

NUCLEAR REGULATORY COMMISSION

10 CFR Part 71

RIN: 3150 - AG71

**COMPATIBILITY WITH IAEA TRANSPORTATION SAFETY STANDARDS (TS-R-1) AND
OTHER TRANSPORTATION SAFETY AMENDMENTS**

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations on packaging and transporting radioactive material. This rulemaking will make the regulations compatible with the latest version of the International Atomic Energy Agency (IAEA) standards and codify other applicable requirements. This final rule also makes changes in fissile material exemption requirements to address the unintended economic impact of NRC's emergency final rule entitled "Fissile Material Shipments and Exemptions" (February 10, 1997; 62 FR 5907). Lastly, this rule addresses a petition for rulemaking submitted by International Energy Consultants, Inc.

EFFECTIVE DATE: This final rule is effective on (insert date 1 year after the date of publication). The amendments to § 71.19 are effective on (insert date 5 years after date of publication).

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I. Background

Before developing and publishing a proposed rule, the NRC began an enhanced public-participation process designed to solicit public input on the Part 71 rulemaking. The NRC issued a Part 71 issues paper for public comment (65 FR 44360; July 17, 2000). The issues paper presented the NRC's plan to revise Part 71 and provided a summary of all changes being considered, both International Atomic Energy Agency (IAEA)-related changes and NRC-initiated changes. The NRC received 48 public comments on the issues paper. The NRC enhanced public participation process included establishing an interactive website and holding three facilitated public meetings: a "roundtable" workshop at NRC Headquarters, Rockville, MD, on August 10, 2000, and two "townhall" meetings - one in Atlanta, GA, on September 20, 2000, and a second in Oakland, CA, on September 26, 2000. Oral and written comments, received from the public meetings by mail and through the NRC website, in response to the issues paper were considered in drafting the proposed rule.

The NRC published the proposed rule in the Federal Register on April 30, 2002 (67 FR 21390) for a 90-day public comment period. In addition to approving the publication of the proposed rule, the Commission also directed the NRC staff to continue the enhanced public participation process. The NRC staff held two public meetings to discuss the proposed rule. The first meeting was held in Chicago, Illinois, on June 4, 2002, and the second was held at the TWFN Auditorium, NRC Headquarters, on June 24, 2002. In addition, the Department of Transportation (DOT) staff participated in these meetings. Transcripts of these meetings were made available for public review on the NRC website. The public comment period closed on July 29, 2002. A total of 192 comments were received. Although many comments were

received after the closing date, all comments were analyzed and considered in developing this final rule.

Past NRC-IAEA Compatibility Revisions.

Recognizing that its international regulations for the safe transportation of radioactive material should be revised from time to time to reflect knowledge gained in scientific and technical advances and accumulated experience, IAEA invited Member States (the U.S. is a Member State) to submit comments and suggest changes to the regulations in 1969. As a result of this initiative, the IAEA issued revised regulations in 1973 (Regulations for the Safe Transport of Radioactive Material, 1973 edition, Safety Series No. 6). The IAEA also decided to periodically review its transportation regulations, at intervals of about 10 years, to ensure that the regulations are kept current. In 1979, a review of IAEA's transportation regulations was initiated that resulted in the publication of revised regulations in 1985 (Regulations for the Safe Transport of Radioactive Material, 1985 edition, Safety Series No. 6).

The NRC also periodically revises its regulations for the safe transportation of radioactive material to make them compatible with those of the IAEA. On August 5, 1983 (48 FR 35600), the NRC published a revision of 10 CFR Part 71. That revision, in combination with a parallel revision of the hazardous materials transportation regulations of DOT, brought U.S. domestic transport regulations into general accord with the 1973 edition of IAEA transport regulations. The last revision to Part 71 was published on September 28, 1995 (60 FR 50248), to make Part 71 compatible with the 1985 IAEA Safety Series No. 6. The DOT published its corresponding revision to Title 49 on the same date (60 FR 50291).

The last revision to the IAEA Safety Series 6, Safety Standards Series ST-1, was published in December 1996, and revised with minor editorial changes in June 2000, and redesignated as TS-R-1.

Historically, the NRC has coordinated its Part 71 revisions with DOT, because DOT is the U.S. Competent Authority for transportation of hazardous materials. “Radioactive Materials” is a subset of “Hazardous Materials” in 49 CFR under DOT authority. Currently, DOT and NRC co-regulate transport of nuclear material in the United States. The NRC is continuing with its coordinating effort with the DOT in this rulemaking process. Refer to the DOT's corresponding rule for additional background on the positions presented in this final rule.

Scope of 10 CFR Part 71 Rulemaking.

As directed by the Commission, the NRC staff compared TS-R-1 to the previous version of Safety Series No. 6 to identify changes made in TS-R-1, and then identified affected sections of Part 71. Based on this comparison, the NRC staff identified 11 areas in Part 71 that needed to be addressed in this rulemaking as a result of the changes to the IAEA regulations. The NRC staff grouped the Part 71 IAEA compatibility changes into the following issues:

(1) Changing Part 71 to the International System of Units (SI) only; (2) Radionuclide Exemption Values; (3) Revision of A_1 and A_2 ; (4) Uranium Hexafluoride (UF_6) Package Requirements; (5) Introduction of the Criticality Safety Index Requirements; (6) Type C Packages and Low Dispersible Material; (7) Deep Immersion Test; (8) Grandfathering Previously Approved Packages; (9) Changes to Various Definitions; (10) Crush Test for Fissile Material Package Design; and (11) Fissile Material Package Design for Transport by Aircraft.

Eight additional NRC-initiated issues (numbers 12 through 19) were identified by Commission direction and NRC staff consideration for incorporation in Part 71. These NRC-

initiated changes are: (12) Special Package Authorizations; (13) Expansion of Part 71 Quality Assurance (QA) Requirements to Certificate of Compliance (CoC) Holders; (14) Adoption of the American Society of Mechanical Engineers (ASME) Code for Fabrication of Spent Fuel Transportation Packages; (15) Change Authority for Dual-Purpose Package Certificate Holders; (16) Fissile Material Exemptions and General License Provisions; (17) Decision on Petition for Rulemaking on PRM-71-12, Double Containment of Plutonium; (18) Contamination Limits as Applied to Spent Fuel and High-Level Waste (HLW) Packages; and (19) Modifications of Event Reporting Requirements. The first 18 issues were published for public comment in an issues paper in the Federal Register on July 17, 2000 (65 FR 44360). Also, the authority citation for Part 71 has been corrected to include section 234.

This final rule has been coordinated with DOT to ensure that consistent regulatory standards are maintained between NRC and DOT radioactive material transportation regulations, and to ensure coordinated publication of the final rules by both agencies. The DOT also published its proposed rule regarding adoption of TS-R-1 April 30, 2002 (67 FR 21328).

II. Analysis of Public Comments

As previously stated, the NRC held two facilitated public meetings in 2002 to discuss and hear public comments on the proposed rule. (Three other facilitated public meetings were held in 2000 before drafting the proposed rule.) Each of these meetings was transcribed by a court reporter. The meeting transcripts and condensed summaries of the comments made in the meeting are available to the public on the NRC's interactive rulemaking website at <http://ruleforum.llnl.gov>, and the Public Document Room (PDR) located at One White Flint North, 11555 Rockville Pike, Room O-1F23, Rockville, MD. The NRC has made copies of

publicly released documents available on the website at <http://www.nrc.gov/waste/spent-fuel-transp.html>.

This section provides a summary of the general comments not associated with the 19 issues but rather with general topics related to this rule and the rulemaking process. These are organized under the following subheadings: Compatibility with IAEA and DOT standards, Regulatory Analysis (RA) and Environmental Assessment (EA), State Regulations, Terrorism, Adequacy of NRC Regulations and Rulemaking Process, Proposed Yucca Mountain Facility, and Miscellaneous (including comments to DOT). A summary of public comments associated with a specific issue is included in Section III of this Supplementary Information.

Compatibility with IAEA and DOT standards.

Comment. Several commenters generally supported NRC's efforts to be consistent with IAEA regulations. The particular reasons for this support varied among commenters but included such issues as approving of harmonization and encouraging NRC's coordination with DOT. For example, some commenters stated that harmonization enhances the industry's ability to import shipments and conduct business in compliance with both national and international regulations. One commenter urged the NRC to move swiftly to complete this rulemaking effort and to remain consistent with DOT regulations. One commenter stated that uniform international regulations were in the public's best interest for the safe movement of nuclear materials. Further, this commenter urged the NRC to accelerate the "harmonization" with international regulations to simplify procedures for companies that ship nuclear waste both domestically and internationally.

Response. The NRC acknowledges these comments, and the NRC continues to work to finalize this rule as expeditiously as possible. As with the issuance of the proposed rule, the

NRC will continue to coordinate closely with the DOT in this effort to ensure consistency between regulations for the transportation of certain radioactive materials.

Comment. A commenter supported harmonization but said that adoption of new or modified requirements into the domestic regulations for transportation of radioactive materials must be justified in terms of cost and the need for improved safety and performance. The commenter added that some of the changes, including the additional technical complexity of the proposed regulations (e.g., nuclide specific thresholds), are not warranted based on the history of performance in the transportation of radioactive materials.

Another commenter noted several areas of incompatibility between DOT and NRC proposed rules. The commenter also suggested that NRC work with DOT to agree on a consistent approach in organizing the A_1 and A_2 values for international shipments in Table A-1. A third commenter noted that DOT has already issued a proposed rule, HM 232, which focuses on using the registration program to affect the enhancement and security of radioactive materials in transport.

Response. NRC's goal is to harmonize our transportation regulations to be consistent with IAEA and DOT, while ensuring that the requirements adopted will benefit public health, safety, and the environment. The NRC has conducted an evaluation of the radionuclide-specific thresholds (the exemption values), including a regulatory analysis and an environmental assessment, and concluded that adoption of these values is warranted, in spite of the technical complexity. NRC has been working with the DOT. The NRC has completed a regulatory analysis that supports harmonization in terms of cost and regulatory efficiency.

Comment. One commenter stated that NRC should use the latest medical knowledge from independent sources [i.e., not IAEA or International Commission on Radiological Protection (ICRP) data] regarding the medical effects of radiation.

Response. The NRC considers a variety of sources of information concerning the health effects attributed to exposure to ionizing radiation. Two primary sources of information are the National Research Council/National Academy of Sciences (NAS) and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). Both groups provide an independent and comprehensive evaluation of the health risks associated with radiation exposure. The NRC currently is sponsoring an NAS review of information from molecular, cellular, and animal studies of radiation, other environmental exposures, and epidemiologic studies to evaluate and update previous reviews of the health risks related to exposure to low-level ionizing radiation. These studies focus on the latest published information available.

Comment. Several commenters questioned the credibility of the IAEA and the ICRP because these organizations are not publicly accountable. Three of the commenters further questioned the process of the NRC simply accepting what the IAEA does, noting that agencies in Europe have challenged ICRP assumptions. One of these commenters stated that regulated or potentially regulated bodies should be allowed more involvement in the IAEA decisionmaking process. Furthermore, the suggested lack of public involvement led one commenter to express a general lack of trust for these organizations and question the credibility of their conclusions. This lack of public involvement was at issue with another commenter who added that the proposal would only “make things easier for the transportation and nuclear industries at the expense of public health.”

Response. The United States is represented at the IAEA for transportation issues through the DOT acting as Competent Authority (the official U.S. representative organization). The NRC consults with DOT on issues related to nuclear material transport. NRC disagrees with the statement that the NRC simply accepts what the IAEA does. When the NRC (and the

DOT) seeks to amend its regulations to harmonize with IAEA's, it does so through a deliberate and open process via rulemaking. The public has been afforded in the past, and will continue to be afforded, the opportunity to comment on DOT's and NRC's proposed rulemakings. This effort can result in NRC regulations not matching the IAEA guidance. Further, the NRC does not "simply accept" the IAEA standards. In many instances, the NRC has chosen to implement regulations that differ from the IAEA's. Issues 7 and 11 of this final rule, discussed elsewhere in this Supplementary Information, are just two examples of where NRC has differed from the IAEA requirements by implementing more stringent requirements.

Information on the IAEA and ICRP can be found at their respective websites: www.iaea.org and www.icrp.org. These websites provide background on each organization that should address the concerns about the credibility of each organization.

Comment. One commenter stated that the burden of proof for departing from IAEA standards is shifted by the regulators to the regulated entities. Another commenter suggested that the burden of proof for rejecting the proposed regulatory changes is being shifted to citizens and stakeholders.

Response. Both the NRC and DOT are participating members of the IAEA and have direct input to the development of new transportation standards. Before DOT or NRC proposes U.S. regulations for harmonization with IAEA standards, each agency completes a technical evaluation and makes a determination if each new standard should be adopted by the U.S. The public involvement process for rulemaking solicits stakeholders to suggest changes to proposed rule language or to suggest the rejection of a proposed regulatory change. With sufficient justification, public comments have resulted in modification to regulatory text.

Comment. One commenter asked if either NRC standards or IAEA's could protect the public from "real world" problems. The commenter inquired how NRC accounts for the fact that

a cask might burn for longer than existing standards require it to withstand fire. The commenter believed that such rationales were particularly relevant in light of recent incidents, such as the Baltimore Tunnel fire and the Arkansas River bridge accident.

Response. The NRC notes the questions on how realistic the transportation standards established by the NRC and the IAEA are. Both NRC and IAEA standards require that cask designs be able to withstand hypothetical accident conditions. The conditions bound (or are more severe than) those conditions that would be expected in the vast majority of real world accidents and therefore provide protection for the cask designs. Additionally, the NRC has periodically revisited and evaluated the effects of actual accidents to look at the forces and the challenges that would be presented to casks in “real world” transportation accidents. For example, in response to the Baltimore Tunnel fire, the NRC staff has conducted two sets of independent analyses and has determined that the conditions that existed in the fire would not have caused a breach of a current spent fuel transportation cask design had it been located in the tunnel for the duration of the fire.

Comment. One commenter stated that the timeline by which NRC would adopt IAEA requirements should be changed. The commenter also stated that the current 2-year cycle for changes is too frequent.

Response. The timeline for adopting IAEA standards and the cycle for making changes at the IAEA are beyond the scope of this rulemaking.

Comment. One commenter stated that the proposed rule might allow weakening of transportation cask safety testing and increase the risk of the release of radioactive materials during transportation accidents.

Response. This concern is acknowledged, but the NRC does not believe that this rule weakens testing standards.

Comment. One commenter stated that all radioactive shipments should be regulated and labeled so that transportation workers and emergency responders are aware of the risk.

Response. The comments are acknowledged. DOT regulations include requirements for labels, markings, and placarding packages and conveyances of radioactive materials, and training of Hazmat workers. Existing and proposed regulations for the transportation of radioactive materials consider the potential risk to workers and emergency responders of exposure to these materials. The NRC believes the thresholds for regulation of the transportation of radioactive materials are suitably protective of workers and emergency responders.

Comment. One commenter pointed out that due to the increase in the number of nuclear shipments, the NRC and DOT must strengthen their standards to protect the millions of people, thousands of schools, and hundreds of hospitals residing directly along transportation routes.

Response. The NRC routinely reevaluates the effectiveness of its regulations to ensure that it is meeting its mission to protect the public health and safety. In regulating safe and secure transport of spent nuclear fuel, the NRC has conducted risk studies to consider the fact that a large number of shipments might be made to a future geological repository using current generation cask designs. These studies have confirmed that the current NRC regulations support safe shipments in large numbers to a centrally located storage facility.

Comment. On behalf of the nuclear industry, one commenter said that harmonization is logical in terms of cost and safety. Harmonized rules and uniform standards and criteria allow members of the nuclear industry to know how safe a package is, regardless of where it comes from. Because many other nations have already adopted many of these proposed rules, U.S.

transporters are already required to meet these standards in many cases. The commenter also voiced support for exempting certain domestic shipments from these international regulations.

Response. Harmonization with TS-R-1 should maintain the safety of shipments of radioactive materials while eliminating the need to satisfy two different regulatory requirements (i.e., domestic versus international shipments). The NRC believes that by clarifying and simplifying shipping requirements, harmonization will help all who are involved in the transport of radioactive material to comply successfully with regulations.

Comment. One commenter stated that there has already been much deliberation over the proposed regulations. He stated that his organization and the industry at large have been looking at these proposed changes for well over 10 years.

Response. The comments are acknowledged.

Comment. One commenter stated that harmonization is a “value neutral process” and isn’t necessarily good or bad.

Response. Harmonization can be viewed as a value neutral process, although the NRC believes that harmonizing domestic and international regulations generally improves efficiency and safety in the transport of radioactive material. NRC’s proposed changes are based upon the careful evaluation of specific issues and provisions in TS-R-1. At this level, the NRC believes that the negative (i.e., costs) or positive (i.e., benefits) value of a particular change can be assessed effectively. These costs and benefits have been carefully evaluated in our decisionmaking process.

Comment. Four commenters opposed harmonizing rules. One commenter opposed harmonization because it “appears to be occurring to satisfy demands of the nuclear industry and affected governmental bodies” to facilitate commerce, rather than in the interest of public safety. Another commenter noted that the primary objective of these changes should be to

protect public health, safety, and the environment. Another commenter argued that harmonization should not be used as a justification for violating a country's sovereignty or a State's right to maintain stringent standards. The commenter said that U.S. rules were already harmonized before these proposed changes and that the authors of international regulations should not dictate U.S. regulations. The fact that other countries have adopted the IAEA regulations is not sufficient justification for the U.S. to adopt these regulations. The commenter agreed that some degree of harmonization makes sense but emphasized that the U.S. needs to maintain control over its own rules.

Response. The IAEA periodically updates international regulations for the safe transport of radioactive material in response to advances in scientific knowledge and technical experience. These changes are implemented with the purpose of improving public safety, as well as facilitating commerce. The U.S. has substantial input into the IAEA development of these periodic revisions through official representation by the DOT. While the NRC aims to harmonize its regulations closely with those issued by the IAEA, NRC independently evaluates proposed changes in the interest of protecting public health, safety, and the environment. This rule reflects this extensive process; NRC routinely suggests adoption or partial adoption of certain provisions and nonadoption of others.

Comment. Two commenters asked if NRC could quantifiably prove that harmonization is necessary. One asked if NRC's failure to comply with the IAEA regulations has disrupted commerce or jeopardized public safety, and whether members of the international community have accused the U.S. of disrupting commerce by not complying with these regulations.

Response. DOT and NRC accomplish harmonization by adopting domestic rules that are compatible with international rules. DOT and NRC rules may differ from those of IAEA where it is necessary to reflect domestic practices. However, these differences are kept to a

minimum because regulatory differences can lead to confusion and errors and result in unsafe conditions or events. U.S. failure to comply with international safety regulations could easily result in disruption of U.S. participation in international radioactive material commerce, with no commensurate justifiable safety benefit, because other IAEA Member States are under no obligation to accept shipments that do not comply with international regulations.

Comment. One commenter wanted to know how the IAEA drafted its regulations and statistics. The commenter questioned who the IAEA is and why NRC should accept its statistics. The commenter also asked how much input the American public has had on these regulations and noted that Congress and the public have previously rejected IAEA regulations.

Response. The comments concerning the IAEA standards development process and U.S. citizen input to that process are both beyond the scope of this rulemaking. However, as noted in the public meetings held to obtain comments on the proposed rule, DOT is mandated by law to help formulate international transportation standards, and to ensure that domestic regulations are consistent with international standards to the degree deemed appropriate. The law permits DOT the flexibility to accept or reject certain of the international standards. The NRC/DOT evaluation of the IAEA standards has resulted in the two parallel sets of final rule changes. Rejection of an IAEA standard could be based on technical criteria as well as on public comment on proposed rules. The IAEA has Member States that develop standards as a collegial body, and the U.S. is one of those Member States.

Comment. Several commenters urged NRC to improve its scientific understanding and basis for the proposed rulemaking. Two commenters suggested that NRC complete the comprehensive assessments of TS-R-1 and future IAEA standards, the Package Performance Study (PPS), and real cask tests before proceeding with this rulemaking. A commenter stressed that ICRP does not represent the full range of scientific opinion on radiation and health

and ignores concepts such as the bystander effect and synergism of radiation with other environmental contaminants. This commenter also stated that the exposure models used to justify certain exposure scenarios are inadequate.

Response. The NRC acknowledges these comments and notes that NRC participates or monitors the work of major, national and international, scientific organizations in the fields of health physics and radiation protection. As such, NRC has access to the latest scientific advances. Moreover, the NRC has completed an assessment of TS-R-1 as part of the development of this rule. The PPS is a research project independent of this rulemaking. Also, see the following comment regarding the ICRP.

Comment. Several commenters stated that the IAEA rulemaking process is not democratic, and their documents are not publicly available and were developed without public knowledge or input. One commenter suggested that the public should have had an opportunity to “comment on or otherwise participate in the earlier formation of the IAEA rules.” Another commenter proposed that the NRC act as an intermediary between public opinion and IAEA by improving communications with the public and regulated bodies, providing advanced notice of rulemakings, and receiving comments on proposed rules.

Response. The NRC acknowledges the comments about the IAEA rulemaking process, the ICRP representation of scientific opinion, and the observation on NRC’s role as intermediary between the American public and the IAEA, but each of these comments brings up issues that are beyond the scope of the proposed rulemaking. Therefore, no NRC action is necessary. The NRC notes that the IAEA has begun to discuss ways to foster public participation in its standards development process.

Comment. Several commenters stated that IAEA and ICRP regulations should not dictate domestic U.S.-based regulations. Two commenters stated that IAEA does not

necessarily consider the risk-informed, performance-based standards that are important to rulemaking in the U.S. The commenters added that the NRC must recognize that while IAEA standards generally have good technical bases, they are consensus standards that do not necessarily consider the risk-informed, performance-based aspects of regulations that we have developed in the U.S.

Response. The NRC acknowledges the comment about IAEA and ICRP regulations dictating U.S. based regulations and notes that this comment is not accurate and is considered to be an opinion. The NRC is a participating member of both the IAEA and the ICRP, and neither body dictates to the NRC what regulations or standards must be adopted. As a participant, the NRC suggests transportation standard changes and as such, the NRC both proposes and comments on the language of new standards. This participation permits the NRC to infuse its ideas on risk-informed regulations, when possible.

Comment. The effort to harmonize regulations was supported by several commenters. One commenter spoke for Agreement States and expressed support for harmonizing regulations. Two others explained that the benefit of harmonization would be consistent national and international regulations and improved safety, yet U.S. regulators (and regulations) would retain the legal authority to act when and as necessary. Another commenter emphasized that given how new information is found all the time and the IAEA is on a 2-year standards revision schedule, it does not make sense to hold back harmonizing U.S. standards with international standards pending the outcome of any studies.

Response. The NRC believes that its effort to promote regulatory harmonization will maintain and/or improve safety, increase regulatory efficiency and effectiveness, as well as reduce unnecessary regulatory burden. The NRC's aim is to harmonize its regulations with IAEA regulations by adopting many of the provisions in TS-R-1. However, the NRC does not

propose wholesale adoption of TS-R-1, but only when adoption provides the best opportunity to maintain and/or improve public safety, health, and the environment.

Regulatory Analysis (RA) and Environmental Assessment (EA).

Comment. Several commenters found the RA to be deficient in various aspects. One commenter asserted that updated quantitative data should be included in the RA that would include the following information: the number of exempt and nonexempt packages; the number of exempt and nonexempt shipments; the average number of packages per shipment; and the detailed information on curie counts by shipment categories. The commenter noted that all stakeholders are affected by these deficiencies, notably public information groups and Western States.

Two commenters focused on the RA's cost analysis with one stating that no changes should be made without a cost analysis and the other stating that the RA had not adequately considered the cost of the proposed rule. The second of these commenters stated that specific dose information, calculations, and information regarding the impact of the new regulations should have been included in the draft RA and EA. They found the RA to be deficient because of its failure to recognize likely impacts of the changes to the double containment of plutonium regulations, particularly regarding the agreement between the Western Governors' Association, the individual Western States, and the Department of Energy (DOE) for a system of additional transportation safeguards.

Response. Quantitative data was requested throughout the rulemaking process. These requests were made during the development of the proposed rule, and a request was again made in the proposed rule. Where this information was available, it was used in the

development of NRC's proposed positions. To the extent that information was provided, it has been considered in the development of NRC's final position.

Comment. One commenter asserted that the proposed rule is a major Federal action, thus deserving of a full Environmental Impact Statement (EIS). The commenter also stated that an EIS dating from 1977 and a study dating from 1985 do not suffice as adequate analysis of the proposed rule's impact, due to changes "in population, in land use, in the transportation system, in laws, in issues of national security."

Response. NRC acknowledges this comment and notes that it has prepared an EA. Based on the results of the EA, the NRC staff has concluded that this rule is not a major Federal action requiring an EIS. As noted in the proposed rule, NRC is interested in receiving additional data, and to the extent that the data was received, it was included in the analyses leading up to the final rule.

Comment. One commenter said that the EA and the rulemaking are too carefully tied together. The commenter said that this fact precludes NRC from actually finding an environmental impact from the rule.

Response. The draft EA is a study that is required as part of a rulemaking to ensure that the potential impacts to public health and safety and the environment are adequately evaluated as part of the decisionmaking process. As such, the rule and the EA are necessarily "tied together."

Comment. Two commenters found the EA to be deficient in various aspects. One commenter stated that specific dose information, calculations, and information regarding the impact of the new regulations should have been included in the draft EA and RA.

A commenter believes that the EA and RA lack the following pieces of information: the number of exempt and nonexempt packages; the number of exempt and nonexempt

shipments; the average number of packages per shipment; and the detailed information on curie counts by shipment categories. One commenter believes that the EA should include transportation scenarios, updated data rather than 1982 data, and a quantitative analysis along with a qualitative analysis.

The NRC was criticized for a portion of the EA (page 43), which first identifies information necessary to make a risk-informed decision on the proposed regulation and then discusses the lack of information in the EA. The commenters noted a discrepancy in NRC's efforts, particularly the number of NRC staff and resources devoted to this rulemaking for the past 2 years versus the lack of resources devoted to updating the 1982 data. They stated that the costs associated with the Type C package changes were not included in the EA and that process irradiators are shipping sources equaling about 50 million curies, much greater than the curie count listed in the proposed rulemaking.

Response. The draft EA and RA were developed based on the best information available to the NRC at the time. As part of the rulemaking process, NRC solicited additional information on the costs and benefits of the proposed positions. The information that was made available has been considered in NRC's final decision. The majority of the proposed changes are such that the specific dose information and calculations are not required to determine the appropriateness of adopting or not adopting the change being considered.

Comment. One commenter expressed concerns about NRC's findings of "no significant impact" on radionuclide-specific activity values for a number of issues. The commenter requested that more detailed information be provided "on how many and which radionuclide levels will rise or fall" as a result of proposed changes. The commenter also asked the NRC to define its use of "significantly" and to explain how it determined the level of "risk."

Response. Detailed information on the identity of radionuclides whose specific activity values rise or fall relative to the previous definition of 70 Bq/g (0.002 μ Ci/g) may be determined by inspection of Table A-2. The context for "significantly" is provided in the background section. NRC has used estimated dose to the public, as determined through the use of radionuclide transport scenarios, as an indicator of risk.

State Regulations.

Comment. One commenter asked if these new regulations would threaten a State's right to regulate radioactive materials that NRC has deregulated. Two commenters stated opposition to the proposed rule due to their belief that it would lower standards. The first commenter stated that the proposed rule would override State and local laws that are stricter than Federal regulations while the second commenter stated that the proposed rule would reduce environmental protection. Four commenters added that "harmonization" with international law was a poor and ultimately insufficient justification to weaken U.S. regulations.

Response. State and local governments do not have broad authority to set regulations for the transportation of radioactive materials that are stricter or more stringent than those of the Federal government. In accordance with Section 274b of the Atomic Energy Act, as amended, Agreement States must be compatible with the NRC programs for the regulation of certain radioactive materials to assume authority for the regulations of these materials from the NRC. Because of this, the Commission developed the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" which became effective on September 3, 1997 (62 FR 46517). One of the provisions of this Policy Statement is that an Agreement State should adopt program elements that apply to activities that have direct and significant effects in multiple jurisdictions' elements in an essentially identical manner as those of the NRC (see

definition of Compatibility Category B in Section VI of this Notice). This is needed to eliminate any conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of radioactive materials on a nationwide basis. Those Part 71 requirements applicable to materials regulated by Agreement States are designated as Category B and must be adopted in an essentially identical manner as those of the NRC because they apply to activities that have direct and significant effects in multiple jurisdictions.

Terrorism Concerns.

Comment. Six commenters expressed concern with the increased threat of terrorism and its impact on radioactive material transport. One commenter suggested that shipping standards be strengthened due to both an increased threat of terrorist attacks and the decline in rail, highway, air, and waterway infrastructure. Two commenters stated that they were concerned that many of the new regulations would make transported radioactive material more vulnerable to terrorist attacks and wanted to know how NRC anticipated responding to the threat of these attacks. Three commenters mentioned that the threat of terrorism should be taken into account when changing container regulations, with one commenter highlighting double versus single containment of plutonium. The final commenter stated that the NRC should reconsider the scope of the proposed rule due to the “altered circumstances of our nation’s vulnerability to terrorist attack.” The commenter also suggested that the proposed rule be withdrawn and that the NRC “recalculate the full adverse consequences and the full long-term financial, health, and environmental costs to the public, the nation, and the economy of worst case terrorist actions.” The commenter also stated that in a time of increased national security threats, the safety of containerization must be maximized.

Response. As discussed on the NRC's website (see www.nrc.gov/what-we-do/safeguards/911/faq.html), most shipments of radioactive materials involve mildly radioactive materials such as pharmaceuticals, ores, low-level radioactive waste, and consumer products containing radionuclides (e.g., watches, smoke detectors). A variety of Federal and State government agencies regulate the shipment of radioactive materials.

High-level nuclear waste materials, such as spent nuclear fuel, are transported in very heavy, robust containers called "casks." Over the past 30 years, approximately 1300 shipments of commercially generated spent fuel have been made throughout the U.S. without any radiological releases to the environment or harm to the public. Federal regulations provide for rigorous standards for design and construction of shipment casks to ensure safe and secure transport of their hazardous contents. Casks must meet extremely demanding standards to ensure their integrity in severe accident environments. Therefore, the design of casks would make any radioactive release extremely unlikely. After September 11, 2001, the NRC issued advisories to licensees to increase security measures to further protect the transportation of specific types of radioactive materials, including spent fuel shipments. Additional measures have been taken for licensees shipping specific quantities of radioactive material.

Comment. Another commenter, who lives near a route proposed for shipping nuclear waste across the country, recommended that NRC strengthen radioactive transport regulations. One commenter opposed the adoption of new transport regulations that reduce the protection to the public from transporting nuclear wastes.

Response. The NRC believes that the regulations contained in Part 71 adequately protect public health and safety. The changes being adopted will not result in any undue increase in risk to public health, safety, or the environment.

Comment. Several commenters were concerned that the proposed regulations may increase vulnerability to terrorist threats using radioactive materials. A commenter believes that labeling radioactive materials could aid terrorists by identifying the packages as radioactive, while another commenter stated that shipments with or without labels provided potential terrorists with the materials for a dirty bomb. Another commenter requested that NRC put protective measures into place at ports and to guard all nuclear shipments with U.S. military forces. One commenter stated that nuclear shipments should be transported at off-peak hours while all side roads, tunnels, bridges, overpasses, railroad crossings, access to exit ramps, etc., should be secured before the transport vehicle arrives, and that NRC should create a “vehicle-free” buffer zone ahead and behind the shipment. This same commenter advocated FBI background checks on all transporters, drivers, and crew workers involved with nuclear transport. Two commenters asserted that all new rules should be mindful to the threat of terrorism, which would be superior to considering terrorism in separate rules.

Response. The NRC acknowledges these comments and notes that NRC has taken immediate regulatory actions to address the potential for terrorist activities; these include issuing orders and advisories to its spent fuel licensees prior to initiating rulemaking which takes a longer time, and initiating shipment vulnerability studies. Also, the NRC will make the necessary rule changes.

Adequacy of NRC Regulations and Rulemaking Process.

Comment. Three commenters believe that the NRC should better account for low-level radiation. One commenter stated that NRC should use the latest medical knowledge from independent sources (i.e., not IAEA or ICRP data) regarding the medical effects of radiation. Another commenter stated that low-level radiation could cause cell death, cancer, genetic

mutations, leukemia, birth defects, and reproductive, immune, and endocrine system disorders. This commenter added that long-term exposure to low levels of ionizing radiation could be more dangerous than short-term exposure to high levels. Another commenter, who was similarly concerned with low dose and low dose-rate radiation, stated that “arguments of nuclear industry proponents that new information need not be considered is invalid and since the NRC’s legal mandate is to protect the public’s health and safety” the NRC needs to consider “cautionary information that is now available in the peer reviewed literature.” The commenter suggested that NRC not focus on the “standard man” but instead focus on the “most susceptible portions of the population – ova, embryo, fetus, rapidly growing young child, elderly, and those with impaired health” [when drafting regulations]. Lastly, the commenter implied that NRC should attempt to “assess and incorporate impacts of additive exposures to other forms of life and to ecosystems” as well as the impacts associated with “an individual recipient of the combinations of and synergies among radiation and other contaminants to which people are exposed.”

Response. As discussed on the NRC’s website (see <http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/bio-effects-radiation.html>), radiation may kill cells, induce genetic effects, and induce cancer at high doses and high dose rates. However, for low levels of radiation exposure at low dose exposure rates, biological effects are so small they may not be detected. No birth defects or genetic disorders among the children born to atomic bomb survivors from Hiroshima and Nagasaki have been observed at low doses of radiation (< 25 rad). Consequently, few if any similar effects are expected from exposure to low doses of ionizing radiation. Recently, concern has been expressed that long-term exposure to low levels of radiation may be more dangerous than short-term exposures to high levels. However, there is no epidemiology data, published in peer reviewed journals, to support this concern. Humans have evolved in a world constantly exposed to low levels of ionizing radiation. The average

radiation exposure in the U.S. from natural sources is 3.0 mSv (300 mrem) per year. Although radiation may cause cancers at high doses and high dose rates, there is no current data that unequivocally establishes the occurrence of cancer following exposure to low doses and dose rates -- below about 100 mSv (10,000 mrem). People living in areas having high levels of background radiation -- above 10 mSv (1,000 mrem) per year, such as Denver, Colorado, have shown no adverse biological effects.

The NRC actively and continually monitors research programs and reports concerning the health effects of ionizing radiation exposure. NRC staff monitors the Low Dose and Low Dose Rate Research Program sponsored by the Department of Energy (DOE). The research project is designed to better understand the biological responses of molecules, cells, tissues, organs, and organisms to low doses of radiation. NRC also is co-funding a review of the Biological Effects of Ionizing Radiation (BEIR) by the National Research Council. The BEIR committee will also review and evaluate molecular, cellular, and animal exposure data and human epidemiologic studies to evaluate the health risks related to exposure to low-level ionizing radiation. Both groups provide a comprehensive evaluation of the health risks associated with radiation exposure.

Finally, existing regulatory guidance suggests that protection of individuals (humans) is also protective of the environment. IAEA Technical Report Series No. 332 (Effects of Ionizing Radiation on Plants and Animals at Levels Implied by Current Radiation Protection Standards) suggests that, in most cases, the environment is being protected by protecting humans. Other empirical evidence suggests that the current system of radiological protection does not harm the environment, even in areas of gross contamination surrounding accident sites such as Chernobyl.

Although many occupational and public areas occupied by individuals may contain materials that result in both radiation and chemical exposure, the NRC has no regulatory authority over any of the materials present including chemicals other than source, byproduct, or special nuclear material, to include chemicals. In many situations, exposures to chemicals and non-NRC regulated materials are under the purview of the U.S. Environmental Protection Agency (EPA).

Comment. Seven commenters opposed the proposed rule because of increased exposure, danger to public health, and increased public health risk.

Response. The NRC disagrees that the proposed rulemaking will result in any undue increase in exposure, endangerment to public health, or increase in health risk. See earlier comment responses for further details.

Comment. One commenter stated that U.S. agencies have not adequately represented public opinion regarding transportation safety. The commenter was concerned that the number of irradiated fuel and plutonium shipments in the nation will increase as the proposed regulations weaken container safety standards.

Response. The DOT and NRC represent the United States before the IAEA, DOT as the U.S. Competent Authority supported by the NRC. Both agencies have information and are aware of public opinion regarding transportation safety in the United States. The NRC disagrees with the comment that U.S. agencies have not adequately represented public opinion. Additionally, NRC prepares its rules in compliance with Administrative Procedure Act (APA) requirements. The APA requires that public comments be requested, considered, and addressed before a final rule is adopted unless there are exigent reasons to bypass the public comment process.

Although the number of irradiated fuel and plutonium shipments in the future may increase, the number of shipments to be made is independent of this final rule. Lastly, the comment that the regulation weakens transportation container safety standards is a statement of opinion without supporting data or information.

Comment. One commenter suggested that NRC staff needs to address fully any comments submitted by the public, even when the NRC might consider these comments beyond the scope of the proposed rule.

Response. Although NRC is careful to address all comments with the scope of the rulemaking, there are instances when a comment is sufficiently outside the scope of a proposed action that it need not be addressed. NRC resources need to be used to address issues related to the rulemaking for efficiency and effectiveness.

Comment. One commenter stated that the proposed rule did not specifically incorporate “issues to improve the protective adequacy of the regulations” that were raised by the public during meetings held in 2000. The commenter stated that “changes that were adopted in response to public comments in 2000 must be specified in a revised Proposed Rule.” The commenter also asked that further public meetings be held before DOT and NRC proceed with further revisions of the transportation regulations.

