CMR 120.000 and to the regulations of other agencies (such as the United States Department of Transportation, the United States Postal Service and the United States Nuclear Regulatory Commission) having jurisdiction over means of transport. The requirements of 105 CMR 120.770 are in addition to, and not in substitution for, other requirements

(C) The regulations in 105 CMR 120.770 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 105 CMR 120.770 authorizes possession of licensed material.

(D) Exemptions from the requirement for license are specified in 105 CMR 120.774. General licenses for which no package approval is required are issued in 105 CMR 120.777 to 120.782. The general license in 120.777 requires that an NRC certificate of compliance or other package approval be issued for the package to be used under this general license. The transport of licensed material or delivery of licensed material to a carrier for transport is subject to the operating control requirements and procedures of 105 CMR 120.785 through 120.793 to the quality assurance requirements of 105 CMR 120.794, and to the general provisions of 105 CMR 120.771 through 120.775, including referenced United States Department of Transportation regulations.

(E) The regulations in 105 CMR 120.770 apply to any person required to obtaina certificate of compliance or an approved compliance plan from the NRC pursuant to 10 CFR 76 if the person delivers radioactive material to a common or contract carrier for transport or transports the material outside the confines of the person's plant or other authorized place of use.

120.772: Definitions

The following terms are as defined here for the purpose of 105 CMR 120.770. To ensure compatibility with international transportation standards, all limits in this part are given in terms of dual units: The International System of Units (SI) followed or preceded by U.S. standard or customary units. The U.S. customary units are not exact equivalents but are rounded to a convenient value, providing a functionally equivalent unit. For the purpose of 105 CMR 120.770, either unit may be used.

~~As used in 105 CMR 120.770, the following definitions apply:~~

A_1 means the maximum activity of special form radioactive material permitted in a Type A package. This value is either listed in Appendix A, Table A-1, of 105 CMR 120.770, or may be derived in accordance with the procedures prescribed in Appendix A of 105 CMR 120.770.

A_2 means the maximum activity of radioactive material, other than special form material, LSA, and SCO material, permitted in a Type A package. This value is either listed in Appendix A, Table A-1, of 105 CMR 120.770, or may be derived in accordance with the procedures prescribed in Appendix A of 105 CMR 120.770.

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

Certificate of Compliance (CoC) means the certificate issued by the Commission under subpart D of this part which approves the design of a package for the transportation of radioactive material.

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

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

(3) For transport by any aircraft.

~~Closed Transport Vehicle means a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the radioactive material. The enclosure may be either temporary or permanent but shall limit access from top, sides, and ends. In the case of packaged materials, it may be of the "see-through" type.~~

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 §§ 71.22, 71.23, and 71.59.

Deuterium means, for the purposes of §§ 71.15 and 71.22, deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.

DOT means the U.S. Department of Transportation.

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

Fissile Material means the radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, ~~plutonium-238, plutonium-239, plutonium-241, uranium-233, or 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 105 CMR 120.772: Fissile Material. [1] Certain exclusions from fissile material controls are provided in 105 CMR 120 77?.

Graphite means, for the purposes of 105 CMR 120.77? and 120.78?, graphite with a boron equivalent content less than 5 parts per million and density greater than 1.5 grams per cubic centimeter.

~~Fissile Material Package means a fissile material packaging together with its fissile material contents.~~

Low Specific Activity (LSA) Material means radioactive material with limited specific activity which is nonfissile or excepted under 105 CMR 120.78?, and which ~~that~~ satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups:

(d) 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 Appendix A ~~Mill tailings, contaminated earth, concrete, rubble, other bulk debris, and activated material in which the radioactive material is essentially uniformly distributed, and the average specific activity does not exceed 10^{-6} A_2/g.~~

(2) LSA-II.

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

(b) Other ~~M~~ material in which the activity is distributed throughout and the average specific activity ~~radioactive material is essentially uniformly distributed, and the average specific activity~~ does not exceed 10^{-4} A_2/g for solids and gases, and 10^{-5} A_2/g for liquids.

(3) LSA-III. Solids (*e.g.*, consolidated wastes, activated materials), excluding powders, that satisfy the requirements of 105 CMR 120.7??, in which:

(a) The radioactive material is distributed throughout a solid or a collection of solid objects, ~~essentially uniformly 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.*);

(b) 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 A_2; and,

(c) The estimated average specific activity of the solid does not exceed 2 x 10^{-3} A_2/g.

