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Notice of Rulemaking Hearing

Hearings will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, Tennessee Code Annotated, Section 4-5-204. For questions and copies of the notice, contact the person listed below.

Agency/Board/Commission: Environment and Conservation
Division: Radiological Health
Contact Person: Beth Murphy
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Any Individuals with disabilities who wish to participate in these proceedings (to review these filings) and may require aid to facilitate such participation should contact the following at least 10 days prior to the hearing:

ADA Contact: ADA Coordinator
12th Floor L&C Tower
401 Church Street
Address: Nashville, Tennessee 37243
1-866-253-5827 (toll free) or (615)532-0200
Phone: Hearing impaired callers may use the TN Relay Service at 1-800-848-0298
Email: beverly.evans@tn.gov

Hearing Location(s) (for additional locations, copy and paste table)

Address 1:	17 th Floor Conference Room, L&C Tower		
Address 2:	401 Church Street		
City:	Nashville, Tennessee		
Zip:	37243		
Hearing Date :	08/09/10		
Hearing Time:	1:00 p.m.	<input checked="" type="checkbox"/> CST	<input type="checkbox"/> EST

Additional Hearing Information:

Oral or written comments are invited at the hearing. In addition, written comments may be submitted to Beth Murphy at the Division of Radiological Health, Central Office, address below, prior to or following the public hearing. However, the Division must receive comments in its Central Office by 4:30 p.m. (CST), August 9, 2010, in order to assure consideration.

Copies of draft rules are available for review in the Public Access Areas of the following Departmental Environmental Assistance Centers:

Nashville Environmental Field Office
711 R. S.Gass Boulevard
Nashville, TN 37243
(615) 687-7000 / 1-888-891-8332

Knoxville Environmental Field Office
3711 Middlebrook Pike
Knoxville, TN 37921
(865) 594-6035 / 1-888-891-8332

Chattanooga Environmental Field Office
 State Office Building
 540 McCallie Avenue, Suite 550
 Chattanooga, TN 37402-2013
 (423) 634-5781 / 1-888-891-8332

Memphis Environmental Field Office
 8383 Wolf Lake Drive
 Bartlett, TN 38133-4119
 (901) 371-3000

Copies are available for review also at the Division of Radiological Health, Central Office:

Division of Radiological Health
 L & C Annex, Third Floor
 401 Church Street
 Nashville, TN 37243-1532
 (615) 532-0364

The "DRAFT" rules may be accessed for review also at the Department's World Wide Web Site located at <http://www.state.tn.us/environment/rad>.

Revision Type (check all that apply):

- Amendment
 New
 Repeal

Rule(s) (ALL chapters and rules contained in filing must be listed. If needed, copy and paste additional tables to accommodate more than one chapter. Please enter only **ONE** Rule Number/Rule Title per row.)

Chapter Number	Chapter Title
1200-02-04	General Provisions
Rule Number	Rule Title
1200-02-04-.04	Definitions
1200-02-04-.13	Deliberate Misconduct

Chapter Number	Chapter Title
1200-02-10	Licensing and Registration
Rule Number	Rule Title
1200-02-10-.12	General Requirements for the Issuance of Specific Licenses
1200-02-10-.17	Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas
1200-02-10-.24	Registration
1200-02-10-.26	Records
1200-02-10-.30	Packaging and Transportation of Radioactive Material

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <http://state.tn.us/sos/rules/1360/1360.htm>)

Chapter 1200-02-04
General Provisions

Amendments

Subparagraph (u) of Paragraph (1) of Rule 1200-02-04-.04 Definitions is amended by deleting the subparagraph and substituting the following so that, as amended, subparagraph (u) shall read as follows:

- (u) 'Fissile material' means the radionuclides: plutonium-239, plutonium-241, uranium-233, uranium-235 or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only, are not included in this definition. Certain exclusions from fissile material controls are provided in 1200-02-10-.30(5)(b).

Subparagraph (bb) of Paragraph (1) of Rule 1200-02-04-.04 Definitions is amended by deleting the subparagraph and substituting the following so that, as amended, subparagraph (bb) shall read as follows:

- (bb) 'Low specific activity (LSA) material' means radioactive material with limited specific activity which is nonfissile or is excepted under 1200-02-10-.30(5)(b), and which satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups:

1. LSA-I.

- (i) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing only naturally occurring radioactive radionuclides which are not intended to be processed for the use of these radionuclides; or
- (ii) Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures; or
- (iii) Radioactive material for which the A_2 value is unlimited; or
- (iv) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with Schedule 10-6 in the Appendix of Chapter 1200-02-10.

2. LSA-II.

- (i) Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or
- (ii) Other material in which the activity is distributed throughout, and the average specific activity does not exceed $1(E-4) A_2/g$ for solids and gases, and $1(E-5) A_2/g$ for liquids.

3. LSA-III. Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of the U.S. NRC regulations 10 CFR 71.77, in which:

- (i) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.); and
- (ii) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that even under loss of packaging, the loss of

radioactive material per package by leaching, when placed in water for seven days, would not exceed 0.1 A₂; and

- (iii) The estimated average specific activity of the solid does not exceed 2(E-3) A₂/g.