Response. The current rule stems from NRC’s scoping efforts in 2000, and no rule changes were adopted by the Commission at that time. For this proposed rulemaking, public meetings were held in Chicago, IL, as well as in Rockville, MD (as previously noted). NRC accepted and included all comments received, even those received after the July 29, 2002, deadline. For these reasons, the NRC believes its proposed rulemaking meets the intent of conducting an “enhanced public participation process.”

Comment. Eleven commenters requested an extension to the comment period. One commenter said that the proposed rule is written in a manner difficult for the public and even watchdog groups to understand. Because the proposal would affect large portions of the general public by dramatically changing the standards of radioactive transport, the commenter urged the NRC to extend the comment period. Two commenters suggested that the NRC extend the comment period 180 additional days beyond the July 29, 2002, deadline to allow both the public and the NRC more time for further consideration. Commenters added that the proposed rule was not urgent and required further analysis and research. Finally, one commenter stated that the proposed rule's July 29, 2002, deadline for receipt of public comments would prevent it from accounting for the impact of Yucca Mountain. The commenter suggested that a 1- or 2-month rulemaking extension would be beneficial.

Response. The NRC believes the 90-day public comment period was of sufficient length, especially in view of the availability of the proposed rule on the Secretary of the Commission's website for over a year (i.e., the Commission decided to make the proposed rule available to the public in March 2001, while it was under consideration). Therefore, the public had the opportunity to comment prior to the official comment period. Moreover, while not required to do so, the NRC chose to accept and consider comments received after the July 29, 2002, deadline. Further, as part of the NRC public participation process, NRC held two open meetings accessible to the public at which the NRC answered questions on the proposed rule and accepted comments. As part of the proposed rule, the NRC solicited additional information from the public which was considered in the development of the final rule.

Comment. One commenter suggested that the NRC separate the comment period for the EA and RA from the comment period for the proposed rule.

Response. The commenter's suggestion is noted but is not feasible to implement because the proposed rule and its supporting RA and EA must be considered concurrently within the rulemaking proceeding.

Comment. One commenter asked if there is any systematic process by which the NRC has performed or will perform a cost-benefit analysis of these proposed regulations.

Response. Whenever the NRC pursues a cost-benefit analysis (otherwise known as a regulatory analysis), the NRC works diligently to ensure that monetized, quantitative, and qualitative data are included. These data are studied to avoid including faulty and/or misleading data. The draft regulatory analysis in NUREG/CR-6713 has been revised to take into account the quantitative and qualitative data contained in the public comments on the proposed rule.

Comment. Two commenters asked for clarification of the proposed rulemaking's scope in light of the May 10, 2002, letter from Commission Chairman Richard A. Meserve.

Response. Former Chairman Meserve's May 10, 2002, letter to Senator Richard Durban provides information on questions posed by the Senator on transportation of spent fuel and nuclear waste to the proposed repository at Yucca Mountain, Nevada. The letter provides information on the NRC's certification process of cask designs, the safety record of spent fuel casks, and the NRC's authority with respect to transportation of radioactive materials and its relationship with DOT and DOE. The issues raised by this letter do not affect the amendments to Part 71.

Comment. One commenter asked if the NRC was aware that, on February 23, 2002, Chicago Mayor Richard M. Daley and 17 other mayors signed a letter to President Bush that expressed concerns about nuclear waste transportation. The commenter also made reference to the fire in the Baltimore tunnel and wondered about safety if the fire had involved radioactive materials.

Response. The NRC searched its Agency Wide Document Access and Management System (ADAMS), and no record was found for this letter; however, the NRC is aware of concerns about spent nuclear fuel transportation issues that have been voiced by public officials. There has been significant interest in the Baltimore tunnel fire that occurred on July 18, 2001, by State and local officials, and the impact that such a fire might have had on a shipment of spent nuclear fuel, had such a shipment been in the tunnel during the time of the fire. In response to the Baltimore Tunnel fire, the staff has conducted two sets of independent analyses and has determined that the conditions that existed in the fire would not have caused a breach of a spent fuel transportation cask of recent design vintage had it been located in the tunnel for the duration of the fire.

Comment. One commenter stated that changes in the scientific community's understanding of radiation injury would affect the risk assessments and other aspects of the proposed rule. The commenter said that both the DOE Biological Effects Division's and NASA's study of the impacts of low dose radiation impacts may require that NRC reconsider its current standards.

Response. The DOE is funding a 10-year Low Dose Radiation Research Program to understand the biological responses of molecules, cells, tissues, organs, and organisms to low doses of radiation. Using traditional toxicological and epidemiological approaches, scientists have not been able to demonstrate an increase in disease incidence at levels of exposure close to background. Using new techniques and instrumentation to measure biological and genetic changes following low doses of radiation, it is believed that a better understanding will be developed concerning how radiation affects cells and molecules and provide a more complete scientific input for decisions about the adequacy of current radiation standards. These data are reviewed by other groups like NAS and UNSCEAR to provide an independent review of this

health effects information. NRC reviews the programs and data being generated by the DOE and NASA-sponsored research as well as the reports published by the NAS and UNSCEAR. All of these data sources are used by the NRC for estimating radiological risk, establishing protection and safety standards, and regulating radioactive materials.

Comment. Several commenters expressed concern and doubts about the data used to develop the proposed rule and the information the NRC provided to support its proposal. One commenter urged NRC to ensure that the adopted rule represents a risk-informed, performance-based approach. Two commenters criticized the proposed rule for not accounting for an expected increase in radioactive shipments. Given such an increase, one commenter criticized the NRC for using 20-year old data to justify rule changes that will reduce public safety. This commenter claimed that the data was out-of-date, inaccurate, not independently verified, and did not consider the concepts of radiation's synergistic effects when combined with other toxins. Another commenter argued that DOT and NRC should use more current data and future projections including the expected increases in actual nuclear shipments to estimate the impacts of the rule change. Realistic scenarios and updated data must be used to project doses and thus estimate the impacts of the proposed rule's changes, rather than relying on old data, ICRP, and reliance on computer model scenarios (or simply stating the lack of data). In addition, DOT and NRC should include the expected increases in actual nuclear shipments. Another commenter expressed doubt that the proposed rule's technical benefits are legitimate and stated that these benefits are not supported in the draft EA. One commenter stated that the NRC should wait to adopt any new regulations until there is more information available about the costs and benefits of such regulations.

Response. The IAEA developed its latest standards through a cooperative process where experts from member nations proposed and supported changes to the previous version

of the safety standards. The NRC has provided detail on the justification for the proposed changes in the statements of consideration for this rulemaking. The commenter did not provide sufficient detail on which data were of concern for NRC to further address.

The comment that the NRC is relying on 20-year old data for justification of its regulations is unfounded. The NRC has completed risk studies related to the safety of transportation as recently as 2001 and is currently engaged in a research program that will include the full scale testing of casks.

The comments about the quality of data and benefits are considered to be the opinion of the commenter and were not substantiated. Lastly, the NRC notes that a cost-benefit analysis has already been conducted and is reflected in the NRC's RA.

Comment. Four commenters expressed concern that there is inadequate quantitative data to support the risk-based approach of the proposed rule and that some of the provisions are based on incorrect or outdated information. Two commenters were specifically concerned that DOE and some commercial nuclear facilities are negligent in keeping radiation exposure and release records. These commenters questioned how NRC data was gathered and noted that a failure to keep accurate records constrains NRC's ability to determine whether the proposed harmonization is economically justifiable. Furthermore, these commenters added that lack of records undermines the NRC claim that hundreds of thousands of radioactive material shipments are conducted safely every year.

Response. See response to comment above. Also, the NRC notes that the commenter's statements regarding DOE and commercial facilities' negligence is an opinion and was not supported by factual evidence.

Comment. Three commenters stated that pertinent documents and data were not readily available or were too difficult to access for the general public. One commenter

requested improved public access to “sources of codes and IAEA documents that were cited by reference in the draft” rule.

Response. The NRC staff worked diligently to ensure that rulemaking documents, including all supporting documents, were available either electronically, over the internet, or in hard-copy upon the public’s request in a timely fashion. This includes facilitating public access to the internet site of the publisher of IAEA documents in the U.S.

Comment. Four commenters stated that the NRC should finish the PPS and consider its results before finalizing the proposed rulemaking as well as the rules governing irradiated fuel containers. Another commenter requested that the PPS be completed and thoroughly analyzed before this rulemaking is carried out because the current design requirements for irradiated fuel containers are inadequate and should be improved.

Response. The NRC believes that shipments of spent fuel in the U.S. are safe using the current regulations and programs. This belief is based on the NRC's confidence in the shipping containers that it certifies, ongoing research in transportation safety, and compliance with safety regulations and the conditions of certificates that have resulted in an outstanding transport safety record. Thus, an established system of regulatory controls protects every U.S. shipment of spent fuel from commercial reactors. The PPS is part of an ongoing confirmatory research program to reassess risks as shipment technologies change and analytical capabilities improve.

Comment. Three commenters urged the NRC to require more stringent testing of transport packages in real-world (not computer-modeled) testing.

Response. NRC regulations permit certifications through testing, analyses, comparison to similar approved designs, or combinations of these methods. A full scale testing is not

necessary for the NRC to achieve confidence that a design satisfies the regulatory tests, as long as the analyses are based on sound and proven analytic techniques.

Comment. One commenter suggested that the NRC ensure that the economic value of these regulations is not skewed. That is, the commenter does not want the needs of one particular industry to shape the regulations, when the regulations could have a greater impact on a different industry.

Response. The overall value or impact of the proposed changes results from the interaction of several influencing factors. It is the net effect of the influencing factors that governs whether an overall value or impact would result for several different attributes (i.e., different industries or the public). Similarly, a single regulatory option could affect licensee costs in multiple ways. A value-impact analysis, such as was undertaken as part of this rulemaking effort, quantifies these net effects and calculates the overall values and impacts of each regulatory option. A decision on which regulatory option is recommended takes into account the overall values and impacts of the rulemaking.

Comment. One commenter stressed that when the NRC has decision makers review public comments, the NRC staff should look at primary documents instead of summary documents. The commenter cited NUREG/CR-6711 as an example where the regulator runs the risk of having decision makers read summaries of public comments without understanding the underlying context and content.

Response. In our decisionmaking process, the NRC did not rely on a summary document to support the development of the proposed rule. NRC used primary documents to fully understand the underlying context and content of the technical information. The summary documents the commenter refers to were developed to provide the public with a comprehensive, yet condensed, version of the underlying information. Further, these

underlying documents were also made available to the public on the NRC website during the rulemaking process.

Comment. One commenter asked which countries have already adopted the proposed guidelines.

Response. The IAEA conducted a survey in September 2002, in which the IAEA requested information from each Member State as to its plans for implementing TS-R-1. Based on that survey, many States have already implemented the new requirements of TS-R-1 (e.g., European Commission, Germany, and Australia). Other States have indicated that they are actively implementing these requirements and intend to finalize implementation by the end of 2003. No State indicated that it would not adopt these standards. This survey is available at <http://www-rasaneet.iaea.org/downloads/radiation-safety/MSResponses2002.pdf>

Comment. One commenter requested clarification on NRC assumptions for future radioactive materials transportation. Specifically, the commenter wanted to know whether NRC is assuming the amounts will increase or remain consistent with past levels.

Response. The NRC's draft RA and EA relied on existing information to determine the future impacts of the proposed changes. NRC solicited information on the costs and benefits for each of the proposed changes as part of the proposed rule. The NRC considered available information on future radioactive material shipments in its decisionmaking process. Information that was received as part of the public comment process was considered in developing NRC's final position. The NRC staff conducted some sensitivity studies, see for example Comparison of A₁ and A₂ new and old values in the EA, Table A-1, Appendix A.

Comment. Two commenters opposed weakening regulations that would reduce the public safety and health through new definitions or accepted concentration values. One commenter worried that the proposed rule would weaken regulatory control, allowing increased

quantities of radioactive materials and wastes “into the lives of individual citizens without their knowledge or approval,” thus violating “the most fundamental premises of radiation protection.”

Response. The NRC acknowledges the concerns but believes that the rule continues to protect the public’s health and safety in a risk-informed manner.

Comment. One commenter particularly opposed NRC and DOE studies, including the EIS to review alternative policies for disposal and recycling of radioactive metals. The commenter requested that the NRC maintain stringent controls on all materials being recycled, disposed, or otherwise reused. Two commenters expressed opposition to the proposed rule due to a belief that the proposed rule would deregulate radioactive wastes and materials and allow the deliberate dispersal of radioactive materials into raw materials and products that are used by the public and are available on the market.

Response. The NRC acknowledges the commenters’ references to DOE and NRC studies related to the disposal and recycling of radioactive metals. This rule is not related to the referenced studies.

Comment. One commenter expressed concern that NRC’s proposed regulations could increase the variety of materials that are regulated as “radioactive” for transportation purposes.

Response. The rule does not expand the scope of regulated radioactive material.

Comment. One commenter expressed concern that the proposed rule enables commercial and military nuclear industries to “revive and expand, thereby generating ever more wastes to be stored, transported and ultimately . . . sequestered from the biosystem.”

Response. The comment is beyond the scope of this rulemaking.

Proposed Yucca Mountain Facility.

Comment. One commenter expressed opposition to sending shipments of nuclear materials to the proposed Yucca Mountain facility.

Response. Potential shipments to the proposed geologic repository at Yucca Mountain are beyond the scope of this rulemaking.

Comment. Two commenters raised issues related to the possible approval of the Yucca Mountain site. One commenter expressed concern about the safety of dry casks. The commenter asked if the NRC was aware of the accident at the Point Beach Nuclear Plant in Wisconsin on May 28, 1996, and how similar the dry casks that will ship radionuclides to Yucca Mountain will be to the casks used at Point Beach. The commenter noted that once one buries a dry cask, one cannot change it; therefore, the U.S. will have to be sure that it uses safe casks. The second commenter urged the NRC to consider the transportation issues associated with the possible approval of the Yucca Mountain site as the NRC makes rules pertaining to the packaging and transportation of radioactive materials.

Response. The Nuclear Waste Policy Act (NWPA) requires DOE to use casks certified by NRC for transport to Yucca Mountain, if licensed. Transport casks are generally not the same as storage or disposal casks. Issues regarding the licensing of the Yucca Mountain site and the safety of spent fuel storage or disposal casks are beyond the scope of the proposed rulemaking. The NRC believes compliance with the regulations in Part 71 provides for safe transport package designs.

Comment. Three commenters expressed belief that increases in future shipments have not been adequately considered in the rulemaking. The first commenter stated that these regulations could have important implications for the shipment of high-level radioactive waste.

The commenter asked if NRC had considered the financial impact of the opening of the Yucca Mountain facility before proposing the regulations.

Response. This comment is primarily focused on future shipments to Yucca Mountain. The Commission has not received any application relative to the Yucca Mountain site, and a final decision has not been made on opening the site itself. Any conclusion made now by the NRC on future shipments would be purely speculative. ~~and would have no bearing on this rulemaking.~~ Moreover, the commenter did not specify which aspect of the proposed rule would have a significant bearing on the Yucca Mountain facility.

The NRC did not identify where major impacts would result, none were identified that would impact spent fuel shipments. Furthermore, the existing regulations pertaining to spent fuel have been in effect for a significant time and have resulted in more than 1000 spent fuel shipments being conducted without any negative impacts to public health and safety.

Comment. Two commenters asked how NRC factored the possible approval of the Yucca Mountain repository into our rulemaking. One commenter urged NRC to seriously consider the likely increase of radioactive material transportation in Illinois, Michigan, and Wisconsin that will occur if the Yucca Mountain repository is approved. The commenter also provided data from DOE's Yucca Mountain EIS on projected transportation volume through Illinois.

Response. The comments are acknowledged. However, they are beyond the scope of this rulemaking. As part of the rulemaking process, NRC solicited information on the costs and benefits, as well as other pertinent data, on the proposed changes. NRC appreciates the commenter's submission of data related to projected transportation volumes of high-level waste. The NRC believes compliance with the regulations in Part 71 provides for safe transport package designs.

Miscellaneous (including comments to DOT).

Comment. One commenter opposed any use of radioactive materials entirely.

Response. This comment is beyond the scope of the rulemaking. This rule deals solely with regulations that govern the transportation of certain types of radioactive materials and does not address issues related to the use of radioactive materials in commerce.

Comment. One commenter included a comment letter that was previously submitted in September 2000, discussing all of the issues in this rulemaking. The letter was resubmitted because the commenter believes that the NRC did not respond to the comments previously and might have lost the original comment letter. The commenter also included several diagrams and an article entitled “New Developments in Accident Resistant Shipping Containers for Radioactive Materials” by J. A. Sisler. This article discusses the safety tests required for shipping containers.

Response. The current proposal stems from NRC’s scoping meetings held in August and September 2000, to solicit public comments on the Part 71 Issues Paper. NRC accepted all verbal and written comments received at the meetings or later in a letter form and considered these comments in developing the proposed rule.

Comment. One commenter stated that the public’s opinion is that nuclear power and weapons should remain sequestered from the environment and the public for as long as they remain hazardous.

Response. The comment is beyond the scope of the rulemaking. This rule deals solely with regulations that govern the transportation of certain types of radioactive materials and does not address the use of nuclear power or weapons.

Comment. One commenter expressed a general distrust of business and urged NRC to consider recent cases of dishonesty in business when formulating regulations.

Response. The comment is beyond the scope of this rulemaking.

Comment. One commenter expressed concern that inaccurate reporting, inspection failures, and faulty equipment all occur in the nuclear transport industry and may contribute to mishaps in transit.

Response. The NRC is aware of the potential for accidents in transporting nuclear material and has considered the accident history of nuclear transportation in estimating the risks of shipping. The NRC believes that this rule provides adequate protection of the public and workers in normal transport conditions and in accident conditions.

Comment. One commenter recommended that all radioactive shipments be tracked, labeled, and publicly reported, including shipments being made in secret without the consent of the American public.

Response. The NRC acknowledges the commenter's suggestion about tracking, labeling, and reporting shipments. Current regulations include requirements for labels and markings for packages that contain radioactive materials. There are notification requirements for NRC licensees applicable to shipments of spent nuclear fuel. Current NRC/DOT requirements for tracking and labeling radioactive shipments provide adequate protection of public health and safety.

Comment. Several commenters were concerned about the public reporting requirements pertaining to the shipping of radioactive materials. Two commenters believe that NRC should publicly report all radioactive shipments.

Response. The NRC has regulations in 10 CFR Part 73 (Physical Protection of Plants and Materials) that deal with the reporting of shipments of spent fuel nuclear fuel. This rule deals only with Part 71; therefore, these comments are beyond the scope of this rulemaking.

Comment. Several commenters expressed concern with the tracking and labeling aspects of the proposed rule. Two commenters urged the NRC to track, label, and publicly report all radioactive shipments. One commenter believes that the words “radioactive materials” should not be removed from shipping placards because personnel and volunteers understand the plain English warning better than technical language. This commenter also suggested that the warnings be written in several languages. In addition, one commenter stated that the standard symbol, the black and yellow “windmill” for radiation, should adorn all containers.

Response. Tracking and labeling shipments are part of the responsibility of the shipper of the licensed material in accordance with NRC and DOT regulations. Reporting all radioactive shipments would be an administrative burden with minimal benefit. The NRC’s regulations do require a shipper to provide advance notification of a shipment of spent nuclear fuel to both the NRC and to the Governor or designee of a State through which the shipment would be passing. The information is considered safeguards information and cannot be released to the public.

Comment. One commenter expressed support for NRC’s acknowledging DOT’s responsibility to ensure the safe shipment of spent nuclear fuel.

Response. The comment is acknowledged. No further response is required.

Comment. One commenter requested a clarification of the current status of DOT’s regulations for international shipments regarding exempt quantities and concentrations.

Response. This request has been forwarded to DOT for consideration. The commenter should refer to DOT’s proposed rule found at 67 FR 21328 dated April 30, 2002.

Comment. One commenter expressed concern with how the proposed regulations fit into the hierarchy of Federal, State, and local regulations. The commenter noted that DOT regulations expressly preempt and supersede State and local regulations.

Response. The State regulations augment the overall national program for the protection of public health and safety of citizens from any hazards incident to the transportation of radioactive materials. States usually adopt the Federal transportation regulations by reference. The combined efforts of DOT, NRC, and the Agreement States assure that the applicable Federal regulations are observed with respect to packaging and transportation of radioactive materials on a nationwide basis. This is accomplished through DOT, NRC, and State and local government inspection and enforcement efforts.

Comment. One commenter expressed concern that the DOT definition of “radioactive material” is now defined as “any material having a specific activity greater than 70 Bq per gram (0.002 micro curie per gram).” According to the commenter, the effect of this new definition would be to enable much more radioactivity to be exempt, thus allowing more radioactive material to move unregulated in commerce.

Response. This referenced definition change also exists in the NRC final rule. As described in the background section of this rule, NRC has analyzed the impact on dose to the public from changing the definition of “radioactive material” from the current definition 70 Bq/g (0.002 μ Ci/g) for all radionuclides to radionuclide-specific exemption values. After considering transport scenarios, NRC concluded that the new radionuclide-specific definition would result in an overall reduction in dose to the public when compared to the current definition.

Comment. One commenter noted that, in Table 1, the listings for Th (nat) and U (nat) (68 FR 21482) do not refer to footnote b. Because this is inconsistent with the text of the preamble, the commenter concluded that it is a typographical error that should be corrected.

Response. The comment is acknowledged and was considered in developing the final rule.

Comment. One commenter urged the NRC to consider “the relationships between and among the exposures associated with these packaging, container, and transportation regulations and all other sources of radiation exposures,” to protect the public from “adverse impacts on their health and genetic integrity.”

Response. The comment is acknowledged and has been considered in developing the final rule.

Comment. Three commenters expressed concern with the role of State and local governments. One commenter believes that certain States are already burdened with unusually high concentrations of hazardous and radioactive materials transport. Another commenter asked about “the status of non-Agreement States with respect to compatibility” and also wanted further “explanation of the extent to which a State or Agreement State may deviate from NRC program elements, definitions, and standards.” One commenter stated that county sheriffs and the proper State officials should be notified in advance of spent nuclear fuel shipments scheduled to pass through their jurisdictions.

Response. It is NRC practice to seek input and comments from State and local governments on any NRC proposed rules. For example, in December 2000, the NRC staff forwarded the Part 71 proposed rule to the Agreement States for comment before sending the rule to the Commission. Once the rule is published for public comments, NRC considers comments from all State and local governments, and as such, they play an important role in the NRC regulatory process. State officials designated by the Governor are notified in advance of spent nuclear fuel shipments made by NRC licensees.

Comment. Several commenters criticized the proposed rule for acquiescing to the desires of the nuclear and radiopharmaceutical industries to weaken transport regulations at the expense of increased public risk.

Response. The proposed rule was developed to maintain compatibility with the IAEA transportation standards as well as to issue other NRC-initiated changes. Part 71 has been revised twice in the past 20 years to stay compatible with IAEA regulations. The risk to the public from transportation of radioactive materials were considered in the development of the NRC regulations.

Comment. Two commenters expressed concern over implications for worker safety. These commenters asked if workers would be protected from and informed of leaks and whether there is sufficient money to pay lawsuit damages. They stated that exposure to the transport vehicle itself should not exceed 10 millirems/year, and all crew compartments should be heavily shielded to reduce exposure. One commenter then asserted that workers should be trained to handle radioactive materials and informed of the risks involved.

Response. NRC radioactive material transportation regulations have always been issued and enforced to protect the worker and the public health and safety. When shippers of radioactive material follow these regulations, they are taking all the protective measures called for in NRC (and DOT) regulations to protect the crew and public. The NRC and DOT regulations require worker training.

Comment. Several commenters believe that the proposed regulations increased public risk and weakened protection of public health. One commenter stated that additional independent oversight of the transport casks should be conducted regarding quality control to determine whether they are adequate for cross-country transport. This commenter also believes that the testing criteria for containers should be more demanding and require real-world conditions. Another commenter stated that nuclear shipments should be transported at off-peak hours and also supported the creation of a “vehicle-free” buffer zone ahead and behind the shipment.

Response. The commenters did not specify how the proposed rulemaking would increase public risk and weaken protection of public health. When NRC developed the proposed rule, all known potential impacts were carefully considered. NRC does not believe that any part of the proposal will result in a significant impact on public health and safety. NRC's quality assurance programs and inspections determine when additional oversight is warranted. The request for additional and more demanding testing is not specific; it does not specify how and why particular testing procedures are inadequate. These procedures have been carefully verified by NRC to ensure adequate safety.

NRC does not support the commenter's suggestion to transport at "off-peak" hours and use a buffer zone as an NRC safety requirement. There is no safety basis to justify restricting travel only to off-peak hours, and creating (and enforcing) buffer zones could result in greater traffic impacts and safety issues. Moreover, using these restrictions is not warranted based on the safe shipment of more than 1000 containers without incident.

Comment. One commenter urged the NRC to prohibit transport of long-lived spent nuclear fuel via air or via barge across large waterways. The commenter also urged NRC to disallow the transport of such fuel in combination with people, animals, or plants.

Response. Existing NRC and DOT regulations establish requirements that must be met for safe shipment of spent nuclear fuel by transportation modes (i.e., truck, barge, or air). The commenter's second recommendation is noted, but it is beyond the scope of the proposed rule.

Comment. One commenter stated that dumping radioactive material into oceans or landfills and incineration of such materials should never be allowed.

Response. The comment is acknowledged. However, it is beyond the scope of this rulemaking, and therefore no further response is required.

Comment. One commenter suggested that NRC, in concert with other agencies, identify and recover formerly regulated nuclear materials that have been deregulated or have escaped from control in the past.

Response. This comment is beyond the scope of this rule.

Comment. One commenter requested an explanation of how NRC's official proposal on the changes in packaging and transporting of radioactive materials would affect industrial radiology.

Response. Generally, industrial radiography cameras are designed to meet NRC requirements for Type B transportation packages. Of the 11 IAEA adoption issues and the 8 NRC-initiated issues, none have a significant impact upon the transport package design requirements for radiography cameras.

Comment. One commenter expressed support for compatibility among the Agreement States. This commenter indicated that it is appropriate for States to have the ability to develop materials necessary for intrastate shipments. However, for interstate shipments, the commenter stated that it is necessary for one State to be compatible with the rest of the country for the country to be compatible with the world.

Response. NRC notes that the commenter's views are consistent with the Commission's Policy Statement on the Adequacy and Compatibility of Agreement State Programs.

Comment. Several commenters urged NRC to improve its scientific understanding and bases for the proposed rulemaking. Two commenters suggested that NRC complete the comprehensive assessments of TS-R-1 and future IAEA standards, the PPS, and real cask tests before proceeding with this rulemaking.

Response. NRC believes it has an adequate technical basis to make determinations on the adoption of regulatory changes to address the issues that are the subject of this rulemaking. The ongoing PPS is beyond the scope of this rulemaking.

III. Discussion

This section is structured to present and discuss each issue separately (with cross references as appropriate). Each issue has four parts: Summary of NRC Final Rule, Affected Sections, Background, and Analysis of Public Comments on the Proposed Rule.

A. TS-R-1 Compatibility Issues.

Issue 1. Changing Part 71 to the International System of Units (SI) Only.

Summary of NRC Final Rule. The NRC has decided to continue using the dual-unit system (SI units and customary units) in Part 71. This will not conflict with TS-R-1, which uses SI units only, because TS-R-1 does not specifically prohibit the use of a dual-unit system.

We have decided not to change Part 71 to use SI units only nor to require NRC licensees and holders and applicants for a Certificate-of-Compliance (CoC) to use SI units only because doing so will conflict with NRC's Metrication Policy (61 FR 31169; June 19, 1996) which allows a dual-use system. The NRC did not make metrication mandatory because no corresponding improvement in public health and safety would result; rather, costs would be incurred without benefit. Moreover, as noted in the proposed rule (67 FR 21395-21396), the change to SI units only could result in the potential for adverse impact on the health and safety of workers and the general public as a result of unintended exposure in the event of shipping

accidents, or medical dose errors, caused by confusion or erroneous conversion between the currently prevailing customary units and the new SI units by emergency responders or medical personnel.

Affected Sections. None (not adopted).

Background. TS-R-1 uses the SI units exclusively. This change is stated in TS-R-1, Annex II, page 199: "This edition of the Regulations for the Safe Transport of Radioactive Material uses the International System of Units (SI)." The change to SI units exclusively is evident throughout TS-R-1. TS-R-1 also requires that activity values entered on shipping papers and displayed on package labels be expressed in SI units (paragraphs 543 and 549). Safety Series No. 6 (TS-R-1's predecessor) used SI units as the primary controlling units, with subsidiary units in parentheses (Safety Series 6, Appendix II, page 97), and either unit was permissible on labels and shipping papers (paragraphs 442 and 447).

The NRC Metrication Policy allows a dual-unit system to be used (SI units with customary units in parentheses). The NRC Metrication Policy was designed to allow market forces to determine the extent and timing for the use of the metric system of measurements. The NRC is committed to work with licensees and applicants and with national, international, professional, and industry standards-setting bodies [e.g., American National Standards Institute (ANSI), American Society for Testing and Materials (ASTM), and American Society of Mechanical Engineers (ASME)] to ensure metric-compatible regulations and regulatory guidance. The NRC encouraged its licensees and applicants, through its Metrication Policy, to employ the metric system wherever and whenever its use is not potentially detrimental to public health and safety, or its use is economic. The NRC did not make metrication mandatory by rulemaking because no corresponding improvement in public health and safety would result,

but rather, costs would be incurred without benefit. As a result, licensees and applicants use both metric and customary units of measurement.

According to the NRC's Metrication Policy, the following documents should be published in dual units: new regulations, major amendments to existing regulations, regulatory guides, NUREG-series documents, policy statements, information notices, generic letters, bulletins, and all written communications directed to the public. Documents specific to a licensee, such as inspection reports and docketed material dealing with a particular licensee, will be issued in the system of units employed by the licensee.

Currently, Part 71 uses the dual-unit system in accordance with the NRC Metrication Policy.

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC staff's responses for this issue follows:

Comment. Eight commenters stated they appreciated the NRC's decision to maintain both the international and the familiar system of becquerels and curies and sieverts and rem.

Response. No response is necessary.

Issue 2. Radionuclide Exemption Values.

Summary of NRC Final Rule. The final rule adopts, in §§ 71.14, 71.88 and Appendix A, Table A-2, the radionuclide activity concentration values and consignment activity limits in TS-R-1 for the exemption from regulatory requirements for the shipment or carriage of certain radioactive low-level materials. In addition, the final rule provides an exemption from regulatory requirements for 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 applicable values. These amendments conform Part 71 with TS-R-1 and with DOT's parallel IAEA compatibility rulemaking for Title 49.

During the development of TS-R-1, it was recognized that there was no technical justification for the use of a single activity-based exemption value for all radionuclides for defining a material as radioactive for transportation purposes (a uniform activity concentration basis) and that a more rigorous technical approach would be to base radionuclide exemptions on a uniform dose basis. The values and limits in TS-R-1, and adopted in Appendix A, Table A-2, establish a consistent dose-based model for minimizing public exposure. Overall, NRC's analysis shows that the new system would result in lower actual doses to the public than the uniform activity concentration basis system. NRC's regulatory analysis indicated that adopting the radionuclide-specific exemption values contained in TS-R-1 is appropriate from a safety, regulatory, and cost perspective. Moreover, the final rule assures continued consistency between domestic and international regulations for the basic definition of radioactive material in transport.

Affected Sections. Sections 71.14, 71.88, and Appendix A.

Background. The DOT previously used an activity concentration threshold of 70 Bq/g (0.002 μ Ci/g) for defining a material as radioactive for transportation purposes. DOT regulations applied to all materials with activity concentrations that exceeded this value. Materials were exempt from DOT's transportation regulations if the activity concentration was equal to or below this value. The 70-Bq/g (0.002- μ Ci/g) activity concentration value was applied collectively for all radionuclides present in a material.

In § 71.10, the NRC used the same activity concentration threshold as a means of determining if a radioactive material was subject to the requirements of Part 71. Materials were exempt from the transportation requirements in Part 71 if the activity concentration was equal to

or below this value. Although the materials may be exempt from any additional transportation requirements under Part 71, it is important to note that the requirements for controlling the possession, use, and transfer of materials under Parts 30, 40, and 70 continue to apply, as appropriate, to the type, form, and quantity of material. Basically, the radionuclide exemption values mean that licensed low radioactivity materials are not required to be handled as hazardous materials while they are being transported. These exemption values do not mean that these materials are released from other regulatory controls, including the controls that apply to the disposal or release of radioactive material.

During the development of TS-R-1, it was recognized that there was no technical justification for the use of a single activity-based exemption 70-Bq/g (0.002- μ Ci/g) value for all radionuclides. It was concluded that a more rigorous technical approach would be to base radionuclide exemptions on a uniform dose basis, rather than a uniform activity concentration basis.

By 1994, the IAEA had developed Safety Series No. 115 (also known as Basic Safety Standard, or BSS) and a set of principles for determining when exemption from regulation was appropriate. One exemption criterion was the effective dose expected to be incurred by a member of the public from a practice (e.g., medical use of radiopharmaceuticals in nuclear medicine applications) or a source within a practice should be unlikely to exceed a value of 10 μ Sv (1 mrem) per year. IAEA researchers developed a set of exposure scenarios and pathways which could result in exposure to workers and members of the public. These scenarios and pathways were used to calculate radionuclide exemption activity concentrations and exemption activities which would not exceed the recommended dose.

To investigate the exemption issue from a transportation perspective during the development of TS-R-1, IAEA Member State researchers calculated the activity concentration

and activity for each radionuclide that would result in a dose of 10 μSv (1 mrem) per year to transport workers under various BSS and transportation-specific scenarios. Due to differences in radionuclide radiation emissions, exposure pathways, etc., the resulting radionuclide-specific activity concentrations varied widely. The appropriate activity concentrations for some radionuclides were determined to be less than 70 Bq/g (0.002 $\mu\text{Ci/g}$), while the activity concentrations for others were much greater. However, the calculated dose to transport workers that would result from repetitive transport of each radionuclide at its exempt activity concentration was the same [(10 μSv) (1 mrem)] per year. For the single activity-based value, the opposite was true [i.e., the exempt activity concentration was the same for all radionuclides (70 Bq/g) (0.002 $\mu\text{Ci/g}$)], but the resulting doses under the same transportation scenarios varied widely, with annual doses ranging from much less than 10 μSv (1 mrem) per year for some radionuclides to greater than 10 μSv (1 mrem) per year for others. A comparison of the transportation scenario doses resulting from the single [70 Bq/g (0.002 $\mu\text{Ci/g}$)] activity concentration value and the radionuclide-specific activity concentration values shows that the radionuclide activity concentration values reduced the variability in doses that were likely to result from exempt transport activities.

The basis for the exemption values indicates that materials with very low hazards can be safely exempted from the transportation regulations (see draft Advisory Material for the Regulations for the Safe Transport of Radioactive Material, TS-G-1.1, paragraphs 107.5 and 401.3). If the exemptions did not exist, enormous amounts of material with only slight radiological risks (materials which are not ordinarily considered to be radioactive) would be unnecessarily regulated during transport.

Some of the lower activity concentration values might include naturally occurring radioactive material (NORM). As an example, ores may contain NORM. Regarding the

transport of NORM, one petroleum industry representative stated that there are no findings that indicate the current standard fails to protect the public, and that there is no benefit in making the threshold more stringent. Further, it would have a significant impact on their operations. Other similar comments were received during the public meetings. The overall impact would be that some material formerly not subject to the radioactive material transport regulations may need to be transported as radioactive material and therefore meet the corresponding applicable DOT transport requirements.

IAEA recognized that application of the activity concentration exemption values to natural materials and ores might result in unnecessary regulation of these shipments and established a further exemption for certain types of these materials. Paragraph 107(e) of TS-R-1 further exempts: "natural material and ores containing naturally occurring radionuclides which 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 paragraphs 401-406."

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC staff's responses for this issue follows:

Comment. One commenter opposed the reuse of radioactive materials in other products, arguing that this is not based on sound science, but on commercial judgment. Several commenters expressed general objections to the proposal to exempt certain amounts of radionuclides from transportation regulatory control and urged NRC to help prevent more radioactive waste from being deregulated. Seven commenters stated that adopting these exemptions would remove a significant barrier to the purposeful release of radioactive materials from nuclear power and weapons production into raw materials that can be used to make daily

items (e.g., hip replacements, braces, and toothbrushes) that come into contact with members of the public.

Another commenter stated that the exempted levels could potentially provide a back door to recycle and release of radioactive material.

One commenter said that the NRC's stated objectives to facilitate nuclear transportation and harmonize international standards should not supersede the NRC's mandate to protect public health and safety. The commenter also stated that the proposed regulations do not do enough to protect public health. The commenter opposed the technically significant motive for adopting exemption values, which is to facilitate radioactive "release" and "recycling" or dispersal of nuclear waste into daily commerce and household items.

One commenter stated that NRC regulations should not treat radioactive materials like nonradioactive materials. Two other commenters criticized the proposed regulations for treating radioactive substances as if they were not radioactively contaminated.

Response. The transportation exemption values do not establish thresholds for the release of radioactive material to unlicensed parties or to the environment. They do not relieve the recipient from regulations that apply to the use or release of that material. Also, the transportation regulations do not authorize the possession of licensed material [§ 71.0(c)]. Thus, no unauthorized party may receive or possess radioactive material just because the material is exempted from transportation requirements. Radioactive material transported under the rule remains subject to separate regulatory safety requirements regarding possession, use, transfer, and disposal.