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

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

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

Normal Form Radioactive Material means radioactive material which has not been demonstrated to qualify as special form radioactive material.

Nuclear Waste means a quantity ofsource, byproduct or special nuclear material required to be in US Nuclear Regulatory Commission-approved specification packaging while transported to, through or across a state boundary to a disposal site, or to a collection point for transport to a disposal site.

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 DOT regulations in 49 CFR part 173.

designated only as Type B. Limitations on its use are specified in §71.19.

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[1] Agency jurisdiction extends only to "special nuclear material in quantities not sufficient to form a critical mass" as defined in 105 CMR 120.001 5.

Regulations of the U.S. Nuclear Regulatory Commission (NRC) means the regulations in 10 CFR 71 for purposes of 105 CMR 120.770.

Special Form Radioactive Material means radioactive material which 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 five millimeters (0.2 inch); and

(3) It satisfies the test requirements specified by the Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on March 31, 1996, and constructed prior to April 1, 1998, may continue to be used. A special form encapsulation either designed or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.

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

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:

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

(b) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $4x10^4$ Bq/cm^2 (1.0 microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or $4x10^3$ Bq/cm^2 (0.1 microcurie/cm^2) for all other alpha emitters; and,

(c) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $4x10^4$ Bq/cm^2 (one microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or $4x10^3$ Bq/cm^2 (0.1 microcurie/cm^2) for all other alpha emitters.

(2) SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:

(a) The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 400 Bq/cm^2 (10^{-2} microcurie/cm^2) for beta and gamma and low toxicity alpha emitters or 40 Bq/cm^2 (10^{-3} microcurie/cm^2) for all other alpha emitters;

(b) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $8x10^5$ Bq/cm^2 (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or $8x10^4$ Bq/cm^2 (two microcuries/cm^2) for all other alpha emitters; and,

(c) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $8x10^5$ Bq/cm^2 (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or $8x10^4$ Bq/cm^2 (two microcuries/cm^2) for all other alpha emitters.

Type A Quantity means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in 105 CMR 120.795: *Appendix A* or may be determined by procedures described in 105 CMR 120.795: *Appendix A*.

~~Type A Package means a packaging that, together with its radioactive contents limited to A_1 or A_2 as appropriate, meets the requirements of 49 CFR 173.410 and 173.412 and is designed to retain the integrity of containment and shielding required by 105 CMR 120.770 under normal conditions of transport as demonstrated by the tests set forth in 49 CFR 173.465 or 173.466, as appropriate.~~

~~Type B Package means a Type B packaging together with its radioactive contents.[2]~~

~~Type B Packaging means a packaging designed to retain the integrity of containment and shielding when subjected to the normal conditions of transport and hypothetical accident test conditions set forth in 10 CFR Part 71.~~

Type B Quantity means a quantity of radioactive material greater than a Type A quantity.

Unirradiated Uranium means uranium containing not more than 2×10^{3} Bq of plutonium per gram of uranium-235, not more than 9×10^{6} Bq of fission products per gram of uranium-235, and not more than 5×10^{-3} g of uranium-236 per gram of uranium-235.

Uranium - Natural, Depleted, Enriched.

(1) Natural Uranium means uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).

(2) Depleted Uranium means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(3) Enriched Uranium means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

GENERAL REGULATORY PROVISIONS

120.773: 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 105 CMR 120.774.~~

Except as authorized in a general license or a specific license issued by the Agency, or as exempted in 105 CMR 120.775, no licensee may:

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

(B) Transport licensed material.

120.77~~5~~ 4: Transportation of Licensed Material

~~U.S. Department of Transportation; particularly the regulations of the U.S. Department of Transportation in the following areas~~ :

(a) Packaging--49 CFR part 173: subparts A, B, and I.

(b) Marking and labeling--49 CFR part 172: subpart D; and §§ 172.400 through 172.407 and §§ 172.436 through 172.441 of subpart E.

(c) Placarding--49 CFR part 172: subpart F, especially §§ 172.500 through 172.519 and 172.556; and appendices B and C.

(d) Accident reporting--49 CFR part 171: §§ 171.15 and 171.16.

(e) Shipping papers and emergency information--49 CFR part 172: subparts C and G.

(f) Hazardous material employee training--49 CFR part 172: subpart H.

(g) Security plans--49 CFR part 172: subpart I.

(h) Hazardous material shipper/carrier registration--49 CFR part 107: subpart G.