Subparagraph (II) of Paragraph (1) of Rule 1200-02-04-.04 Definitions is amended by deleting the subparagraph and substituting the following so that, as amended, subparagraph (II) shall read as follows:

- (II) 'Package' means the packaging together with its radioactive contents as presented for transport.
1. 'Fissile material package' or Type AF package, Type BF package, Type B(U)F package or Type B(M)F package means a fissile material packaging together with its fissile material contents.
 2. 'Type A package' means a Type A packaging together with its radioactive contents. A Type A package is defined and must comply with the U.S. DOT regulations in 49 CFR 173.
 3. 'Type B package' means a Type B packaging together with its radioactive contents. On approval by the USNRC, a Type B package design is designated by the USNRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lbs/in²) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in USNRC regulations 10 CFR 71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see USDOT regulations in 49 CFR 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in 10 CFR 71.19.

Subparagraph (bbb) of Paragraph (1) of Rule 1200-02-04-.04 Definitions is amended by deleting the subparagraph and substituting the following so that, as amended, subparagraph (bbb) shall read as follows:

- (bbb) 'Special form radioactive material' means radioactive material that satisfies the following conditions:
1. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
 2. The piece or capsule has at least one dimension not less than 5 mm (0.2 in); and
 3. It satisfies the requirements specified by the U.S. Nuclear Regulatory Commission 10 CFR 71.75. A special form encapsulation designed in accordance with the U.S. NRC requirements of 10 CFR 71.4 in effect on June 30, 1983 (see 10 CFR 71, revised as of January 1, 1983), and constructed before July 1, 1985, and a special form encapsulation designed in accordance with U.S. NRC requirements of 10 CFR 71.4 in effect on March 31, 1996, (see 10 CFR 71, revised as of January 1, 1983), and constructed before April 1, 1998, may continue to be used. Any other special form encapsulation shall meet the specifications of this definition.

Subparagraph (eee) of Paragraph (1) of Rule 1200-02-04-.04 Definitions is amended by deleting the subparagraph and substituting the following so that, as amended, subparagraph (eee) shall read as follows:

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

1. SCO-I: A solid object on which:
 - (i) The removable (non-fixed) contamination on the accessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 1 E-4 microcurie (4 becquerels) per square centimeter (cm²) for beta and gamma and low toxicity alpha emitters or 1 E-5 microcuries (0.4 becquerel) per cm² for all other alpha emitters;
 - (ii) The fixed contamination on the accessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 1 microcurie (4 E+4 becquerels) per square centimeter (cm²) for beta and gamma and low toxicity alpha emitters or 0.1 microcurie (4 E+3 becquerels) per cm² for all other alpha emitters; and
 - (iii) The removable (nonfixed) contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 1 microcurie (4 E+4 becquerels) per square centimeter (cm²) beta and gamma and low toxicity alpha emitters or 0.1 microcurie (4 E+3 becquerels) per cm² for all other alpha emitters.

2. SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:
 - (i) The removable (nonfixed) contamination on the accessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 1 E-2 microcurie (400 becquerels) per square centimeter (cm²) for beta and gamma and low toxicity alpha emitters or 1 E-3 microcurie (40 becquerels) per cm² for all other alpha emitters;
 - (ii) The fixed contamination on the accessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 20 microcuries (8 E+5 becquerels) per square centimeter (cm²) for beta and gamma and low toxicity alpha emitters or 2 microcuries (8 E+4 becquerels) per cm² for all other alpha emitters; and
 - (iii) The removable (nonfixed) contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 20 microcurie (8 E+5 becquerels) per square centimeter (cm²) for beta and gamma and low toxicity alpha emitters or 2 microcurie (8 E+4 becquerels) per cm² for all other alpha emitters.

Paragraph (1) of Rule 1200-02-04-.04 Definitions is amended by adding new subparagraphs (sss) through (gggg) so that subparagraphs (sss) through (gggg) shall read as follows:

- (sss) 'Certificate holder' means a person who has been issued a certificate of compliance or other package approval by the U.S. Nuclear Regulatory Commission (U.S. NRC).
- (ttt) 'Certificate of Compliance (CoC)' means the certificate issued by the U.S. NRC under 10 CFR 71 subpart D which approves the design of a package for the transportation of radioactive material.
- (uuu) 'Close reflection by water' means immediate contact by water of sufficient thickness for maximum reflection of neutrons.
- (vvv) 'Consignment' means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.
- (www) 'Containment system" means the assembly of components of the packaging intended to retain the radioactive material during transport.
- (xxx) 'Criticality safety index (CSI)' means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of

control of accumulation of packages containing fissile material during transportation. Determination of the criticality safety index is described in 1200-02-10-.30(10), (11), and 10 CFR 71.59.