Comment. One commenter stated that the use of "or" in proposed § 71.14 (a)(2) (67 FR 21448) suggests that there is no consignment limit if the exempt activity concentration

limits are not exceeded. NRC was asked to replace "or" by "and" to prevent deliberate dilution of radioactive material to obtain exemption from transport regulations.

Response. The comment is correct in that the consignment activity limit does not apply to materials that do not exceed the exempt activity concentration. Under the final rule, the transport regulations apply only to radioactive material for which both the activity concentration for an exempt material and the activity limit for an exempt consignment are exceeded, so the use of "or" in the regulatory text is correct. When describing materials that are subject to the regulations, "and" is the correct term; when describing materials that are not subject to the regulations, "or" is the correct term. Because § 71.14 defines materials that are not subject to the regulations, "or" is the correct term.

Material consignments that exceed the exempt activity concentration, but not the exempt consignment limit, are not regulated in transport due to the small quantity of material being transported. Material consignments that exceed the exempt consignment limit, but not the exempt activity concentration, are not regulated in transport due to the low radioactivity concentration of the material being transported. The NRC has no information to support the notion that radioactive material is diluted to obtain exemption from transport regulations. The NRC does not propose any regulatory action in this regard.

Comment. One commenter expressed concern both that the proposed rule would exempt radionuclide values at various levels and that an international body created these exemption levels.

Response. The activity concentration exemption values do vary by radionuclide. However, the doses to the public estimated to occur from using these values under the transport scenarios are low. The U.S. participated in assessing the dose impacts from the use of the exemption values in transport.

Comment. Another commenter asked if it is really necessary for NRC to adopt the entire IAEA rule to accomplish its goals.

Response. There are a number of specific goals associated with this rulemaking, one of which is harmonization of NRC regulations with IAEA's TS-R-1 and DOT regulations. NRC is not adopting TS-R-1 in its entirety in this rulemaking. However, with respect to revising exemption values, the NRC staff believes adoption of the exemption values from TS-R-1 is warranted to maintain consistency between domestic and international regulations.

Comment. One commenter asked if the NRC told DOT that the American public has rejected these proposed standards three times in the past decade, and if DOT has advised IAEA of these objections. The commenter said that if the IAEA has not been informed of the American public's resistance to these regulations, NRC needs to inform the agency (DOT and IAEA) immediately.

Response. The NRC acknowledges this comment, including both the NRC's and DOT's earlier opposition to the IAEA proposed exemption values. This rule is the first time that IAEA exemption values are adopted and are being carried out for maintaining compatibility with international transportation regulations.

Comment. One commenter asked about the amount of money being spent regulating levels below the exemption values. The commenter asked if more money would be spent attempting to verify the proposed exemption values than would be saved by deregulating them. The commenter wanted to know if there is any guarantee that money saved by deregulating levels below the exemption values will be spent on improving public safety in other areas.

Response. The NRC believes the benefits of the exemption values will outweigh the costs. NRC analyses lead the NRC staff to believe that the increase in regulatory efficiency between regulatory agencies and the facilitation of international shipments make the exemption

values advantageous overall. Further, as part of this rulemaking, NRC specifically requested information on the costs and benefits of the proposed changes. To the extent this information was received, it was considered in the development of NRC's position. Lastly, it is beyond the scope of this rulemaking to guarantee that any money saved will be spent on improving public safety elsewhere.

Comment. One commenter suggested that the NRC could not determine costs or savings from the proposed radionuclide exemption values, in part because the NRC does not know what amounts will be exempted. The commenter also explained that although NRC could attempt to do projections based on the current industry, NRC could not know what amounts would be exempted in the future.

Response. The NRC fully realizes the difficulties associated with predicting the impacts of implementing the exemption values. The NRC also agrees that it is difficult to predict what amounts would be exempted under this final rule, just as it is difficult to assess the amount of material exempted under the current regulations. However, a large majority of commercial radioactive materials are shipped in highly purified forms that far exceed the exemption levels. NRC expects this would continue to be the case under the exemption values. For all of these reasons, the NRC staff explicitly asked for data on the anticipated impacts of the proposed rule. The NRC staff used these data to aid decisionmaking. In general, the NRC expects that the increase in regulatory efficiency among regulatory agencies and the facilitation of international shipments will outweigh any increased costs of shipments resulting from the changes in the exemption values.

Comment. One commenter requested that a cost-benefit analysis be done to account for both the proposed rule's complexity and its enforcement difficulties. The commenter notes

that no cost-benefit analysis had been done on this issue and that the NRC chose it subjectively.

Response. The draft regulatory analysis considered the benefits and costs associated with adoption of the radionuclide exemption values from TS-R-1 using the best available information. In addition, the NRC decided to adopt the dose-based exemption values because the NRC believes these values would actually reduce exposure in transport by establishing a consistent dose-based model for minimizing public exposure. This benefit is in addition to the expected harmonization and financial benefits. NRC disagrees with the commenter's assertion that the exemption values were chosen subjectively. NRC used the best available information and gathered as much information as possible from the public, the regulated community, and outside experts. The purpose of this rulemaking, with its public meetings and public comment period, is to ensure that all affected parties have adequate opportunity to register their comments and provide supporting materials to justify their position (and thus better influence the development of NRC's final position).

Comment. Another commenter stated that the technical benefits of the proposed rule do not outweigh the associated costs and efforts.

Response. Because NRC staff are unclear what the commenter means by "technical benefits," NRC cannot specifically respond to this comment. Overall, NRC believes that the benefits that will accrue with adoption of exemption values from TS-R-1 (e.g., harmonization with other regulatory agencies and facilitation of international shipments) will outweigh the costs (e.g., administrative changes, determining whether packages are exempt, and regulating previously exempt packages).

Comment. One commenter opposed the proposed exemption values because they were not derived directly and did not directly involve public input or a cost-benefit analysis.

Response. A preliminary RA that evaluated possible costs and benefits was conducted as part of the development of this rule. Additional information obtained during the rulemaking process was considered in determining NRC's final position on adopting the TS-R-1 exemption values.

Comment. One commenter stated that, although the revised limits are not expected to create any significant burden to the Naval Nuclear Propulsion Program, use of the new limits could create a cumbersome work practice for some shipments. All low-level shipments that are currently exempt will require a detailed evaluation to ensure that activity concentrations for each radionuclide are acceptable. For example, thoriated tungsten weld rods and soil from site excavations would require individual isotope analyses at an additional expense. The commenter stated that the current 70-Bq/g activity concentration limit for domestic shipments should be retained.

Response. The comment is consistent with others from the shipping community (i.e., the radionuclide activity concentration and activity exemption values are likely to be more cumbersome to work with but do not pose an undue burden). The NRC agrees that expenses may be involved in achieving compliance with these values but notes that expenses are also associated with determining compliance with the current 70-Bq/g (0.002- μ Ci/g) value. Most shipments of radioactive materials involve materials that have been processed to concentrate radioactivity. These materials are known by shippers to greatly exceed the exemption values, and are packaged and transported in accordance with the radioactive material transportation safety regulations. Thus the exemption values are irrelevant to the majority of radioactive material shipments, such as most shipments in the Naval Nuclear Propulsion Program and most shipments in industry as well. The exemption values are relevant to shipments of low activity concentration. For these shipments, shippers will need to establish either by process

knowledge or analysis whether a shipment exceeds the exemption values and is regulated in transport as a radioactive hazardous material, or does not exceed the exemption values and may shipped as non-hazardous material (regular freight). Most shipments that minimally exceed the exemption values are likely to be transported as limited quantities, which would impose a minimal regulatory burden on shippers. Overall, NRC believes that the benefits that will accrue with adoption of exemption values from TS-R-1 (e.g., harmonization with other regulatory agencies and facilitation of international shipments) will outweigh the costs (e.g., administrative changes, determining whether packages are exempt, and regulating previously exempt packages).

Comment. Two commenters stated that the proposed rule would increase industry's regulatory burden. In particular, the NRC was told that the proposed rule is too conservative and would unnecessarily burden industry, particularly in the case of bulk shipments of contaminated materials. The proposed exemption thresholds would increase worker exposure to radioactive materials.

Response. NRC acknowledges that the exemption values impose some new complexity and economic burden on industry. However, NRC believes that the increase in costs will be minimal. The NRC believes that the exemption values represent a good balance between economic and public health interests. From an economic perspective, the increased costs of the exemption values are outweighed by the benefits of conforming to other regulatory agencies and facilitating international shipments. NRC staff recognizes that preshipment requirements under the exemption values may increase some low-level exposures, but the NRC still expects that the shift to a consistent set of dose-based exemption values will minimize the potential dose to transport workers.

Comment. One commenter stated that, although cost reduction was one incentive for the rule, the proposed rule as written was so complicated that enforcement costs would rise.

Response. NRC acknowledges the comment and, as previously discussed, NRC believes that any additional enforcement or other costs will be minimal due to the anticipated benefits of having only one set of shipping requirements, as well as the cost savings that would result from moving some materials outside the scope of transport regulation.

Comment. Two commenters stated that the proposed regulations failed to properly implement IAEA exemption values regarding naturally occurring radioactive material, which would dramatically expand the universe of regulated materials and increase the burden on the regulated community. One commenter stated that other agencies, such as the Occupational Safety and Health Administration (OSHA), afford adequate protection from naturally occurring radioactive materials for workers and the public, and therefore NRC should not enter this regulatory arena. This commenter also stated that the proposed exemption values would also lead to a conflict with the Resources Conservation and Recovery Act (RCRA), which stipulates that waste disposal sites may not accept radioactive materials of more than 70 Bq/g.

Another commenter specifically noted that the NRC has not implemented the exemption provisions for phosphate ore and fertilizer; zirconium ores; titanium minerals; tungsten ores and concentrates; vanadium ores; yttrium and rare earths; bauxite and alumina; coal and coal fly ash. The commenter urged NRC to consider the activity concentration of the parent nuclide in determining exemption values.

Response. Section 71.14(a)(1) provides the same exemption for low level materials (e.g., natural materials and ores) that IAEA provides in TS-R-1 paragraph 107(e). The exemption multiple for activity concentration (10 times the values listed in 10 CFR Part 71, Table A-2) applies to natural material and ores containing naturally occurring radionuclides

which are not intended to be processed for use of these radionuclides. If the materials identified in the comment meet the definition and are not being processed to use radionuclides, the exemption multiple would apply. Thus, the burden indicated by the commenter would not occur.

The activity concentration for exempt material applies to each radionuclide listed in Table A-2. For radionuclides in secular equilibrium with progeny, the listed activity concentration applies to the listed radionuclide (as parent), and was determined considering the contribution from progeny. Table A-2, as published on April 30, 2002; 67 FR 21472, contains several typographical errors, including the omission of the reference to footnote (b) for the U (nat) and Th (nat) radionuclides. These errors have been corrected in this final rule.

Comment. One commenter was concerned that the exemption values in TS-R-1 could result in the unnecessary regulation of certain materials that are currently exempt from NRC regulation under § 40.13. The commenter urged NRC to allow unimportant quantities to remain exempt. The commenter was concerned that the public and operators of RCRA disposal facilities may question the safety of materials that were previously exempt but are not exempt under the new regulations. The commenter pointed out that the actual risk would not change because RCRA will not change.

Response. Materials that are exempt (i.e., not licensed) under § 40.13 are not subject to Part 71 under the current or final transportation regulations. Nothing in this final rule affects the exemption status of materials subject to Part 40.

RCRA sites can continue to use the 70-Bq/g (0.002- μ Ci/g) value as a material acceptance criterion at their option. The final rule establishes new exemption values for radioactive materials in transport that differ from 70 Bq/g (0.002 μ Ci/g) that might be used (for nontransport purposes) at RCRA sites. However, the final rule does not preclude the shipment

of materials to RCRA sites in a manner that would satisfy both transportation and site safety regulations.

Comment. Nine commenters expressed opposition to the exemption values. One commenter argued that the proposed guidelines should allow no exemptions. Two commenters stated that the proposed exemptions would negatively impact public health. Two commenters argued that the redefinition would pose a threat to public health. Two commenters opposed weakening regulations that would reduce the public safety and health through new definitions or accepted concentration values. Two commenters emphasized that there is no justification for increasing allowable concentrations because there are ramifications beyond transportation, and that using a dose-based system is less measurable, enforceable, and justifiable.

Some commenters added that if NRC needed to adopt risk-based standards, NRC should adopt the standards that would reduce the allowable exemptions. One commenter criticized the proposed rule for increasing the allowable contamination in materials. One commenter disagreed with the current 70 becquerels-per-gram exemption level and urged NRC to change only the exemption levels to make them more protective for isotopes whose exempt concentrations go down.

One commenter also stated that NRC had not actively participated in determining the proposed exemption values.

Response. NRC disagrees with the comment that no exemptions should be allowed. Because almost all materials contain at least trace quantities of radioactivity, if there were no exemptions, essentially all materials transported in commerce would be treated as radioactive materials. This would entail considerable expense and impact on commerce without commensurate benefit to public health and safety.

The NRC disagrees that the proposed exemptions would negatively impact public health. The NRC's analysis of the radionuclide-specific exemption values indicates the overall dose impact of their adoption would be low, and lower than that of the single-value exemption currently in place. Please see the Background section under this issue for further details.

The NRC acknowledges the comment that there is no justification for increasing allowable concentrations. However, the NRC believes the benefits of the exemption values will outweigh the costs. NRC analyses lead the NRC staff to believe that the increase in regulatory efficiency between regulatory agencies and the facilitation of international shipments make the exemption values advantageous overall. The NRC finds the low uniform-dose approach that was used in the development of the exemption values to be acceptable.

Although additional measurements may be necessary under the new requirements, the industry has not indicated that these requirements pose an undue burden. The NRC does not believe the radionuclide exemption values would be less enforceable than the current single exemption value.

Lastly, as a working participating member of the IAEA, both NRC and DOT staff participated in the development of the exemption values.

Comment. One commenter requested information on calculations for dose impacts to members of the public, particularly regarding recycling and the possibility of exempting materials that pose a radiation hazard to the public.

Response. An assessment of public dose that might result from adopting the exempt activity concentrations and exempt activities per consignment under transportation scenarios may be found at the following reference: A. Carey et al. The Application of Exemption Values to the Transport of Radioactive Materials. CEC Contract CT/PST6/1540/1123 (September

1995). The NRC has performed no assessment regarding recycling because that is beyond the scope of this rulemaking.

Comment. A commenter requested the risk and biokinetic data supporting the proposed exemption values. The commenter also wanted to know more about who determines what data NRC uses, including the physiological data used to justify the change in dose models.

Response. The basic radiological protection data used in the development of the exempt activity concentrations and exempt activities per consignment may be found at the following reference: International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA 1996.

Comment. Two commenters stated that it is unclear how or why the risk decreases for 222 of the 382 listed radioisotopes, when the allowable concentrations for those radioisotopes increase to above 70 becquerels. The commenters asked how the "risk or dose goes down" while some exempt quantities could lead to more than the "worker doses to members of the public from unregulated amounts of exempt quantities of radioisotopes."

Response. Under the previous system, radioactive materials exceeding the 70-Bq/g (0.002- μ Ci/g) activity concentration were regulated in transport. Although the 70-Bq/g (0.002- μ Ci/g) value applied to all radionuclides, different radionuclides resulted in different doses to the public when transported at that activity concentration (as calculated using the transport scenarios). The transport scenario doses for many radionuclides when transported at 70 Bq/g (0.002 μ Ci/g) are less than the reference dose of 0.01 mSv/y (1 mrem/y). However, for other radionuclides, the transport scenario doses at 70 Bq/g (0.002 μ Ci/g) are greater than the reference dose of 0.01 mSv/y (1 mrem/y). Under the radionuclide-specific approach, the calculated doses are more representative, and the average dose (considering all radionuclides)

is lower than under the 70-Bq/g (0.002- μ Ci/g) approach. Overall, the NRC's analysis shows that the new system would result in lower actual doses to the public than the current system.

Comment. Another commenter urged NRC to either make exemption values more stringent or not adopt any new values at all.

Response. The comment provides no justification to make the exemption values more stringent. The IAEA and other Member States have adopted the new system. Failure to adopt the new system would put the U.S. at a competitive disadvantage in international commerce without commensurate benefit to public health and safety and would allow the continued shipment of exempt materials that are calculated to produce higher doses to workers and members of the public.

Comment. One commenter asked that NRC provide a separate activity concentration threshold, and suggested 2,000 picocuries per gram, for samples collected for laboratory analysis in situations where relevant data is unavailable. The commenter believes that the current proposed threshold of 2.7 picocuries per gram is too restrictive for samples acquired for laboratory analysis.

Response. Although data is apparently unavailable for the samples the commenter refers to, it appears the samples are minimally radioactive and, therefore, could be shipped as a limited quantity, one of the least burdensome shipments. As we received no other comment on this issue, the commenter's concern does not appear to be widespread. The NRC has concluded that the information and justification provided do not warrant the introduction of a provision in Part 71 that would not be compatible with TS-R-1.

Comment. One commenter asked that NRC provide for expeditious transportation of discrete solid sources encountered in public areas. The commenter noted that Part 71 currently permits a source of up to 2.7 millicuries to be transported as a limited quantity, even if no

relevant data about the source is available. The commenter then asked NRC to retain this arrangement for sources encountered in public areas because it has been a useful provision.

Response. The quantities involved (2.7 mCi) would not normally require NRC-certified packaging, thus the current Part 71 rulemaking would have little bearing upon them. The NRC understands that DOT has a system of exemptions in place, which has been coordinated with State regulators, to facilitate the safe and timely transport of sources discovered in the public domain.

Comment. One commenter asked about the proposed mechanism for approving nondefault exemption values. Some commenters requested further information on how default exemption values could be calculated from the A_1 and A_2 values.

Response. The scenarios used to develop the exemption values were selected to model exposures that could result from relatively close and long duration exposure times to exempt materials. The scenarios used in the Q-system were selected to model exposures that could result from shorter-term exposure to the contents of a damaged Type A package following an accident. Because of the differences in the exposure scenarios and the resulting differences in the equations used to calculate the values, the Q-system cannot be used to calculate activity limits for exempt consignments or exempt activity concentrations.

Comment. One commenter stated that the landfill disposal of NORM is outside NRC jurisdiction when technologically advanced NORM is involved with RCRA-regulated hazardous constituents. The commenter explained that numerous RCRA landfills around the country have adopted the EPA- and State-approved programs for the disposal of NORM. The commenter wondered how the proposed changes in radionuclide exemption values would affect the regulations governing these landfills.

Response. Part 71 has no direct effect on the regulations governing the licensing or operation of landfills. The comment is beyond the scope of this rulemaking.

Comment. Two commenters opposed the regulation of NORM ores and natural materials, including materials derived from those substances, because it does not include appropriate exemptions and will result in unjustified increased costs and transportation burdens and liabilities.

Response. This rule does not extend NRC's scope of regulation of radioactive material. If a material, such as NORM, was not previously subject to NRC regulation, it would not be subject to regulation under this final rule. For regulatory consistency, both DOT and NRC publish the radionuclide exemption tables, including the 10 times exemptions for natural materials and ores containing NORM. Also, Part 71 only applies to material licensed by the NRC, and NRC does not regulate NORM.

Comment. One commenter suggested that NRC reevaluate the proposed factor for the allowance of NORM. This commenter recommended that NRC consider using a factor of 100 rather than 10, because many materials are not hazardous and do not require more stringent shipping regulations.

Response. The comment does not provide compelling data to support the requested change. Furthermore, the requested change would result in the U.S. being noncompatible with international transportation regulations. Therefore, no change is made.

Comment. One commenter stated that this rule has taken the focus off of more important issues in place of issues that are of less concern, such as the regulation of NORM. The commenter stated that lowering exemption values could distract attention from materials that would otherwise be of concern to law enforcement, particularly regarding transportation across U.S. borders.

Response. The exemption values are considered by shippers when preparing radioactive materials for transport. The NRC staff does not believe these rule changes will affect law enforcement activities.

Comment. One commenter was concerned that "uranium and thorium levels in phosphate, gypsum, and coal cannot be considered safe simply because they are naturally occurring. The commenter added that from a public health point of view, there is no need to determine whether alpha emissions above the 70-Bq/g (0.002- μ Ci/g) threshold are naturally occurring or man-made, their effect on somatic cells and germ cells is the same." The commenter was concerned that NRC has not proposed sufficient regulations regarding the "shipment of ores and fossil fuels with regard to radioactive levels of naturally occurring radionuclides." The commenter requested that NRC provide an analysis of the "regulatory burden of radionuclide HMR on the fertilizer, construction, and fossil-fuel energy industries."

Response. NRC's transportation regulations apply to NRC licensees that transport licensed material and require that licensees comply with U.S. DOT Hazardous Materials Regulations. The DOT regulations previously included the 70-Bq/g (0.002- μ Ci/g) value in the definition of radioactive material, and materials determined to be less than that activity concentration did not satisfy DOT's definition of a radioactive material and were not regulated as hazardous material in transport. The DOT definition applied regardless of whether the material was naturally occurring or not.

With regard to burden, this rule adopts a change in the transportation exemption for radioactive materials from a single value to radionuclide-specific values. In its proposed rule, NRC requested specific information on the impact of that change. The information provided to NRC is presented in the regulatory analysis accompanying this rule.

Comment. One commenter suggested that NRC not use the wording in § 71.14(a)(1), "Natural materials . . . that are not intended to be processed for the use of these radionuclides . . . ," because it unreasonably requires the shipper to know the intended use of the material. The commenter emphasized that NRC should base transport regulations solely on the radiological properties of the material shipped.

Response. This provision applies to a subset of the industry that processes an ore that contains radioactive material, not for the radioactive material, but for some other element, mineral, or material. For example, this provision would apply to the processing of an ore during which thorium or uranium was produced incidentally in a waste stream, but would not apply to the processing of an ore to extract thorium or uranium for use or sale. NRC staff believes the industry can reasonably be expected to determine the intent for processing the ore when that ore is shipped to a consignee.

Comment. One commenter indicated that, should the exemption values be adopted in a way that departs from IAEA, newly regulated entities could face high monetary penalties for failure to comply with the regulations due to DOT's enforcement penalty policies. The commenter noted that DOT regulations preempt and supersede State and local regulations, so these regulations make it more difficult for people to protect themselves from the dangers of exposure to radiation.

Response. The NRC staff believes the rule adopts the exemption values in a manner that is compatible with the IAEA regulations and with a parallel DOT final rule.

Comment. One commenter asked the NRC if States whose regulations are more protective than the proposed rule would have to abandon those regulations if NRC adopted the proposed rule.

Response. States do not have regulations that are more protective than those in this rulemaking for the transportation of radioactive materials. State regulations in this area are essentially identical to those of the Federal Government to eliminate any conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of radioactive materials on a nationwide basis.

Comment. One commenter stated that there is no way to know how much is being exempted in terms of curies or becquerels because there is no limit on the number of negligible doses from exemptions.

Response. The dose criteria used in determining the activity concentrations for exempt materials ensure that the doses (from either single or multiple sources) do not reach unacceptable levels, and will therefore be far below public dose limits. Quantifying exempted materials (i.e., those materials that are not regulated as radioactive material in transport) would impose a significant burden without commensurate benefit to public health and safety.

Comment. One commenter expressed concern that, for some members of the public, exposure could be over 100 millirem per year. The commenter understood from the proposed rule that the dose-based exemption values are designed to deal with transport worker exposures in the range of 25 to 50 millirem per year. The commenter requested information about how the expected annual dose to transport workers changes under the proposed rule, particularly if it increases or decreases.

Response. The NRC staff notes that exposures to members of the public are more likely to be over 1 mSv (100 mrem) per year under the current single exemption value than under the radionuclide-specific system. However, these are dose estimates; the transport scenarios used to estimate these doses overstate actual doses by overstating exposure periods

in a year (50-400 hrs/yr) and exposure distances [less than 1.52 m (5 ft)] to radioactive materials in transport.

For those radionuclides with a relatively low estimated dose for transport at 70 Bq/g (0.002 $\mu\text{Ci/g}$) under the transport scenarios, the estimated dose will increase under the dose-based exemptions; for those radionuclides with a relatively high estimated dose for transport at 70 Bq/g (0.002 $\mu\text{Ci/g}$) under the transport scenarios, the estimated dose will decrease under the dose-based exemptions. Even in those instances where the estimated dose increases under the final rule, the dose remains low and the average dose (considering all radionuclides) is lower under the radionuclide-specific system.

Comment. One commenter questioned the composition of a list of 20 representative nuclides used to estimate the average annual dose per radionuclide. The commenter asserted that, among the 20 representative nuclides, a minority of nuclides whose doses decrease in the proposed regulations were overrepresented. The commenter stated that most of the dose concentrations increase, some of them dramatically.

Response. The 20 radionuclides referred to were chosen to be representative of the radiation types (alpha, betas of various energies, and gamma) most commonly encountered in transport and were used to provide a representative measure of the proposed rule's likely impact.

Although the radionuclide activity concentration values more often exceed 70 Bq/g (0.002 $\mu\text{Ci/g}$) than fall below it, the distribution of all the new exemption values centers just above 70 Bq/g (0.002 $\mu\text{Ci/g}$).

It is recognized that the exempt activity concentration for some radionuclides [those radionuclides with very low doses under the transport scenarios when transported at 70 Bq/g (0.002 $\mu\text{Ci/g}$)] will increase under a dose-based exemption system. However, the measure of

impact from the change in exemption values is the estimated dose, and that remains low, even for radionuclides where the exempt activity concentration increases above 70 Bq/g (0.002 $\mu\text{Ci/g}$). The radiation protection benefit from the radionuclide-specific approach is that the highest potential doses are reduced as well as the average dose from all radionuclides.

Comment. One commenter noted that there is no precedent for exempt quantities in NRC regulations and that this will create a new category. The commenter questioned the logic of creating such a category.

Response. The DOT transportation safety regulations for radioactive materials have always had a de facto "exemption value" built into the definition of "radioactive material." NRC regulations either replicate or include references to DOT regulations. Any material with an activity below the 70-Bq/g (0.002- $\mu\text{Ci/g}$) threshold was not defined as radioactive for the purposes of the regulations and therefore was not subject to the regulations (i.e., exempt). Without the exempt activity for consignments value, any quantity of material that exceeded the exempt activity concentration, no matter how small, would be regulated in transport as radioactive material. The exempt consignment value is included to prevent the regulation of trivial quantities of material as hazardous material in transport.

Comment. One commenter stated that the threat of terrorism should be taken into account when exempting radionuclides from transport regulations and changing container regulations.

Response. The nature of exempt materials is that they are either of very low activity concentration or very low total activity. In both cases, these materials present little hazard and would not be attractive as targets for terrorist activities.

Comment. One commenter expressed concern that the revised exempt concentrations in Table A-2 are a significant change in the requirements for the transportation of unimportant quantities of source materials.

Response. Although the comment expresses concern that the exempt activity concentration values represent a significant change in the requirements for unimportant source material, it does not provide data or justification for this statement. NRC acknowledges that the internationally developed transportation exemption values do not align precisely with preexisting, domestic requirements in Part 30 or Part 40 that were developed for other licensing purposes. However, the current 70-Bq/g (0.002- μ Ci/g) exemption value does not align precisely with Part 30 or Part 40 requirements either. In most cases, the differences in the regulatory requirements do not appear to be that significant, and the industry has not provided data that demonstrate that the impact from the change for actual shipments would be significant. NRC has no basis to change its conclusion in the final RA that the overall benefits of achieving compatibility by adopting the exemption values outweigh the associated costs, or its belief that permitting natural materials and ores to be shipped at 10 times the Table A-2 values minimizes the impacts.

Comment. Five commenters supported NRC's efforts in the proposed rule. One of these commenters supported lower concentrations for the radioactive isotopes because the proposed rulemaking increases public risk. Another stated that it was important to ensure consistency between international and domestic regulations and that while individual radionuclide levels may be raised or lowered by the proposed rule, overall the estimated dose would be significantly lower. Another commenter agreed with NRC's proposal to adopt the radionuclide exemption values in TS-R-1, particularly the inclusion of exempt consignment

quantities in the regulations. Another commenter expressed general support for ensuring consistency between domestic and international regulations.

Response. NRC acknowledges the comments on revising radionuclide exemption values. NRC staff agrees with the commenters who stated that consistency between international and domestic regulations is a high priority, and that the exemption values overall will result in lower public exposure. However, while promulgating lower exemption levels could reduce the already low public health risks, NRC believes that the exemption values offer the best balance between economic and public health concerns.

Comment. One commenter stated that the proposed exemption values were too complex because it is too complicated to maintain more than half of all exemption values at 70 Bq/g (0.002 μ Ci/g) and to reduce those that are more protective.

One commenter said that there are no comparable exemptions in existing regulations.

Response. The NRC does not believe that the proposal to maintain more than half of the activity concentration exemption values at 70 Bq/g (0.002 μ Ci/g), while reducing the activity concentration exemption values for the remaining radionuclides, is warranted because the resulting exemption system would be inconsistent, have no defined dose basis, and would be incompatible with that of the IAEA and other Member States.

The final rule introduces exemptions from the application of the hazardous materials transportation regulations for materials in transit. However, the definition of “radioactive materials” in the transportation regulations has, for decades, contained a minimum activity concentration value [i.e., any material with an activity concentration less than 70 Bq/g (0.002 μ Ci/g)]; effectively, the definition has contained an exemption value. The final rule changes the structure of the exemption from a single activity concentration value applicable to

all radionuclides to individual activity concentration and consignment activity values that are specified for each radionuclide.

Comment. Several commenters expressed concern about the health effects of these regulations. One commenter opposed reliance on the ICRP arguing that ICRP does not take into consideration important information on the health impacts of radiation such as synergism with other contaminants in the environment and the bystander effect, in which cells that are near cells that are hit, but are not themselves hit by ionizing radiation, exhibit effects of the exposure. One commenter stated that the NRC did not consider the new evidence that low doses of radiation are more harmful per unit dose than was previously known. This commenter further noted that there are synergistic effects and other types of uncertainties in radiation health effects. Three commenters opposed the radionuclide exemption value tables citing the use of outdated data, lack of data, and/or the lack of calculations for more than 350 radionuclides. One commenter stated that NRC radiation standards are outdated and should be subject to rigorous review, including independent outside experts. One commenter stated that ICRP does not represent the full spectrum of scientific opinion on radiation and health and does not take into account certain health impacts of radiation. One commenter noted that ICRP and IAEA risk models only look at fatal cancers and ignore nonfatal cancers, years of lost life, and the bystander effect. The commenter also asserted that these agencies' reports do not accurately reflect risk and that low levels of radiation are more damaging than the models are predicting.

Response. The Board of Governors of the International Atomic Energy Agency stated in 1960, that "The Agency's basic safety standards . . . will be based, to the extent possible, on the recommendations of the International Commission on Radiological Protection (ICRP)." The ICRP is a nongovernmental scientific organization founded in 1928 to establish basic principles

and recommendations for radiation protection; the most recent recommendations of the ICRP were issued in 1991 [INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, 1990 Recommendations of the International Commission on Radiological Protection, Publication No. 60, Pergamon Press, Oxford and New York (1991)]. The IAEA Basic Safety Standards (from which the exemption values are taken) were developed with full IAEA Member State participation (including the U.S.) and have taken the ICRP recommendations into account. NRC rejects the comment that the data used to develop the exemption values are outdated or inadequate. In general, NRC believes ICRP reports provide a widely held consensus view by international scientific authorities on radiation dose responses and accepts their principal conclusions. Furthermore, the NRC notes that fundamental research into radiation dose effects is beyond the scope of this rulemaking. For that information, NRC relies on national and international scientific authorities.

Comment. The NRC was criticized by commenters for not having developed and pursued actual transport exposure scenarios for every radionuclide to justify the exemptions. One commenter also noted that although NRC has not carried out calculations for transportation scenarios for over 350 of the listed radionuclides, individual exempt concentration and quantity values have been assigned to each radionuclide. The commenter further concluded that NRC has technical data to support the conclusion that these exemption values will pose no risk to the public. Another commenter stated that it was unclear why NRC performed calculations for only 20 of the 350 isotopes. The commenter noted that because NRC only modeled 20 of the radionuclides, NRC has not collected complete data for the other radionuclides; otherwise, they would have been also modeled. The commenter further stated that NRC should either lower the exemption values or withdraw the values and perform further studies.

Response. NRC selected a subset of 20 radionuclides believed to be representative of the most commonly transported radionuclides. Exempt activity concentration and consignment activity values were calculated for all the radionuclides listed in Table A-2, not just the 20 selected to be used in NRC's impact analysis. NRC used the 20 radionuclides to illustrate that the impact from activity concentration exemption values for materials commonly transported in significant quantities is less than that from the current single exemption value.

Comment. One commenter expressed concern that NRC had arbitrarily determined the radionuclide values.

Response. The A_1 and A_2 values in Table A-1 and the exempt activity concentration values and exempt activity values in Table A-2 are not arbitrary values. The derivation of these values is dose based and provided in the references in TS-R-1.

Comment. One commenter expressed opposition to the exemption values because they raised the allowable exempt concentrations and allowed for exempt quantities, which are currently not permitted.

Response. The current definition of radioactive material is specified only in terms of a minimum activity concentration. Conceivably, this leads to the regulation of any quantity of material that exceeds that activity concentration, even minute quantities, as a radioactive material in transport. To address this issue, an activity limit for exempt consignments has been introduced that specifies a minimum activity that must be exceeded for a material to be regulated as a radioactive material in transport.

As with the exempt activity concentration values, the exempt activity values in Table A-2 were taken from the BSS exemption values. The doses associated with the use of these exempt activity values were estimated using the same scenarios used for assessing the impact of the exempt activity concentration values. The results are that doses are low, and that for 19

of the 20 representative radionuclides examined, the dose from the radionuclide exempt activity value is less than that from the exempt activity concentration value.

Comment. One commenter asked if there is any possibility that NRC could simply decline to adopt the sections of the proposed rules that relate to radionuclide exemption values.

Response. NRC's and DOT's approach in this compatibility rulemaking is to adopt the provisions of IAEA's TS-R-1 as proposed unless adoption would pose a significant detriment to radioactive material transport commerce, or is unjustified. The NRC has determined that the exemption change is justified based on its regulatory analysis and public comments.

Comment. One commenter stated that NRC should ensure that no member of the public would receive a dose above 1mrem/year from any practice or source, and should clarify what is meant by "practice" and "source." One commenter stated that the current HMR standard of 70 Bq/g (0.002 Ci/g) should be maintained as the minimum standard for the protection of public health and transport worker safety. The commenter opposed the replacement of this standard with the radionuclide-specific values per the IAEA's TS-R-1 for the following reasons:

a) There is no radiation risk level which is sufficiently low as to be of no regulatory concern;

b) There are no collective radiological impacts which are sufficiently low as to be of no regulatory concern; and

c) No one will be able to determine if proposed exempt sources are safe.

One commenter noted that the current and proposed regulations have 50 and 23 millirem being average doses, respectively. To adequately protect public health, the average dose should be no more than one millirem. One commenter stated the assumptions

and scenarios that NRC and DOT used to justify the adoption of these exemption values fail to prove that these exemptions will have either no or an insignificant effect.

One commenter stated that the proposed exemption values are based on unrealistic models. The commenter said that the exempt levels do not appear to reflect the material's longevity in the environment and hazard to living creatures. One commenter stated that the standards should be based on the most vulnerable members of the population, and NRC should adopt stricter values. Two commenters argued that, using the existing dose models, some of the exempt quantities could lead to high public doses from unregulated amounts of exempt quantities of radioisotopes. Another commenter opposed reliance on computer model scenarios that may not be realistic to project doses, citing that this lack of realism to justify certain exposure scenarios is inadequate. One commenter stated that it is unclear in the proposed regulations what the exact dose impact will be in converting from an empirical exemption value to a dose-based exemption value. The commenter's understanding is that while there is a reduction in dose for the results that were calculated, the standard deviation and median dose values both decrease. One commenter was concerned that the proposed exemption values are not adequately protective for transportation scenarios, because the IAEA transportation exemption values for some radionuclides are too high to meet safety goals. The commenter added that the average annual dose for a representative list of 20 radionuclides (see April 30, 2002; 67 FR 21396) is too high to be safe. Some commenters stated that NRC should tighten controls on radioactive materials instead of loosening them because NRC admitted that the proposed increases in exempt concentrations of radioactive materials would reduce public safety. One commenter stated that the public is told not to worry about the proposed exemption values because it will only be exposed to one millirem of radioactive material. However, the commenter noted that the 20 most commonly shipped materials with

the new exemption values are at 23 millirem. Therefore, the commenter was confused about what it meant to only be exposed to one millirem of radioactive material. One commenter stated that the proposed exemption values would not enforce the principle of limiting exposure to less than 1 mrem/yr. Four other commenters opposed the proposed definition of “radioactive materials,” one doing so in the name of national security. This commenter argued that there are no low-level nuclear wastes and that there is no safe threshold for exposure to radioactive materials.

Response. The terms "practice" and "source" are used in the context of the IAEA's BSS, and have the meanings provided in the glossary of that document.

A criterion for the BSS exemption of practices "without further consideration" (Schedule I, paragraph I-3) is that the effective dose expected to be incurred by any member of the public due to the exempted practice is of the order of 0.01 mSv (1 mrem) or less in a year. Estimates of doses resulting from the use of the exemption values in the transport scenarios have been specifically examined and may result in doses that exceed 0.01 mSv/yr (1 mrem/yr) [an average of 0.23 mSv/yr (23 mrem/yr) for 20 commonly transported radionuclides]. However, the dose estimates for the use of the exempt activity concentration values are less than those resulting from the use of the current 70-Bq/g (0.002- μ Ci/g) activity concentration [an average of 0.5 mSv/yr (50 millirem/yr) for the same 20 radionuclides]. The NRC staff notes that there have been no adverse public health impacts identified from the use of the current exemption value. Because the annual doses estimated to result from the use of the radionuclide-specific exemption values are low, and on average are lower than the dose estimates for the current 70-Bq/g (0.002- μ Ci/g) activity concentration, the NRC staff believes that changing from the 70-Bq/g (0.002- μ Ci/g) value to the radionuclide-specific exemption values will result in no adverse impact on public health and safety.