(2) The licensee shall also note DOT regulations pertaining to the following modes of transportation ~~The licensee shall also comply with the U.S. Department of Transportation regulations pertaining to the following modes of transportation~~ :

(a) Rail--49 CFR part 174: subparts A through D and K.

(b) Air--49 CFR part 175.

(c) Vessel--49 CFR part 176: subparts A through F and M.

(d) Public Highway--49 CFR part 177 and parts 390 through 397.

(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 105 CMR 120.242 ~~6~~(E).

(B) If, for any reason, the regulations of the U.S. Department of Transportation are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of 49 CFR Parts 170 through 189 appropriate to the mode of transport to the same extent as if the shipment was subject to the regulations.

120.775 ~~4~~: Exemptions

(A) Any physician licensed by a State to dispense drugs in the practice of medicine is exempt from 105 CMR 120.774 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 10 CFR part 35 or the equivalent Agreement State regulations.

(B ~~A~~) Common and contract carriers, freight forwarders, and warehouse workers who are subject to the requirements of the U.S. Department of Transportation in 49 CFR 170 through 189 or the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual), Section 124.3 incorporated by reference, 39 CFR 111.11 (1974), and the U.S. Postal Service are exempt from

~~to 49 CFR Part 173. A Type B package approved prior to September 6, 1983 was designated only as Type B. Limitations on its use are specified in 105 CMR 120.778.~~

~~(B) Any licensee is exempt from the requirements of 105 CMR 120.770 to the extent that the licensee delivers to a carrier for transport a package containing radioactive material having a specific activity not greater than 70 Bq/gm (0.002 microcurie per gram).~~

(C) ~~With the exception of 105 CMR 120.775 and 120.786,~~ A ~~a~~ licensee is exempt from all requirements of 105 CMR 120.770, with respect to shipment or carriage of the following low-level materials: ~~packages, provided the packages contain no fissile material, or the fissile material exemption standard of 10 CFR 71.53 are satisfied:~~

(1) 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 Appendix A, Table A–2, of 105 CMR 120.770.

(2) Materials for which the activity concentration is not greater than the activity concentration values specified in Appendix A, Table A–2 of this part, or for which the consignment activity is not greater than the limit for an exempt consignment found in Appendix A, Table A–2, of 105 CMR 120.770.

(C) Fissile materials meeting one of the following requirements are exempt from the 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 2 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) (a) (1) Low concentrations of solid fissile material commingled with solid nonfissile material, provided that:

1. There is at least 2000 grams of solid nonfissile material for every gram of fissile material, and
2. There is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile material.

(b) 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.

(c) 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.

(2) A package in which the only radioactive material is low specific activity (LSA) material or surface contaminated objects (SCO), provided the external radiation level at three meters from the unshielded material or objects does not exceed ten mSv/h (one rem/h); or,

(3) Packages transported between locations within the United States which contain only americium or plutonium in special form with an aggregate radioactivity not to exceed 740 Gbq (20 curies).

(D) A licensee is exempt from all requirements of 105 CMR 120.770, other than 105 CMR 120.775 and 120.786, with respect to shipment or carriage of low specific activity (LSA) material in group LSA-I, or surface contaminated objects (SCOs) in group SCO-I.

provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[3]

(C) Persons who transport radioactive material pursuant to the general licenses in 105 CMR 120.776(A) or (B) are exempt from the requirements of 105 CMR 120.200 and 120.750 to the extent that they transport radioactive material.

120.777: General License: Nuclear Regulatory Commission - 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, or other approval has been issued by the Nuclear Regulatory Commission.

(B) This general license applies only to a licensee who has a quality assurance program approved by the Nuclear Regulatory Commission as satisfying the provisions of subpart H of 10 CFR 71.

(C ~~B~~) This general license applies only to a licensee who:

(1) Has a copy of the specific license, certificate of compliance, or other approval by the Nuclear Regulatory Commission 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 Nuclear Regulatory Commission, as applicable, and the applicable requirements of 105 CMR 120.770;

(3) Before the licensee's first use of the package, submits in writing to: ATTN: Document Control Desk, Director, Spent Fuel Project Office, 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.

~~(3) Prior to the licensee's first use of the package, has registered with the Nuclear Regulatory Commission; and,~~

~~(4) Has a quality assurance program required by 105 CMR 120.790.~~

(D ~~C~~) The general license in 105 CMR 120.777(A) applies only when the package approval authorizes use of the package under this general license.