- (yyy) 'Deuterium' means, for the purposes of 1200-02-10-.30(5)(b) and 1200-02-10-.30(10), deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.
- (zzz) 'DOT' and 'U.S. DOT' mean the United States Department of Transportation. U.S. DOT regulations are found in Code of Federal Regulations Title 49 Transportation.
- (aaaa) 'Graphite' means, for the purposes of 1200-02-10-.30(5)(b) and 1200-02-10-.30(10), graphite with a boron equivalent content less than 5 parts per million and density greater than 1.5 grams per cubic centimeter.
- (bbbb) 'Licensed material' means radioactive, by-product, source, or special nuclear material received, possessed, used, or transferred under a general or specific license issued by the Division pursuant to the regulations in this chapter, or issued by the U.S. NRC or an agreement state pursuant to equivalent regulations.
- (cccc) 'Optimum interspersed hydrogenous moderation' means the presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results.
- (dddd) 'Spent nuclear fuel or Spent fuel' means fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least 1 year's decay since being used as a source of energy in a power reactor, and has not been chemically separated into its constituent elements by reprocessing. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with fuel assemblies.
- (eeee) 'State' means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.
- (ffff) 'SRPAR' means State Regulations for Protection Against Radiation.
- (gggg) 'Unirradiated uranium' means uranium containing not more than $2E+3$ Bq of plutonium per gram of uranium-235, not more than $9E+6$ Bq of fission products per gram of uranium-235, and not more than $5E-3$ g of uranium-236 per gram of uranium-235.

Authority: T.C.A. §§ 68-202-203 and 68-202-206.

Rule 1200-02-04-.13 Deliberate Misconduct is amended by deleting the rule and substituting the following so that Rule 1200-02-04-.13 shall read as follows:

- (1) This rule applies to any—
 - (a) Licensee or registrant;
 - (b) Certificate holder;
 - (c) Quality assurance program approval holder;
 - (d) Applicant for a license, certificate, or quality assurance program approval;
 - (e) Contractor (including a supplier or consultant) or subcontractor, to any person identified in subparagraph (1)(d) of this rule; or
 - (f) Employees of any person identified in subparagraphs (1)(a) through (1)(e) of this rule.

- (2) A person identified in paragraph (1) of this Rule who knowingly provides to any entity, listed in subparagraphs (1)(a) through (1)(e) of this rule, any components, equipment, materials, or other goods or services that relate to a licensee's, registrant's, certificate holder's, quality assurance program approval holder's, or applicant's activities under these regulations, shall not:
- (a) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant, certificate holder, quality assurance program approval holder, or any applicant to be in violation of any rule, regulation or order; or any term, condition, or limitation of any license, or registration, or certificate issued by the Division; or
 - (b) Deliberately submit to the Division, a licensee, a registrant, a certificate holder, a quality assurance program approval holder, an applicant for a license or registration, certificate, or quality assurance program approval, or a licensee's, registrant's, applicant's, certificate holder's, or quality assurance program approval holder's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Division.
- (3) A person who violates subparagraph 1200-02-04-.13(2)(a) or (b) may be subject to possible civil and criminal penalties.
- (4) For the purposes of subparagraph 1200-02-04-.13(2)(a), deliberate misconduct by a person means an intentional act or omission that the person knows:
- (a) Would cause a licensee, registrant, certificate holder, quality assurance program approval holder, or applicant for a license, registration, certificate, or quality assurance program approval to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license, or registration, or certificate issued by the Division; or
 - (b) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order or policy of a licensee, registrant, certificate holder, quality assurance program approval holder, applicant, or the contractor or subcontractor of any of them.

Authority: T.C.A. §§ 68-202-203 and 68-202-206.

Chapter 1200-02-10
Licensing and Registration

Amendments

Paragraph (4) of Rule 1200-02-10-.12 General Requirements for the Issuance of Specific Licenses is amended by adding subparagraph (n) so that, subparagraph (n) shall read as follows:

- (n) Each person licensed under this chapter shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with 1200-02-10-.16, licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Division considers important to decommissioning consists of:
 1. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.
 2. As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible

contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

3. Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years, of the following:
 - (i) All areas designated and formerly designated restricted areas as defined in paragraph (62) of Rule 1200-02-05-.32;
 - (ii) All areas outside of restricted areas that require documentation under part (4)(n)1 of Rule 1200-02-10-.12;
 - (iii) All areas outside of restricted areas where current and previous wastes have been buried as documented under Rule 1200-02-05-.137; and
 - (iv) All areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in Rule 1200-02-10-.36, or apply for approval for disposal under Rule 1200-02-05-.121.
4. Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

Authority: T.C.A. §§ 68-202-203 and 68-202-206.

Subparagraph (d) of paragraph (3) of Rule 1200-02-10-.17 Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas is amended by adding part 3 so that the new part shall read as follows:

3. Records required by paragraphs (4) and (6) of Rule 1200-02-10-.26 have been received.

Authority: T.C.A. §§ 68-202-203 and 68-202-206.