In addition, the transport scenarios are based on exposure periods (40-500 hours per year) and exposure distances [less than 1.52 m (5 ft)] that overstate actual exposures to workers and greatly overstate actual exposures to the public. The models used to develop the exemption values consider the exposure pathways that are significant for assessment of impact on public health and safety, including external exposure, inhalation and ingestion, and contamination of the skin.

The length of the exposure periods and the close distance assumptions make multiple exposures for the full duration at those distances to multiple radionuclides very unlikely. The dose estimates are sufficiently low that NRC believes any actual multiple exposures would also be acceptably low. Neither NRC nor DOT has any information to suggest that multiple exposures to materials regulated under the current 70-Bq/g (0.002- μ Ci/g) minimum activity concentration is of concern.

The NRC believes that regulatory efficiency requires that exemption values be established for determining when material in transport should be subject to radioactive material transport safety regulations. The NRC believes adoption of the radionuclide-specific exemption values is warranted because it achieves international compatibility without negative public health impact or undue burden.

Comment. One commenter stated that the proposed regulations were unclear as to the exact definition of “per radionuclide.”

Response. The term "per radionuclide" means that the doses estimated to result from the use of the exemption values were determined for each radionuclide.

Comment. One commenter expressed the lack of understanding of the concept of the "millirem." To this end, the commenter said that "millirem" is a fluid, unenforceable, and unverifiable term.

Response. The term "millirem" is a combination of the prefix "milli," meaning one-thousandth, and "rem," an acronym for Roentgen Equivalent Man, a radiation dosimetry unit. Units of radiation doses, including rem, are defined in § 20.1004.

Comment. One commenter requested that NRC track, label, and publicly report all radioactive shipments of any kind, and reject the exemption tables. The commenter believed that "harmonization" was not an adequate justification for increasing public risk.

Response. The NRC believes that the current regulations require appropriate measures for hazard communication during transportation. As noted previously, the public risk from the transportation of exempt materials, as measured by the average dose, will actually decrease.

Comment. One commenter stated that the new exemption values will result in bulk shipments of decommissioning soil and debris being classed as LSA (Low Specific Activity) rather than being exempted from regulation. The commenter quantified the percentage of his shipments that would now be classed as LSA. The commenter stated that the increase in LSA-classified shipments will result in minimal additional costs.

Response. No response is required.

Comment. One commenter expressed opposition to the changes in definitions that could include changing exemption values, particularly because this is not subject to an EA.

Response. This rule adopts the TS-R-1 exempt material activity concentrations and exempt consignment activity limits as found in Table A-2 of the proposed rule. In essence, use of both of these values will replace the current definition for "radioactive material" found in 49 CFR 173.403, and applied in current 10 CFR 71.10. Within the revision to Part 71, reference to the exemption values will be added to the new § 71.14, "Exemption for low-level materials," to provide an exemption from NRC requirements during the transportation of these

materials. Estimated impacts from this revision are included in the EA prepared to support this rulemaking.

Comment. One commenter stated that the redefinition would pose a threat to national security.

Response. NRC does not believe adoption of the exemption values for radioactive materials in transport will have any bearing on national security.

Comment. One commenter expressed concern that the NRC proposed regulations could increase the variety of materials that are regulated as "radioactive" for transportation purposes.

Response. It is possible that materials that were not regulated under the previous DOT definition based on 70 Bq/g (0.002- μ Ci/g) would be newly regulated under the exemption values. However, a material consignment must exceed both the activity concentration for exempt material and the activity limit for exempt consignment to be regulated under the final DOT and NRC regulations. It is NRC's position that regulation of such material consignments as radioactive material in transport is appropriate.

Comment. One commenter asked the NRC to explain how NRC's official proposal on the changes in packaging and transporting of radioactive materials would affect industrial radiography.

Response. The final rule does not affect the transportation of standard industrial radiography devices.

Comment. One commenter stated that in "no case should NRC Part 71 definitions be relaxed or downgraded merely to provide 'internal consistency and compatibility with TS-R-1.'" The commenter stated that those who "wish to engage in trans-boundary trade in nuclear materials can be required to meet stiffer U.S. import requirements" than those elsewhere in the

world. The existing NRC staff justification is “a very lame dog that won’t hunt,” and regulatory relaxation is “both arbitrary and capricious and unacceptable.” The commenter stated that NRC should have definitions with full clarity, and no changes should be allowed that reduce safety levels or relax requirements. The commenter was especially troubled with the proposed change to “radioactive material” because this change would “allow shipments of radioactively contaminated materials that are declared to be exempted according to the concentrations and consignment limits shown in the Exemption Tables.”

Response. NRC believes that the amended definitions and new adoptions to support definitions for individual Issues are sufficiently justified and not arbitrary and capricious.

Issue 3. Revision of A_1 and A_2 .

Summary of NRC Final Rule. The final rule adopts, in Appendix A, Table A-1 of Part 71, the new A_1 and A_2 values from TS-R-1, except for molybdenum-99 and californium-252. The final rule does not include A_1 and A_2 values for the 16 radionuclides that were previously listed in Part 71 but which do not appear in TS-R-1.

The A_1 and A_2 values were revised by IAEA based on refined modeling of possible doses from radionuclides. The NRC believes that these changes are based on sound science, incorporating the latest in dosimetric modeling and that the changes improve the transportation regulations. The regulatory analysis indicates that adopting these values is appropriate from a safety, regulatory, and cost perspective. Further, adoption of the new A_1 and A_2 values will be an overall benefit to public and worker health and international commerce by ensuring that the A_1 and A_2 values are consistent within and between international and domestic transportation regulations. The NRC is not adopting the A_1 value for californium-252 because the IAEA is considering changing the value that appears in TS-R-1 back to what presently appears in

Part 71. The NRC is not adopting the A_2 value for molybdenum-99 for domestic commerce because this would result in a significant increase in the number of packages shipped, and therefore in potential occupational doses, due to the lower A_2 value in TS-R-1.

Affected Sections. Appendix A.

Background. The international and domestic transportation regulations use established activity values to specify the amount of radioactive material that is permitted to be transported in a particular packaging and for other purposes. These values, known as the A_1 and A_2 values, indicate the maximum activity that is permitted to be transported in a Type A package. The A_1 values apply to special form radioactive material, and the A_2 values apply to normal form radioactive material. See § 71.4 for definitions.

In the case of a Type A package, the A_1 and A_2 values as stated in the regulations apply as package content limits. Additionally, fractions of these values can be used (e.g., $1 \times 10^{-3} A_2$ for a limited quantity of solid radioactive material in normal form), or multiples of these values (e.g., $3,000 A_2$ to establish a highway route controlled quantity threshold value).

Based on the results from an updated Q-system (see draft Advisory Material for the Regulations for the Safe Transport of Radioactive Material, TS-G-1.1, Appendix I), the IAEA adopted new A_1 and A_2 values for radionuclides listed in TS-R-1 (see paragraph 201 and Table I). IAEA adopted these new values based on calculations which were performed using the latest dosimetric models recommended by the ICRP in Publication 60, "1990 Recommendations of the ICRP." A thorough review of the Q-system also included incorporation of data from updated metabolic uptake studies. In addition, several refinements were introduced in the calculation of contributions to the effective dose from each of the pathways considered. The pathways themselves are the same ones considered in the 1985 version of the Q-system: External photon dose, external beta dose, inhalation dose, skin and

ingestion dose from contamination, and dose from submersion in gaseous radionuclides. A thorough, up-to-date radiological assessment was performed for each radionuclide of potential exposures to an individual should a Type A package of radioactive material be involved in an accident during transport. The new A_1 and A_2 values reflect that assessment.

While the dosimetric models and dose pathways within the Q-system were thoroughly reviewed and updated, the reference doses were unchanged. The reference doses are the dose values which are used to define a "not unacceptable" dose in the event of an accident. Consequently, while some revised A_1 and A_2 values are higher and some are lower, the potential dose following an accident is the same as with the previous A_1 and A_2 values. The revised dosimetric models are used internationally to calculate doses from individual radionuclides, and these refinements in the pathway calculations resulted in various changes to the A_1 and A_2 values. In other words, where an A_1 or A_2 value has increased, the potential dose is still the same -- the use of the revised dosimetric models just shows that a higher activity of that radionuclide is actually required to produce the same reference dose. Conversely, where an A_1 or A_2 value has decreased, the revised models show that less activity of that nuclide is needed to produce the reference dose.

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC staff's responses for this issue follows:

Comment. One commenter stated that the NRC should not reduce the numbers and types of material subject to shipping regulations. The commenter was concerned that the proposed rule would:

- (1) exempt numerous radionuclide shipments from any regulation;
- (2) increase worker exposure and the difficulty of enforcement;
- (3) create an inconsistency with other Federal radionuclide standards; and

(4) otherwise reduce the protections afforded the public during radionuclide transportation.

Another commenter stated that the revisions' rationale does not justify such weakening, that inconsistency with IAEA standards is an inadequate justification for the proposed changes because there has been no demonstration that inconsistencies have caused any difficulty.

Finally, one commenter stated that increasing the A_1 and A_2 values should not be allowed and added that conforming with IAEA regulations is an insufficient justification to increase "levels of exposure to American citizens." Further, the commenter stated that avoiding "negative impacts on the nuclear industry are not justifiable reasons for NRC to relax any standards for protection of the public."

Response. The NRC disagrees with the first commenter. The final rule does not exempt numerous radionuclide shipments, nor increase worker exposure, nor reduce protection to the public, nor create an inconsistency with other Federal standards.

The NRC disagrees with the second commenter that the final rule weakens the regulations. Conforming NRC regulations to the IAEA regulations is not the sole justification; it is also adopting sound science, incorporating the latest in dosimetric modeling and that the changes improve the transportation regulations. The regulatory analysis indicates that adopting these values is appropriate from a safety, regulatory, and cost perspective.

Comment. One commenter suggested that the NRC organize the A_1 and A_2 tables to be sorted alphabetically by name rather than symbol, because the people who will use these tables most frequently will be more familiar with the spelling of the name rather than the chemical symbol. In addition, using the full name will make the tables easier to use and will be more consistent with the June 1, 1998, Presidential memo, "Plain Language in Government Writing."

Response. The comment is acknowledged; however, the tables will remain sorted as proposed to maintain consistency with the current DOT and IAEA regulations.

Comment. One commenter stated that the dose to workers could increase due to their need to handle more packages. The commenter also stated that the demand for molybdenum-99, the principal isotope used in medical imaging, would likely increase with the aging population.

Response. The proposed A_1 and A_2 values should result in only a minimal change in occupational risk. The proposed A_1 and A_2 values are based on the same reference doses as the current values, and only the dosimetric models were revised, leading to the updated values. In general, the proposed A_1 and A_2 values are within a factor of about three of the current values; very few radionuclides have proposed A_1 and A_2 values that are outside this range.

Currently in Part 71, the A_2 value for Mo-99 is 0.5 TBq (13.5 Ci) for international transport and 0.74 TBq (20 Ci) for domestic transport. The NRC originally proposed an A_2 value of 0.6 TBq (16.2 Ci) for Mo-99, but commenters suggested that adopting the lower A_2 value for domestic use would only result in an increase in the number of packages shipped and, thus, in a potential increase in occupational dose. Therefore, NRC will retain the current Mo-99 A_2 value of 0.74 TBq (20 Ci) for domestic shipments.

Comment. One commenter indicated that the proposed A_1 and A_2 values were "far reaching." The commenter was concerned by the lack of data supporting these significant changes but generally supported the changes.

Response. NRC does not believe that the proposed changes to the A_1 and A_2 values are "far reaching." NRC does not believe there is a lack of data on the proposed changes to the A_1 and A_2 values. Instead, the information on the Q-system, the details of the exposure

pathways, and the actual IAEA A_1 and A_2 values are contained in the guidance document for TS-R-1, TS-G 1.1, and Safety Series 7.

The revisions of the A_1 and A_2 values are based on a reexamination/new assessment of the dosimetric models used in deriving the content limits for Type A packages. The overall impact of the reexamination resulted in improved methods for the evaluation of the content limits for special form (denoted by A_1) and nonspecial form (denoted by A_2) radioactive material. Internationally, as increased knowledge and scientific methods are gained and applied in the areas of health physics, radioactive material packaging, and radioactive material transportation, it is appropriate to take advantage of that knowledge and information and apply it to the IAEA regulations. This has occurred with the revision of the A_1 and A_2 values. The IAEA applied the newly-revised Q-system to the same uptake scenarios it used for the 1985 regulations. Thus, the same dose criteria, which were used in the assessment of the 1985 A_1 and A_2 values, were also used to determine the new A_1 and A_2 values in TS-R-1.

While some of the A_1 and A_2 values have increased, some values remain unchanged, and some values decreased, the overall safety implications for TS-R-1 remain the same as those used in the 1985 IAEA regulations.

Within the Q-system, a series of exposure routes are considered which may result in radiation exposure to persons near a Type A package of radioactive material that has been involved in an accident. The exposure routes include external photon dose, external beta dose, inhalation dose, skin and ingestion dose due to contamination transfer, and submersion (exposure to vapor/gas) dose.

Comment. One commenter requested more explanation of the implications of revision of the A_1 and A_2 values. The commenter requested simple summaries for both special form and normal materials.

Response. See response to the preceding comment. Special form radioactive material and normal form radioactive material are defined in § 71.4. In general, special form radioactive material is subjected to various tests found in § 71.75, “Qualification of special form radioactive material.” These materials are known to be nondispersible (will not disperse contamination). Thus, in a transportation scenario, special form radioactive material could be considered relatively safer in transport by the fact that it poses only a direct radiation hazard (and not a contamination hazard). On the other hand, radioactive material that has not been tested to the requirements of § 71.75 or has not passed these tests has not qualified to be considered special form radioactive material. Such material is called nonspecial form (commonly known as normal form) radioactive material. In general, these materials pose both a radiation and contamination hazard in that they are considered to be dispersible. As an example, consider the A_1 and A_2 values for actinium-227 ($A_1 = 9\text{E-}1 \text{ TBq (} 2.4\text{E}1 \text{ Ci)}$; $A_2 = 9\text{E-}5 \text{ TBq (} 2.4\text{E-}3 \text{ Ci)}$). Notice the tremendous difference between A_1 and A_2 . This example demonstrates that in special form, a much larger amount of activity can be placed in a Type A package because the special form material has been sealed or encapsulated and has proven its robustness by passing the test requirements of § 71.75. The same encapsulation and testing is not true for the nonspecial form (A_2) value. This is where the applicability of health physics and metabolic uptake come into consideration for determining the A_1 and A_2 values for each individual radionuclide.

Comment. One commenter asked if the justification for the change is the shift in accepted dose models from ICRP 26 and 30 to 60 and 66. The commenter requested data supporting the shift in dose models.

Response. The most recent recommendations of the ICRP were issued in 1991 (1990 Recommendation of the International Commission on Radiological Protection, Publication

No. 60, Pergamon Press, 1991). Within TS-R-1, IAEA applied the values from ICRP 60 and 66, thus the shift in dose models. This data can be found in the ICRP 60 and 66 documents.

Comment. One commenter noted that ICRP and IAEA risk models only look at fatal cancers and ignore nonfatal cancers, years of lost life, and the bystander effect. The commenter asserted that the ICRP and IAEA reports do not accurately reflect risk and that low levels of radiation are more damaging than the models are predicting.

Response. The NRC acknowledges this comment but notes that a response to similar concerns expressed is provided in the first comment of Section II - Analysis of Public Comments, under the heading: Adequacy of NRC Regulations and Rulemaking Process.

Comment. One commenter asked if these revisions would actually expand the number of containers that have to meet test standards.

Response. Within Part 71, NRC approves packages and shipping procedures for fissile radioactive materials and for licensed materials in quantities that exceed A_1 or A_2 . NRC will continue to apply the regulations in Part 71 to Type B and fissile radioactive material packages. NRC is not aware of an expansion of the container inventory which will have to meet test standards due to an increase in any individual A_1 or A_2 value.

Comment. One commenter said that the scientific basis for the changes to the A_1 and A_2 values is understood and justified. However, the commenter urged NRC to maintain the exception (found in Table A-1 of Appendix A to Part 71) to allow the domestic A_2 limit of 20 Ci for Mo-99, which, the commenter states, is necessary to allow domestic manufacturers to continue to provide Mo-99 generators to the diagnostic nuclear medicine community. The commenter said that changing the A_2 limit to the TS-R-1 value would result in an increase in the number of packages shipped and, thus, an increase in the doses received by manufacturers, carriers, and end users.

Response. NRC agrees with this commenter concerning the revision to the A_1 and A_2 values and the scientific background used to support the changes. Further, the commenter has indicated that the TS-R-1 A_2 value for molybdenum-99 would increase the number of packages shipped and, thus, an increase the radiation exposure to various workers. Accordingly, to reduce these concerns NRC will retain the current A_2 value for molybdenum-99 ($7.4E-1$ TBq; $2.0E1$ Ci) as stated in the proposed rule and as found in Table A-1 for domestic transport. NRC is aware that by adopting this value (as opposed to the current value for molybdenum-99 in TS-R-1), the number of shipments of molybdenum-99 and the associated radiation exposure may be reduced.

Comment. One commenter indicated that revising the A_1 and A_2 values might have an adverse impact on currently certified casks. The commenter stated that the proposed regulation does not ensure that transport casks certified under previous revisions will still be usable without modification or analysis in the future.

Response. Although NRC staff could revise cask certificates if necessary, no changes are known to be needed to accommodate the revised A_1 and A_2 values.

Comment. One commenter stated that because DOE is the principal shipper of californium-252 under the current exemption value, the potential impacts to industry could not be assessed.

Response. NRC is aware of the limited and safe transportation of californium-252 by DOE.

Comment. One commenter stated that by omitting the A_1 and A_2 values for 16 radionuclides, the Commission would have to set these values upon future request of a licensee. The commenter recommended that the NRC not delete these values from Part 71,

Appendix A, to save NRC the cost and resources necessary to establish these values in the future.

Response. NRC agrees that more time and effort may be needed to reintroduce these 16 radionuclides into Appendix A at some time in the future, as compared to retaining their names and symbols but not publishing actual A_1 and A_2 values for them. Instead, the reference to the general values for A_1 and A_2 provided in Table A-3 would be used without NRC approval for shipping these radionuclides. Further, to maintain consistency/harmonization with future IAEA transport standards, NRC may adopt a revised list of A_1 and A_2 values, should there be revisions to Table 1 in future editions of the IAEA transport standards.

Comment. Four commenters agreed with NRC's efforts to revise A_1 and A_2 values.

Response. The NRC acknowledges these comments.

Comment. Several commenters disagreed with the NRC staff's position. One commenter opposed weakening the present standard of radiation protection during transportation, particularly because NRC is proposing to ship radioactive wastes to a repository. Another commenter expressed concern that many, if not most, of the A_1 and A_2 values, both current and proposed in the NRC's Part 71 regulations, appear to have been arbitrarily chosen and are unsafe. Another commenter stated that any additional costs "must be borne by licensees and beneficiaries of use of materials." Another commenter asked the NRC not to adopt the exemption values contained in Table 2 of TS-R-1.

Response. NRC does not consider the adoption of the A_1 and A_2 values from TS-R-1 to be a weakening of the present standards for packaging and transporting radioactive material. The NRC believes the revision of the A_1 and A_2 values to be based on sound science and that it provides adequate protection to the public and workers. Furthermore, there is not a direct connection between adopting the revised A_1 and A_2 values into Part 71 and the package

standards and safety requirements which will be imposed on the transport packages for high-level waste en route to a geologic repository.

The process used to determine the appropriate A_1 and A_2 value assigned to each radionuclide is based on several factors. These include the type of radiation emitted by the radionuclide (e.g., alpha, beta, or gamma), the energy of that radiation (i.e., strong alpha emitter, strong gamma emitter, weak beta emitter, etc.), and the form of the material (nondispersible as applied to special form radioactive material, or dispersible as applied to nonspecial form radioactive material). All of these factors have been modeled in the IAEA's Q-system to determine the appropriate value to be assigned to each radionuclide. Thus, the values have not been arbitrarily obtained, and they are not unsafe. Further, the revision to the A_1 and A_2 values in TS-R-1 has maintained the same level of safety as was applied in determining the A_1 and A_2 values for the radionuclides in the 1985 IAEA transportation standards. Thus, there is no weakening of the intended safety aspects of the new A_1 and A_2 values.

Comment. Several commenters noted various typographical errors. The first commenter noted that Footnote 2 to Table A-1 is incorrect and should instead read, "See Table A-4." The second commenter noted an error in the proposed Table A-1 for the A_2 (Ci) value for Pu-239, suggesting that the correct value should be 2.7×10^{-2} Ci, as evidenced from the A_2 (TBq) value for Pu-239 and the similar Table 1 in the IAEA TS-R-1 regulations and Table 10A in the proposed DOT regulations.

Response. NRC acknowledges the comment, and corrections have been made to the final rule.

Comment. One commenter addressed changing a number of the radionuclide values. The commenter suggested that the radionuclide Al-26 value for specific activity in 10 CFR 71,

Table A-1, should be changed from 190 Ci/g to 0.019 Ci/g. The A_1 and A_2 values in both 10 CFR 71 Table A-1 and 49 CFR 173.435 for Ar-39 appear reversed from that listed in IAEA TS-R-1. The radionuclide Be-10 value for specific activity in 10 CFR 71 Table A-1 should be changed from 220 Ci/g to 0.022 Ci/g. The radionuclide Cs-136 value for specific activity in 49 CFR 173.435 should be changed from 0.0027 TBq/g to 270 TBq/g. The radionuclide Dy-165 value for A_2 (Ci) in 10 CFR 71 Table A-1 should be changed from 0.16 to 16 Ci. The radionuclide Eu-150 (long-lived) value for A_1 (TBq) in 10 CFR 71 Table A-1 and 49 CFR 173.435 is not consistent with the IAEA TS-R-1 value of 0.7. The radionuclide Fe-59 value for A_2 (TBq) in 10 CFR 71 Table A-1 is in error. The radionuclide Ho-166m value for A_2 (TBq) in 10 CFR 71 Table A-1 should be 0.5. The radionuclide K-43 value for A_2 (TBq) in 10 CFR 71 Table A-1 should be 0.6. The radionuclide Kr-81 value for A_1 (TBq) in 49 CFR 173.435 should be 40, A_1 (Ci) in 49 CFR 173.435 should be 1100. The radionuclide Kr-85 value for A_2 (TBq) in 49 CFR 173.435 should be 10; A_2 (Ci) in 49 CFR 173.435 should be 270. The radionuclide La-140 value for A_2 (Ci) in 49 CFR 173.435 should be 11. The radionuclide Lu-177 value for A_2 (TBq) in 49 CFR 173.435 should be 0.7; A_2 (Ci) in 49 CFR 173.435 should be 19. The radionuclide Mn-52 value for specific activity (Ci) in 49 CFR 173.435 should be 4.4E+05. The radionuclide Np-236 (long-lived) value for A_1 (TBq) in IAEA TS-R-1 is 9; A_2 (TBq) in IAEA TS-R-1 is 0.02, different from the values in both 49 CFR 173.435 and 10 CFR 71, Table A-1. The radionuclide Pt-197m value for A_2 (TBq) in 49 CFR 173.435 should be 0.6; A_2 (Ci) in 49 CFR 173.435 should be 16. The radionuclide Pu-239 value for A_2 (Ci) in 10 CFR 71, Table A-1, should be 0.027. The radionuclide Pu-240 value for specific activity (Ci) should be 0.23 Ci/g. The radionuclide Ra-225 value for A_2 (Ci) in 10 CFR 71, Table A-1, should be 0.11. The radionuclide Ra-228 value for A_2 (TBq) in 10 CFR 71, Table A-1, should be 0.02. The radionuclide Rh-105 value for A_2 (Ci) in 10 CFR 71, Table A-1, is in error. The radionuclide Sc-46 value for A_1 (TBq) in 10

CFR 71, Table A-1, should be 0.5. The radionuclide Sn-119m value for A_2 (TBq) in 10 CFR 71, Table A-1, should be 30. The radionuclide Sn-126 value for specific activity (TBq) in 10 CFR 71, Table A-1, should be 0.001. The radionuclide H-3 value for A_2 (TBq) in 10 CFR 71, Table A-1, should be 40. The radionuclide Ta-179 value for A_1 (TBq) in 10 CFR 71, Table A-1, should be 30. The radionuclide Tb-157 value for A_1 (TBq) in 10 CFR 71, Table A-1, should be 40; value for specific activity (TBq) in 10 CFR 71, Table A-1, should be 0.56 TBq/g. The radionuclide Tb-158 value for A_2 (Ci) in 10 CFR 71, Table A-1, should be 27; value for specific activity (TBq) in 10 CFR 71, Table A-1, should be 0.56 TBq/g.

The radionuclide Tb-160 value for A_1 (Ci) in 10 CFR 71, Table A-1, should be 27. The radionuclide Tc-96 value for A_1 (TBq) in 10 CFR 71, Table A-1, should be 0.4. The radionuclide Tb-96m value for A_1 (TBq) in 10 CFR 71, Table A-1, should be 0.4; value for A_2 (TBq) in 10 CFR 71, Table A-1, should be 0.4. The radionuclide Tc-97 value for specific activity (TBq) in 10 CFR 71, Table A-1, should be 5.2E-05; value for specific activity in 10 CFR 71, Table A-1, should be 0.0014. The radionuclide Te-125m value for A_2 (Ci) in 10 CFR 71, Table A-1, should be 24. The radionuclide Te-129 value for A_1 (TBq) in 10 CFR 71, Table A-1, should be 0.7; value for A_2 (TBq) in 10 CFR 71, Table A-1, should be 0.6. The radionuclide Te-132 value for A_1 (TBq) in 10 CFR 71, Table A-1, should be 0.5. The radionuclide Th-227 value for A_2 (Ci) in 10 CFR 71, Table A-1, should be 0.14. The radionuclide Th-231 value for A_2 (TBq) in 10 CFR 71, Table A-1, should be 0.02. The radionuclide Th-234 value for A_1 (TBq) in 10 CFR 71, Table A-1, should be 0.3. The radionuclide Ti-44 value for A_1 (TBq) in 10 CFR 71, Table A-1, should be 0.5; value for A_2 (TBq) in 10 CFR 71, Table A-1, should be 0.4, value for A_2 (Ci) in 10 CFR 71, Table A-1, should be 10. The radionuclide Tl-200 value for A_1 (TBq) in 10 CFR 71, Table A-1, should be 0.9. The radionuclide Tl-204 value for A_2 (TBq) in 10 CFR 71, Table A-1, should be 0.7. The radionuclide U-230, U-232, U-233, and U-234 values for medium and slow

lung absorption, and U-236 values for slow lung absorption are not consistent with IAEA TS-R-1. The comment points out that the Table values published in the Federal Register for the proposed rule did not match TS-R-1.

Response. NRC accepts the comment and has updated the values in the final rule, Table A-1, to be consistent with TS-R-1. Appropriate changes have been made in the final rule.

Comment. Three commenters stated that the A_2 value for molybdenum-99 and the A_1 and A_2 values for californium-252 should be retained for domestic use only packages.

Response. NRC agrees with the comment. (See 67 FR 21399; April 30, 2002, for more details.)

Issue 4. Uranium Hexafluoride (UF₆) Package Requirements.

Summary of NRC Final Rule. The final rule provides, in new § 71.55(g), a specific exception for certain uranium hexafluoride (UF₆) packages from the requirements of § 71.55(b). The exception allows UF₆ packages to be evaluated for criticality safety without considering the in leakage of water into the containment system provided certain conditions are met, including that the uranium is enriched to not more than 5 weight percent uranium-235. The rule makes Part 71 compatible with TS-R-1, paragraph 677(b). Other uranium hexafluoride package requirements in TS-R-1 (paragraphs 629, 630 and 631) do not necessitate changes for compatibility because NRC uses analogous national standards and addresses package design requirements in its design review process.

The specific exception being placed into the regulations for the criticality safety evaluation of certain uranium hexafluoride packages does not alter present practice which has allowed the same type of evaluation under other more general regulatory provisions. NRC has decided to provide this specific exception: (1) to be consistent with the worldwide practice and

limits established in national and international standards (ANSI N14.1 and IS 7195) and current U.S. regulations [49 CFR 173.417(b)(5)]; (2) because of the history of safe shipment; and (3) because of the essential need to transport the commodity.

Affected Sections. Section 71.55

Background. Requirements for UF₆ packaging and transportation are found in both NRC and DOT regulations. The DOT regulations contain requirements that govern many aspects of UF₆ packaging and shipment preparation, including a requirement that the UF₆ material be packaged in cylinders that meet the ANSI N14.1 standard. NRC regulations address fissile materials and Type B packaging designs for all materials.

TS-R-1 contains detailed requirements for UF₆ packages designed for transport of more than 0.1 kilogram (kg) UF₆. First, TS-R-1 requires the use of the International Organization for Standardization (ISO) 7195, "Packaging of Uranium Hexafluoride for Transport." Second, TS-R-1 requires that all packages containing more than 0.1 kg UF₆ must meet the "normal conditions of transport" drop test, a minimum internal pressure test, and the hypothetical accident condition thermal test (para 630). However, TS-R-1 does allow a competent national authority to waive certain design requirements, including the thermal test for packages designed to contain greater than 9,000 kg UF₆, provided that multilateral approval is obtained. Third, TS-R-1 prohibits UF₆ packages from using pressure relief devices (para 631). Fourth, TS-R-1 includes a new exception for UF₆ packages regarding the evaluation of criticality safety of a single package. This new exception [para 677(b)] allows UF₆ packages to be evaluated for criticality safety without considering the in leakage of water into the containment system. Consequently, a single fissile UF₆ package does not have to be subcritical assuming that water leaks into the containment system. This provision only applies when there is no contact between the valve body and the cylinder body under accident tests, and the valve remains leak-

tight, and when there are quality controls in the manufacture, maintenance, and repair of packages coupled with tests to demonstrate closure of each package before each shipment.

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC responses for this issue follows:

Comment. Five commenters expressed support for the proposed changes to UF₆ package rules that continue the current practice of moderator exclusion for UF₆. One commenter cited the strong safety record applying these rules as evidence that the practice is adequate. Two commenters objected to the 5 percent enrichment limit provision in proposed § 71.55(g), and a third commenter expressed concern with the enrichment limit. One commenter noted that the safety case for the specific enrichment to use can be a part of the package certification application and, therefore, does not need to be specified by rule. The same commenter further noted that arguments that water in leakage is not a realistic scenario for a UF₆ cylinder regardless of enrichment and that the 5 percent limit, if imposed for transportation, could have very high cost implications in light of pending decisions to use higher enrichments in the fuel cycle. One commenter suggested that the rule retain the limit of 5 percent for the existing ANSI N14.1 Model 30B cylinder, but that the rule also contain provisions that permit greater than 5 percent enrichments in an “improved UF₆ package with special design features” to accommodate future industry plans.

Response. The NRC’s decision to exempt uranium hexafluoride cylinders from § 71.55(b) with a limiting condition of 5 weight percent enriched uranium was made based on:

(1) consistency with the worldwide practice and limits established in national and international standards (ANSI N14.1 and IS 7195) and current U.S. regulations [49 CFR 173.417(b)(5)];

(2) the history of safe shipment; and

(3) the essential need to transport the commodity.

The NRC staff believes that further expansion of the practice of authorizing shipment of materials in packages that do not meet § 71.55(b), without a strong technical safety basis and without full understanding of the potential reduction in safety margins, is not prudent or necessary at this time. In addition, provisions are available to request approval of alternative package designs that could be used for the shipment of uranium hexafluoride with uranium enrichments greater than 5 weight percent under the provisions of § 71.55(b) or § 71.55(c). Merits of a new or modified design that included special design features could be reviewed and approved under the provisions of § 71.55, including § 71.55(c).

Because package certification is directly tied to the regulations, any assessment of the safety of enrichments greater than 5 weight percent uranium-235, considering the potential or probability of water in leakage, would not be part of the safety case of an application if the enrichment limit is not included as part of the regulation.

Although it is correct that the water in leakage scenario is not changed for enrichments less than or greater than 5 weight percent, it is not clear that the safety margins against accidental nuclear criticality for all enrichments would be the same if water were introduced into the containment vessel accidentally. Because these margins are undefined at this time, it does not seem prudent or necessary to modify the regulatory standard that was based on worldwide practice in existence today. Future changes in the fuel cycle that could necessitate transport of enrichments greater than 5 weight percent uranium-235 could result in new packages designed to meet the normal fissile material package standards in § 71.55(b), as are required for other commodities, or could include special design features that would enhance nuclear criticality safety for transport for approval under the provisions of § 71.55(c). Alternatively, a safety assessment could be developed for possible transport of enrichments greater than 5 weight

percent to support some future rulemaking to modify § 71.55(g) to increase the enrichment limitation.

For the previously mentioned reasons, the NRC staff has retained the 5 percent enrichment limit in the final rule.

Comment. One commenter stated an opinion that all UF₆ packages should have overpacks and noted that the proposed rule should resolve this issue.

Response. The NRC staff does not agree with the position that all UF₆ packages be required by rule to incorporate an overpack. Design and performance standards for fissile UF₆ packages are stated in Part 71, and design and performance standards for nonfissile UF₆ packages appear in DOT regulations. Use of specific design features (e.g., overpacks) to meet regulatory standards is left to designers.

Comment. One commenter expressed concern that NRC had not provided data to back up its proposal to “relax the current packaging requirements” in § 71.55(b) for UF₆. The commenter stated that NRC should not adopt this proposal unless it can provide justification for doing so. The commenter was also concerned that NRC’s EA does not address any impacts associated with this proposal.

Response. The NRC staff disagrees with the commenter’s assertion that adoption of § 71.55(g) is a relaxation of current packaging requirements in § 71.55(b). As noted by the commenter, NRC’s proposed rule (67 FR 21400) explains that the new § 71.55(g) provisions are consistent with existing worldwide practice for UF₆ packages. This worldwide practice has been in use since its development in the 1950s, and the functioning of the nuclear fuel cycle in the U.S. relies upon transport of this commodity. The exception was limited to 5 weight percent enriched uranium consistent with the worldwide practice and limits established in national and international standards (ANSI N14.1 and IS 7195) and current U.S. regulations [49 CFR

173.417(b)(5)]. The new regulatory text replaces the more general “special features” allowances with a more explicit provision pertaining to certain UF₆ packages.

Comment. Two commenters expressed opposition for the relaxation of testing for radioactive transport containers. One commenter stated that the drop test, minimum internal pressure test, and the hypothetical accident condition test must be accompanied by the thermal test to assure public protection in the event of an accident. One commenter cited both the Baltimore tunnel fire and the Arkansas bridge incident as justifications for not allowing any exemptions.

Response. The NRC staff reviewed these comments and determined that they concern the nonfissile UF₆ packaging issues discussed in Issue 6 in the DOT’s proposed rulemaking (April 30, 2002; 67 FR 21337), not the fissile UF₆ package matters in Issue 4 in the related NRC proposed rulemaking. The NRC staff noted that the commenter’s letter was jointly addressed to NRC and DOT for resolution in their final rule.

Issue 5. Introduction of the Criticality Safety Index Requirements.

Summary of NRC Final Rule. The final rule adopts the TS-R-1 (paragraphs 218 and 530). Paragraph 218 results in NRC incorporating a Criticality Safety Index (CSI) in Part 71 that is determined in the same manner as current Part 71 “Transport Index for criticality control purposes,” but now it must be displayed on shipments of fissile material (paragraphs 544-545) using a new “fissile material” label. NRC’s adoption of TS-R-1 (paragraph 530) increases the CSI-per package limit from 10 to 50 for fissile material packages in nonexclusive use shipments. (The previous Transport Index criticality limit was 10.) The TI is determined in the same way as the “TI for radiation control purposes” and continues to be displayed on the traditional “radioactive material” label. The basis for these changes that makes Part 71

compatible with TS-R-1 is that NRC believes the differentiation between criticality control and radiation protection would better define the hazards associated with a given package and, therefore, provide better package hazard information to emergency responders. The increase in the per package CSI limit may provide additional flexibility to licensees by permitting the increased use of less expensive, nonexclusive use shipments. However, licensees will still retain the flexibility to ship a larger number of packages of fissile material on an exclusive use conveyance. The adoption of the CSI values would make Part 71 consistent with TS-R-1 and, therefore, would enhance regulatory efficiency.

Affected Sections. Sections 71.4, 71.18, 71.20, 71.59

Background. Historically, the IAEA and U.S. regulations (both NRC and DOT) have used a term known as the Transport Index (TI) to determine appropriate safety requirements during transport. The TI has been used to control the accumulation of packages for both radiological safety and criticality safety purposes and to specify minimum separation distances from persons (radiological safety). The TI has been a single number which is the larger of two values: the "TI for criticality control purposes"; and the "TI for radiation control purposes." Taking the larger of the two values has ensured conservatism in limiting the accumulation of packages in conveyances and in-transit storage areas.

TS-R-1 (paragraph 218) has introduced the concept of a CSI separate from the old TI. As a result, the TI was redefined in TS-R-1. The CSI is determined in the same way as the "TI for criticality control purposes," but now it must be displayed on shipments of fissile material (paragraphs 544 and 545) using a new "fissile material" label. The redefined TI is determined in the same way as the "TI for radiation control purposes" and continues to be displayed on the traditional "radioactive material" label.