(E ~~D~~) For a Type B or fissile material package, the design of which was approved by the Nuclear Regulatory Commission before April 1, 1996, the general license is subject to the additional restrictions of 10 CFR 71.19. ~~105 CMR 120.778.~~

~~120.778: General License - Previously Approved Packages~~

~~(A) A Type B package previously approved by the Nuclear Regulatory Commission, but not designated as B(U) or B(M) in the identification number of the Nuclear Regulatory Commission Certificate of Compliance, may be used under the general license of 105 CMR 120.777 with the following additional conditions:~~

~~(1) Fabrication of the packaging was satisfactorily completed before August 31, 1986, as demonstrated by application of its model number in accordance with Nuclear Regulatory Commission regulations at 10 CFR 71.85(C);~~

~~without the designation "-85" in the identification number of the Nuclear Regulatory Commission Certificate of Compliance, may be used under the general license of 105 CMR 120.777 with the following additional conditions:~~

~~(1) Fabrication of the packaging was satisfactorily completed before April 1, 1999, as demonstrated by application of its model number in accordance with Nuclear Regulatory Commission regulations at 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. Department of Transportation regulations at 49 CFR 173.403; and,~~

~~(3) A serial number which uniquely identifies each packaging which conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging.~~

120.779: General License: U.S. 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 105 CMR 120.770; and,

(3) Has a quality assurance program as required by 105 CMR 120.790.

(C) This ~~e~~ general license in 105 CMR 120.779(A) 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.

(D) The general license specified in 105 CMR 120.779 expires in October 1, 2008.

120.780: General License - Use of Foreign Approved Package

(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 which has been revalidated by the U.S. Department of Transportation as meeting the applicable requirements of 49 CFR 171.12.

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

(C) This general license applies only to a licensee who:

(1) Has a quality assurance program approved by United States Nuclear Regulatory Commission;

(2 ~~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; and,

(2) Complies with the terms and conditions of the certificate and revalidation, and with the applicable requirements of 105 CMR 120.770~~; and~~, with respect to the quality assurance provisions of subpart H of 10 CFR 71, the licensee is exempt from design, construction, and fabrication considerations.

(B) The general license applies only to a licensee who has a quality assurance program approved by the Commission as satisfying the provisions of subpart H of 10 CFR 71. ~~This general license applies only a licensee who has a quality assurance program approved by the Nuclear Regulatory Commission as satisfying the provisions of 10 CFR Part 71 subpart H.~~

(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. ~~Except as provided in 105 CMR 120.781(D), this general license applies only when a package contains no more than a Type A quantity of radioactive material, including only one of the following:~~

~~(1) Up to 40 grams of uranium-235;~~

~~(2) Up to 30 grams of uranium-233;~~

~~(3) Up to 25 grams of the fissile radionuclides of plutonium, except that for encapsulated plutonium-beryllium neutron sources in special form, an A_1 quantity of plutonium may be present; or,~~

~~(4) A combination of fissile radionuclides in which the sum of the ratios of the amount of each radionuclide to the corresponding maximum amounts in 105 CMR 120.781(C)(1), (2), and (3) does not exceed unity.~~

(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 paragraph (E) of 105 CMR 120.781;

(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:

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

(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 I or II, as appropriate;

(4) If Table II 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 I values for X, Y, and Z must be used to determine the CSI if:

TABLE I —— Mass Limits for General License Packages Containing Mixed Quantities of Fissile Material or Uranium-235 of Unknown Enrichment per 105 CMR 120.781(E)

Fissile Materials	Fissile material mass mixed with moderating substances having an average hydrogen density less than or equal to H_2O. (grams)	Fissile material mass mixed with moderating substances having an average hydrogen density greater than H_2O[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 H_2O.

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

120.782: 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 105 CMR 120.782. This material need not be contained in a package which meets the standards of subparts E and F of 10 CFR 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 approved by the Commission as satisfying the provisions of 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 radioactive material; and,

(2) Contains less than 500 total grams of beryllium, graphyte, or hydrogenous material enriched in deuterium.