Subpart (i) of Part 1 of subparagraph (d) of paragraph (3) of Rule 1200-02-10-.24 Registration is amended by deleting subpart (i) and substituting the following so that, as amended, subpart (i) shall read as follows:

- (i) For purposes of the eighteen percent (18%) fee, the first inspection performed on an x-ray tube on or after the effective date of these rules, will establish a new baseline date for that tube. Previous baseline dates will be reset to the last day of the month of performance of the previous inspections.
 - (I) Each subsequent inspection of a tube shall be performed during the same month as the preceding inspection or the month immediately following, resulting in "baseline periods" of from 59 days to 62 days, depending upon applicable new 2 month periods, according to the schedule set out in subparagraph (3)(a) of Rule 1200-02-10-.27.
 - (II) An inspection performed prior to or after the applicable new 2 month period shall establish a new baseline date for that tube.
 - (III) An inspection performed after the applicable new two month period shall not qualify the registrant for the eighteen percent (18%) fee.

- (IV) An inspection performed prior to the applicable new 2 month period and meeting all other requirements found in paragraphs (3), (4) and (5) of Rule 1200-02-10-.27 shall qualify the registrant for the eighteen percent (18%) fee.

Authority: T.C.A. §§ 68-202-203 and 68-202-206.

Rule 1200-02-10-.26 Records is amended by adding paragraph (6) so that the new paragraph (6) shall read as follows:

- (6) Prior to license termination, each licensee shall forward the records required by subparagraph (4)(n) of Rule 1200-02-10-.12 to the Division.

Authority: T.C.A. §§ 68-202-203 and 68-202-206.

Rule 1200-02-10-.30 Packaging and Transportation of Radioactive Material is amended by deleting the rule in its entirety and substituting the following so that, as amended, Rule 1200-02-10-.30 shall read as follows:

1200-02-10-.30 Packaging and Transportation of Radioactive Material

- (1) Except as authorized in a general license or a specific license issued by the Division, or as exempted in this rule, no licensee may:
 - (a) Deliver licensed material to a carrier for transport; or
 - (b) Transport licensed material.
- (2) Any physicians as defined in subparagraph (1)(nn) of Rule 1200-02-04-.04 is exempt from paragraph (3) or Rule 1200-02-10-.30 with respect to transport by the physician of licensed material for use in the practice of medicine. However, any physician operating under this exemption must be licensed under Chapter 1200-02-07 or 10 CFR part 35.
- (3) A licensee who, under a general or specific license, transports licensed material outside its site of authorized use or on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of this rule and with the applicable requirements of the U.S. DOT regulations in 49 CFR parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport.
 - (a) The licensee shall particularly note U.S. DOT in the following areas:
 - 1. Packaging: 49 CFR part 173, subparts A and B and I;
 - 2. Marking and labeling: 49 CFR 172, subpart D, 172.400 through 172.407, and 172.436 through 172.441 of subpart E;
 - 3. Placarding: 49 CFR part 172, subpart F, especially 172.500 through 172.519, 172.556 and appendices B and C;
 - 4. Accident reporting: 49 CFR part 171, 171.15 and 171.16;
 - 5. Shipping papers and emergency information: 49 CFR part 172, subparts C and G;
 - 6. Hazardous material employee training: 49 CFR part 172, subpart H;
 - 7. Hazardous material shipper/carrier registration: 49 CFR part 107, subpart G; and
 - 8. Security plans: 49 CFR part 172, subpart I.
 - (b) The licensee shall also note U.S. DOT regulations pertaining to the following modes of transportation:

1. Rail: 49 CFR part 174, subparts A through D and K;
 2. Air: 49 CFR part 175;
 3. Vessel: 49 CFR part 176, subparts A through F and M; and
 4. Public highway: 49 CFR part 177 and parts 390 through 397.
- (4) If U.S. DOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the U.S. DOT specified above in subparagraph (3)(a) to the same extent as if the shipment or transportation were subject to U.S. DOT regulations. A request for modification, waiver or exemption from those requirements, and any notification referred to in those requirements, shall be filed with, or made to, the Director of the Division of Radiological Health at the address given in Rule 1200-02-04-.07.
- (5) Exemptions.
- (a) Exemption for low-level materials.
1. A licensee is exempt from all requirements of this rule with respect to shipment or carriage of the following low-level materials:
 - (i) Natural material and ores containing naturally occurring radionuclides 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 A-2 of Schedule 10-6 in the Appendix to Chapter 1200-02-10.
 - (ii) Materials for which the activity concentration is not greater than the activity concentration values specified in Table A-2 of Schedule 10-6, or for which the consignment activity is not greater than the limit for an exempt consignment found in Table A-2 of Schedule 10-6 in the Appendix to Chapter 1200-02-10.
 2. A licensee is exempt from all requirements of this rule other than paragraphs (3), (4) and (13) of Rule 1200-02-10-.30, with respect to shipment or carriage of the following packages, provided the packages contain no fissile material or the fissile material exemption standards of subparagraph (5)(b) or Rule 1200-02-10-.30 or 10 CFR 71.15 are satisfied:
 - (i) A package containing no more than a Type A quantity of radioactive material;
 - (ii) A package in which the only radioactive material is low specific activity (LSA) material or surface contaminated objects (SCO), provided the external radiation level at 3 meters from the unshielded material or objects does not exceed 10 mSv/h (1 rem/h); or
 - (iii) A package transported within locations within the United States that contains plutonium in special form with an aggregate radioactivity not to exceed 20 curies (.74 TBq).
 3. A licensee is exempt from all requirements of this rule other than paragraphs (3), (4) and (13) or Rule 1200-02-10-.30, with respect to shipment or carriage of low-specific-activity (LSA) material in group LSA-I, or surface contaminated objects (SCO's) in group SCO-I.
- (b) Exemption from classification as fissile material.
1. Fissile material meeting the requirements of at least one of the subparts (i) through (vi) of this part are exempt from classification as fissile material and from the fissile material package standards of 10 CFR 71.55 and 71.59, but are subject to all other requirements of this rule, except as noted.