TS-R-1 (paragraph 530) also increased the allowable per package TI limit [for criticality control purposes (new CSI)] from 10 to 50 for nonexclusive use shipments. No change was made to the per package radiation TI limit of 10 for nonexclusive use shipments. As noted above, a consolidated radiation safety and CSI existed in the past. In this consolidated index, the per package TI limit of 10 was historically based on concerns regarding the fogging of photographic film in transit, because film might also be present on a nonexclusive use conveyance. Consequently, when the single radiation and criticality safety indexes were split into the TI and CSI indexes, the IAEA determined that the CSI per package limit, for fissile material packages that are shipped on a nonexclusive use conveyance, could be raised from 10 to 50. The IAEA believed that limiting the total CSI to less than or equal to 50 in a nonexclusive use shipment provided sufficient safety margin, whether the shipment contains a single package or multiple packages. Therefore, the per package CSI limit, for nonexclusive use shipments, can be safely raised from 10 to 50, thereby providing additional flexibility to shippers. Additionally, no change was made to the per package CSI limit of 100 for exclusive use shipments.

The NRC believes the differentiation between criticality control and radiation protection would better define the hazards associated with a given package and, therefore, provide better package hazard information to emergency responders. The increase in the per package CSI limit may provide additional flexibility to licensees by permitting the increased use of less expensive, nonexclusive use shipments. However, licensees will still retain the flexibility to ship a larger number of packages of fissile material on an exclusive use conveyance.

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC staff's responses for this issue follows:

Comment 1. One commenter requested a basic explanation of the CSI and TI. The commenter questioned if the proposed changes would increase public risk. Another commenter asked for clarification on how NRC would calculate CSI for radiological shipments to ensure that a shipment is under limits.

Response. The requested explanation was provided during the June 4, 2001, public meeting at which the first comment was made (see NRC rulemaking interactive website at <http://ruleforum.llnl.gov>). In addition, the proposed rule contains background on the CSI; regarding increased public risk. The draft RA concluded the change is appropriate from a safety perspective. Also, see Background discussion for this issue.

Comment. One commenter expressed opposition to the text that would restrict accumulations of fissile material to a total CSI of 50 in situations where radioactive materials are stored incident to transport. The commenter added that this would effectively remove the ability to transport internationally and/or by multiple modes under exclusive use conditions and would negatively impact the international movement of fissile materials under nonproliferation programs. The commenter further noted that this provision would apply only to shipments to or from the U.S., thus creating a disadvantage for American businesses in the international market.

Response. The NRC agrees with these comments. The intent of the storage phrase was to permit segregation of groups of stored packages, consistent with IAEA and DOT requirements, but the NRC staff believes that the proposed text did not accommodate that practice. DOT requirements restrict accumulation of packages during transport, based on summing the packages' CSI or TI, including during storage incident to transport. In light of the division of regulatory responsibilities explained in the NRC-DOT Memorandum of Understanding (44 FR 38690; July 2, 1979), the NRC exemptions for carriers-in-transit in

10 CFR 70.12, and DOT's proposed 49 CFR 173.457 (67 FR 21384; April 30, 2002), the NRC staff believes that storage in transit provisions proposed in §§ 71.59(c)(1), 71.22(d)(3), and 71.23(d)(3) are unwarranted. The NRC has deleted the phrase "or stored incident to transport" from these sections.

Comment. One commenter stated that in proposed §§ 71.59(c)(1), (2) and (3), and 71.55(f)(3), the values of 50.0 and 100.0 should be changed to 50 and 100 to be consistent with the application of the CSI.

Response. The NRC staff did not intend nor does it believe that there is a substantive difference between "50" and "50.0" as used in Part 71. In proposing to use the decimal place, the NRC staff was attempting to increase precision when the CSI is exactly 50.0 and promote consistency as the CSI is by definition rounded to the nearest tenth. However, the NRC staff noted that both DOT's proposed rule and IAEA TS-R-1 use "50" without a decimal place. The NRC staff agrees that consistency amongst the three rules is desirable unless a reason exists for differentiating. Accordingly, conforming changes have been made to the Part 71 final rule.

Comment. One commenter expressed opposition to the rounding of the CSI provision in the proposed rule, because it is inconsistent with TS-R-1 and places additional limits on the array size of shipments.

Response. The commenter correctly observes that § 71.59(b) requires all nonzero CSIs to be rounded up to the first decimal place and that the corresponding TS-R-1 requirement (paragraph 528) does not require such rounding. Rounding up the CSI is necessary to ensure that an unanalyzed number of packages are not transported together; rounding a CSI down would permit such situations. The NRC staff notes that this U.S. provision predates the currently contemplated changes for compatibility with TS-R-1 (viz., the existing

U.S. domestic regulations are also different than the 1985 IAEA transport regulations in this respect).

Consistent with the NRC proposal, the IAEA's implementing guidance for TS-R-1 (i.e., TS-G-1.1 at para. 528.3) states, "The CSI for a package . . . should be rounded up to the first decimal place" and "the CSI should not be rounded down." The NRC staff noted that the IAEA's guidance, however, does observe that use of the exact CSI value may be appropriate in cases when rounding results in less than the analyzed number of packages to be shipped.

The NRC staff believes that the rule is compatible with IAEA TS-R-1. Furthermore, because the domestic convention on rounding predates this rulemaking for compatibility with 1996 TS-R-1, and because the statements of consideration did not explicitly discuss the rounding practice, the potential elimination of the rounding practice is beyond the scope of the current rulemaking action.

Comment. Three commenters expressed agreement with NRC's proposed position. One of the three commenters expressed support for the NRC's CSI proposal, reasoning that it provides more accurate communication regarding radioactive material in transport, especially in conjunction with the TI for radiation exposure. The commenter noted that the CSI is important to ensure consistency between domestic and international movements of fissile material. Another commenter stated that use of the CSI would "remove a source of confusion with the old TI values. The resulting enhancement of the safety of shipments makes the extra efforts necessary to implement these proposals worthwhile."

Response. No response is necessary.

Comment. One commenter stated that the CSI "should be set so as to maximize protective benefit for workers and the public without regard for added costs to licensees and users." The commenter added that there doesn't seem to be a "strong argument against

adoption" of the IAEA CSI but then stated that the increase from 10 to 50 per package does not have adequate justification. Further, the commenter stated that if cost reduction for licensees is the only reason for this change, then the proposal is unacceptable.

Response. The CSI is derived to prevent nuclear criticality for single packages and arrays of packages, both in incident-free and accident conditions of transport. Therefore, the NRC staff has determined that the application of the CSI does support protection of workers and the public. The basis for increasing the accumulation of packages from 10 TI under the old system to 50 CSI in the new system is given in the proposed rule (at 67 FR 21401), and it is not a solely economic basis. Specifically, the limit of 10 TI was based on radiation damage to film, so when the TI and CSI were split in 1996, a separate limit on package accumulation based on criticality prevention, of 50 CSI, became warranted.

Issue 6. Type C Packages and Low Dispersible Material.

Summary of NRC Final Rule. The final rule does not adopt the Type C or Low dispersible material (LDM) requirements for plutonium air transport as introduced in the IAEA TS-R-1. NRC decided not to adopt Type C or LDM requirements because the U.S. regulations in §§ 71.64 and 71.71 governing plutonium air transportation to, within, or over the United States contains more rigorous packaging standards than those in the IAEA TS-R-1. Furthermore, the NRC's perception is that there is a lack of current or anticipated need for such packages, and NRC acknowledges that the DOT import/export provisions permit use of IAEA regulations.

Affected Sections. None (not adopted).

Background. TS-R-1 introduced two new concepts: the Type C package (paragraphs 230, 667-670, 730, 734-737) and the LDM. The Type C packages are designed to withstand

severe accident conditions in air transport without loss of containment or significant increase in external radiation levels. The LDM has limited radiation hazard and low dispersibility; as such, it could continue to be transported by aircraft in Type B packages (i.e., LDM is excepted from the TS-R-1 Type C package requirements). United States regulations do not contain a Type C package or LDM category but do have specific requirements for the air transport of plutonium (§§ 71.64 and 71.74). These specific NRC requirements for air transport of plutonium would continue to apply.

The Type C requirements apply to all radionuclides packaged for air transport that contain a total activity value above 3,000 A_1 or 100,000 A_2 , whichever is less, for special form material, or above 3,000 A_2 for all other radioactive material. Below these thresholds, Type B packages would be permitted to be used in air transport. The Type C package performance requirements are significantly more stringent than those for Type B packages. For example, a 90-meter per second (m/s) impact test is required instead of the 9-meter drop test. A 60-minute fire test is required instead of the 30-minute requirement for Type B packages. There are other additional tests, such as a puncture/tearing test, imposed for Type C packages. These stringent tests are expected to result in package designs that would survive more severe aircraft accidents than Type B package designs.

The LDM specification was added in TS-R-1 to account for radioactive materials (package contents) that have inherently limited dispersibility, solubility, and external radiation levels. The test requirements for LDM to demonstrate limited dispersibility and leachability are a subset of the Type C package requirements (90-m/s impact and 60-minute thermal test) with an added solubility test, and must be performed on the material without packaging for nonplutonium materials. The LDM must also have an external radiation level below 10 mSv/hr (1 rem/hr) at 3 meters. Specific acceptance criteria are established for evaluating the

performance of the material during and after the tests (less than 100 A₂ in gaseous or particulate form of less than 100-micrometer aerodynamic equivalent diameter and less than 100 A₂ in solution). These stringent performance and acceptance requirements are intended to ensure that these materials can continue to be transported safely in Type B packages aboard aircraft.

In 1996, the NRC communicated to the IAEA that the NRC did not oppose the IAEA adoption of the newly created Type C packaging standards (letter dated May 31, 1996, from James M. Taylor, EDO, NRC, to A. Bishop, President, Atomic Energy Control Board, Ottawa, Canada). However, Mr. Taylor stated in the letter that to be consistent with U.S. law, any plutonium air transport to, within, or over the U.S. will be subject to the more rigorous U.S. packaging standards. Industry needs to be aware of changes or potential changes based on new IAEA standards.

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC staff's responses for this issue follows:

Comment. Four commenters expressed support for NRC's proposal to not adopt the requirements for Type C packages and LDM. One commenter also expressed support for the NRC's decision to ensure that there is a mechanism for reviewing validations of foreign approvals. One commenter stated that the IAEA specification is too broad and that NRC and DOT should work with IAEA to reduce the scope to a few packages containing fissile oxides of plutonium, but there is no need for this package to transport Class 7 materials.

Two commenters stated that the benefits did not justify the costs of the proposed changes and strongly supported the NRC position not to adopt the Type C requirements. One commenter stated that many parties are asking IAEA to modify the Type C requirements. The commenter urged NRC to see how these change proposals will affect the Type C requirements

before adopting them into the U.S. regulations. Additionally, the commenter stated that the need for Type C packages for all radioactive material has not been demonstrated.

Response. The NRC staff acknowledges these comments that endorse the position to not adopt Type C package requirements at this time, for the reasons specified in the proposed rule (67 FR 21402). The NRC staff agrees that Type C issues will likely receive further consideration in future IAEA rule cycles. No further response is necessary.

Comment. Two commenters stated that the threat of terrorism should be taken into account when exempting radionuclides from transport regulations and changing container regulations. One commenter stated that the fact of the September 11, 2001, attacks needs to be accounted for with upgraded Types B and C testing, which are currently believed to be insufficient. The commenter added that these tests should "assure the highest probability that packages will survive unbreached."

Response. The NRC acknowledges the concern expressed regarding the threat of terrorism. However, the NRC does not propose adopting Type C and LDM requirements at this time. The NRC staff notes that the IAEA is conducting further evaluations on Type C package requirements, which may result in other changes for safety and security purposes. Also, see Section II, above, for general comments on terrorism.

Comment. One commenter asked if workers will be protected and notified when handling Type C packages and plutonium, and whether they will be notified that there will be increased hazards once the proposed rule is effective.

Response. The requested information on worker protection was provided at the public meeting at which the comment was made. Application of DOT's regulations, including hazardous materials training requirements, package radiation limits, and contamination limits, will protect workers for Type C packages just as for other shipments. In addition, the

robustness of the packaging would provide protection in accidents. Thus, changes to the probability or consequences of releases in accidents do not result from proposed changes to Type C packages. The NRC does not propose adopting IAEA Type C or LDM standards at this time, and domestic regulations were not revised.

Comment. One commenter recommended that the NRC “adopt these provisions in order to better the goal of compatibility with IAEA regulations.” This commenter continued by stating that “industry would then have a basis for developing such a package if desirable.”

Response. These comments recommend adoption of Type C standards in the interest of the goal of IAEA compatibility and speculate that a domestic Type C package regulation and certification might be desirable in the future. The NRC staff does not believe that deferring domestic rules on Type C packages makes U.S. regulations incompatible with IAEA regulations (viz., the U.S. and IAEA rules are not identical but they are compatible). The NRC staff believes there is not a need to adopt Type C standards at this time because of the reasons specified in the proposed rule (67 FR 21402) and

- (a) The perception of a lack of a current or anticipated need,
- (b) The DOT import/export provisions that permit use of IAEA regulations, and
- (c) The existing U.S. regulations and laws covering plutonium air transport.

This can be reevaluated during future periodic rulemakings for IAEA compatibility, as necessary. In addition, the proposed rule stated that upon request from DOT, NRC would perform a technical review of Type C packages against IAEA TS-R-1 standards. The comments do not indicate a current need; therefore, the NRC staff has decided to retain the position explained in its proposed rule to not adopt Type C or LDM requirements.

Comment. One commenter said that air transport of plutonium and other radionuclides should be prohibited under all circumstances. The commenter stated that "low dispersible materials" is a faulty concept regarding air transport and urged NRC to abandon this concept.

Response. The NRC staff disagrees with the comments that air transport of plutonium and other radionuclides should be prohibited under all circumstances. These practices are recognized in multiple U.S. laws and regulations, and have been carried out with an excellent safety record. Consistent with the position expressed in the proposed rule, the NRC decided not to adopt the low dispersible material provisions at this time.

Issue 7. Deep Immersion Test.

Summary of NRC Final Rule. The final rule adopts the requirement for an enhanced water immersion test (deep immersion test) which is applicable to any Type B or C packages containing activity greater than $10^5 A_2$. The purpose of the deep immersion test is to ensure recoverability. The basis for expanding the scope of the deep immersion test to include additional Type B or C packages containing activity greater than $10^5 A_2$ was due to the fact that radioactive materials, such as plutonium and high-level radioactive waste, are increasingly being transported by sea in large quantities. The threshold defining a large quantity as a multiple of A_2 is considered to be a more appropriate criterion to cover all radioactive materials and is based on a consideration of potential radioactive exposure resulting from an accident. Also, the NRC is retaining the current test requirements in § 71.61 of "one hour w/o collapse, buckling or leakage of water." The NRC is retaining this acceptance criterion of "w/o collapse, buckling, or leakage" as opposed to the acceptance criterion specified in TS-R-1 of only "no rupture" of the containment. NRC has determined that the term "rupture" cannot be determined

by engineering analysis and the term “w/o collapse, buckling or leakage of water” is a more precise definition for acceptance criterion.

Affected Sections. Sections 71.41, 71.51, 71.61.

Background. TS-R-1 expanded the performance requirement for the deep water immersion test (paragraphs 657 and 730) from the requirements in the IAEA Safety Series No. 6, 1985 edition. Previously, the deep immersion test was only required for packages of irradiated fuel exceeding 37 PBq (1,000,000 Ci). The deep immersion test requirement is found in Safety Series No. 6, paragraphs 550 and 630, and basically stated that the test specimen be immersed under a head of water of at least 200 meters (660 ft) for a period of not less than 1 hour, and that an external gauge pressure of at least 2 MPa (290 psi) shall be considered to meet these conditions. The TS-R-1 expanded immersion test requirement (now called enhanced immersion test) now applies to all Type B(U) [Unilateral] and B(M) [Multilateral] packages containing more than 10^5 A₂, as well as Type C packages.

In its September 28, 1995 (60 FR 50248), rulemaking for Part 71 compatibility with the 1985 edition of Safety Series No. 6, the NRC addressed the new Safety Series No. 6 requirement for spent fuel packages by adding § 71.61, “Special requirements for irradiated nuclear fuel shipments.” Currently, § 71.61 is more conservative than Safety Series No. 6 with respect to irradiated fuel package design requirements. It requires that a package for irradiated nuclear fuel with activity greater than 37 PBq (10^6 Ci) must be designed so that its undamaged containment system can withstand an external water pressure of 2 MPa (290 psi) for a period of not less than 1 hour without collapse, buckling, or inleakage of water. The conservatism lies in the test criteria of no collapse, buckling, or inleakage as compared to the “no rupture” criteria found in Safety Series No. 6 and TS-R-1. The draft advisory document for TS-R-1 (TS-G-1.1,

paragraphs 657.1 to 657.7) recognizes that leakage into the package and subsequent leakage from the package are possible while still meeting the IAEA requirement.

The Safety Series No. 6 test requirements were based on risk assessment studies that considered the possibility of a ship carrying packages of radioactive material sinking at various locations. The studies found that, in most cases, there would be negligible harm to the environment if a package were not recovered. However, should a large irradiated fuel package (or packages) be lost on the continental shelf, the studies indicated there could be some long-term exposure to man through the food chain. The 200-meter (660-ft) depth specified in Safety Series No. 6 is equivalent to a pressure of 2 MPa (290 psi), and roughly corresponds to the continental shelf and to depths that the studies indicated radiological impacts could be important. Also, 200 meters (660 ft) was a depth at which recovery of a package would be possible, and salvage would be facilitated if the containment system did not rupture. (Reference Safety Series No. 7, paragraphs E-550.1 through E-550.3.)

The expansion in scope of the deep immersion test was due to the fact that radioactive materials, such as plutonium and high-level radioactive wastes, are increasingly being transported by sea in large quantities. The threshold defining a large quantity as a multiple of A_2 is considered to be a more appropriate criterion to cover all radioactive materials and is based on a consideration of potential radiation exposure resulting from an accident.

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC staff's responses for this issue follows:

Comment. One commenter stated that a 1-hour test is "wholly inadequate as a risk basis, given that as many as 100,000 shipments of highly irradiated 'spent' fuel are anticipated to being moved transcontinentally on highways and railroads." The commenter added that

"barge shipments should be prohibited outright." Finally, the commenter recommended more stringent immersion testing for shipping canisters.

Response. The NRC acknowledges the comment. However, the NRC believes it is already moving towards more stringent standards with this rule. The 1-hour test is sufficient to demonstrate structural integrity and prevent inleakage. Most hydrostatic testing of components are for durations much less than 1 hour. A test duration of 1 hour is reflective of a practical requirement that will ensure the desired package performance. While a longer duration test may appear to be more reflective of the actual immersion times that might exist following an accident, the duration of the test must be considered in conjunction with the purpose of the test and the acceptance criteria specified for successfully passing the test.

The purpose of the deep immersion test, as described in IAEA TS-G-1.1, paragraphs 657.1 to 657.7, is to ensure package recoverability. The acceptance criterion specified in TS-R-1 is that there be no "rupture" of the containment system. As described in the rule, NRC believes that a more precisely defined acceptance criterion of no "collapse, buckling, or inleakage of water" is preferable. Type B package designs that are capable of withstanding a 1-hour test without "collapse, buckling, or inleakage of water" are likely to be sufficiently robust that a longer duration test would not produce significantly greater structural damage.

Comment. One commenter suggested that the deep immersion test should consider the possibility that the cask could already be damaged or ruptured at the time of immersion. The commenter asked if there has been an analysis of the dissemination of radionuclides at high pressures for partially or completely ruptured casks. The commenter stated that this issue is relevant due to the frequent transportation of radioactive waste across the Great Lakes and between the U.S. and other nations, such as Russia.

Response. The acceptance criterion for the deep immersion test is no “collapse, buckling, or inleakage of water.” If a cask is already damaged or ruptured at the time of immersion, then the immersion test becomes a moot point because the acceptance criterion cannot be met. Studies have been performed, including the IAEA-sponsored Coordinated Research Project on "Severity, probability and risk of accidents during the maritime transport of radioactive material," that examined the potential radiological consequences of such accidents. The report of the Coordinated Research Project, IAEA-TECDOC-1231, is available online at: <http://www.iaea.org/ns/rasanet/programme/radiationsafety/transportafety/Downloads/Files2001/t1231.pdf>

Comment. One commenter stated that if older, previously certified packages can no longer be "grandfathered," it will take significant effort to show that these packages meet the deep immersion test and will result in little safety benefit for the shipments.

Response. The commenter's connection between immersion testing and grandfathering (see Issue 8) of existing certified packages is not obvious. Under current NRC regulations (§ 71.61), a package for irradiated nuclear fuel with activity greater than 37 PBq (10^6 Ci) must meet the immersion test requirement. Under the revised requirement, these same packages could be used for shipment of irradiated nuclear fuel containing activity greater than 10^5 A₂ and would not require additional immersion testing (because the packages must already comply with the test requirement).

Comment. Three commenters expressed support for NRC's position on this issue. One commenter stated that the proposed rule's deep immersion test provisions would increase cask safety.

Response. No response is required.

Comment. One commenter urged the NRC to require more stringent testing procedures for both old and new shipping containers (including longer drops; greater crash impacts; longer and higher pressure water submersion; leakage resistance; higher, longer, more intense fire temperatures; and much greater explosive forces). Another commenter requested that NRC change its standards so that casks damaged in sequential tests would be required to survive immersion at depths greater than those in the proposed rule.

Response. The NRC acknowledges this comment but believes that it has adequate package testing requirements in the rule.

Comment. One commenter asked if containers that were not currently certified to carry over one million curies would become authorized to carry over one million curies under the proposed rule.

Response. If a package design is not currently certified to carry over one million curies, its status will not be changed by this rulemaking. Any restrictions on a package design imposed through the NRC-issued CoC remain unaffected.

Comment. One commenter stated that the cost of compliance was grossly underestimated, particularly for demonstrating cask integrity at 200 meters.

Response. NRC staff appreciates the comment and fully understands the importance of accurate cost data. As part of the proposed rulemaking, the NRC specifically requested cost-benefit information on this issue as well as a number of other issues. To the extent NRC received data from public comments, these data were considered in developing its final decision.

Comment. One commenter asked if the deep immersion test would apply to all packages shipped across Lake Michigan.

Response. Under the proposed rule, the deep immersion test would be applied to any Type B or C package that contains greater than $10^5 A_2$, regardless of the transport mode. Therefore, the immersion test requirement would be applicable to all shipments involving a package with an activity exceeding $10^5 A_2$, including any across Lake Michigan.

Comment. One commenter asked if the deep immersion test actually requires a physical test. If the deep immersion test did not actually require a physical test, the commenter asked NRC to clarify what it means by "test." The commenter also wanted NRC to clarify to what the test specifically applies.

Response. As cited in the IAEA advisory document TS-G-1.1, paragraph 730.2: "The water immersion test may be satisfied by immersion of the package, a pressure test of at least 2 MPa, a pressure test on critical components combined with calculations, or by calculations for the whole package." In answer to the commenter's specific question, a physical test is not required, and calculational techniques may be used. Regarding what the test specifically applies to, ST-2, Section 730.3, states that: "The entire package does not have to be subjected to a pressure test. Critical components such as the lid area may be subjected to an external gauge pressure of at least 2 MPa and the balance of the structure may be evaluated by calculation." Thus, testing may be performed physically, by analysis, or by a combination of the two.

Comment. One commenter stated that industry supports the NRC position on deep immersion testing.

Response. The comment is acknowledged.

Comment. One commenter expressed concern that the deep immersion test only requires that packages be submerged for 1 hour. The concern is based on the belief that it is unlikely a package could be recovered within an hour following a real accident.

Response. The 1-hour time limit only applies to the immersion test and is the minimum time that the package shall be subjected to the test conditions. It is not expected that a package could be recovered within 1 hour of an accident involving submergence of the package. In fact, in the IAEA advisory document TS-G-1.1, paragraph 657.7 states: "Degradation of the total containment system could occur with prolonged immersion and the recommendations made in the above paragraphs (657.1 through 657.6) should be considered as being applicable, conservatively, for immersion periods of about 1 year, during which recovery should readily be completed."

Comment. One commenter asked NRC to clarify its assertion that the immersion test is stricter than the IAEA's test because the NRC's language does not allow collapse, buckling, or any leakage of water.

Response. TS-R-1, paragraph 657, states, in part, that for a package subjected to the enhanced water immersion test (NRC uses the term deep immersion test), there would be no "rupture of the containment system." The term rupture is not a defined engineering term in the IAEA literature related to TS-R-1. Further, the IAEA advisory document TS-G-1.1, paragraph 730.3, states, in part, that some degree of buckling or deformation is acceptable during the enhanced water immersion test. Lacking specificity to the term rupture, the NRC imposed specific, and it believes conservative, requirements that do not allow collapse, buckling, or inleakage of water for a package undergoing the deep immersion test.

Issue 8. Grandfathering Previously Approved Packages.

Summary of NRC Final Rule. The final rule adopts the following grandfathering provisions for previously approved packages in Section 71.19:

(1) Packages approved under NRC standards that are compatible with the provisions of the 1967 edition of Safety Series No. 6 may no longer be fabricated, but may be used for a 4-year-period after the effective date of the final rule;

(2) Packages approved under NRC standards that are compatible with the provisions of the 1973 or 1973 (as amended) editions of Safety Series No. 6 may no longer be fabricated; however, may still be used;

(3) Packages approved under NRC standards that are compatible with the provisions of the 1985 or 1985 (as amended 1990) editions of Safety Series No. 6, and designated as "-85" in the identification number, may not be fabricated after December 31, 2006, but may be continued to be used; and

(4) Package designs approved under any pre-1996 IAEA standards (i.e., packages with an "-85" or earlier identification number may be resubmitted to the NRC for review against the current standards. If the package design described in the resubmitted application meets the current standards, the NRC may issue a new CoC for that package design with a "-96" designation.

Thus, the final rule adopts, in part, the provisions for grandfathering contained in TS-R-1. The NRC believes that packages previously approved under the 1967 edition of Safety Series No. 6 lack the enhanced safety enrichments which have been incorporated in the packages approved under the provisions of the 1973, 1973 (as amended), 1985 and 1985 (as amended) editions of Safety Series No. 6. For example, later designs demonstrate a greater degree of leakage resistance and are subject to quality assurance requirements in Subpart H of Part 71. Furthermore, NRC believes that by discontinuing the use of package designs that have been approved to Safety Series No. 6, 1967, for both domestic and international transport of radioactive material, it will ensure safety during transportation and thus will increase public

confidence. However, NRC has not adopted the immediate phase out of 1967-approved packages as the IAEA has, instead, NRC implemented a 4-year transition period for the grandfathering provision on packages approved under the provisions of the 1967 edition of Safety Series No. 6. This period provides industry the opportunity to phase out old packages and phase in new ones, or demonstrate that current requirements are met. NRC recognizes that when the regulations change there is not necessarily an immediate need to discontinue use of packages that were approved under previous revisions of the regulations. The final rule includes provisions that would allow previously-approved designs to be upgraded and to be evaluated to the newer regulatory standards. Note that in 1996, IAEA first published that the 1967-approved packages would be eliminated from use. Thus, at a minimum, with the 4-year phase out of these older packages, industry will have had at least 10 years (i.e., until 2007) to evaluate its package designs and prepare for the eventual phase out.

Affected Sections. Section 71.19.

Background. Historically, the IAEA, DOT, and NRC regulations have included transitional arrangements or “grandfathering” provisions whenever the regulations have undergone major revision. The purpose of grandfathering is to minimize the costs and impacts of implementing changes in the regulations on existing package designs and packagings. Grandfathering typically includes provisions that allow: (1) continued use of existing package designs and packagings already fabricated, although some additional requirements may be imposed; (2) completion of packagings that are in the process of being fabricated or that may be fabricated within a given time period after the regulatory change; and (3) limited modifications to package designs and packagings without the need to demonstrate full compliance with the revised regulations, provided that the modifications do not significantly affect the safety of the package.

Each transition from one edition of the IAEA regulations to another (and the corresponding revisions of the NRC and DOT regulations) has included grandfathering provisions. The 1985 and 1985 (as amended 1990) editions of Safety Series No. 6 contained provisions applicable to packages approved under the provisions of the 1967, 1973, and 1973 (as amended) editions of Safety Series No. 6. TS-R-1 includes provisions which apply to packages and special form radioactive material approved under the provisions of the 1973, 1973 (as amended), 1985, and 1985 (as amended 1990) editions of Safety Series No. 6.

TS-R-1 grandfathering provisions (see TS-R-1, paragraphs 816 and 817) are more restrictive than those previously in place in the 1985 and 1985 (as amended 1990) editions of Safety Series No. 6. The primary impact of these two paragraphs is that packagings approved under the 1967 edition of Safety Series No. 6 are no longer grandfathered; i.e., cannot be used. The second impact is that fabrication of packagings designed and approved under Safety Series No. 6 1985 (as amended 1990) must be completed by a specified date. Regarding special form radioactive material, TS-R-1 paragraph 818 does not include provisions for special form radioactive material that was approved under the 1967 edition of Safety Series No. 6. Special form radioactive material that was shown to meet the provisions of the 1973, 1973 (as amended), 1985, and 1985 (as amended 1990) editions of Safety Series No. 6 may continue to be used. However, special form radioactive material manufactured after December 31, 2003, must meet the requirements of TS-R-1. Within current NRC regulations, the provisions for approval of special form radioactive material are already consistent with TS-R-1.

In TS-R-1, packages approved under Safety Series No. 6, 1973 and 1973 (as amended) can continue to be used through their design life, provided the following conditions are satisfied: (1) Multilateral approval is obtained for international shipment; (2) Applicable TS-R-1 quality assurance (QA) requirements and A_1 and A_2 activity limits are met; and (3) If applicable, the

additional requirements for air transport of fissile material are met. While existing packagings are still authorized for use, no new packagings can be fabricated to this design standard. Changes in the packaging design or content that significantly affect safety require that the package meet current requirements of TS-R-1.

TS-R-1 further states that those packages approved for use based on the 1985 or 1985 (as amended 1990) editions of Safety Series No. 6 may continue to be used with unilateral approval until December 31, 2003, provided the following conditions are satisfied: (1) TS-R-1 QA requirements and A_1 and A_2 activity limits are met; and (2) If applicable, the additional requirements for air transport of fissile material are met. After December 31, 2003, use of these packages for foreign shipments may continue under the additional requirement of multilateral approval. Changes in the packaging design or content that significantly affect safety require that the package meet current requirements of TS-R-1. Additionally, new fabrication of this type of packaging must not be started after December 31, 2006. After this date, subsequent package designs must meet TS-R-1 package approval requirements.

Analysis of Public Comments on the Proposed Rule.

The NRC notes that although there were a significant number of comments reflecting opposition to the proposed grandfathering change to the regulation, the majority of these comments were received from two commenters representing the same company. The remaining comments reflected opinions ranging from strong opposition to any grandfathering of designs to full support for the proposed rule change. Accordingly, following discussions with the DOT, NRC changed the transition period from 3 years in the proposed rule to 4 years in the final rule. With the effective date for this final rule being one year, the transition period is effectively 5 years. A review of the specific comments and the NRC staff's responses for this issue follows.

Comment. One commenter stated that the IAEA standards are consensus based and that NRC must recognize they do not necessarily consider the risk-informed, performance-based aspects of regulations that are developed in the United States. The commenter added that NRC regulations should also provide allowance for domestic-only applications, which would include, for example, the grandfathering provision. While the IAEA provisions must apply to international shipments, for domestic-only shipments the grandfathering provision would allow the continued use of existing packages manufactured to the 1967 standard, but prohibit the manufacture of any new packages.

Response. The NRC staff finding is to phase out those packages approved to Safety Series No. 6, 1967 Edition, over a 4-year period after effective date of of this final rule. This allows industry adequate time to phase out old packages, phase in new ones, or resubmit a package design for review against the current standards. NRC considers it undesirable to be incompatible with IAEA with respect to this provision. In eliminating the grandfathering of these older designs, the IAEA concluded and NRC agrees that the continuance of packages that could not be shown to meet later standards was no longer justified. As described, certain packages approved under the 1967 edition of the regulations may lack safety enhancements that later designs have incorporated. The NRC acknowledges the comment about risk-informed, performance-based regulations but notes that the applicability of this change was not justified.

Comment. One commenter suggested that NRC require far more stringent testing procedures for both old and new shipping containers (longer drops; greater crash impacts; longer and higher pressure water submersion; leakage resistance; higher, longer, more intense fire temperatures; and much greater explosive forces). Another commenter stated that “packages and containers should be subject to upgraded safety testing and more rigorous

standards than have been required in the past,” especially after the events of September 11, 2001.

Response. The NRC acknowledges these comments and notes that the commenters did not provide justification for the proposed changes. Packages designed to regulations that are based on the 1973 and later editions of Safety Series 6, in general, may include safety enhancements, including designs, that demonstrate a greater degree of leakage resistance. Major changes in the physical test parameters for Type B packages are not being considered at this time, either by NRC or the IAEA. NRC is confident that packages designed to meet the current Type B standards provide a high degree of safety in transport, even under severe transportation accidents.

Comment. One commenter objected to any grandfathering of casks. The commenter stated that “it will be a number of years before appreciable amounts of ‘spent’ fuel can be transported for more permanent disposition” and that this “gives a substantial window of time for design, development, and proof testing of new, better shipping casks.”

Response. The NRC and DOT have in place comprehensive regulations that will support the safety of a large scale shipping campaign to a central geologic repository should one ever be built. Such safety is reliant upon the use of certified casks with robust design and regulations that address training of staff dealing with shipments and use of routes that minimize potential dose to the public. The safety record of shipments of spent fuel both here and overseas has been excellent. NRC regulations are compatible with IAEA regulations with respect to grandfathering previously approved designs. These provisions allow continued use of designs approved to earlier regulatory standards; however, the provisions include certain restrictions with respect to package modifications and fabrication. These provisions have been adopted to allow a transition to newer regulations while maintaining a high level of safety in

transport. Packages that were approved to the 1967 IAEA standards are being phased out because they may not include safety enhancements of later designs.

Comment. One commenter stated that accurate data are not currently available to forecast cost-benefit impacts. The commenter urged NRC to work with those who hold Type B packages to determine whether they want to maintain these packages. A second commenter stated that the costs of requiring the replacement of 1967-specification packages are substantial and that the benefits of requiring the replacements for domestic use are zero. The commenter also stated that the NRC should allow usage periods to be extended long enough to ensure that the “money’s worth” has been obtained. The commenters added that NRC should not propose changes when no harm or hazard has been demonstrated.

Response. The NRC has made the decision to begin a 4-year phase out of packages that have been approved to Safety Series No. 6, 1967. However, NRC will allow package designs to be submitted for review against the current requirements (TS-R-1). Based on this pathway, over the 4-year period (after effective date of the final rule), industry can determine which Type B packages they choose to submit for review to the current requirements or have phased out. NRC has no current plans to contact individual design holders of affected package designs to suggest an action on their part.

In evaluating the cost and benefits associated with the proposed phasing out of the 1967-based packages, the NRC staff considered that these designs may fall into one of the following five categories:

(1) Package designs that may meet current safety standards with no modifications but have not been submitted for recertification. This category includes package designs for which there is probably sufficient supporting technical safety basis to support certification under

current requirements. For example, test data and engineering analyses probably exist and are still relevant to the current safety standards.

Costs associated with these package designs include the following:

- (a) Development of an application (\$10-\$50K); and
- (b) Review costs for NRC certification (\$20K for 135 hours - nonspent fuel amendment).

The total costs might be expected to be in the range of \$30 - \$70K per package design.

(2) Package designs that can be shown to meet current safety standards with probably relatively minor design changes.

Costs associated with these package designs include the following:

- (a) Design analysis and physical testing for modifications (\$10K - \$100K);
- (b) Development of revised package application (\$10K - \$50K - based on approximately 200 staff hours of work);
- (c) Review costs for NRC certification (\$20K - based on 135 staff hours for review of nonspent fuel amendment requests); and
- (d) Packaging modifications to fleet of packagings (minor - \$200 per packaging, major - \$5K per packaging).

The total cost would be expected to be in the range of \$40K to \$170K depending on the modifications in the design or testing information. This does not include the costs for making the physical changes in the packagings, which could vary significantly for different package types and different design modifications, in addition to the number of packagings that needed to be modified.

For packages in Categories 1 and 2, NRC staff believe that the expense of recertifying the design should be reasonable and is small when considering the length of time these

package designs have already been in service (longer than 20 years). There is additional financial incentive for upgrading these designs, because upgrading would allow additional packagings to be fabricated and allow certificate holders to request a wide range of modifications, both to the package design and the authorized contents.

(3) Package designs that may meet current safety standards but are impractical to recertify.

This category is intended to capture the special nature of spent fuel casks that were certified to the 1967 IAEA standards. These package designs may be considered separately for several reasons, including:

(a) Domestic regulatory design standards for spent fuel casks existed before standards for other package types;

(b) QA requirements were applied to this type of package, whereas other package types were not subjected to the same level of QA either for design or fabrication; and

(c) These packages normally have a limited specific use and are, therefore, not present in large numbers in general commerce.

For packages in this category, NRC staff will be willing to review an application under the exemption provisions of § 71.8 that requests an exemption to specific performance requirements for which demonstration is not practical. The applicant would be free to propose, for example, additional operational controls that would provide equivalent safety. The exemption request could use risk information in justifying the continued use of these existing packagings.

Costs associated with these package designs include the following:

(a) Development of application, including risk information (\$150K); and

(b) NRC review costs (\$40,000 - based on 270 staff hours for a "non-standard" spent fuel package amendment request).