(E)(1) The value for the CSI must be greater than or equal to the number calculated by the following equation:

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

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

~~For packages where fissile material is mixed with substances having an average hydrogen density greater than water, this general license applies only when a package contains no more than a Type A quantity of radioactive material, including only one of the following:~~

~~(1) Up to 29g of uranium-235;~~

~~(2) Up to 18g of uranium-233;~~

~~(3) Up to 18g of fissile radionuclides of plutonium; or,~~

~~(4) A combination of fissile radionuclides in which the sum of the ratios of the amount of each radionuclide to the corresponding maximum amounts in 105 CMR 120.781(D) (1), (2), and (3) does not exceed unity.~~

~~(E) Except for the beryllium contained within the special form plutonium-beryllium sources authorized in 105 CMR 120.781(C), this general license applies only when beryllium, graphite, or hydrogenous material enriched in deuterium is not present in quantities exceeding 0.1% of the fissile material mass.~~

~~(F)(1) Except as specified in 105 CMR 120.781(F)(2) for encapsulated plutonium-beryllium sources, this general license applies only when, a package is labeled with a transport index not less than the number given by the following equation, where the package contains x grams of uranium-235, y grams of uranium-233, and z grams of the fissile radionuclides of plutonium:~~

~~Minimum Transport Index = (0.25x + 0.33y + 0.4z).~~

~~(2) For a package in which the only fissile material is in the form of encapsulated plutonium-beryllium neutron sources in special form, the transport index based on criticality considerations may be taken as 0.025 times the number of grams of the fissile radionuclides of plutonium.~~

~~(3) Packages which have a transport index greater than ten are not authorized under the general license provisions of 105 CMR 120.770.~~

~~120.782: General License: Fissile Material, Limited Moderator per Package~~

~~oils, are not present, except that polyethylene may be used for packing or wrapping;~~

~~(5) Uranium-233 is not present, and the amount of plutonium does not exceed 1% of the amount of uranium-235;~~

the number of grams of uranium-235 in the package divided by the maximum allowable number of grams per package in accordance with 105 CMR 120.782: TABLE I or TABLE II as applicable.

TABLE I

PERMISSIBLE MASS OF URANIUM-235 PER FISSILE MATERIAL PACKAGE [NONUNIFORM DISTRIBUTION]

Uranium enrichment in weight percent of uranium-235 not exceeding	Permissible maximum grams of uranium-235 per package
24	40
20	42
15	45
11	48
10	51
9.5	52
9	54
8.5	55
8	57
7.5	59
7	60
6.5	62
6	65
5.5	68
5	72
4.5	76
4	80
3.5	88
3	100
2.5	120
2	164
1.5	272
1.35	320
1	680*
0.92	1200*

~~3.5~~	~~92~~
~~3~~	~~112~~
~~2.5~~	~~148~~
~~2~~	~~240~~
~~1.5~~	~~560*~~
~~1.35~~	~~800*~~

~~*Pursuant to the Agency's agreement with the Nuclear Regulatory Commission, jurisdiction extends only to 350 grams of uranium-235.~~

~~(C) The licensee has a quality assurance program approved by Nuclear Regulatory Commission.~~

PACKAGE APPROVAL STANDARDS

120.783: External Radiation Standards for All Packages

(A) Except as provided in paragraph (B) of 105 CMR 120.783, each package of radioactive materials offered for transportation must be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 2 mSv/h (200 mrem/h) at any point on the external surface of the package, and the transport index does not exceed 10.

(B) A package that exceeds the radiation level limits specified in paragraph (A) of 105 CMR 120.783 must be transported by exclusive use shipment only, and the radiation levels for such shipment must not exceed the following during transportation:

(1) 2 mSv/h (200 mrem/h) on the external surface of the package, unless the following conditions are met, in which case the limit is 10 mSv/h (1000 mrem/h):

(a) The shipment is made in a closed transport vehicle;

(b) The package is secured within the vehicle so that its position remains fixed during transportation; and,

(c) There are no loading or unloading operations between the beginning and end of the transportation;

(2) 2 mSv/h (200 mrem/h) at any point on the outer surface of the vehicle, including the top and underside of the vehicle; or in the case of a flat-bed style vehicle, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load or enclosure, if used, and on the lower external surface of the vehicle; and

(3) 0.1 mSv/h (10 mrem/h) at any point 2 meters (80 in) from the outer lateral surfaces of the vehicle (excluding the top and underside of the vehicle); or in the case of a flat-bed style vehicle, at any point 2 meters (6.6 feet) from the vertical planes projected by the outer edges

shipment controls. The instructions must be included with the shipping paper information.

(D) The written instructions required for exclusive use shipments must be sufficient so that, when followed, they will cause the carrier to avoid actions that will unnecessarily delay delivery or unnecessarily result in increased radiation levels or radiation exposures to transport workers or members of the general public.