- (i) Individual package containing 2 grams or less fissile material.
 - (ii) 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.
 - (iii) (I) Low concentrations of solid fissile material commingled with solid nonfissile material, provided that:
 - I. There is at least 2000 grams of solid nonfissile material for every gram of fissile material, and
 - II. There is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile material.
 - (iii) (II) 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.
 - (iv) Uranium enriched in uranium-235 to a maximum of 1 percent by weight, and with total plutonium and uranium-233 content of up to 1 percent of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5 percent of the uranium mass.
 - (v) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of 2 percent by mass, with a total plutonium and uranium-233 content not exceeding 0.002 percent 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.
 - (vi) Packages containing, individually, a total plutonium mass of not more than 1000 grams, of which not more than 20 percent by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.
- (6) General license: U.S. NRC–approved package.
- (a) A general license is hereby issued to any licensee of the Division to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance or other approval has been issued by the U.S. Nuclear Regulatory Commission.
 - (b) This general license applies only to a licensee who:
 - 1. Has a copy of the certificate of compliance, or other approval of the package, and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment;
 - 2. Complies with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of Subparts A, G and H of 10 CFR 71;
 - 3. Submits in writing to the Director, Division of Radiological Health, at the address given in Rule 1200-02-04-.07, before the licensee's first use of the package, the licensee's name and license number and the package identification number specified in the package approval; and
 - 4. Has submitted to the Division and received Division approval for a quality assurance program that satisfies the provisions found in Subpart H of 10 CFR 71.

- (d) This general license applies only when the package approval authorizes use of the package under this general license.
 - (e) For a Type B or fissile material package, the design of which was approved by U.S. NRC before April 1, 1996, the general license is subject to the additional restrictions in paragraph (7) of this rule.
- (7) Previously approved package.
- (a) A Type B package previously approved by U.S. NRC but not designated as B(U) or B(M) in the identification number of the U.S. NRC Certificate of Compliance, may be used under the general license in paragraph (6) of this rule with the following additional conditions:
 1. Fabrication of the packaging was satisfactorily completed by August 31, 1986, as demonstrated by application of its model number in accordance with 10 CFR 71.85(c);
 2. A package used for a shipment to a location outside the United States is subject to multilateral approval, as defined in U.S. DOT 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.
 - (b) A Type B(U) package, a Type B(M) package, a low specific activity (LSA) material package or a fissile material package, previously approved by the U.S. NRC but without the designation '-85' in the identification number of the U.S. NRC Certificate of Compliance, may be used under the general license in paragraph (6) of this rule with the following additional conditions:
 1. Fabrication of the package was 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 as defined in U.S. DOT 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.
- (8) Reserved
- (9) General license: Use of foreign approved package.
- (a) A general license is issued to any licensee of the Division 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 U.S. DOT as meeting the applicable requirements of 49 CFR 171.12.
 - (b) This general license applies only to a licensee who:
 1. Has a copy of the applicable certificate, the revalidation and the drawings and other documents referenced in the certificate, relating to the use and maintenance of the packaging and to the actions to be taken before shipment;
 2. Complies with the terms and conditions of the certificate and revalidation and with the applicable requirements of this rule. With respect to the quality assurance provisions of 10 CFR Part 71, the licensee is exempt from design, construction, and fabrication considerations; and
 3. Has submitted to the Division and received Division approval for a quality assurance program that satisfies the provisions found in Subpart H of 10 CFR 71.
 - (c) This general license applies only to shipments made to or from locations outside the United States.