(4) Package designs that cannot be shown to meet current safety standards.

Costs associated with these package designs include the following:

(a) Development of new designs (\$100-150K);

(b) Analysis and physical tests (\$50K for prototype + 100K);

(c) Development of package application;

(e) NRC review costs (\$40,000 - based on 270 staff hours for review of new designs for nonspent fuel); and

(f) Fabrication costs (\$50K per package).

The cost information for development of new designs and the analysis and testing of these newly designed packages (Category 4) were provided to NRC by industry commenters during the public comment period.

(5) Packages for which the safety performance of the package design under the current safety standards is not known. This is due primarily to a lack of documentation available regarding the package design and performance.

NRC staff believes it is appropriate to phase out the use of designs that fall into Categories 4 and 5. NRC staff believes that there are package designers that may be willing and able to develop new designs provided there is a financial incentive. With the continued use of packages that cannot be shown to meet current standards, there will be no financial incentive to upgrade designs. In addition, most packagings certified to the 1967 design standards are more than 20 years old. Although proper maintenance of transportation packagings is required, it is not clear that the service life of many types of packagings would justify continued use.

The cost estimates associated with NRC review are based on historical information gathered over years of performing technical reviews of transportation package designs. There are many factors that significantly influence the review time associated with performing staff technical reviews for new package designs and amendments. Some of the most important factors are: quality of the application, design margins in the package, and a clear and unambiguous demonstration that the regulatory acceptance criteria have been met. The costs previously cited are not considered maximum or minimum but are representative and conservative averages based on receipt of a complete and high-quality package application.

The estimates of costs associated with development of designs, testing, and preparation of application are extrapolated from information provided by commenters to the proposed rule

Comment. One commenter stated that packages that were manufactured to the 1967 safety standard should be allowed to continue in domestic service, unless a safety problem is identified. This commenter provided monetized data to show how expensive our proposed position could be.

Response. In the final rule published September 28, 1995 (60 FR 50254), NRC wrote: “NRC believes that the international package standards should be used by the United States for both domestic and international shipments, to the extent practicable. However, based on a history of safe use under earlier safety standards, and the absence of unfavorable operational data, NRC will allow the continued use of existing packages in domestic transport until the end of their useful lives. NRC will not allow, however, the continued fabrication of packages to the old designs. This action permits use of existing packages. It does not perpetuate package designs that can be discarded or upgraded to satisfy the new standards.”

Further, in the April 30, 2002 (67 FR 21405) proposed rule, NRC wrote “The NRC recognizes that when the regulations change there is not an immediate need to discontinue use

of packages that were approved under previous revisions of the regulations. Part 71 has included provisions that would allow previously-approved designs to be upgraded and to be evaluated to the newer regulatory standards. NRC believes that packages approved under the provisions of the 1967 edition of Safety Series No. 6, and which have not been updated to later editions, may lack safety enhancements which have been included in the packages approved under the provision of the 1973, 1973 (as amended), 1985 and 1985 (as amended 1990) editions of Safety Series No. 6. Therefore, the NRC believes that it is appropriate to begin a phased discontinuance of these earlier packages (1967-approved) to further improve transport safety.”

NRC adopted the 1985 IAEA standards on April 30, 2002 (60 FR 50254), which allowed continued use of 1967 packages. In 1996, however, IAEA published new regulations in TS-R-1 which discontinued grandfathering these older designs. NRC agrees with IAEA's position that continuance of these older designs is no longer justified. Therefore, to be compatible with IAEA, NRC will begin a phased discontinuance of the packages approved to Safety Series No. 6, 1967 after adoption of a final rule.

The NRC has justified phasing out these designs based on the following:

Safety standards have been upgraded three times since these designs were initially evaluated and approved. In some cases, the documented safety basis for these designs is substantially incomplete. Although NRC knows of no imminent safety hazards posed by use of these packages, it is judged to be prudent to be consistent with IAEA in phasing out these designs. In addition, the performance of the package in a transportation accident may not be known until a challenging accident occurs. The safety of a package in routine, incident-free transport, may not be a good predictor of safety in a transportation accident.

Opportunity was provided to upgrade these designs to later regulatory standards; however, applicants chose not to provide an application to show that the designs met later safety standards. That opportunity still exists and should be used by package owners that rely on these packages for transporting their products.

Although there is a financial impact for phasing out these designs, it is judged that there will also be a financial benefit to package designers that choose to develop replacement packages that meet current domestic and international safety standards.

Comment. One commenter stated that the proposed rule has no discernible safety benefit to adopting TS-R-1 on this issue, there is no direct economic information on the effect of implementing this proposal, and NRC has requested cost-benefit information from the regulated community.

Response. The NRC does not agree that there is no safety benefit in adopting TS-R-1 provisions on grandfathering. The NRC believes that packages approved to later safety standards (after 1967) may include important safety enhancements. The grandfathering provision allows a 4-year phase out period. Based on this pathway, over the impending 4-year period (after effective date of the final rule), certificate holders can determine which Type B packages they choose to have phased out or reviewed to the current requirements. The commenter accurately notes that NRC has solicited cost information regarding this proposal.

Comment. Three commenters stated that the proposed rule's effort to phase out 1967-specification packages would negatively impact their own businesses. One commenter argued that phasing out these packages would have such a high cost that it would drive many small nuclear-shipping businesses out of business with no ready successors. Another commenter stated that phasing out these packages would cost about \$20-\$25 million and could force some entities out of business, which could create an unintended side-effect of orphaning over 1,000

radioactive sources of considerable size. Another commenter discussed his business of designing, manufacturing, servicing, shipping and disposing of devices (principally calibrators and irradiators) that use Type B quantities of Cobalt-60 or Cesium-137 sources, and the process of shipping radioactive sources and how it relates to his business. The commenter discussed the impact of phasing out 1967-specification packages. The commenter argued that phasing out these packages for domestic shipments would impose substantial economic, safety, and environmental costs without any benefits.

Response. The NRC believes that packages approved under the provisions of the 1967 edition of Safety Series No. 6, and which have not been upgraded to later editions, may lack safety enhancements which have been included in packages developed to later standards. NRC is seeking to be compatible with the IAEA on the issue of grandfathering and is not seeking to put shipping companies out of business. Therefore, NRC will begin to phase out those packages that have been approved to Safety Series No. 6, 1967, 4 years after adoption of a final rule. The NRC believes that many of the suggested orphaned sources would qualify as Type A quantities and would not be negatively impacted by the phase out of the 1967-approved packages.

Comment. One commenter opposed NRC's proposal on this issue because it will have detrimental effects on his business. The commenter explained that his company has 1,200 new packages built to the 1967 Safety Series No. 6 specifications that will be used in a contract that runs through 2006. The company estimates that replacing these packages would cost \$5,000-\$10,000 per package, which overall would devastate the contract and be ruinous to the business. The commenter believes that packages should be removed from service when they no longer meet the safety requirements they were designed to meet or if a new safety issue

with the package is identified which would prevent the package from meeting its intended safety function; neither of these conditions have been identified for the package.

Response. With the adoption of the final rule, the opportunity exists to have packages that were built to the 1967 Safety Series No. 6 specifications reevaluated to the current standards. Since August 1986, fabrication of new packages to the old (1967) specifications has not been authorized by NRC. The comment supports NRC's pre-1995 position that, based on satisfactory performance, the 1967-type packages could continue to be used. The new packages suggested in the comment are assumed to have been fabricated in accordance with DOT regulations. However, NRC's and DOT's current position, which is consistent with the IAEA's on grandfathering, is to phase out the packages with these old designs over a 4-year period. This time period will allow certificate holders to determine which packages they will phase out or resubmit to NRC for evaluation to the current standards. Industry needs to be aware of changes or potential changes based on IAEA rules. Note in 1996, IAEA first published that the 1967-approved packages would be eliminated, and 5 years later (i.e., 2001) the international regulations were implemented. Thus, as a minimum, with the 4-year phase out of the 1967-approved packages, industry will have had at least 10 years (i.e., until 2006) to evaluate their package designs, evaluate those designs that will not meet the new standards, and prepare for the eventual phase out.

Comment. One commenter stated that eliminating 1967-specification packages would cause severe harm. The commenter argued that many businesses would have to requalify, relicense, and rebuild virtually all of their current shipping containers at a very high cost. The commenter noted that the RA did not take these costs into account. The commenter argued that prohibiting the use of 1967-specification packages would create thousands of orphan

sources, creating a public health risk, and that these sources could only be moved at very high costs.

Response. The NRC notes that businesses may choose to requalify, relicense, or rebuild their packages. Based on the long history associated with grandfathering various packages, NRC believes that a 4-year time period will allow certificate holders adequate opportunity to make a responsible business decision as to which pathway to proceed - phasing a package design out or resubmitting it for evaluation to the current standards.

Comment. One commenter stated that certain containers excluded by the proposed legislation couldn't be easily replaced because no alternative packaging currently exists at comparable prices. The commenter explained that designing, testing, and licensing a new package is expensive (approximately \$500,000) and usually takes over a year to accomplish

Response. The NRC acknowledges the comment about the cost and time to design a new package. The staff notes that from the time the IAEA TS-R-1 became effective to the date when NRC's grandfathering phase out became effective will have been a significant and sufficient amount of time for designers to learn about the new requirements, to adopt design and fabrication effort accordingly, such that new and conforming packages would be available for use when needed by shippers.

Comment. One commenter stated that the RA lacks consideration of costs to industry and health and safety benefits of the proposed changes. The commenter believes that there were no arguments to be made and that the only rationale would be harmonization with the IAEA, which is not binding under U.S. law.

Response. The NRC disagrees that the only rationale for this rulemaking is harmonization with the IAEA. NRC continues to believe that harmonizing NRC's and DOT's regulations, when appropriate, will prove beneficial to NRC, industry, and the general public.

NRC believes that packages approved to the 1967 standards lack safety enhancements that were included in packages approved to later editions of Safety Series No. 6 (i.e., 1973 and 1985).

Comment. One commenter stated that numerous participants in this market sector are small entities within the meaning of the Regulatory Flexibility Act and would be adversely affected by the proposed rule, and neither agency's draft RA accounts for this fact.

Response: The NRC disagrees with this comment. The Commission certified in Section XI. of this notice that this rule will not have a significant economic impact on a substantial number of small entities. This rule affects NRC licensees, including operators of nuclear power plants, who transport or deliver to a carrier for transport, relatively large quantities of radioactive material in a single package. These companies do not generally fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards adopted by the NRC (10 CFR 2.810).

Only one small entity commented on the proposed changes suggesting that small entities would be negatively affected by the rule. Reviewing records of licensed QA programs, NRC found that only 15 of the 127 NRC licensed QA programs were small entities. Furthermore, of these 15 companies' NRC staff expect that only 2 or 3 would be negatively affected by the final rule, given these companies' lines of business and day-to-day operations. Based on this data, it is believed there will not be significant economic impacts for a substantial number of small entities.

Comment. One commenter asked how important this issue is to the future success of small businesses that routinely transport Type B quantities of radioactive materials domestically. The commenter found it difficult to understand why some packages with proven

safety records would “unjustly” be phased out for domestic shipments in as little as 2 years after the proposed rule is issued.

Response. To be compatible with the IAEA on grandfathering, NRC has made a decision to phase out those packages that may lack safety enhancements found in other packages. This phase out will impact packages approved to Safety Series No. 6, 1967, and will begin 4 years after effective date of the final rule. This phase out is consistent with NRC’s belief that packages approved to the 1967 edition of Safety Series No. 6 may lack safety enhancements that are included in packages approved to later editions.

Comment. One commenter supported grandfathering casks made for the 1967 standards for domestic shipping and urged NRC to retain the A_2 value for molybdenum-99 and the A_1 and A_2 values for californium-252, also for domestic shipping.

Response. NRC will retain the current A_2 value for molybdenum-99 (7.4E-1 TBq; 2.0E1 Ci) and the A_2 value for californium-252 (0.1 TBq; 2.7 Ci) (see Table A-1). The NRC is not adopting the A_1 value for californium-252 because the IAEA is considering changing the value that appears in TS-R-1 back to what presently appears in Part 71. For reasons stated in the previous response to comments, NRC will not allow grandfathering of packages certified to the 1967 standard.

Comment. Because IAEA does not necessarily consider the risk-informed, performance-based aspects of regulations that the NRC has developed in the United States, a commenter suggested that the NRC should consider the unique aspects of U.S.-only applications. The commenter also suggested that the package identification number should be revised to the appropriate identification number prefix together with a suffix of “-96” provided that such packages shall be for domestic use only and no additional packages be fabricated.

Response. The NRC does not agree with this suggestion because it would allow continued use of B() packages for domestic use. NRC has determined that only those packages that have enhanced safety features (i.e., post-1967 package designs) will be allowed to be used and manufactured beyond the 4-year phase-out period for all use (domestic and international). When a package design designated as B() (i.e., approved to Safety Series No. 6, 1967) is submitted to NRC for review to the current standards, the NRC may revise the package identification number to designate the package design as a B, BF, B(U), B(M), etc, and may assign the "-96" suffix to indicate that the design has met the requirements of Part 71. Those submitted package designs that do not meet the current standard will not be assigned the "-96" suffix.

Comment. One commenter stated that adopting the revised "grandfathering" provision rule would have a significant impact on the commenter's operations. The commenter highlighted how their operational need to store fuel would cause unnecessary handling of fuel, especially in light of design parameters to which their existing containers must adhere. Replacement of certified containers with satisfactory safety records is believed unnecessary by the commenter.

Furthermore, the commenter added that, if adopted, this proposal would eliminate the flexibility to use M-130 containers on an "as needed" basis. The commenter stated that these containers are safe and asked that NRC consider allowing certified containers with satisfactory safety records to continue to be "grandfathered."

Response. The NRC acknowledges the comment but notes that the certificate holder could choose to request a recertification before use beyond the 4-year phase-out period, which begins after the effective date of the final rule.

Comment. One commenter was concerned that, in departing from IAEA grandfathering standards, NRC is placing the burden entirely on the regulated industry to develop the justification for such a departure. The commenter asserted that this is a problem because there was no basis for having adopted the IAEA grandfathering standards in the first place.

Response. In the interest of maintaining compatibility with the IAEA regarding approved package designs to support the NRC's decision to be consistent with IAEA on the grandfathering issue (i.e., phasing out the Safety Series No. 6, 1967 package designs), and to allow only those package designs with enhanced safety features to continue to be used as viable packages, NRC will phase out the 1967-approved B() packages over a 4-year period after the effective date of the final rule. Thus, NRC does not agree with the comment "departing from IAEA grandfathering standards" because NRC is making an effort to adopt the IAEA grandfathering standards. The primary difference between the IAEA and the NRC on this issue, however, is that IAEA has made an immediate phase out of the 1967-approved packages, while NRC will phase out the same packages over a 4-year period.

Comment. One commenter requested specific information on the types and numbers of packages that would be affected and the timetable under which packages would be excluded.

Response. The response to this comment is found at 67 FR 21406; April 30, 2002. NRC does not require certificate holders or licensees to submit information concerning the number of packages made to a particular CoC.

Comment. One commenter stated that a regular 2-year reconsideration of package design regulations will lead to a situation where package designers and users will constantly be trying to keep up with ever-changing regulations.

Response. NRC is aware of this concern and does not anticipate major changes to the IAEA packaging standards every 2 years. Additionally, NRC participates in the 2-year IAEA revision process and will work with the IAEA and other member nations to assure that proposed changes include appropriate justification with respect to cost and safety.

Comment. One commenter disagreed with the proposed grandfathering rule, stating that 1967-specification packages have operated successfully for years and that there is no health or safety reason for phasing them out. The commenter stated that extending the transition period beyond 4 years would delay the negative economic impacts of excluding these packages. The commenter did agree with the stricter standards for new packages in the proposed legislation. The commenter also agreed with the phase out of 1967-specification packages from international sources.

Response. NRC agrees that the 1967-approved packages have appeared to provide adequate performance in the past. However, these packages lack the safety enhancements that other similar packages currently have in place (i.e., post-1967 approved packages). Therefore, NRC believes the time has come to phase out those package designs before a safety issue occurs and to capitalize on those packages that have incorporated the safety enhancements described in the proposed rule (67 FR 21406; April 30, 2002). This phase out of the 1967 approved package designs is consistent with the NRC's decision to be compatible with the IAEA on the grandfathering issue.

Comment. One commenter expressed concern about the backfitting issue and indicated that NRC should demonstrate that the basis for IAEA's position is tenable in the U.S., or develop an independent satisfactory basis for their position. The commenter stated that this is particularly important with regard to grandfathering packages when there may be different environments for international and domestic shipments.

Response. The NRC does not support allowing the continued use of the 1967-approved packages for domestic-use only. The NRC will continue to phase out those package designs that currently meet Safety Series No. 6, 1967, over a 4-year period after adoption of a final rule. This approach is consistent with the NRC's desire to be compatible with the IAEA on the grandfathering issue.

Comment. One commenter said that the proposed 3-year transition period is too long.

Response. NRC has used the 4-year time line in previous rulemakings and believes that this time period adequately supports those steps that could be taken regarding grandfathering; namely, phase out old package designs, phase in new package designs, or submit an existing package design for review against the current standard.

Comment. One commenter was concerned that the proposed rule would essentially remove from service any and all containers that could be used to transport isotopes from DOE's Advanced Test Reactor for medical or industrial use.

Response. As with other package designs approved to the 1967 standards, it is expected that certificate holders may request review of these designs to the current regulatory standards.

Comment. Two commenters asserted that there is no safety benefit to phasing out the 1967-specification packages. One of these commenters noted that packages built to the 1967-specifications have an excellent safety record and that NRC and DOT agree that the level of safety of the 1967-specification is satisfactory. The commenter stated that the phase out may be required for international shipping but not for domestic shipping. The other commenter provided information on the high cost of recertification and stated that these costs would likely drive companies out of business.

Response. NRC is aware of the safety record of those packages approved to Safety Series No. 6, 1967. However, NRC has made a decision based on safety to be compatible with the IAEA on the issue of grandfathering previously approved packages. Therefore, NRC will begin a 4-year phase out of those package designs approved to the 1967 standards. While the IAEA has immediately terminated the use of 1967-approved packages, the NRC has elected to terminate their use over a 4-year period after effective date of the final rule. Any package design impacted by the 4-year phase out may be submitted to NRC for review against the current standards. While this review may be costly, it ensures package safety during transport and is compatible with the IAEA.

Comment. One commenter asserted that the 1967-specification packages may be impossible to replace at any cost because these devices lack the "QA Paper" required under the NRC's regulations at 10 CFR Part 71. The commenter stated that these packages serve unique functions and that phasing them out would leave thousands of Type B sources stranded, and the cost of moving them would be prohibitive. The commenter raised concerns about exposure to these immovable packages and terrorism threats.

Response. NRC is aware that packages built to the 1967 standards were not subject to QA requirements and that fabrication documents may not be available. This is one reason why the NRC decided to incorporate new standards in NRC regulations and discontinue use of the packages certified to the 1967 standards.

Comment. One commenter said that currently approved DOT specification packages should continue to be approved for domestic shipments. The commenter based this suggestion on the fact that packages that are currently accepted for use and proven to be safe should continue to be used until they reach the end of their useful life. The commenter did not believe

that the costs that would be associated with phasing out safely used transportation packages could be justified on the basis of harmonization of regulations with TS-R-1.

Response. NRC has made a decision based on safety to phase out the package designs that do not include the safety enhancements that other packages currently maintain. Thus, the package designs that were approved to Safety Series No. 6, 1967, will be phased out over a 4-year period after adoption of the final rule. This approach is consistent with the NRC decision to eliminate these types of packages for transportation of radioactive materials. The safety enhancements for post-1967 package designs can be found in the proposed rule (67 FR 21406; April 30, 2002).

Comment. One commenter urged the NRC to accept Competent Authority Certificates for foreign-made Type B packages without requiring revalidation by a U.S. Competent Authority. The commenter stated that revalidation of foreign-made packages for which a country has issued a Competent Authority Certificate other than the United States in accordance with TS-R-1 is a redundancy that provides no additional benefit.

Response. General license provisions in Part 71 authorized use of foreign-approved designs for import or export shipments provided that DOT has revalidated the certificate. DOT may choose to request NRC technical review of those designs. NRC experience has been that review of those designs has been useful in identifying possible safety issues.

Comment. One commenter stated that there needs to be an effective date applied to some or all of the proposed rule changes to grandfather existing approved transport cask designs. Without that, all Part 71 CoC holders will be subject to backfit for compliance with no commensurate safety benefit. The commenter urged NRC to perform a comprehensive evaluation of what impact the proposed changes will have on existing dual-purpose certificate holders if a grandfather clause is not included in the rule.

Response. NRC is committed to working with DOT and the IAEA to assure that future changes in package performance standards are limited to those that are justified and are shown to be significant with respect to safety.

Comment. One commenter urged NRC to provide a flexible CoC design concept, which would permit internal packages whose dimensions and weight fell within defined ranges (rather than being unique), to be linked with one outerpack design of specific dimensions for shipment, thus minimizing the number of separate CoCs to be obtained.

Response. Grandfathering provisions in § 71.13 include certain restrictions with respect to changes to previously approved designs. However, for designs approved under the current regulations, a CoC can be issued to show ranges for dimensions and weights at the request of a certificate holder. The application for such a provision should include an evaluation that shows that the ranges of weights and dimensions would not negatively affect the performance of the package and its ability to meet the requirements of Part 71.

Comment. One commenter requested specification of the means by which existing packages that were built before required compliance with NRC QA standards can be qualified under the new regulations, without requiring full, unobtainable “QA Paper” compliance.

Response. Packagings constructed to designs approved under the 1967 regulations were, in general, not subject to QA requirements in Part 71. This was a consideration in NRC's decision to discontinue the use of packages certified to the 1967 standards and to remain compatible with IAEA on the grandfathering provisions. QA requirements in Subpart H of Part 71 include provisions for existing packagings with respect to QA.

Comment. One commenter suggested that NRC change the “timely renewal” principle so as to enable holders of 1967-specification packages that submit substantially complete applications for new or requalified packages at least 1 year ahead of the ultimate phase-out

date to continue shipments past the phase-out deadline, pending NRC's action on their request for certification or recertification.

Response. NRC does not agree with this comment or the suggested approach. In 1996, IAEA rules indicated that package designs approved to Safety Series No. 6, 1967, would be eliminated. The NRC is revising its rules to maintain compatibility with these IAEA rules. Therefore, the idea of phasing out these packages has been public knowledge for 7 years. IAEA rules regarding the elimination of the 1967-approved packages were implemented in 2001 (5 years after being published). NRC has posed a phase out of these package designs beginning 4 years after adoption of a final rule (i.e., in 2006). Thus, the overall timeframe already encompasses 10 years. NRC does not believe that industry should be able to take advantage of this already lengthy timeframe and submit package design paperwork so late in the process.

Comment. Two commenters expressed support for the proposed rule on this issue. One commenter encouraged NRC to accept the IAEA transitional requirements including the phase out of Type B specification packages and the termination of authorization of Safety Series 6 (1967) packages. The commenter said that these packages were not designed and constructed according to standards where their continued use would be consistent with the intent of the regulations.

Response. NRC acknowledges these comments. NRC will begin a 4-year phase out of the packages designed to Safety Series No. 6, 1967, after adoption of the final rule.

Comment. One commenter expressed support for NRC's proposal to allow continued safe use of existing packaging through incorporation of the TS-R-1 transitional arrangement provisions.

Response. NRC acknowledges this comment.

Comment. One commenter suggested that changes to A_1 and A_2 exemption values were relevant to grandfathering transport casks. The commenter believed that the NRC grandfathering proposal could adversely impact currently certified casks by not guaranteeing that casks certified under previous revisions “will still be usable without modification or analysis in the future.”

Response. The A_1 and A_2 values were last changed in Part 71 in 1995 (see 60 FR 50248; September 28, 1995) to make the NRC regulations compatible with Safety Series No. 6, 1985. With those changes and the adoption of new LSA definitions came the awareness that a licensee, when using a CoC-controlled transport container, had to apply the new A_1 or A_2 value for a given radionuclide, determine the appropriate LSA limit, yet not exceed the activity limit for which the transport package was tested, and which was based on the old (pre-September 28, 1995) A values. A very similar scenario also exists regarding the new A_1 and A_2 values and the existing transport containers. In other words, the new A_1 and A_2 values would be used as the limits for a shipment by a licensee, but the transport container’s activity limit would still be based on the pre-September 28, 1995, A values. Should a package design be submitted for review to the current Part 71, that design would be subject to the current (i.e., TS-R-1) A_1 and A_2 values that are part of this final rule. Thus, while NRC is aware of the commenter’s concern, industry has already had to respond to a similar situation after April 1, 1996, when the September 28, 1995, final rule became effective.

Comment. One commenter expressed support for the phase out of the 1967-specification containers for international shipping to comply with IAEA regulations. However, the commenter opposed the phase out for domestic shipping, arguing that as long as these packages are performing their function safely, then there is no benefit to the phase out and extremely high economic costs. The commenter stated that there would be huge environmental

costs to the creation of hundreds or thousands of new orphan sources. The commenter stated that there would be large economic costs of these orphan sources because they will have to be kept secure. The commenter noted that no facility in possession of one of these devices will ever be able to terminate its license or perform a close-out radiation survey, and sale or shutdown will be impossible.

Response. The NRC has made a decision to phase out those package designs that have been approved to Safety Series No. 6, 1967, for both domestic and international transport of radioactive material. NRC believes that package designs that include the safety enhancements (see 67 FR 21406; April 30, 2002) better suit the goals of the NRC and its desire to ensure safe transport of all radioactive materials. NRC will work closely with those licensees who may have sources that cannot be easily transported as a direct result of this rule to provide a suitable resolution. This could result in economic incentives for package designers to develop new packages to retrieve orphan sources. This could also result in the development and certification of a new generation of Type B packages that could meet current safety standards and fulfill that need for transport of certain radiation sources.

Comment. One commenter discussed the economic impacts of phasing out 1967-specification packages on the entire nuclear waste-shipping industry, estimating the total costs to the sector at over \$1 billion. The commenter argued that these estimates refuted the projection in both NRC'S and DOT'S rulemaking notices, and the NRC's draft RA that did not expect any significant costs to be associated with the implementation of the rule. To arrive at this estimate, the commenter predicted three possible outcomes and discussed these scenarios in the comment letter. In two scenarios, the customers would have to design and construct new containers and ship them at high costs. The commenter discussed these costs in detail. In the

third scenario, large amounts of radioactive sources would be orphaned and would remain immovable indefinitely.

Response. Based on the information provided by this commenter and others regarding the costs of replacement packages, the NRC developed an estimated cost of impacts, as previously described. The estimate is based on either showing that the old designs meet current standards or replacing older designs. The NRC does not have not sufficient information to substantiate the large costs estimated in this comment, partly because NRC does not collect information regarding the number of individual packagings fabricated to each design. However, based on staff's knowledge, the following financial impacts specified in the comment may not be reasonable:

1. The commenter claims that the cost of design, testing, and licensing of new designs is estimated as \$12 to \$98 million. Based on the assessment provided, even assuming that about half of the current 1967-based designs do not meet current safety standards and would need to be phased out, the total costs to industry would not approach these values. The derivation of these values cannot be substantiated by information available to the NRC.

2. Cost of construction of new overpacks is stated as \$7 to \$13 million. These costs do not seem consistent with NRC knowledge of the number of overpack designs currently in use.

3. Loss of existing overpacks and the loss of value of existing devices are estimated from \$500 to over \$1,000 million. The derivation of this value cannot be substantiated by information available to the NRC.

Comment. One commenter stated that phasing out 1967-specification containers would cause many nuclear-shipping firms to go out of business, which would create thousands of orphan sources that are unshippable and unmovable. The commenter stated that NRC would be responsible for storing and securing these sources indefinitely and protecting worker

and public safety. The commenter noted that this could create national security concerns with the potential for theft by terrorists. The commenter stated that as long as these sources are immovable, an entity could not conduct a final radiation survey and terminate its license, forcing the entity to remain indefinitely on NRC or Agreement State rolls.

Response. The commenter provided no justification for the opinion that shipping firms would be forced to go out of business. The NRC believes that if this situation occurs, package designers would be motivated to develop new packages to retrieve orphan sources. This could result in the development and certification of a new generation of Type B packages (that would incorporate the current package standards) that could fulfill that need.

Comment. One commenter stated that new containers would be adequate, if they could be feasibly built. The commenter also stated that the existing containers are adequate. The commenter stated that orphan sources created by "sunset" on use of existing 1967-specification containers decrease protection of public health and safety protection.

Response. Regarding transport of radioactive material, NRC believes that phasing out those package designs approved to Safety Series No. 6, 1967, will assure transport safety due to the fact that the package designs will have enhanced safety features that the 1967-approved packages lack. Furthermore, NRC is aware that packagings built to the 1967 standards were not subject to QA requirements, and that fabrication documents may not be available. NRC does not agree that this fact (lack of QA paperwork) enhances public confidence. Public confidence may be increased by removal of such shipping packages. NRC will work closely with licensees who may have a source that has been impacted by the elimination of its package to ensure that, on a case-by-case basis, a suitable resolution is determined.

Comment. One commenter stated that orphan sources should be considered in risk assessments and in assessing the costs and benefits of the proposed ban on 1967-

specification containers. The commenter believes that when these factors are taken into consideration, they argue overwhelmingly against the proposed change.

Response. The comment is acknowledged. The phase out of the Safety Series No. 6, 1967, packages will occur over a 4-year period after adoption of the final rule. Thus, should orphan sources result as consequence of this rule, industry will have a minimum of 3 years to establish a program and a means to eliminate them from its inventory.

Comment. One commenter stated that any modification of current requirements must not operate to prevent a device built to be transported in DOT Specification 20WC containers, and which has integral shielding and housing that is part of its “packaging” for regulatory purposes, from being shippable merely because it was not constructed fully under the Part 71 QA rubric. The commenter warns that the device would become, overnight, an “orphan source.”

Response. Applicability of NRC QA requirements is specified in Subpart H of Part 71, including provisions for fabrication of packagings approved for use before January 1, 1979. Substantive technical changes to the QA provisions in Part 71 are not being made as part of this rulemaking. Transport of packages that were built for the DOT Specification 20WC overpacks would require that the package, which includes the device within the overpack, be evaluated and certified to the new regulations after the 3-year phase-out period.

Comment. One commenter stated that the U.S. is not bound to IAEA requirements for domestic shipping. The commenter notes that NRC and DOT have already deviated from the IAEA standards on other domestic-only issues.

Response. NRC acknowledges these comments and adds that the NRC has made a decision based on safety considerations not to deviate from the IAEA on the grandfathering

issue for packages. Thus, the NRC will move forward to phase out those packages approved to Safety Series No. 6, 1967.

Comment. One commenter stated that both NRC and DOT have misassessed the impact of their proposals on small entities protected by the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. The commenter stated that NRC fails to consider the many small entities that would be adversely impacted by phasing out the 1967-specification packages. The commenter also disagreed with DOT's argument that international uniformity will help small entities by the discarding of dual systems of regulation. The commenter noted that in the U.S., unlike in Europe, many firms do not have to deal with international shipping at all. The commenter disagreed with DOT's argument that the proposed phase-in period of 2 years would provide a smooth transition to the NRC approval process. The commenter believes that the 2-year window was not adequate.

Response. The NRC acknowledges these comments. This commenter was the only small entity that made comments on this issue. Therefore, it is not clear to the NRC that many small entities would be adversely affected by this phase out. Further, NRC has made a decision based on safety considerations not to deviate from the IAEA on the grandfathering issue for packages. The NRC will move forward to phase out those packages over a 4-year period after adoption of the final rule. This time period should allow all businesses to assess their particular packages and either have them phased out or resubmit them to the NRC for review to the current standards. (The NRC staff notes that DOT has decided to adopt a 4-year transition period for DOT specification packages.)

Comment. One commenter stated that there is no reason to compel removal of properly inspected, properly maintained 1967-specification packages from service for U.S. domestic shipments of special form Type B quantities of radioactive material. The commenter

argued that requiring owners and users to inspect and maintain older packages, or to convert to newer packages, would ensure safety. The commenter concurred that it is reasonable to ban further construction of 1967-specification packages.

Response. The packages approved to Safety Series No. 6, 1967, may lack the safety enhancements possessed by post-1967 approved packages. Thus, NRC will phase out these packages over a 4-year period including production of new packages to these old standards. Alternatively, owners and users of older packages have the opportunity to submit an application showing that the design, or a modified design, meets the current regulations. Recertification of these designs then would allow continued fabrication of additional packagings.

Comment. One commenter stated that NRC and DOT should not subscribe to the useful lifetime limitations for shipping packages implicit in the IAEA's intended biennial review of its regulations. The commenter stated that the cost of such forced obsolescence on an ongoing basis would raise the cost of transportation unwarrantedly.

Response. NRC believes that those packages approved to Safety Series No. 6, 1967, do not reflect the current safety standards. Thus, these packages will be eliminated over a 4-year period after adoption of a final rule. NRC does not anticipate that the future biennial changes within IAEA standards will be as significant as the changes found in the 1996 TS-R-1 standards. Therefore, based on the summary of the impact that will occur on various packages (see 67 FR 21406; April 30, 2002), NRC will move forward with the elimination of certain packages for radioactive material transport.

Comment. One commenter noted that there is a potential for substantial delay in approving new designs or recertifying existing designs. The commenter stated that any "sunset" deadline on the use of any package design being phased out under this proposal should permit its continued use pending an ultimate decision by the NRC on either recertification of the

existing design or approval of a new design, as long as (1) a good-faith, substantially complete application for approval or recertification, as the case may be, has been filed with the NRC at least 12 months before the nominal “sunset date” on use of the existing design; and (2) the application for approval or certification is clearly related in the application to a design which is subject to the “sunset” provision.

Response. The NRC has published guidance for applicants to use regarding package approval. The purpose of the guidance is to document practices used by NRC staff to review applications for package approval. This guidance is available in NUREG-1609, “Standard Review Plan for Transportation Packages for Radioactive Material,” and NUREG-1617, “Standard Review Plan for Transportation Packages for Spent Nuclear Fuel.” Using this guidance will assist applicants to prepare a suitable application which will facilitate NRC review and ensure that such a review is concluded in a timely fashion. Note that these NUREG documents are available full-text on the NRC website (www.nrc.gov/NRC/NUREGS/indexnum.html). Regarding the “sunset” issue, note that eliminating the 1967 packages was first published by IAEA in 1996 (i.e., 7 years ago) and that the international regulations were implemented 5 years later in 2001. Industry should be aware of pending changes or possible changes based on IAEA rules. Therefore, including an additional 4-year implementation period [i.e., to 2007 (at least)] makes at least 11 years that industry has had the opportunity to evaluate its package designs, identify designs that may not meet the new standards, and prepare for the eventual phase out. The commenter is essentially requesting another year of use while the paperwork is in review. NRC does not agree with this approach.

Comment. One commenter asserted that if a specific “sunset” date is chosen, it should be significantly longer than the ones proposed by either NRC or DOT to date. The commenter also requested that NRC and DOT should agree on a common “sunset” date.

Response. The NRC and DOT have adopted a suitable transition date for eliminating packages approved to Safety Series No. 6, 1967. Both agencies believe that a 4-year phase-out period is adequate.

Comment. One commenter urged that the NRC allow for a substantially longer transitional time than now proposed. The commenter argued that the time necessary to design, fabricate, test, and complete NRC’s review of a new CoC design would be much greater than the 2-year transition period proposed by DOT. The commenter stated that this would cause a shipping hiatus.

Response. The NRC published the issues paper at 65 FR 44360; July 17, 2000, which indicated the position on the issues associated with compatibility with the IAEA on many different issues, including grandfathering of those packages approved to Safety Series No. 6, 1967 (see Issue 8). Thus, as a minimum, industry has been aware of the overall proposed impact of phasing out the 1967-approved packages for quite some time. Both NRC and DOT believe that a 3-year phase out period is an adequate time for industry to phase out old packages, phase in new packages, or demonstrate that current requirements are met. The 3-year phase out will commence with the adoption of the final rule.

Comment. One commenter supported grandfathering casks made for the 1967 standards for domestic shipping and urged NRC to retain the A_2 value for molybdenum-99 and the A_1 and A_2 values for californium-252. The commenter also stated that the package identification number should be revised to the appropriate identification number prefix together

with a suffix of “-96” provided that such packages shall be for domestic use only and no additional packages shall be fabricated.

Response. The NRC acknowledges the comments about grandfathering and A₁ and A₂ values for domestic shipping. For the comment about the package identification number, the NRC does not agree with this comment (see earlier response and response below).

Comment. One commenter stated that the unique 1967-packages that cannot be easily replaced should not be replaced. The commenter supported the general concept of phasing out older packages and agreed that use of most 1967-certified packages should be discontinued. The commenter discussed the high costs of requalifying packages as ruinous for some businesses. The commenter argued that this would result in many orphan sources.

Response. The NRC will move forward to phase out the Safety Series No. 6, 1967, packages that may not have the built-in safety enhancements that other (post-1967) packages maintain. The NRC will work in the future on a case-by-case basis with licensees who may have orphaned sources in their inventory as a result of this final rule.

Comment. One commenter stated that if packages can be shown to meet the proposed regulations, the package identification number should be revised to the appropriate identification number prefix together with a suffix of “-96” provided that such packages shall be for domestic use only and no additional packages be fabricated.

Response. The NRC staff disagrees with this comment. Inasmuch as this would allow continued use of B() packages for domestic use, NRC has determined that only those packages that have enhanced safety features (i.e., post-1967 package designs) will be allowed to be used and manufactured beyond the 4-year phase-out period for all use (domestic and international). When a package design is designated as B() (i.e., approved to Safety Series No. 6, 1967) and is submitted to NRC for review to the current standards, the NRC may revise

the package identification number to designate the package design as B, B(U), B(M), etc, and may assign the “-96” suffix.