OPERATING CONTROLS AND PROCEDURES

120.784 ~~3~~: Assumptions as to Unknown Properties of Fissile Material

~~(A) Applicability of Operating Controls and Procedures. A licensee subject to 10 CFR 120.770, who, under a general or specific license, transports licensed material or delivers licensed material to a carrier for transport, shall comply with the requirements of 10 CFR 71 subpart G, with the quality assurance requirements of subpart H of 10 CFR part 71, and with the general provisions of subpart A of 10 CFR 71.~~

(A ~~B~~) 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.

120.785 ~~4~~: Preliminary Determinations

Prior to the first use of any packaging for the shipment of licensed ~~radioactive~~ material:

(A) The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging; ~~The licensee shall ascertain that there are no defects which could significantly reduce the effectiveness of the packaging;~~

(B) Where the maximum normal operating pressure will exceed 35 kPa ~~kilopascal~~ (five lbf/in^2) gauge, the licensee shall test the containment system at an internal pressure at least 50~~%~~ percent higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure;

(C) The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by NRC. Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the Nuclear Regulatory Commission. ~~The licensee shall determine that the packaging has been fabricated in accordance with the design approved by the Nuclear Regulatory Commission; and,~~

determine that: determine that:

(A) The package is proper for the contents to be shipped;

(B) The package is in unimpaired physical condition except for superficial defects such as marks or dents;

(C) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

(D) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

(E) Any pressure relief device is operable and set in accordance with written procedures;

(F) The package has been loaded and closed in accordance with written procedures;

(G) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

(H ~~G~~) Any structural part of the package which 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;

(I) The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable, and within the limits specified in DOT regulations in 49 CFR 173.443

(J) External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in §§ 71.47 at any time during transportation; and,

(K) Accessible package surface temperatures will not exceed the limits specified in §§ 71.43(g) at any time during transportation.

~~(H) The level of removable radioactive) contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable.~~

~~(1) The level of non-fixed (removable) radioactive contamination may be determined by wiping an area of 300 square centimeters of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements must be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. Except as provided in 105 CMR 120.785(H)(2), the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, must not exceed the limits given in 105 CMR 120.785: TABLE III at any time during transport. Other methods of assessment of equal or greater~~

TABLE III

NON-FIXED (REMOVABLE EXTERNAL RADIOACTIVE CONTAMINATION - WIPE LIMITS

Contaminant	Maximum Permissible Limits		
	Bq/cm^2	µCi/cm^2	dpm/cm^2
Beta and gamma emitters and low toxicity alpha emitters	0.4	10^{-5}	22
All other alpha emitting radionuclides	0.04	10^{-6}	2.2

(I) External radiation levels around the package and around the vehicle, if applicable, will not exceed two mSv/h (200 millirems per hour) at any point on the external surface of the package at any time during transportation. The transport index shall not exceed 10.0;

(J) For a package transported in exclusive use by rail, highway or water, radiation levels external to the package may exceed the limits specified in 105 CMR 120.785(A) but shall not exceed any of the following:

(1) Two mSv/h (200 millirems per hour) on the accessible external surface of the package unless the following conditions are met, in which case the limit is ten mSv/h (1000 millirems per hour);

(a) The shipment is made in a closed transport vehicle;

(b) Provisions are made to secure the package so that its position within the vehicle remains fixed during transportation; and,

(c) There are no loading or unloading operations between the beginning and end of the transportation.

(2) Two mSv/h (200 millirems per hour) at any point on the outer surface of the vehicle, including the top and underside of the vehicle, or, in the case of a flat-bed style vehicle, with a personnel barrier, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load (or enclosure, if used), and on the lower external surface of the vehicle; A flat-bed style vehicle with a personnel barrier shall have radiation levels determined at vertical planes. If no personnel barrier is in place, the package cannot exceed two mSv/h (200 millirems per hour) at any accessible surface;

(3) 0.1 mSv/h (ten millirems per hour) at any point two meters from the vertical planes represented by the outer lateral surfaces of the vehicle, or, in the case of a flat-bed style vehicle, at any point two meters from the vertical planes projected from the outer edges of the vehicle; and,

(4) 0.02 mSv/h (two millirems per hour) in any normally occupied positions of the vehicle, except that this provision does not apply to private motor carriers when persons occupying these positions are provided with special health supervision, personnel radiation exposure monitoring devices, and training in accordance with 105 CMR 120.753; and,

~~120.787 6: Air Transport of Plutonium~~

Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in 105 CMR 120.770 or included indirectly by citation of the U.S. Department of Transportation regulations, 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:

(A) The plutonium is contained in a medical device designed for individual human application; or

(B) The plutonium is contained in a material in which the specific activity is not greater than or equal to the activity concentration values for plutonium specified in Appendix A, Table A-2, of 105 CMR 120.770 ~~70 Bq/gm (0.002 microcuries per gram) of material~~ and in which the radioactivity is essentially uniformly distributed; or

(C) The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form and is shipped in accordance with 105 CMR 120.774 ~~5~~; or,

(D) The plutonium is shipped in a package specifically authorized (in the Certificate of Compliance issued by the Nuclear Regulatory Commission for that package) for the shipment of plutonium by air. ~~and the licensee requires, through special arrangement with the carrier, compliance with 49 CFR 175.704, the U.S. Department of Transportation regulations applicable to the air transport of plutonium.~~

(E) For a shipment of plutonium by air which is subject to paragraph (D) of 105 CMR 120.787, 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.

120.788 ~~7A~~: 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 105 CMR 120.242 ~~6~~(E).

~~120.787: Shipment Records~~

~~Each licensee shall maintain for a period of three years after shipment a record of each shipment of licensed material not exempt under 105 CMR 120.774, showing, where applicable:~~

~~(A) Identification of the packaging by model number and serial number;~~

~~(B) Verification that the packaging, as shipped, had no significant defects;~~

~~(C) Volume and identification of coolant;~~

(G) Address to which the shipment was made; and,

(H) Results of the determinations required by 105 CMR 120.785 and by the conditions of the package approval.

120.788: Reports

The licensee shall report to the Agency within 30 days:

(A) Any instance in which there is significant reduction in the effectiveness of any packaging during use;

(B) 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,

(C) Instances in which the conditions of approval in the certificate of compliance were not observed in making a shipment.

120.789: Advance Notification of Shipment of Irradiated Reactor Fuel and Transport of Nuclear Waste

(A) As specified in paragraphs (B), (C) and (D) of 105 CMR 120.789, each licensee shall provide advance notification to the governor of a State, or the governor's designee, of the shipment of licensed material, through, or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage. 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 to the governor, or governor's designee, of each state within or through which the waste will be transported. A list of the mailing addresses of the governors and governors' designees is available upon request from the U.S. Nuclear Regulatory Commission, Document Control Desk, P1-37, Washington, D.C. 20555 Attn: Director, OSP. The list will be published annually in the Federal Register on or about June 30 to reflect any changes in information.

(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 773.37(f). Advance notification is also required under this section for shipment of licensed material, other than irradiated fuel, meeting the following three conditions: only when:

(1) The licensed material is by 10 CFR 71 nuclear waste is required to be in Type B packaging for transportation;

(2) The licensed material nuclear waste is being transported into, within, or through a state 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:

(a) 3000 times the A_1 value of the radionuclides as specified in 105 CMR 120.795:

(2) A notification delivered by mail must be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

(3) A notification delivered by any other means than mail must reach the office of the governor or of the governor's designee at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

(a) 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).

(b) The list will be published annually in the Federal Register on or about June 30 to reflect any changes in information.

(c) A list of the names and mailing addresses of the governors' designees is available on request from the Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(4) The licensee shall retain a copy of the notification as a record for 3 years.

(D) *Information to be furnished in advance notification of shipment.* Each advance notification of shipment of irradiated reactor fuel or nuclear waste must contain the following information:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste shipment;

(2) A description of the irradiated reactor fuel or nuclear waste contained in the shipment, as specified in the regulations of DOT in 49 CFR 172.202 and 172.203(d);

(3) The point of origin of the shipment and the 7-day period during which departure of the shipment is estimated to occur;

(4) The 7-day period during which arrival of the shipment at State boundaries is estimated to occur;

(5) The destination of the shipment, and the 7-day period during which arrival of the shipment is estimated to occur; and

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

(E) *Revision notice.* A licensee who finds that schedule information previously furnished to a governor or governor's designee, in accordance with this section, will not be met, shall telephone a responsible individual in the office of the governor of the State or of the governor's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for 3 years

(F) *Cancellation notice.* (1) Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified, and to the Director, Division of Nuclear Security, Office of Nuclear Security and Incident Response.