(10) General license: Fissile material

- (a) A general license is issued to any licensee of the Division or U.S. NRC to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this paragraph. The fissile material need not be contained in a package which meets the standards of 10 CFR Part 71 subparts E and F of U.S. NRC regulations; 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 submitted to the Division and received Division approval for a quality assurance program that satisfies the provisions found in Subpart H of 10 CFR 71.
- (c) The general license applies only when a package's contents:
1. Contain less than a Type A quantity of fissile 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 which:
1. Has been determined in accordance with subparagraph (e) of this rule;
 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) 1. The value for the CSI must be greater than or equal to the number calculated by the following equation:

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

2. The calculated CSI must be rounded up to the first decimal place;
3. The values of X, Y, and Z used in the CSI equation must be taken from Tables RHS 7-3 or 7-4, as appropriate;
4. If Table RHS 7-4 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
5. Table RHS 7-3 values for X, Y, and Z must be used to determine the CSI if:
 - (i) Uranium-233 is present in the package;
 - (ii) The mass of plutonium exceeds 1 percent of the mass of uranium-235;
 - (iii) The uranium is of unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or
 - (iv) Substances having a moderating effectiveness (i.e., an average hydrogen density greater than H₂O) (e.g., certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

Table RHS 7-3. Mass Limits for General License Packages Containing Mixed Quantities of Fissile Material or Uranium-235 of Unknown Enrichment per subparagraph (10)(e) of Rule 1200-02-10-.30

Fissile material	Fissile material mass mixed with moderating substances having an average hydrogen density less than or equal to H ₂ O (grams)	Fissile material mass mixed with moderating substances having an average hydrogen density greater than H ₂ O ^a (grams)
²³⁵ U (X)	60	38
²³³ U (Y)	43	27
²³⁹ Pu or ²⁴¹ Pu (Z)	37	24

^a When 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 RHS 7-4 Mass Limits for General License Packages Containing Uranium-235 of Known Enrichment per subparagraph (10)(e) of Rule 1200-02-10-.30

Uranium enrichment in weight percent of ²³⁵ U not exceeding	Fissile material mass of ²³⁵ U (X) (grams)
24	60
20	63
15	67
11	72
10	76
9.5	78
9	81
8.5	82
8	85
7.5	88
7	90
6.5	93
6	97
5.5	102
5	108
4.5	114
4	120
3.5	132
3	150
2.5	180
2	246
1.5	408
1.35	480
1	1,020
0.92	1,800

(11) General license: Plutonium-beryllium special form material.

- (a) A general license is issued to any licensee of the Division or the U.S. NRC 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 rule. This material need not be contained in a package which 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 submitted to the Division and received Division approval for a quality assurance program that satisfies the provisions found in Subpart H of 10 CFR 71.
- (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 1000 g of plutonium, provided that: plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 g of the total quantity of plutonium in the package.
- (d) The general license applies only to packages labeled with a CSI which:
 - 1. Has been determined in accordance with subparagraph (e) of this rule;
 - 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) 1. The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$\text{CSI} = 10 \left[\frac{\text{Grams of } ^{239}\text{Pu} + \text{grams of } ^{241}\text{Pu}}{24} \right]; \text{ and}$$

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

(12) Fissile Material: Assumptions as to Unknown Properties of Fissile Material.

- (a) 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.

(13) Preliminary determinations.

- (a) Before the first use of any packaging for the shipment of licensed material:
 - 1. The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging or impact compliance with the standards specified in 10 CFR 71.
 - 2. Where the maximum normal operating pressure will exceed 35 kPa (5 lbf/in²) gauge, the licensee shall test the containment system at an internal pressure at least 50 percent (50%) higher than the maximum normal operating pressure, to verify the capability of that system to maintain its structural integrity at that pressure; and
 - 3. The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight and a package identification number assigned by the U.S.

Nuclear Regulatory Commission (U.S. NRC). Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the U.S. NRC.

(b) Reserved.

(14) Routine determinations.

(a) Before each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this rule and of the license. The licensee shall determine that:

1. The package is proper for the contents to be shipped in accordance with 49 CFR 173.401 through 435;
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, 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 in accordance with 10 CFR 71, Subpart F;
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 the design requirements of 10 CFR 71.45;
9. The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable and within the limits specified in U.S. DOT regulations 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.

(b) Reserved.

(15) Air transport of plutonium.

(a) Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this rule or included indirectly by citation of 49 CFR Chapter I, as may be applicable, the licensee shall assure that plutonium in any form, whether for import, export or domestic shipment, is not transported by air or delivered to a carrier for air transport unless:

1. The plutonium is contained in a medical device designed for individual human application; or
2. The plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for plutonium specified in Schedule 10-6: Determination of A_1 and A_2 in the Appendix to Chapter 1200-02-10 and in which the radioactivity is essentially uniformly distributed; or

3. The plutonium is shipped in a single package containing no more than an A₂ quantity of plutonium in any isotope or form and is shipped in accordance with paragraphs (3) and (4) of Rule 1200-02-10-.30; or
 4. The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the U.S. Nuclear Regulatory Commission.
- (b) Nothing in subparagraph (a) of this paragraph is to be interpreted as removing or diminishing the requirements of 10 CFR 73.24.
- (c) For a shipment of plutonium by air that is subject to part (a)4 of this paragraph, the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, U.S. Department of Transportation regulations applicable to the air transport of plutonium.
- (16) 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 subparagraphs (5)(a) and (b) of Rule 1200-02-05-.115.
- (17) Records.
- (a) Each licensee shall maintain, for a period of three (3) years after shipment, a record of each shipment of licensed material not exempt under paragraph (5) of Rule 1200-02-10-.30~~(9)~~, showing where applicable:
1. Identification of the packaging by model number and serial number;
 2. Verification that there are no significant defects in the packaging, as shipped;
 3. Volume and identification of coolant;
 4. Type and quantity of licensed material in each package and the total quantity of each shipment;
 5. For each item of irradiated fissile material:
 - (i) Identification by model number and serial number;
 - (ii) Irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and
 - (iii) Any abnormal or unusual condition relevant to radiation safety;
 6. Date of the shipment;
 7. For fissile packages and for Type B packages, any special controls exercised;
 8. Name and address of the transferee;
 9. Address to which the shipment was made; and
 10. Results of the determinations required by paragraph (14) of Rule 1200-02-10-.30~~(11)~~ and by the conditions of the package approval.
- (b) The licensee shall make available to the Division for inspection, upon reasonable notice, all records required by this rule. Records are only valid if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.
- (18) The licensee shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include results of the determinations required by paragraph (13) of Rule 1200-02-10-.30~~(11)~~; 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 shall identify the inspector or data recorder, the type of observation, the results, the acceptability

and the action taken in connection with any deficiencies noted. The records shall be retained for three (3) years after the life of the packaging to which they apply.

- (19) Inspection and tests. In addition to the requirements in paragraph 1200-02-10-.27(4) and Rule 1200-02-10-.28, the licensee shall notify the Director, Division of Radiological Health, at the address given in Rule 1200-02-04-.07, at least 45 days before fabrication of a package to be used for the shipment of licensed material having a decay heat load in excess of 5 kW or with a maximum normal operating pressure in excess of 103 kPa (15 lbf/in²) gauge.
- (20) Reports. The licensee shall report to the Director, Division of Radiological Health, within 30 days:
- (a) Any instance in which there is significant reduction in the effectiveness of any approved Type B, or fissile, packaging during use;
 - (b) Details of any defects with safety significance in Type B, or fissile, packaging after first use, with the means employed to repair the defects and prevent their recurrence; or
 - (c) Instances in which the conditions of approval in the certificate of compliance were not observed in making a shipment.
- (21) Advance notification of shipment of irradiated reactor fuel and nuclear waste.
- (a) As specified in subparagraphs (b), (c) and (d) of this paragraph, each licensee shall provide advance notification to the governor of Tennessee, or the governor's designee, and to the Director, Division of Radiological Health, of the shipment of licensed material through or across the boundary of the State, before the transport, or delivery to a carrier for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.
 - (b) Advance notification is required under this section for shipments of irradiated reactor fuel in quantities less than that subject to advance notification requirements of 10 CFR 73.37(f). Advance notification is also required under this section for shipment of licensed material, other than irradiated fuel, meeting the following three conditions:
 1. The licensed material is required by 10 CFR 71 to be in Type B packaging for transportation;
 2. The licensed material is being transported to or across the State boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and
 3. The quantity of licensed material in a single package exceeds the least of the following:
 - (i) 3000 times the A₁ value of the radionuclides as specified in Schedule 10-6, Table A-1 for special form radioactive material;
 - (ii) 3000 times the A₂ value of the radionuclides as specified in Schedule 10-6, Table A-1 for normal form radioactive material; or
 - (iii) 1000 TBq (27,000 Ci).
 - (c) Procedures for submitting advance notification.
 1. The notification shall be made in writing to the office of each appropriate governor or governor's designee and to the Director, Division of Radiological Health.
 2. A notification delivered by mail shall be postmarked at least seven (7) days before the beginning of the seven (7) day period during which departure of the shipment is estimated to occur.
 3. A notification delivered by any other means than mail shall reach the office of the governor, or of the governor's designee, and of the Director, Division of Radiological Health, at least four (4) days before the beginning of the seven (7) day period during which departure of the shipment is estimated to occur.
 - (i) A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30, 1995 (60 FR 34306).
 - (ii) The list will be published annually in the Federal Register on or about June 30 to reflect any changes in information.

- (iii) A list of the names and mailing addresses of the governors' designees is available on request from the Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.
 - (iv) The licensee shall retain a copy of the notification as a record for three (3) years.
- (d) Information to be furnished in advance notification of shipment. Each advance notification of shipment of irradiated reactor fuel or nuclear waste shall contain the following information:
 - 1. The name, address and telephone number of the shipper, carrier and receiver of the irradiated reactor fuel or nuclear waste shipment;
 - 2. A description of the irradiated reactor fuel or nuclear waste contained in the shipment, as specified in the regulations of U.S. DOT in 49 CFR 172.202 and 172.203(d);
 - 3. The point of origin of the shipment and the seven (7) day period during which departure of the shipment is estimated to occur;
 - 4. The seven (7) day period during which arrival of the shipment at the State's boundaries is estimated to occur;
 - 5. The destination of the shipment and the seven (7) day period during which arrival of the shipment is estimated to occur; and
 - 6. A point of contact, with a telephone number, for current shipment information.
- (e) Revision notice. A licensee who finds that schedule information previously furnished to the governor, or governor's designee, and to the Director, Division of Radiological Health, in accordance with this section, will not be met, shall telephone a responsible individual in the office of the governor of the State, or of the governor's designee, and of the Division of Radiological Health and inform those individuals of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for three (3) years.
- (f) Cancellation notice.
 - 1. Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State, or to the governor's designee, previously notified, and to the Director, Division of Radiological Health.
 - 2. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for three (3) years.

(22) Quality Assurance

(a) Quality Assurance Requirements.

- 1. This subparagraph describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this paragraph, "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. The licensee, certificate holder, and applicant for a CoC are responsible for the quality assurance requirements as they apply to design, fabrication, testing, and modification of packaging. Each licensee is responsible for the quality assurance provision which applies to its use of a packaging for the shipment of licensed material subject to this paragraph.
- 2. Establishment of program. Each licensee, certificate holder, and applicant for a CoC shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of 10 CFR 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee, certificate holder, and applicant for a CoC shall execute the

applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

3. Approval of program. Before the use of any package for the shipment of licensed material subject to this paragraph, each licensee shall obtain Division approval of its quality assurance program and file a description of its quality assurance program, including a discussion of which requirements of this paragraph are applicable and how they will be satisfied.
4. Radiography containers. A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of subparagraph (8)(b) of Rule 1200-02-08-.04 or equivalent Nuclear Regulatory Commission, or Agreement State requirement, is deemed to satisfy the requirements of parts (6)(b)4 and (22)(a)2 of Rule 1200-02-10-.30.

(b) Quality assurance organization.

1. The licensee¹, certificate holder, and applicant for a CoC shall be responsible for the establishment and execution of the quality assurance program. The licensee, certificate holder, and applicant for a CoC 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. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.
2. The quality assurance functions are—
 - (i) Assuring that an appropriate quality assurance program is established and effectively executed; and
 - (ii) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.
3. The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom to—
 - (i) Identify quality problems;
 - (ii) Initiate, recommend, or provide solutions; and
 - (iii) Verify implementation of solutions.

(c) Quality assurance program.

1. The licensee, certificate holder, and applicant for a CoC shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of 10 CFR 71.101 through 71.137. The licensee, certificate holder, and applicant for a CoC shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee, certificate holder, and applicant for a CoC shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.
2. The licensee, certificate holder, and applicant for a CoC, through its quality assurance program, shall provide control over activities affecting the quality of the identified

¹ While the term "licensee" is used in these criteria, the requirements are applicable to whatever design, fabrication, assembly, and testing of the package is accomplished with respect to a package before the time a package approval is issued.

materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee, certificate holder, and applicant for a CoC shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee, certificate holder, and applicant for a CoC shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

3. The licensee, certificate holder, and applicant for a CoC shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:

- (i) The impact of malfunction or failure of the item to safety;
- (ii) The design and fabrication complexity or uniqueness of the item;
- (iii) The need for special controls and surveillance over processes and equipment;
- (iv) The degree to which functional compliance can be demonstrated by inspection or test; and
- (v) The quality history and degree of standardization of the item.

4. The licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.

(d) Handling, storage, and shipping control.

The licensee, certificate holder, and applicant for a CoC shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.

(e) Inspection, test, and operating status.

1. The licensee, certificate holder, and applicant for a CoC shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of the inspections and tests.

2. The licensee shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

(f) Nonconforming materials, parts, or components.

The licensee, certificate holder, and applicant for a CoC shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations.

Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

(g) Corrective action.

The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

(h) Quality assurance records.

The licensee, certificate holder, and applicant for a CoC shall maintain sufficient written records to describe the activities affecting quality. The records must include the instructions, procedures, and drawings required by 10 CFR 71.111 to prescribe quality assurance activities and must include closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures which establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee, certificate holder, and applicant for a CoC shall retain these records for 3 years beyond the date when the licensee, certificate holder, and applicant for a CoC last engage in the activity for which the quality assurance program was developed. If any portion of the written procedures or instructions is superseded, the licensee, certificate holder, and applicant for a CoC shall retain the superseded material for 3 years after it is superseded.

(i) Audits.

The licensee, certificate holder, and applicant for a CoC shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Follow up action, including reaudit of deficient areas, must be taken where indicated.

Authority: T.C.A. §§ 68-202-203 and 68-202-206.

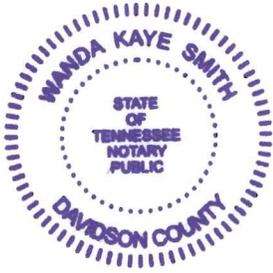
I certify that the information included in this filing is an accurate and complete representation of the intent and scope of rulemaking proposed by the agency.

Date: June 8, 2010

Signature: Debra G. Shults

Name of Officer: Debra G. Shults

Title of Officer: Deputy Director



Subscribed and sworn to before me on: June 8, 2010

Notary Public Signature: Wanda K Smith

My commission expires on: My Commission Expires November 7, 2012

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Tre Hargett

Tre Hargett
Secretary of State

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