Issue 9. Changes to Various Definitions.

Summary of NRC Final Rule. The final rule adopts the TS-R-1 definition of Criticality Safety Index (CSI). NRC believes this provides internal consistency and compatibility with TS-R-1. Additionally, the following definitions have been revised to improve their clarity and maintain consistency with DOT: *A₁*, *A₂*, *Consignment*, *LSA-I*, *LSA-II*, *LSA-III*, and *Unirradiated uranium*. NRC believes that terms must be clearly defined so that they can be used to accurately communicate requirements to licensees. By modifying existing definitions and adding new definitions, the licensee would benefit through more effective understanding of the requirements of Part 71.

Affected Sections. Section 71.4.

Background. The changes implemented by NRC in this rulemaking require changes to various definitions in § 71.4 to provide internal consistency and compatibility with TS-R-1. These terms must be clearly defined so that they can be used to accurately communicate requirements to licensees. By modifying existing definitions and adding new definitions, the licensee benefits from a more effective understanding of the requirements of Part 71.

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC staff’s responses for this issue follows:

Comment. Four commenters generally supported the proposal. One commenter specifically asked that NRC and DOT agree on the definition of “common terms” before issuance of the final rules.

Response: The DOT and the NRC continue to coordinate rulemaking efforts to ensure regulatory consistency.

Comment. One commenter stated that “‘Radioactive materials’ and ‘contamination’ should not be redefined as presented in the draft rule; the new definitions would expand exemptions and the deregulation and recycling of more nuclear materials and wastes.” Another commenter expressed concern over the omission of a definition for “contamination.”

Response. The comments appear to be addressing a DOT concern, as NRC has not proposed to adopt a definition for “contamination” in this rulemaking. Currently, NRC regulations in § 71.87(i) refer to the contamination levels found in DOT regulations. The NRC notes that contamination levels/concerns are not criteria for packaging approval within Part 71. Rather, they are a factor in safe transport of an actual package of radioactive material.

Comment. One commenter stated that the definition of “person” as stated in § 70.4 should be included under § 71.4 so it is clear that entities such as DOE are not a person under proposed § 71.0(e).

Response. The NRC does not agree with this comment. “Person” is defined within each part of Title 10. It is only these entities who would make shipments of radioactive material under Part 71. Therefore, the NRC will rely on the existing definitions to support the transportation activities found in Part 71.

Comment. Three commenters stated that the definition of LSA-I and LSA-II should agree with the proposed DOT definition. One commenter provided specific information in objection to the proposed definitions of LSA-I and LSA-II.

Response. NRC agrees that the definitions for LSA-I and LSA-II should be consistent between the NRC and DOT regulations. Therefore, NRC modified its regulations appropriately in § 71.4 and changed the definitions for LSA-I and LSA-II to agree with the definitions found in

DOT's final rule. Additionally, NRC noted that DOT adopted the TS-R-1 definition for LSA-III material. To maintain consistency between these regulations, NRC also adopted DOT's definition for LSA-III.

Comment. One commenter stated that defining only the containment system is broad enough to include the confinement system, because defining them differently will be confusing.

Response: NRC acknowledges the comment.

Comment. Three commenters were concerned about the omission of a definition for "consignment." One commenter suggested that NRC use the definition provided in the DOT proposed rule.

Response. NRC is adding a definition for *Consignment* in § 71.4 that is consistent with DOT.

Comment. Two commenters were concerned about the omission of a definition for "unirradiated uranium."

Response. NRC is adding a definition for *Unirradiated uranium* to § 71.4 that is consistent with DOT.

Comment. Two commenters stressed the importance of including the definition of "non-fixed contamination."

Response. NRC disagrees. Section 71.87(i) refers to the nonfixed (removable) contamination regarding the contamination levels found in DOT regulations in 49 CFR 173.443, Table 11. NRC notes that the definition of "nonfixed contamination" has been removed from § 173.403 in DOT's rule. Furthermore, the definition of contamination from TS-R-1, including the definitions for fixed and nonfixed contamination, have also been added to § 173.403 in DOT's proposed rule. Contamination controls are not a function of NRC package approval as

much as they are a factor in safe transport of a package. Thus, it is appropriate to define contamination in DOT's regulations, but not in the NRC's.

Comment. One commenter supported the proposed adoption of the specified definitions, and also urged NRC to adopt the TS-R-1 definitions for confinement system, consignment, contamination, fixed contamination, nonfixed contamination, shipment, and transport index. The commenter also stated that NRC defined LSA-I differently from DOT, and that NRC and DOT should ensure compatibility between the rules.

Response. See response to the previous comments in this issue. NRC agrees that the definition of "*Transport index (TI)*" should be consistent between NRC and DOT regulations. Therefore, NRC modified § 71.4 to include a definition for TI that is consistent with DOT. NRC does not agree, however, with the comment to adopt the TS-R-1 definition of TI, as the definition adopted provides more clarity and explanation for the applicability of the TI.

Issue 10. Crush Test for Fissile Material Package Design.

Summary of NRC Final Rule. The final rule adopts, in § 71.73, the TS-R-1 requirement for a crush test for fissile material package designs and eliminated the 1000 A₂ criterion, but maintained the current Part 71 testing sequence and drop and crush test requirements.

By adopting TS-R-1, the weight and density criteria will apply to fissile uranium material packages, and packages that were previously exempted because of the 1000 A₂ criterion will now require crush testing. Adopting crush test requirements and eliminating the 1000 A₂ criterion is appropriate because not adopting the TS-R-1 requirements would result in an inconsistency between Part 71 requirements and TS-R-1, which could affect international shipments, and fissile material package designs would continue to not be evaluated for criticality safety against a potential crush test accident condition.

The NRC did not adopt the TS-R-1 test sequence requirements because no new information existed to address concerns from a previous rulemaking regarding the difference in test requirements between essentially the same IAEA requirements contained in Safety Series No. 6, and Part 71. The NRC chose to remain more conservative than the IAEA by requiring both a drop and crush test, rather than one or the other as TS-R-1 would permit.

Affected Sections. Section 71.73.

Background. The crush test requirements in TS-R-1 were broadened to apply to fissile material package designs (regardless of package activity). Previously, IAEA Safety Series No. 6 and Part 71 required the crush test for certain Type B packages. This broadened application was created in recognition that the crush environment was a potential accident force that should be protected against for both radiological safety purposes (packages containing more than 1000 A₂ in normal form) and criticality safety purposes (fissile material package design).

Under requirements for packages containing fissile material, TS-R-1, paragraph 682(b), requires tests specified in paragraphs 719-724 followed by whichever of the following is the more limiting:

- (1) the drop test onto a bar as specified in paragraph 727(b) and either the crush test as indicated in paragraph 727(c) for packages having a mass not greater than 500 kg (1100 lbs) and an overall density not greater than 1000 kg/m³ (62.4 lbs/ft³) based on external dimensions, or the 9-meter (30-ft) drop test as defined in paragraph 727(a) for all other packages; or
- (2) the water immersion test as specified in paragraph 729.

Both Safety Series No. 6, paragraph 548, and current § 71.73 require the crush test for packages having a mass not greater than 500 kg (1100 lbs), an overall density not greater than 1000 kg/m³ (62.4 lbs/ft³) based on external dimensions, and radioactive contents greater than

1000 A₂ not as special form radioactive material. Under TS-R-1, the criterion for radioactive contents greater than 1000 A₂ was eliminated for packages containing fissile material. The 1000 A₂ criterion still applies to Type B packages and is also applied to the IAEA newly created Type C package category.

Full compliance with TS-R-1 requirements for fissile material would require changes to the hypothetical accident conditions test sequencing of § 71.73 and would require performance of the 9-meter (30-ft) free drop test or the crush test, but not both, as presently required by § 71.73. The TS-R-1 test requirements are essentially the same as those contained in Safety Series No. 6 (1985 edition). NRC addressed the difference between Safety Series No. 6 and § 71.73 in a previous rulemaking and concluded that the two tests evaluate different features of a package, and both tests are necessary to determine whether a package response is within applicable limits (final rule, 60 FR 50248; Sept. 28, 1995).

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC staff's responses for this issue follows:

Comment. One commenter stated that the additional cost of the crush test for fissile material is estimated at about \$5,000,000. This cost is to design, certify, and manufacture replacement packages currently in use for the shipment of uranium oxide. The commenter thought that currently three to five packages are in use that will need to be modified and recertified.

Response. The information provided by the commenter was considered in the development of NRC's rule.

Comment. One commenter recounted how they were almost crushed under "a boulder the width of the highway in the Wyoming Wind River Range some years ago" and stated that "No vehicle or container could have withstood the impact of that boulder's fall from several

hundred feet above." The commenter also stated that based on such probable events, crush tests must be mandatory, with the cost borne by licensee or user. The commenter added that the NRC needs to implement more rigorous crush and drop tests than its current standard so that it can ensure container survival in the event of severe accidents. The commenter also recommended that because the TS-R-1 document was not readily available, it was "ingenuous, at best, for the NRC to give the references to the actual testing requirements in terms of TS-R-1 paragraph citations."

Response. The recommendation to implement more rigorous crush and drop tests than the current regulatory standards to ensure container survival for severe accidents is noted, but was not justified, and is outside the scope of the current rulemaking. Further, it should be noted that TS-R-1 is readily available online at:

http://www.pub.iaea.org/MTCD/publications/pdf/Pub1098_scr.pdf.

Comment: Three commenters advocated more stringent testing procedures. Specifically, one commenter stated support for NRC's effort to adopt crush tests for all fissile material packages regardless of size or activity (while rejecting the IAEA's option of choosing to perform either a drop or a crush test on a container). The commenter also urged the NRC to use a physical (as opposed to a simulating test using computer modeling) crush test with a full-size package to provide a realistic testing environment. The commenter suggested that the NRC's proposal should include all containers, including the DT-22 (which failed the dynamic crush test) and the 9975 container (which failed the 30-foot drop test). Further, it was noted that the redesigned 9975 container has not yet been "crush tested to show the results of high-speed impact against an unyielding surface." For this unit, the commenter urged NRC to require a physical, as opposed to a simulated, crush test with a full-size package to provide a realistic testing environment. The commenter also stated that the NRC needs to require other

testing and noted that "neither the DT-22 nor the 9975 have been sufficiently tested against fire." Also, the commenter contended that the current test (i.e., burn at 1475 degrees Fahrenheit for 30 minutes) ignores the fact of "more than 20 materials routinely transported on highways that burn at more than twice this temperature." Two commenters suggested that this heat test be made more stringent and realistic. NRC also needs to test these two containers for "durability to terrorist attack with a variety of weapons, such as mortars or anti-tank missiles, under a variety of conditions." Furthermore, "all Type B containers should be subject to rigorous testing for terrorist resistance."

Another commenter expressed concern that the proposed rule would allow the DP-22 package to be licensed and approved, despite the fact that it does not meet either the drop or crush test requirements.

Another commenter expressed concern that crush testing is not required for packages having a mass greater than 500kg, which includes rail SNF waste packages. The commenter suggested that the NRC "require rail transportation casks be subject to crush testing (scaled up to produce impact energies of the magnitude expected in a railway accident)." The commenter cited a 1995 report entitled "Rail Transportation of Spent Nuclear Fuel – A Risk Review" that argued small packages are shipped in large numbers and "as a result demonstrate a higher possibility of experiencing crush loads than large packages would." In addition, the commenter cited how packages transported by North American rail would have a high probability of experiencing dynamic crushing in an accident.

Response. The comment regarding more rigorous testing for all Type B packages for terrorist resistance is noted. Please refer to the second comment in Section II, under the heading: Terrorism Concerns. The comment regarding stringency of heat tests is noted but is outside the scope of the current rulemaking. With respect to comments regarding the DT-22

and 9975 container, NRC staff is not familiar with these designs as they are used within the DOE program and are authorized under DOE's package approval authority. These containers do not currently have an NRC CoC. The NRC staff also is not familiar with the DP-22 design that the commenter alludes to as it does not currently have an NRC CoC. To receive an NRC CoC, it would have to meet the NRC's testing requirements, including drop and crush test if required.

The comment regarding crush testing for packages greater than 500 kg (1100 lb) is acknowledged. The NRC has already gone beyond the IAEA testing requirements in requiring that all Type B packages subject to the crush test must also be subjected to the free drop test. Extending the crush test to other Type B packages [i.e., those exceeding 500 kg (1100 lbs)] is beyond the scope of the current rulemaking.

Regarding the comment on requiring physical crush testing, rather than simulated tests, and the use of full scale packages for physical testing, the NRC staff believes that the use of computer code analysis of finite element models and the use of scale models for physical testing are valid methods for demonstrating compliance with the NRC's package testing requirements. It should be noted that these methods should be NRC approved.

Comment. Three commenters questioned the requirements for both a drop test and a crush test. One commenter requested that if both a crush test and a drop test are required on packages that meet the requirements for the crush test, the rules should specify that this could be carried out on two different packages. The commenter explained that it does not make sense to require both tests for the same package, because in an accident scenario, a single package would not experience both conditions.

Two commenters stated that packages should either pass a drop test or the crush test, but not both. The first commenter said that the rule should state that separate packages should

be used for each test, and that the same package should not be used to pass both tests in sequence. The second commenter said that, "A line for deciding which test a package should undergo could be based on the gross weight of the package."

Response. The current requirements under § 71.73(a) state that: "Evaluation for hypothetical accident conditions is to be based on sequential application of the tests specified in this section, in the order indicated, to determine their cumulative effect on a package or array of packages." However, § 71.73(a) does specifically allow for an undamaged specimen to be used for the immersion test of § 71.73(c)(6). NRC staff is aware that IAEA regulations do not require both the free drop and crush test on a single specimen, but has chosen to remain more conservative in this regard. In the NRC rulemaking for compatibility with IAEA Safety Series No. 6 (September 28, 1995; 60 FR 50248), NRC staff stated the position that: "NRC is requiring both the crush test and drop test for lightweight packages to ensure that the package response to both crush test and drop forces is within applicable limits." NRC staff is not aware of any new information that would cause NRC to deviate from that position.

NRC staff does not agree with the commenter's assertion that performing a drop and crush test is a double drop test. In the drop test from 9 meters (30 feet), the specimen itself is dropped onto an unyielding surface; in the crush test (if required by both the package weight and density criteria), a 500-kg (1100-lb) weight is dropped from 9 meters (30 feet) onto the specimen. These are two independent tests that may have different outcomes depending on the package and the location where maximum damage is expected to occur for each test.

Comment. Two commenters supported NRC's proposal regarding crush test requirements. One commenter expressed support for the NRC's proposal to accept the part of IAEA's rule change under TS-R-1 which requires a crush test for fissile material packages

regardless of size or activity while rejecting the IAEA's option of performing either crush or drop tests of containers.

Response. No response is necessary.

Issue 11. Fissile Material Package Design for Transport by Aircraft.

Summary of NRC Final Rule. The final rule adopts TS-R-1, paragraph 680, Criticality evaluation, in a new § 71.55(f) that only applies to fissile material package designs that are intended to be transported aboard aircraft. Section 71.55 specifies the general package requirements for fissile materials, and the existing paragraphs of § 71.55 are unchanged. Among other requirements, TS-R-1, paragraph 680, requires that packages must remain subcritical when subjected to the tests for Type C packages, because:

- (1) the NRC has deferred adoption of the Type C packaging tests (see Issue 6);
- (2) TS-R-1, paragraph 680 requires Type C tests; and
- (3) paragraph 680 applies to more than Type C packages; only the salient text of paragraph 680 was inserted into § 71.55(f) and applies to domestic shipments.

Adopting this change will provide regulatory consistency. Shippers would have been required to meet the TS-R-1 air transport requirements even if the NRC did not adopt them, because the International Civil Aviation Organization had adopted regulations consistent with TS-R-1 on July 1, 2001. U.S. domestic air carriers require compliance with the ICAO regulations even for domestic shipments. Therefore, these changes are expected to benefit industry by eliminating the need for two different package designs.

Affected Sections. Section 71.55.

Background. TS-R-1 introduced new requirements for fissile material package designs that are intended to be transported aboard aircraft. TS-R-1 requires that shipped-by-air

fissile material packages with quantities greater than excepted amounts (which would include all NRC-certified fissile packages) be subjected to an additional criticality evaluation.

In TS-R-1, paragraph 680, requirements for packages to be transported by air are in addition to the normal condition and accident tests that the package must already meet. Thus:

Type A fissile package by air must:

- (1) withstand normal conditions of transport with respect to release, shielding, and maintaining subcriticality (single package and 5xN array¹);
- (2) withstand accident condition tests with respect to maintaining subcriticality single package and 2xN array); and
- (3) comply with TS-R-1, paragraph 680, with respect to maintaining subcriticality (single package);

Type B fissile package by air must:

- (1) withstand normal conditions of transport and Type B tests with respect to release, shielding, and maintaining subcriticality (single package and 5xN array/normal and 2xN array/accident); and
- (2) comply with TS-R-1, paragraph 680, with respect to maintaining subcriticality.

TS-R-1, paragraphs 816 and 817, state that fissile package designs intended to be transported by aircraft are not allowed to be grandfathered. Consequently, all of these fissile package designs will be evaluated before their use.

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC staff's responses for this issue follows:

¹ N represents the maximum number of fissile material packages that can be shipped on a single conveyance.

Comment. Four commenters supported the NRC's position on this issue. One commenter supported NRC's proposal to ensure consistent review of package designs affected by the requirements of the International Civil Aviation Organization. Another commenter said adoption of Type C packages should be scheduled for future harmonization with IAEA regulations.

Response. The NRC believes the changes create a uniform regulatory framework for the review of package designs for both national and international air shipments.

B. NRC-Initiated Issues.

Issue 12. Special Package Authorizations.

Summary of NRC Final Rule. The final rule adopts, in § 71.41, special package authorizations that will apply only in limited circumstances and only to one-time shipments of large components. Special package authorization regulations are necessary because there are no regulatory provisions in Part 71 for dealing with nonstandard packages, other than the exemption provisions and § 71.41(c). The NRC processing of one-time exemptions for nonstandard packages, such as the Trojan reactor vessel, has required the expenditure of considerable NRC resources. Further, the NRC's policy is to avoid the use of exemptions for recurring licensing actions. Special package authorization requirements will result in enhanced regulatory efficiency by standardizing the requirements to provide greater regulatory certainty and clarity, and will ensure consistent treatment among licensees requesting authorization for shipment of special packages.

Any special package authorization will be issued on a case-by-case basis, and requires the applicant to demonstrate that the proposed shipment would not endanger life or property

nor the common defense and security, following the basic process used by applicants to obtain a CoC for nonspecial packages from NRC.

The applicant will be required to provide reasonable assurance that the special package, considering operational procedures and administrative controls employed during the shipment, would not encounter conditions beyond those for which it had been analyzed and demonstrated to provide protection. The NRC will review applications for special package authorizations. Approval will be based on NRC staff determination that the applicant will meet the requirements of Subpart D of 10 CFR Part 71. If approved, the NRC will issue a CoC or other approval (i.e., special package authorization letter).

NRC will consult with DOT on making the determinations required to issue an NRC special package authorization.

Affected Sections. Section 71.41.

Background. The basic concept for radioactive material transportation is that radioactive contents are placed in an authorized container, or packaging, and then shipped. The packaging, together with its contents, is called the package. In general, the transportation regulations in TS-R-1, 10 CFR Part 71, and 49 CFR are based on the shipment of radioactive contents in a separate, authorized packaging. There are a few exceptions. In cases involving larger quantities of radioactive material, the content to be shipped may itself be a container. A storage tank containing a radioactive residue is an example. It is not necessary for the shipper to place the tank within an authorized packaging if the shipper demonstrates that the tank satisfies the requirements for the packaging. DOT and NRC have jointly provided guidance on such shipments (see "Categorizing and Transporting Low Specific Activity Materials and Surface Contaminated Objects," NUREG-1608, RAMREG-003, July 1998).

As older nuclear facilities are decommissioned, DOT and NRC are being asked to approve the shipment of large components, including reactor vessels and steam generators. These components may contain significant quantities of radioactive material, but they are so large that it may not be practical to fabricate authorized packagings for them. Because the potential shipment of these components was not contemplated when the NRC transportation regulations were developed, the regulations do not specifically address them.

Large components can be shipped under DOT regulations if the components meet the definition of Surface Contaminated Object (SCO) or Low Specific Activity (LSA) material (see 49 CFR 173.403 for SCO and LSA definitions). For example, steam generators that meet the DOT SCO definition are exempt from Part 71 and are shipped under 49 CFR, following guidance provided in NRC Generic Letter 96-07 dated December 5, 1996. This method has been applied to several shipments of steam generators and small reactor vessels to the low level waste disposal facility at Barnwell, SC. NRC and DOT intend to continue employing this approach and method for steam generators and similar components that can be shipped under DOT regulations.

Large components that exceed the SCO and LSA definitions are subject to Part 71. An example is the Trojan reactor vessel which was transported to the disposal facility on the Hanford Nuclear Reservation near Richland, Washington. The Trojan Reactor Pressure Vessel (TRPV) contained approximately 74 PBq (2 million Ci) in the form of activated metal and 5.7 TBq (155 Ci) in the form of internal surface contamination, and was filled with low-density concrete, and weighed approximately 900 metric tons (1,000 tons). Normally, large curie contents are required to be shipped in a Type B packaging, but the TRPV was too large and massive to be shipped within another packaging.

Section 71.8 provides that NRC may grant any exemption from the requirements of the regulations in Part 71 that it determines is authorized by law and will not endanger life or property nor the common defense and security.

Currently no regulatory provisions exist in Part 71 for dealing with nonstandard packages, other than the exemption provisions and § 71.41(c). The NRC's practice is to avoid the use of exemptions for recurring licensing actions. The new rule language will support this practice.

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC staff's responses for this issue follows:

Comment. One commenter stated that relaxation of requirements applicable to large packages could potentially reduce the cost of these shipments for parties who must routinely demonstrate that all shipments, including reactor vessels and larger reactor compartments, are made in compliance with Part 71. However, the commenter asked that the NRC relax the restriction that a special package authorization may be approved only for "one-time shipments" and allow a limited number of shipments to be approved if they are of the same design to avoid repetitious certification requests.

Response. The NRC believes that standardizing the special package authorization process will increase efficiency during the review of large shipment components. These special packages were not provided for specifically in earlier regulations. Establishing a standard process for authorization also will reduce the regulatory burden associated with shipping these packages. The NRC envisions the process for special package authorization to be similar to authorization for Type B packages, with specific criteria for approval judged on a case-by-case basis. The special package authorization is not intended for repeat or routine shipments of components. It is reserved for those unique instances where traditional packaging and

approval methods are impractical. Therefore, NRC is not extending special package authorizations to multiple shipments of the same component.

Comment. One commenter opposed NRC's proposal to allow special package exemptions stating that it would not be a responsible action by NRC and could lead to further requests to loosen regulatory restrictions in the future. The commenter cited the precedent of Shippingport, Trojan, and Yankee Rowe as reason for the concern. The commenter further stated that post-September 11, 2001, NRC "should not assume the legality or safety of any exemptions from full packaging container requirements." The commenter added that the TS-R-1, paragraph 312, "is not in the public interest and should be changed" and NRC should not allow this decision to remain with DOT. The commenter stated that NRC itself admits that DOT uses altered definitions to justify transporting special (large) components without the amount of protection demanded of lesser components; this is unacceptable and a failure by NRC to exercise its mandated responsibility. The commenter also requested the NRC to provide a definition of "reasonable assurance."

This commenter further stated that the "shortcoming of dual regulation is evident in the handoff of regulatory control from one agency to another" and added that it is unacceptable "for NRC to wash its hands of its responsibility for packaging and containers by handing over authority to another agency." The commenter then asked if NRC planned this as "merely a cost reduction for licensees," and stated that NRC needed to provide a justification for this proposal. The commenter also questioned the safety of these shipments.

The commenter also stated that the NRC's focus on high-level waste transport would result in the NRC ignoring allowances for exemptions for lower activity materials and wastes. This would result in these materials and wastes passing from a "regulated status to exemption and release into commerce or unregulated 'disposal' and would 'increase risks to the public that

NRC ignores.” The commenter ended by stating that this “is not an acceptable deregulation, is a capricious failure to protect the general welfare, and is therefore contrary to law” and reiterated the “objection to NRC’s reliance on ‘performance-based risk informed’ regulation that permits less stringent requirements for containment and for transportation.”

Response. The special package authorization does not reduce the protection of public health and safety; rather, it affects the process used to approve nonstandard packages. The special package authorization requirement clearly states that the overall safety in transport for shipments approved under special package authorization will be *at least* [emphasis added] equivalent to that which would be provided if all applicable requirements had been met. The NRC is not adding a definition for the term “reasonable assurance” because it is not used in a regulatory requirement.

It is important to repeat that NRC approval will be required for special package authorizations. In addition, DOT regulations will be modified to recognize NRC’s special package authorizations. The process efficiencies offered by special package authorizations result in more effective and efficient regulation.

The special package authorization will reduce the need for exemptions in the package approval process and will not result in the disposal of radioactive material.

Comment. One commenter stated that the Trojan reactor shipment should not be used as a precedent for special package approval. The commenter reasoned that the Trojan reactor shipment was an easy shipment due to its origin and destination.

Response. The NRC believes the Trojan reactor vessel shipment indicates there is a need for special package approvals because it represents a class of contents that, due to their size, mass, or other unique factors, are impractical to transport within standard radioactive

material packaging. The origin and destination of the Trojan shipment has no bearing on this rule.

Comment. One commenter requested more information about how the NRC is going to approve special packages. The commenter stated that a better explanation of this process would aid regulated bodies in acquiring special package authorization.

Another commenter indicated that with the current proposal, “the special package authorization is not bounded and applicants do not have a common basis for preparation of an application” and requested that the NRC staff establish general criteria against which special packages can be evaluated.

One commenter suggested that NRC establish general criteria for the special package authorization process.

One commenter stated that the “special package” designator should be clearly defined in terms of package size or other appropriate feature to ensure that the rule is applied correctly.

Response. The purpose of this change is to establish general criteria for the authorization of special package designs without the need for the licensee to request an exemption from the current regulations. The NRC agrees that additional information on special package approvals is needed. NRC intends to develop regulatory guidance in this area before this rule is implemented. In the interim, any applications for special package approvals will be considered on a case-by-case basis.

Comment. One commenter requested the NRC to view every shipment of a reactor vessel as a significant process requiring National Environmental Policy Act (NEPA) review. The commenter argued that a NEPA process would allow for public input in the process of decommissioning a reactor vessel.

Response. A NEPA review will not be required for the new special package authorizations. Package approvals authorized by our regulations are specifically excluded from the requirement to prepare an EA pursuant to NEPA [§ 51.22(c)(13)]. In contrast, an EA for the Trojan reactor vessel was thought to be necessary because the NRC did not rely on specific package approval regulations, but rather relied on an exemption from those requirements.

Comment. One commenter suggested that shipping retired reactor vessels should be a separate issue from the exception process.

Response. The NRC disagrees that reactor vessels should be excluded from special package authorization. The NRC believes reactor vessels are an example of the type of shipment that would benefit from special package authorization, because the authorization would follow a more standardized and efficient design review process. NRC's package design review process has been shown to provide adequate protection of public health and safety.

Comment. One commenter stated that no additional limitations should be applied to the conditions under which one could apply for a package authorization. The commenter noted that the few packages that have been authorized have moved without incident and without undue risk to the public, workers, or the environment.

Response. Comment noted. No response necessary.

Comment. Five commenters supported the proposed provisions in § 71.41(d) for special package authorizations. Two of these commenters stated that this revision provides a consistent approach to dealing with the transport of large pieces of equipment and nonstandard items, and that the revision would improve the safety and cost effectiveness of onsite and offsite transfers of large equipment items. Two other commenters supported corresponding with DOT to eliminate duplicitous exemptions, but urged the NRC to work closely to ensure the clear implementation of this proposal.

Response. No response necessary.

Issue 13. Expansion of Part 71 Quality Assurance Requirements to Certificate of Compliance (CoC) Holders.

Summary of NRC Final Rule. The final rule adds the terms "certificate holder" and applicant for a CoC" to Subpart H, Part 71 and adds a new section, § 71.9, on employee protection. Adopting these requirements will ensure that the regulatory scheme of Part 71 will remain more consistent with other NRC regulations in that certificate holders and applicants for a CoC will be responsible for the behavior of their contractors and subcontractors.

This expansion is necessary to enhance NRC's ability to enforce nonconformance by the certificate holders and applicants for a CoC. Although CoC's are legally binding documents, certificate holders and/or applicants and their contractors and subcontractors have not clearly been brought into the scope of Part 71 requirements. This is because the terms "certificate holder" and "applicant for a certificate of compliance" do not appear in Part 71, Subpart H; rather, Subpart H only mentions "licensee" in these regulations. Consequently, the NRC has not had a clear basis to cite applicants for, and holders of CoC's for violations of Part 71 requirements in the same way it has licensees.

The NRC also added a new section (§ 71.9) on employee protection to Part 71. The NRC believes that employee protection regulations should be added for to cover the employees of certificate holders and applicants for a CoC to provide greater regulatory equivalency between Part 71 licensees and certificate holders.

Affected Sections. Sections 71.0, 71.1, 71.6, 71.7, 71.8 , 71.9, 71.91, 71.93, 71.100, and 71.101 through 71.137.

Background. On October 15, 1999 (64 FR 56114), the Commission issued a final rule to expand the QA provisions of Part 72, Subpart G, to specifically include certificate holders and applicants for a CoC. In a Staff Requirements Memorandum (SRM) to SECY-97-214, the Commission directed the staff to consider whether conforming changes to the QA regulations in Part 71 would be necessary because of the existence of dual-purpose cask designs.

The 1999 rule requires that Part 72 licensees, certificate holders, and applicants for a CoC are responsible for assuring that their contractors and subcontractors (e.g., fabricators) are implementing adequate QA programs. Similarly, by this final rule, Part 71 licensees, certificate holders, and applicants for a CoC are responsible under § 71.115 for assuring that their contractors and subcontractors (e.g., fabricators) are implementing adequate QA programs.

Under Part 71, the NRC reviews and approves applications for Type B and fissile material packages for the transport of radioactive material. The NRC's approval of a package is documented in a CoC. Applicants for a CoC are currently required by § 71.37 to describe their QA program for the design, fabrication, assembly, testing, maintenance, repair, modification, and use of the proposed package. Further, existing § 71.101(a) describes QA requirements that apply to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packagings that are important to safety. Type B packages are intended to transport radioactive material that contains quantities of radionuclides greater than the A_1 or A_2 limits for each radionuclide (see Appendix A to Part 71 for examples of A_1 or A_2 limits). Fissile material packages are intended to transport fissile material in quantities greater than the Part 71, Subpart C, general license limits for fissile material (e.g., existing §§ 71.18, 71.20, 71.22, and 71.24).

Although CoCs are legally binding documents, certificate holders or applicants for a CoC and their contractors and subcontractors have not clearly been brought into the scope of Part 71 requirements. This is because the terms "certificate holder" and "applicant for a certificate of compliance" do not appear in Part 71, Subpart H; rather, Subpart H only mentions "licensee" in these regulations. Consequently, the NRC has not had a clear basis to cite certificate holders and applicants for a CoC for violations of Part 71 requirements in the same way it has licensees.

When the NRC has identified a failure to comply with Part 71 QA requirements by certificate holders or applicants for a CoC, it has issued a Notice of Nonconformance (NON) rather than a Notice of Violation (NOV). Although an NON and an NOV appear to be similar, the Commission prefers the issuance of an NOV because:

(1) The issuance of an NOV effectively conveys to both the person violating the requirement and the public that a violation of a legally binding requirement has occurred;

(2) The use of graduated severity levels associated with an NOV allows the NRC to effectively convey to both the person violating the requirement and the public a clearer perspective on the safety and regulatory significance of the violation; and

(3) Violation of a regulation reflects the NRC's conclusion that potential risk to public health and safety could exist. Therefore, the NRC believes that limiting the available enforcement sanctions to administrative actions is insufficient to address the performance problems observed in industry.

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC staff's responses for this issue follows:

Comment. Five commenters supported the NRC's proposed position on this issue.

One commenter recommended that NRC establish and apply a uniform set of QA requirements. Another commenter added that it would like to see the consistent application of QA requirements throughout the regulations.

Response. Expansion of the QA provisions enhances NRC's ability to enforce noncompliance and will ensure broader, uniform application of QA requirements. However, extension of the requirement beyond Part 71 is outside the bounds of this rulemaking.

Issue 14. Adoption of American Society of Mechanical Engineers (ASME) Code.

Summary of NRC Final Rule. The NRC has decided not to incorporate the ASME Code, Section III, Division 3 requirements into Part 71. Public Law 104-113 requires that Federal agencies use consensus standards in lieu of government-unique standards, if this use is practical or inconsistent with other existing laws. Because a major revision to the ASME Code is forthcoming and because the changes in that revision are not yet available for staff and stakeholder review, the NRC staff considered it an imprudent use of NRC and stakeholder resources to initiate rulemaking on the current ASME Code revision only to have the ASME Code requirements change during the Part 71 rulemaking.

Affected Sections. None (not adopted).

Background. Currently, no ASME Code requirements exist in Part 71 for fabrication/construction of spent fuel transportation packages. The NRC considered the adoption of the ASME Boiler and Pressure Vessel (B&PV) Code, Section III, Division 3, for two reasons. First, previous NRC inspections at vendor and fabricator shops (for fabrication of

spent fuel storage canisters and transportation casks) identified quality control (QC) and QA problems. Some of these problems would have been prevented with improved QA programs, and may have been prevented had fabrication occurred under more prescriptive requirements such as the ASME Code requirements. Second, Public Law 104-113, "National Technology Transfer and Advancement Act," enacted in 1996, requires that Federal agencies use, as appropriate, consensus standards (e.g., the ASME B&PV Code), except when there are justified reasons for not doing so.

With respect to conformance to Public Law 104-113, the ASME issued a consensus standard in May 1997, entitled: "Containment Systems and Transport Packages for Spent Fuel and High Level Radioactive Waste," ASME B&PV Code, Section III, Division 3. The ASME Code requires the presence of an Authorized Nuclear Inspector during construction to ensure that the ASME Code requirements are met and the stamping of components (i.e., the transportation cask's containment) constructed to the ASME Code. NRC staff participated, and continues to participate, in the ASME subcommittee that developed the ASME Code requirements. It is the NRC staff's understanding, through participation in the subcommittee, that the ASME Code document is undergoing extensive review and modification and that a major revision will be issued. Therefore, NRC staff believes that inclusion of the ASME Code in Part 71 is not appropriate at this time.

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC staff's responses for this issue follows:

Comment. Four commenters expressed support for the decision not to adopt the ASME code. One commenter said that these are voluntary standards and should not be made into requirements.

Response. No response is required.

Issue 15. Change Authority for Dual-Purpose Package Certificate Holders.

Summary of NRC Final Rule. The final rule does not adopt the proposed change authority in the final rule based on NRC's determination that implementation of the proposed change process would result in new and significant unnecessary regulatory burdens and costs with minimal benefits.

Affected Sections. None.

Background. The Commission approved a final rule to expand the provisions of § 72.48, "Changes, Tests, and Experiments," to include Part 72 certificate holders and licensees (64 FR 53582; October 4, 1999). Part 72 certificate holders and licensees are allowed, under § 72.48, to make certain changes to a spent fuel storage cask's design or procedures used with the storage cask and to conduct tests and experiments without prior NRC review and approval. Part 71 does not contain any similar provisions to permit a CoC holder to change the design of a Part 71 transportation package, without prior NRC review and approval. The NRC has issued separate CoC's under Parts 71 and 72 for dual-purpose spent fuel storage casks and transportation packages. This has created the situation where an entity holding both a Part 71 and Part 72 CoC would be allowed under Part 72 to make certain changes to the design of a dual-purpose cask (e.g., changes that affected a component or design feature that has a storage function, without obtaining prior NRC approval). However, the entity would not be allowed under Part 71 to make changes to the design of this same dual-purpose cask (package) if that component or feature also has a transportation function, without obtaining prior NRC approval, even when the same physical component and change are involved (i.e., the change involves a component that has both storage and transportation functions).

NRC staff recognized a need to consider making both Part 72 and Part 71 more consistent in dealing with design changes of a minor nature. Thus, in SECY-99-054², NRC staff recommended that an authority similar to § 72.48 be created for dual-purpose spent fuel storage casks and transportation packages intended for domestic use only. NRC staff also recommended that this authority be limited to the Part 71 CoC holder.

Since the proposed rule was published, the NRC staff has evaluated comments received from the public and conducted a detailed analysis of the implementation of the change authority, as proposed. Based on this analysis, the staff determined that Subpart I, Type B(DP) package approval should not be included in the final rule.

Proposed § 71.153 stated that the application for a Type B(DP) package shall include an analysis of potential accidents, package response to these potential accidents, and any consequences to the public. Currently, under Part 71, an applicant has to demonstrate, either by test or analysis, that a package design can withstand the cumulative effects Hypothetical Accident Conditions: of a 30-foot drop test, a 40-inch puncture test, a thermal test, and immersion tests as described in § 71.73 and § 71.61, and meet Subpart E - Package Approval Standards. Applicants are not required to perform an independent analysis of potential transportation accidents specific to that design and plans for use, project package responses to “real world” transportation accidents, or determine the consequences to the public from such accidents.

The NRC staff reviewed and considered the comments that were received about this proposed change. The new process included the need to establish a design specific accident assessment for the cask design response to potential “real world” transportation accidents.