(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

~~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 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 105 CMR 120.789(A) shall be made in writing to the office of each appropriate governor, or governor's designee, and to the Agency. A notification delivered by mail must 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 messenger must reach the office of the governor, or governor's designee, 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 year.~~

~~(E) The licensee shall notify each appropriate governor, or governor's designee, and the Agency of any changes to schedule information provided pursuant to 105 CMR 120.789(A). Such notification shall be by telephone to a responsible individual in the office of the governor, or governor's designee, of the appropriate state or states. The licensee shall maintain for three year 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 cancelled, to the governor, or governor's designee, of each appropriate state and to the Agency. A copy of the notice shall be retained by the licensee for three year.~~

QUALITY ASSURANCE

120.790: Quality Assurance Requirements

(A) *Purpose.* The regulations under quality assurance describe quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this subpart, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. 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 subpart.

(B) *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

the requirements of 10 CFR 34.31(b) or equivalent Agreement State requirement, is deemed to satisfy the requirements of 105 CMR 120.777 and 105 CMR 120.790(B).

120.791: Quality Assurance Organization

(A) The licensee[2], 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.

(B) 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 functions that are important to safety have been correctly performed.

120.793: Quality Assurance Program

(A) 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.

(B) 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:

(1) The impact of malfunction or failure of the item to safety;

(2) The design and fabrication complexity or uniqueness of the item;

(3) The need for special controls and surveillance over processes and equipment;

(4) The degree to which functional compliance can be demonstrated by inspection or test; and

(5) The quality history and degree of standardization of the item.

(C) 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.

~~Unless otherwise authorized by the Agency, each licensee shall establish, maintain, and execute a quality assurance program to verify by procedures such as checking, auditing, and inspection that~~

packaging is used.

~~(D) Prior to the use of any package for the shipment of radioactive material, each licensee shall obtain approval by the Agency of its quality assurance program.~~

materials are subject to controls placed on fissile material.

II. (a) For individual radionuclides whose identities are known, but which are not listed in Table A-1, the A_1 and A_2 values contained in Table A-3 may be used. Otherwise, the licensee shall obtain prior Commission approval of the A_1 and A_2 values for radionuclides not listed in Table A-1, before shipping the material.

(b) For individual radionuclides whose identities are known, but which are not listed in Table A-2, the exempt material activity concentration and exempt consignment activity values contained in Table A-3 may be used. Otherwise, the licensee shall obtain prior Commission approval of the exempt material activity concentration and exempt consignment activity values for radionuclides not listed in Table A-2, before shipping the material.

(c) The licensee shall submit requests for prior approval, described under paragraphs II(a) and II(b) of this Appendix, to the Commission, in accordance with 10 CFR 71.1.

~~the determination of the values of A_1 and A_2 requires Department approval, except that the values of A_1 and A_2 in Table A-2 may be used without obtaining Agency approval.~~

III. In the calculations of A_1 and A_2 for a radionuclide not in Table A-1, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter nuclide has a half-life either longer than ten days, or longer than that of the parent nuclide, shall be considered as a single radionuclide, and the activity to be taken into account, and the A_1 or A_2 value to be applied shall be those corresponding to the parent nuclide of that chain. In the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than ten days, or greater than that of the parent nuclide, the parent and those daughter nuclides shall be considered as mixtures of different nuclides.

IV. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:

(a) For special form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} \leq 1$$

where B(i) is the activity of radionuclide I, and $A_1(i)$ is the A_1 value for radionuclide I.

(b) For normal form radioactive material, the maximum quantity transported in a Type A package is:

$$\sum_i \frac{B(i)}{A_2(i)} \leq 1$$

where B(i) is the activity of radionuclide i and $A_1(i)$ and $A_2(i)$ are the A_1 and A_2 values for radionuclide respectively.

(d) Alternatively, the ~~An~~ A_2 value for mixtures of normal form material may be determined as follows:

$$A_2 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$$

where f(i) is the fraction of activity of nuclide i in the mixture and $A_2(i)$ is the appropriate A_2 value for nuclide I~~-i~~.

(e) The exempt activity concentration for mixtures of nuclides may be determined as follows:

$$\text{Exempt activity concentration for mixture} = \frac{1}{\sum_i \frac{f(i)}{[A](i)}}$$

where f(i) is the fraction of activity of radionuclide I in the mixture, and [A] is the activity concentration for exempt material containing radionuclide I.

(f) The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:

$$\text{Exempt consignment activity limit for mixture} = \frac{1}{\sum_i \frac{f(i)}{A(i)}}$$

where f(i) is the fraction of activity of radionuclide I in the mixture, and A is the activity limit for exempt consignments for radionuclide I.

V. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides