety-related functions have been performed correctly.

G. The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom to:

1. Identify quality problems;

2. Initiate, recommend, or provide solutions; and
3. Verify implementation of solutions.

H. Changes to the quality assurance program.

1. Each quality assurance program approval holder shall submit a description of a proposed change to its agency approved quality assurance program that will reduce commitments in the program description as approved by the agency. The quality assurance program approval holder shall not implement the change before receiving approval.

The description of a proposed change to the agency approved quality assurance program must identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the applicable requirements of this section.

2. Each quality assurance program approval holder may change a previously approved quality assurance program without prior agency approval if the change does not reduce the commitments in the quality assurance program previously approved by the agency. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the agency every 24 months. In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, and nonsubstantive changes to punctuation or editorial items, the following changes are not considered reductions in commitment:

   a. The use of a quality assurance standard approved by the agency that is more recent than the quality assurance standard in the licensee's current quality assurance program at the time of the change;

   b. The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles, provided that there is no substantive change to either the functions of the position or reporting requirements;

   c. The use of generic organization charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text, provided that there is no substantive change to the functional relationships, authorities, or responsibilities;

   d. The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the quality assurance program approval holder has committed to on record; and

   e. Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including independence from cost and schedule when opposed to safety considerations.

3. Each quality assurance program approval holder shall maintain records of quality assurance program changes.

I. The licensee shall maintain sufficient written records to describe the activities affecting quality. These records must include the changes to the quality assurance program as required by subsection H of this section, the instructions, procedures, and drawings required by this section to prescribe quality assurance activities, and closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee shall retain these records for three years beyond the date when the licensee last engaged in the activity for which the quality assurance program was developed. If any portion of the quality assurance program, written procedures or instructions is superseded, the licensee shall retain the superseded material for three years after it is superseded.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Website addresses provided in the Virginia Administrative Code to documents incorporated by reference are for the reader's convenience only, may not necessarily be active or current, and should not be relied upon. To ensure the information incorporated by reference is accurate, the reader is encouraged to use the source document described in the regulation.

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