² SECY-99-054; February 22, 1999, “Plans for Final Rule- Revisions to Requirements of 10 CFR Parts 50, 52, and 72 Concerning Changes, Tests, and Experiments.”

Such an accident analysis has not been required for a transportation cask application before. Which accidents would be appropriate, for which routes, under what conditions, for what duration, and with what combinations of forces and assumptions, all would be questions that would need to be answered by CoC holders that have not been required to perform such analysis for cask designs applications.

To provide new guidance for the development of an acceptable accident analysis for a transportation cask, the NRC staff would need to perform significant research on what types of accidents would be required to be included. The NRC staff believes that such an analysis can be performed; however, it did conclude that it had not fully considered the rigor, resources, and time that such a requirement would require, and the detailed associated cost estimates had not been included in the RA for this part of the rule change. In the final rule, the RA has been revised, and the costs of implementation for CoC holders would be significantly higher than that reflected in the proposed rulemaking, and this additional regulatory burden had not been accurately reflected. The Safety Analysis Report (SAR) for Part 71 applications is based, in part, on demonstrating compliance with the Hypothetical Accident Conditions of Part 71. Thus, there is not a clear linkage between the SAR and regulatory conditions for making changes to a design without NRC approval, such as a minimal increase in the probability of an accident sequence or the creation of accidents of a different type.

The proposed § 71.175, "Changes," establishes methods to determine if a proposed change to a Type B(DP) package can be made without prior NRC approval. As stated in a public comment, the language in this section mirrors that in § 72.48. It should be noted that the design and application process under Part 72 does require that an applicant perform an accident analysis as part of its application for approval, but such a requirement has never been incorporated into Part 71 as noted above.

The intent of Subpart I was to allow a certificate holder flexibility to make minor changes to the design of the package to be consistent with the change authority provided under § 72.48 for spent fuel storage casks in a cost and time effective manner. The NRC staff notes that transportation CoCs issued under Part 71 do allow for many changes to be made to package designs without NRC approval, provided the changes do not impact upon compliance with Part 71 standards. For example, changes in the SAR for a transportation package, in general, do not require NRC approval provided the changes do not affect the conditions listed in the CoC or the ability of the package to meet the requirements of Part 71. Additionally, packaging designs drawings that are included as conditions in the CoC do not need to specify fabrication details that are not important to safety. In this way, changes may be made to nonsafety features without modifying the drawings and without NRC review and approval. This is in contrast to the approaches for Part 72 CoCs. It is therefore important that applications for package approval, including packaging design drawings, are developed to focus on the safety features of the design. The staff notes that the current regulatory process for evaluating and approving CoC amendments for transportation packaging can continue to be used and the staff believes such course of action to be more efficient than developing a new regulatory infrastructure. To aid in receiving high quality transportation applications, the staff is preparing an amended standard format and content guide. The staff notes that the current regulatory process for evaluating and approving CoC amendments for transportation packages can continue to be used, and the staff believes such course of action is efficient instead of a new regulatory system that includes minor changes to the design or procedures and does not require substantial resource expenditures for either the applicant or the NRC.

The NRC staff has determined that implementation of the proposed change process would result in new and significant regulatory burdens and costs (see Section 3.4.4 of the RA)

which are beyond those reflected in the proposed rulemaking and, therefore, should not be adopted in this final rulemaking. The staff also recognizes the concerns of public commenters related to the allowance of changes to the design of a Type B(DP) package without prior NRC approval. The staff acknowledges that there would continue to be some inconsistency in the Part 72 and Part 71 amendment processes for a dual-purpose spent fuel storage cask and transportation package, where changes could be made to a component without an amendment under § 72.48, while an amendment would be required if the component had a safety function in the transportation design under Part 71. One factor alleviating this burden is that the Part 71 amendment can be submitted in the future, when transport is planned, and could encompass multiple § 72.48 changes over the years of storage.

The NRC staff still believes that it is a good idea to pursue further analysis of the types of changes that are allowed under § 72.48 and their impact on the needs for amendments to Part 71 CoC's. The staff will endeavor to find ways to streamline Part 71 CoC's or develop additional regulatory guidance to minimize the need for amendments for dual-purpose spent fuel storage cask and transportation packages and address industry's concerns. The staff will determine if the regulations need to be modified after completion of the analysis. If changes are needed, then they will be proposed in future revisions of Part 71.

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC staff's responses for this issue follows:

Comment. One commenter urged NRC to require more stringent testing procedures (drop tests, crash impacts, leakage, etc.) for both new and old shipping containers.

Response. The NRC acknowledges the commenter's suggestion that NRC require more stringent testing for transportation casks. It should be noted that, by conducting and evaluating the results of NRC's transportation studies, the NRC staff has determined that its

current regulations and their testing requirements are adequate to provide reasonable assurance that an approved cask design will perform its functions important to safety under both routine and accident conditions. This has also been demonstrated by the excellent shipping safety record both here and overseas.

Comment. One commenter opposed NRC's proposal to "harmonize" transport and storage of spent nuclear fuel and fissile materials with "a watered down international standard." The commenter said that the Type B(DP) package as proposed does not provide an adequate level of public protection from radiation hazards.

Response. The NRC acknowledges the commenter's opposition to the proposed rule change that would add a regulatory framework for the approval of dual purpose cask designs and a suggestion that these designs would not adequately protect the public from radiation hazards.

Comment. An industry representative voiced support for the change authority that was included in the proposed rule. The commenter added that the QA programs developed under Part 71 were equivalent in effectiveness and caliber to the programs developed under Part 72.

Five commenters expressed their support for the NRC's proposal but requested that the change authorization process be extended to all packages licensed under Part 71. Two of these commenters suggested reasons why licensees should be allowed to make minor changes independent of the CoC holders.

Another commenter stated that the changes allowed for shipping packages licensed under Part 72 should also be allowed for those under Part 71.

Response. As previously discussed, the proposed change is not being implemented for either dual purpose casks or for other transportation casks.

Comment. Seven commenters expressed disapproval of the proposed change authority for dual purpose casks. The first commenter stated that even “minor” design changes made by licensees and shippers could impact the safety of casks and that all changes should be subject to full NRC review. The second commenter suggested that there would not be sufficient experience based on the part of the CoC holders to implement the responsibility effectively, and the third commenter suggested that the rule lacked specificity for adequate implementation and that the rule change would be more effective if each design change were subject to NRC independent inspection. One commenter asserted that the public has a right to know if design changes are being made.

Response. The proposed change process is not being implemented.

Comment. One commenter expressed concern that transporting dual-purpose containers is going to be complicated, especially in instances when there is no available rail access.

Response. The NRC notes that this comment is beyond the scope of this rulemaking.

Comment. Three commenters requested clarifications on various aspects of the change authority. The first of these commenters asked for clarification on what is meant by "minimal changes" with potential safety consequences. They asked that NRC include examples as well as seek, and consider, input from State regulatory agencies when amending certificates of compliance.

The second commenter wanted to know if a certificate holder proposing a minor change would still have to check with the NRC to see if the change was permissible under the proposed change authority. The commenter wanted to know if NRC would be notified before the changes are made. The commenter requested clarification of the procedure for changes under the

proposed change authority. The commenter also requested a more detailed explanation of what constitutes a minor design change with no safety significance.

The last commenter wanted to know what types of changes could be made to dual-purpose spent nuclear fuel casks intended for domestic transport. This point was echoed by the first commenter who recommended that NRC establish guidance for determining when a design or procedural change that enhances one cask function might compromise the effectiveness of the other. NRC should ensure that the interrelationship between the storage and transportation effects of cask changes are considered during the review of certificate amendment requests. Furthermore, the first commenter stated that NRC should consider issuing a single CoC instead of two.

Response. The proposed change process is not being implemented.

Comment. One commenter noted that the eight criteria used to determine if changes require NRC prior approval were extracted verbatim from Parts 50 and 72 and placed into Part 71. The commenter suggested that these criteria be customized before inclusion in Part 71.

Response. The eight criteria used to determine if changes require prior NRC approval are effectively the same as those included in Parts 50 and 72. This motivated the staff to reevaluate how the proposed change process could be implemented and led to the determination that the proposed change process should not be added by this rulemaking as previously discussed.

Comment. One commenter noted that a large number of highly radioactive shipments could take place in dual-purpose containers and that these shipments could be destined for a repository. The commenter explained that even minor design changes would affect waste acceptance at the repository.

Response. This comment deals with detailed transportation and storage plans/designs that will need to be developed by DOE in its effort to design, construct, and operate a facility at the Yucca Mountain Site and is beyond the scope of this rulemaking.

Comment. One commenter expressed support for the design change authority being provided to CoC holders but recommended that the ability to make changes to the transportation design aspects of a dual-purpose package be provided to licensees who use the casks as well. The basis for this recommendation is that the change process included in Part 72 for storage facilities or casks allows licensees to make changes to the storage design without prior NRC approval subject to certain codified tests. Another commenter was concerned that the proposed revisions to change authority would hinder the ability of Part 72 general and specific licensees to effectively manage and control their Dry Cask Storage Program and ensure that changes made in accordance with Part 72 do not impact the Part 71 certification of spent fuel casks.

Response. The proposed change process is not being implemented as previously described.

Comment. Three commenters expressed support for the change authority. One of these commenters asserted that allowing the change authority would allow for more attention to more significant safety issues.

Response. The NRC staff has determined that the proposed change process should not be implemented in this rulemaking.

Comment. Two commenters suggested improvements on the procedures of the change authority. One stated that the 2-year submittal date for application renewal is too long and instead suggested a 30-day requirement. The other commenter stated that the proposed § 71.175(d) change reporting requirements need to allow for a single report to be filed by dual-

purpose CoC holders to comply with the requirements of Parts 71 and 72, to avoid unnecessary duplication of reports. Both stated that the proposed submittal date of 2 years before expiration for the renewal of a CoC or QA program is burdensome and should have a submittal date of only 30 days before expiration, as is required under Part 72. One commenter suggested that a CoC holder should be permitted to submit [change process implementation summary] report for both Part 71 and Part 72 designs as one package instead of having to provide two separate reports.

Response. The NRC has chosen not to include the proposed change process in the final rule.

Comment. One commenter discussed 71/72 SARs for the change authority. The commenter stated that a single 71/72 SAR for generally certified dual-purpose systems should also be permitted as an option for CoC holders. The commenter suggested that the rule language should include provisions for submitting updated transportation Final Safety Analysis Reports (FSARs) for casks already certified and having an approved SAR. The commenter suggested that an FSAR Rev. 0 be submitted to replace the last approved transportation SAR within 2 years of the effective date of the final rule, consistent with the proposed § 71.177(c)(6). The commenter stated that the requirement in proposed § 71.177(c)(7) for an FSAR update to be submitted within 90 days of issuance of an amendment of the CoC is unnecessary and inconsistent with the requirements under Part 72 for the dual-purpose spent fuel storage casks. The commenter stated that this creates an unnecessary administrative burden on CoC holders by requiring extra FSAR updates. The commenter said that this portion of the proposed rule should be deleted.

Response. Regarding the suggestion to permit the submittal of a single SAR for reflecting both the transportation and storage design for a dual-purpose cask, the NRC staff notes that the SAR submittal request is now moot based on the final rule language.

The NRC staff notes that because the entire section for dual-purpose casks is being eliminated from the final rulemaking, the comment regarding the addition of a provision in the rule language for submittal of SAR updates for those transportation casks already certified is not applicable.

The last comment regarding the requirement for the submittal of an updated FSAR within 90 days of an amendment to the transportation CoC is not applicable.

Comment. One commenter expressed a number of concerns about the proposed change process for dual purpose casks. The commenter questioned the NRC position that the change process be implemented by the CoC holder while the licensee would be most familiar with details such as site-specific parameters affecting preparation, loading, and shipment of Type B(DP) packages. The commenter also noted that it has been unable to convince NRC that the level of required detail in the FSAR is excessive and would, therefore, require excessive evaluations with procedure changes that could only be addressed by the CoC holder rather than the licensee who is implementing detailed procedures. The commenter added that industry experience with storage procedures clearly demonstrates that the proposed limitation on procedure evaluation against the Part 71 FSAR by the licensee is unworkable. (This included the commenter refuting several of NRC's justifications for proposing the exclusion of the licensees from § 71.175.)

Response. The proposed change process is not being implemented as previously described.

Comment. One commenter expressed support for the NRC's proposal but requested that the change authorization process be extended to all packages licensed under Part 71. The commenter stated that the major fault in the NRC position regarding the scope of change authority for the licensee is the exclusive focus on changes to the design of the Type B(DP) package. The certificate holder will likely have little onsite involvement with the actual loading of a Type B(DP) package and will, therefore, have little knowledge of the site-specific parameters affecting preparation, loading, and shipment of Type B(DP) packages. The commenter expressed concern that the level of required detail in the FSAR is excessive. The commenter highlighted how industry experience with these storage procedures clearly demonstrates that the proposed limitation on procedure evaluation against the Part 71 FSAR by the licensee is unworkable. (This included the commenter refuting several of NRC's justifications for proposing the exclusion of the licensees from § 71.175.)

Response: The NRC notes that it has decided not to proceed with the change process proposal into a final rule as previously discussed. The commenter did not provide any justification for adding a change process that would be applicable to all package types; therefore, no rule language has been added. The comment about the level of detail in the FSAR being excessive is considered to be an opinion, and no action is being taken in response.

Issue 16. Fissile Material Exemptions and General License Provisions.

Summary of NRC Final Rule. The final rule adopts various revisions to the fissile material exemptions and the general license provisions in Part 71 to facilitate effective and efficient regulation of the transport of small quantities of fissile material. The fissile exemptions (§ 71.15) have been revised to include controls on fissile package mass limit combined with package fissile-to-nonfissile mass ratio. The general license for fissile material (§ 71.22) has

been revised to consolidate and simplify current fissile general license provisions from §§ 71.18, 71.20, 71.22, and 71.24. Under the final rule, the general license is based on mass-based limits and the CSI. In light of comments and applicable DOT requirements, the final rule removes proposed rule language references to “storage incident to transportation.” Also, the exemptions for low level materials in § 71.14 were revised to apply only to nonfissile and fissile-exempt materials.

Affected Sections. Sections 71.4, 71.10, 71.11, 71.18, 71.20, 71.22, 71.24, 71.53, 71.59, and 71.100. (Currently effective § 71.10 was relocated to § 71.14 with additional language. Currently effective §§ 71.18, 71.20, 71.22, 71.24, and 71.53 are replaced by new §§ 71.15 and 71.22.)

Background. The NRC published an emergency final rule amending its regulations on shipments of small quantities of fissile material (62 FR 5907; February 10, 1997). This rule revised the regulations on fissile exemptions in § 71.53 and the fissile general licenses in §§ 71.18 and 71.22. The NRC determined that good cause existed, under Section 553(b)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(B)), to publish this final rule without notice and opportunity for public comment. Further, the NRC also determined that good cause existed, under Section 553(d)(3) of the APA (5 U.S.C. 553(d)(3)), to make this final rule immediately effective. Notwithstanding the final status of the rule, the NRC provided for a 30-day public comment period. The NRC subsequently published in the Federal Register (64 FR 57769; October 27, 1999) a response to the comments received on the emergency final rule and a request for information on any unintended economic impacts caused by the emergency final rule.

The NRC issued this emergency final rule in response to a regulatory defect in the fissile exemption regulation in § 71.53 which was identified by an NRC licensee. The licensee was

evaluating a proposed shipment of a special fissile material and moderator mixture (beryllium oxide mixed with a low concentration of high-enriched uranium). The licensee concluded that while § 71.53 was applicable to the proposed shipment, applying the requirements of § 71.53 could, in certain circumstances, result in an inadequate level of criticality safety (i.e., an accidental nuclear criticality was possible in certain unique circumstances).³

The NRC staff confirmed the licensee's analysis that this beryllium oxide and high-enriched uranium mixture created the potential for inadequate criticality safety during transportation. An added factor in the urgency of the situation was that under the NRC regulations in §§ 71.18, 71.20, 71.22, 71.24, and 71.53, these types of fissile material shipments could be made without prior approval of NRC. For many years, NRC allowed these shipments of small quantities of fissile material based on NRC's understanding of the level of risk involved with these shipments, as well as industry's historic transportation practices. This experience base had led NRC [and its predecessor, the Atomic Energy Commission (AEC)] to conclude that shipments made under the fissile exemption provisions of Part 71 typically required minimal regulatory oversight (i.e., NRC considered these types of shipments to be inherently safe).⁴

³ For transportation purposes, "nuclear criticality" means a condition in which an uncontrolled, self-sustaining, and neutron-multiplying fission chain reaction occurs. "Nuclear criticality" is generally a concern when sufficient concentrations and masses of fissile material and neutron moderating material exist together in a favorable configuration. Neutron moderating material cannot achieve criticality by itself in any concentration or configuration. However, it can enhance the ability of fissile material to achieve criticality by slowing down neutrons or reflecting neutrons.

⁴ The NRC's regulations in Part 71 ensure protection of public health and safety by requiring that Type AF, B, or BF packages used for transportation of large quantities of radioactive materials be approved by the NRC. This approval is based upon the NRC's review of applications which contain an evaluation of the package's response to a specific set of rigorous tests to simulate both normal conditions of transport (NCT) and hypothetical accident conditions (HAC). However, certain types of packages are exempted from the testing and NRC prior approval; these are fissile material packages that either contain exempt quantities (§ 71.53), or are shipped under the general license provisions of §§ 71.18, 71.20, 71.22, or 71.24.

All public comments on the emergency final rule supported the need for limits on special moderators (i.e., moderators with low neutron-absorption properties such as beryllium, graphite, and deuterium). However, the commenters stated that the restrictions were far too limiting (to the point that some inherently safe packages were excluded from the fissile exemption) and could lead to undue cost burdens with no benefit to safety. In addition, the commenters believed that the consignment mass limits set to deter undue accumulation of fissile mass would be extremely costly. Therefore, the commenters recommended that further rulemaking was necessary to resolve these excessive restrictions. Based on the public comments on the emergency final rule, NRC staff contracted with Oak Ridge National Laboratory (ORNL) to review the fissile material exemptions and general license provisions, study the regulatory and technical bases associated with these regulations, and perform criticality model calculations for different mixtures of fissile materials and moderators. The results of the ORNL study were documented in NUREG/CR-5342,⁵ and NRC published a notice of the availability of this document in the Federal Register (63 FR 44477; August 19, 1998). The ORNL study confirmed that the emergency final rule was needed to provide safe transportation of packages with special moderators that are shipped under the general license and fissile material exemptions, but the regulations may be excessive for shipments where water moderation is the only concern. The ORNL study recommended that NRC revise Part 71.

In the October 27, 1999 (64 FR 57769) final rule, the Commission requested additional information on the cost impact of the emergency final rule from the public, industry, and DOE because the NRC staff was not successful in obtaining this information. Specifically, NRC requested information on the cost of shipments made under the fissile material exemptions and general license provisions of Part 71, before the publication of the emergency final rule, and

⁵ NUREG/CR-5342, "Assessment and Recommendations for Fissile-Material Packaging Exemptions and General Licenses Within 10 CFR Part 71," July 1998.

those costs and/or changes in costs resulting from implementation of the emergency rule. One commenter agreed with the NRC approach but stated that, "the limits for those materials containing no special moderators can and should be increased, hopefully back to their pre-emergency rule levels."

As part of NUREG/CR-5342, ORNL performed computer model calculations of k_{eff} (k-effective) for various combinations of fissile material and moderating material, including beryllium, carbon, deuterium, silicon-dioxide, and water, to verify the accuracy of current minimum critical mass values. These minimum critical mass values were then applied to the regulatory structure contained in Part 71, and revised mass limits for both the general license and exemption provisions to Part 71 were determined. Also, ORNL researched the historical bases for the fissile material exemption and general license regulations in Part 71 and discussed the impact of the emergency final rule's restrictions on NRC licensees. ORNL concluded that the restrictions imposed by the emergency final rule were necessary to address concerns relative to uncontrolled accumulation of exempt packages (and thus fissile mass) in a shipment and the potential for inadequate safety margin for exempt packages with large quantities of special moderators.

Based on its new k_{eff} calculations, ORNL suggested that: (1) the mass limits in the general license and exemption provisions could be safely increased and thereby provide greater flexibility to licensees shipping fissile radioactive material; and (2) additional revisions to Part 71 were appropriate to provide increased clarification and simplification of the regulations. Copies of NUREG/CR-5342 may be obtained by writing to the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328. A copy is also available for inspection and copying, for a fee, at the NRC Public Document Room in the

NRC Headquarters at One White Flint North, Room O-1F21, 11555 Rockville Pike, Rockville, MD 20852-2738.

The current restrictions on fissile exempt and general license shipments under §§ 71.53, and 71.18 through 71.24, respectively, are burdensome for a large number of shipments that actually contain no special moderating materials (i.e., packages that are shipped with water considered as the potential moderating material). This problem was clearly expressed in public comments on the emergency final rule. Another regulatory problem is that the current fissile exempt and general license provisions are cumbersome and outdated; this was one of the main conclusions of the ORNL study.

The NRC proposed changes (67 FR 21417) were made on the basis of 17 recommendations contained in NUREG/CR-5342. These changes included: (1) revising § 71.10, "Exemption for low level materials," to exclude fissile material, also redesignate § 71.10 as § 71.14; (2) redesignating § 71.53 as § 71.15, "Exemption from classification as fissile material," and revise the fissile exemptions; (3) consolidation of the existing four general licenses in existing §§ 71.18, 71.20, 71.22, and 71.24 into one general license in new § 71.22, revise the mass limits, and add Type A package, CSI, and QA requirements; and (4) consolidation of the existing general license requirements for plutonium-beryllium sealed sources, which are contained in existing §§ 71.18 and 71.22 into one general license in new § 71.23 and revise the mass limits. Additionally, changes were proposed to be made to § 71.4, "Definitions," and § 71.100, "Criminal penalties."

The NRC also proposed: (1) to adopt the use of the CSI for general licensed fissile packages; and (2) to retain the current per package (CSI) limit of 10, rather than raising the per package limit to 50 (see Issue 5). TS-R-1 does not address the issue of fissile general licenses, so no compatibility issues arise with retention of the current NRC per package limit

of 10. NRC staff believes that because reduced regulatory oversight is imposed on fissile general license shipments (e.g., the package standards of §§ 71.71 and 71.73, fissile package standards of § 71.55, and fissile array standards of § 71.59 are not imposed for fissile general license shipments), retention of the current per package limit of 10 is appropriate. Furthermore, retention of the current per package limit of 10 would not impose a new burden on licensees; rather, licensees shipping fissile material under the general license provisions of §§ 71.22 and 71.23 would not be permitted to take advantage of the relaxation of the per package CSI limit from 10 to 50 that would be permitted for Types AF and B(F) package shipments.

As a result of stakeholder meetings and public comments, the NRC has incorporated the following changes to the proposed language for §§ 71.15 and 71.22 in the final rule:

(1) Small quantities of fissile materials such as environmental samples shipped for testing are judged to be of sufficient low quantity that, if individually packaged, the risk (probability and consequence) of accumulating the number and type of packages needed to present a potential criticality hazard is judged to be inconsequential. Therefore, a new § 71.15(a) has been added to exempt packages containing 2 grams or less fissile material.

(2) Proposed § 71.15(a) [§ 71.15(b) in the final rule] specifically referred to iron as the nonfissile material for calculating limiting ratio of 200:1. Commenters suggested that this would require a new definition (of iron) and would complicate implementation. There is no technical reason to require that iron be identified as the nonfissile materials to be included with a mass ratio of 200:1. Other nonspecial moderating materials such as stainless steel, concrete, etc., are appropriate. The mass ratio wording has been modified. The modification maintains the need for the mass ratio of 200:1, but the required nonfissile material is required to be a solid. As worded, the nonfissile mass can include the packaging mass. It is judged that sufficient distribution of fissile material in small quantities (i.e., 1 g of fissile material per 200 g of solid

nonfissile material) will provide adequate protection against nuclear criticality. This specification ensures that large numbers of packages, containing 15 g of fissile material per package, will remain safely subcritical because of the fissile material dilution and density reduction by nonfissile materials which are not special moderators (e.g., beryllium, graphite, etc.). For example, 1 g of optimally moderated uranium-235 in a mixture at about 0.05 g Uranium-235/cm³ occupies a volume of about 20 cm³. Two hundred grams of aluminum metal at about 2.7 g of aluminum/cm³ occupies a volume of about 74 cm³. As specified, the 15 g of uranium-235 per package will have a diluted volume of about 1,410 cm³ at a density of about 0.01 g uranium-235/cm³ and a density reduction by a factor of 5. Though aluminum is a minor absorber of low-energy neutrons, most other common materials of packaging have moderate neutron-absorbing properties that further ensure safely subcritical accumulations of such packages. The increase in the subcritical mass of ~620 g of optimally moderated uranium-235, permitted by the reduction of fissile material density, is related to the ratio of the densities to the power of 1.8 (see Ref. 1 , pp. 19-22). Given the density reduction of 5 in the above example, the adjusted subcritical mass becomes 11,125 g of uranium-235, requiring in excess of about 741 packages (containing 15 g of uranium-235 per package) to exceed the determined equivalent quantity of material.

(3) Proposed § 71.15(b) [§ 71.15(c) in the final rule], was modified by referring to fissile and nonfissile materials as solid materials instead of using "noncombustible" and "insoluble-in-water." The modification was a pragmatic consideration and was made to avoid reference to the undefined/specified word, "noncombustible," and the phrase, "insoluble-in-water," while addressing the need to avoid fissile and nonfissile liquids/gases that easily could be consolidated or lost (thereby decreasing nuclear criticality safety) in normal and hypothetical accident transportation circumstances. An additional modification, § 71.15(c)(2) in

the final rule, also removes the limit of 350 g in a package and instead specifies criteria for commingling of the material such that, within any selected 360 kg of nonfissile solid material, there can be no more than 180 g of fissile material. Thus, a large rail car with a homogenized distribution of fissile material within a nonfissile waste matrix might exceed the 180 g limit but would be effectively mixed at low enough concentration to enable safe shipment.

(4) The basis for § 71.15(c)(1) is that a 2000:1 mass ratio of nonfissile to fissile material is ~60% of the minimum critical fissile material concentration of 1.33 g uranium-235/L in a 1,600 g SiO₂/L matrix. The 60-percent value is judged to be a reasonably conservative decrease in g uranium-235/g nonfissile material (e.g., SiO₂) to accommodate other nonfissile materials. The minimum critical fissile material concentration in SiO₂ was derived from studies to compare "special" and "natural" neutron moderators with fissile materials. In those studies various systems were examined that had different species of fissile material (i.e., uranium-235, uranium-233, or plutonium-239) combined with water and other nonfissile neutron scatterers/moderators (e.g., polyethylene, beryllium, carbon, deuterium, and SiO₂). SiO₂ was selected for consideration in the transport exemptions because it is judged to be the most representative, arbitrary, and nonspecial moderator matrix for commingling with fissile material. SiO₂ has a very low probability for absorbing neutrons and has a large abundance in nature (i.e., 33 weight percent, second only to oxygen at 49 weight percent). An independent study compared the relative importance of other elements to silicon with dilute fissile materials. Except for the category of special moderators (i.e., deuterium, beryllium, and graphite) and pure forms of magnesium (i.e., magnesium carbonate, magnesium fluoride, magnesium oxalate, magnesium oxide, magnesium peroxide, magnesium silicates) and bismuth (i.e., bismuth basic carbonate, bismuth tri- or penta-fluorides, bismuth oxide), silicon or silicon dioxide is the most

neutronically reactive diluent for fissile materials. The 1.6-g SiO₂/L is representative of dry bulk mean world soil density.

(5) Section 71.15(d) [§ 71.15(c) in proposed rule] has been revised to reflect “mass of beryllium, graphite, and hydrogenous material enriched in deuterium constitute less than 5 percent of the uranium mass” (less than 0.1 percent of the fissile mass being the proposed phrase). This change was made in response to a comment about the difficulty that shippers would experience based on the proposed rule language. The staff reviewed the 0.1 percent of fissile mass language and determined that limiting the low-neutron-absorbing materials to the proposed ratio would be impractical to implement. The final language reflecting 5 percent of the uranium mass assures subcriticality for all moderators of concern and is less burdensome to measure and implement as a requirement.

(6) Section 71.15(e) [§ 71.15(d) in the proposed rule] states “total plutonium and uranium-233 content not exceeding 0.002 percent of the mass of uranium” while the proposed language stated “does not exceed 0.1 percent of the mass of uranium-235.” This change was made in response to a public comment that the proposed rule changes should be consistent with the international regulations. The final language for this section has been revised to be consistent with the 1996 IAEA standards.

(7) Section 71.15(f) [proposed § 71.15(e)] was reworded for clarity but reflects the same requirements and guidance as in the proposed language.

(8) Proposed § 71.22 (e)(5)(iii), Exemption from classification as fissile material, was revised to read “... The uranium is of unknown Uranium-235 enrichment or greater than 24 weight percent enrichment; or....” The reason for the § 71.22(e)(5)(iii) modification was that enrichments of U-235 greater than 24 weight percent were not accommodated in the proposed text. Because the minimum critical mass transition between 24 and 100 weight percent

enrichments of ^{235}U vary slightly, the text was changed to require the use of Table 71-1 values for all enrichments greater than 24 weight percent as well as materials of unknown enrichments. The values in Table 71-1 were developed for 100 weight percent uranium-235 enriched uranium and are conservatively applied down to 24 weight percent uranium-235.

(9) Proposed § 71.22, Table 71-1, was modified in the final rule to replace uranium-235 (Y) with uranium-233 (Y) - change to uranium-233 (Y). The reason is to correct a typographical error in the table.

In the final rule, the NRC has deleted the phrase “or stored incident to transport” from proposed §§ 71.22(d)(3) and 71.23(d)(3). The intent of the storage phrase was to permit segregation of groups of stored packages, consistent with IAEA and DOT requirements, but the NRC staff believes that the proposed text did not accommodate that practice because it did not accommodate storage and segregation of groups of packages. DOT requirements properly restrict accumulation of packages during transport, based on summing the packages’ CSI or TI, including during storage incident to transport. In light of the division of regulatory responsibilities explained in the NRC-DOT Memorandum of Understanding (44 FR 38690; July 2, 1979), the NRC exemptions for carriers-in-transit in § 70.12, and DOT’s revision to 49 CFR 173.457 (67 FR 21384), the NRC staff believes that storage in transit provisions as proposed in §§ 71.22(d)(3) and 71.23(d)(3) are unnecessary.

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC staff’s responses for this issue follows:

Comment. One commenter noted that this is a significant deviation from the TS-R-1 requirement, which now has a 15-g uranium-235 limit as well as a mass consignment limit.

Response. On February 10, 1997 (62 FR 5907), the NRC published a final rule on fissile exemptions. That final rule essentially adopted the 1996 TS-R-1 requirements, including

the 15-g per package limit and 400-g consignment mass limit. Both the consignment mass limit (400 g) and the package mass limit (15 g) were used to control package accumulations. In consideration of comments received on the 1997 rule, the NRC has proposed changes to the fissile exemptions; one of the principal concerns with the 1997 rule was the practicability of the 350-g consignment mass limit (see 67 FR 21418; April 30, 2002). The proposed rule suggested a mass ratio system together with the per package limit to eliminate this consignment mass limit. The IAEA is currently considering changes to the current international regulations in the area of the fissile material exemptions.

Comment. Three commenters indicated that this provision would overly complicate the shipping of fissile material and negatively impact intermodal and international shipping. One commenter noted that the three-tiered system would dramatically complicate the shipping of fissile material because the mass ratio requirement makes it difficult to determine how to classify UF_6 into the three tiers. This same commenter stated that companies that ship internationally will have a difficult time complying with the proposed system as well as the international system and suggested that NRC simplify compliance for these companies. The other commenter stated that if NRC's proposal is adopted as written, shippers would need to have detailed information available regarding the materials in each packaging. The commenter reasoned that this approach assumes that the detailed information would be readily available and disseminated to shippers, and further, shippers making international shipments would likely need to meet both NRC's domestic requirements for determining fissile exempt quantities and the international mass consignment limits, thus further complicating the evaluation of criticality controls for a shipment.

Response. The NRC staff believes that the changes are warranted to alleviate the unnecessary regulatory burden created by the 1997 emergency final rule, including the

consignment mass limit. The changes implemented by the 1997 rule are essentially the same as TS-R-1. These amendments permit greater flexibility for domestic transport, in consideration of the comments received when the U.S. adopted the TS-R-1 approach in 1997. However, NRC recognizes that international transport will also need to comply with IAEA TS-R-1, and the burden has been unchanged. The IAEA is currently considering changes to the current international regulations in the area of the fissile material exemptions. The NRC staff did review the proposed language for the proposed § 71.15(c) and determined that the 0.1 percent ratio of the mass of beryllium, graphite, and hydrogenous material enriched in deuterium to the total fissile mass was a requirement that was difficult to implement and therefore the language has been changed as noted above in the rule language description.

Comment. Several commenters expressed concern about material definitions, with one commenter noting that the definition of iron is unclear. One commenter requested clarification of what constitutes iron with regard to Tier 1 or fissile exempt quantities and specifically asked if steel is considered iron. Another stated that it is difficult to obtain information on materials to carry out the calculations under the proposed regulations.

Response. Many materials have the neutronic properties that would permit them to be considered as the nonfissile material mass to be mixed with up to 15 g of fissile material in a ratio of 200:1. Iron, generic steels, stainless steels, and concrete are good examples of materials for use. Only lead, beryllium, graphite, and hydrogenous material enriched in deuterium should be excluded as noted in the revised text. The wording has been modified and clarified in the final rule.

Comment. One commenter requested that the NRC explain why NRC proposes changing the total shipment CSI in cases where there is storage incident to transport, effectively doing away with an exclusive use condition. The commenter considered this

proposal a significant change in the method of calculating the CSI per consignment and wanted to remind us that the proposed rule maintains segregation and storage requirements.

Response. The “storage incident to transport” language has been deleted. See the comment responses under Issue 5.

Comment. Two commenters said that NRC should clarify how the mass limits for general license packages (found in § 71.22 (a)(3), Tables 71-1 and 71-2) are used for uranium enriched greater than 24 percent. Both commenters stated that highly enriched uranium does not meet the criteria under § 71.22(e)(5). Moreover, if uranium enriched greater than 24 percent cannot be shipped in a DOT 7A, this provision would have significant cost and operational impacts on the DOE.

Response. Uranium enriched to greater than 24 percent can be shipped provided the appropriate X value from Table 71-1 is used in the equation to determine the CSI. The proposed rule had intended § 71.22(e)(3) to guide the reader to using Table 71-1 for uranium-235 enrichments greater than 24 percent. However, the text for § 71.22(e)(5)(iii) has been revised to clarify the use of Table 71-1 for uranium-235 enrichments greater than 24 percent.

Comment. Several commenters discussed the economic impact of the proposed regulation. Two commenters asserted that the regulation will cause an increase in the number of shipments required with an associated increase in costs, with one predicting required transports to increase two- to three-fold. Another warned of significant negative economic consequences if NRC did not retain the current provision for 15 g per package, at least until it is demonstrated unsafe.

Response. These comments appear to be concerned with the rule's restrictions on package accumulation based on CSI due to the “storage incident to transport” language in the

proposed rule. The “storage incident to transport” language has been deleted. Also see the response to second comment under Issue 5.

Comment. One commenter stated that “under no circumstances should the NRC issue general licenses for shipments of radioactive materials and wastes (or, for that matter, for other purposes).” The commenter then added that NRC shouldn’t allow fissile materials to be exempted from packaging and transportation regulations nor should NRC allow “transport subject to even remotely possible criticality accidents during shipment” under any circumstances. The commenter added that it is “an outrage, furthermore, that the NRC had approved an ‘emergency final rule’ allowing shipments of fissile materials in 1997 without affording the public full opportunity for comment...” The commenter cited NRC’s footnote (see 67 FR 21418; April 30, 2002) and stated doubts regarding NRC’s process for requiring NRC’s approval for “all Type AF, B, or BF packages.” The commenter concluded by stating that “NRC approval is virtually guaranteed in almost all cases, whether or not the decision contributes to public health and safety, not to mention the environment.”

Response. The NRC staff believes that current regulations and programs for transporting fissile materials, and in particular the general licensing approach in Part 71, result in a high degree of safety as evidenced by a long record of safe transport of these materials. The staff believes that a graded series of requirements for hazardous materials, including the fissile exemptions and general licenses, remains appropriate.

Comment. Two commenters expressed concern about the use of the Part 110 definitions of “deuterium” and “graphite” in the proposed rule. The commenters suggested that NRC reconsider these definitions because they are inappropriate for the purpose of nuclear criticality safety.

Response. The final rule stipulates that “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.” Materials enriched in deuterium and graphite are often termed special moderators because their very low neutron absorption properties give rise to special consideration for large systems with low concentration of fissile material and, therefore, warrant consideration in the criticality control approach. In the interests of consistency within NRC regulations, the NRC staff believes that the definitions of graphite and deuterium are sufficient for purposes of defining the materials that cannot be used in the § 71.15 determination.

Comment. One commenter opposed the fissile material exemptions.

Response. No response is necessary.

Comment. Two commenters expressed general support for the fissile material exemptions. One of whom expressed support for the graduated exemptions for fissile material shipments because they would allow increasing quantities in shipments, provided that the packages also contained a corresponding increase in the ratio of non-fissile to fissile material. They also appreciated NRC consolidating four fissile material general licenses into one and consolidating existing general license requirements for PuBe sources into one section and updating the mass limits.

Response. The comments are acknowledged. No further response is necessary.

Comment. Several commenters requested that NRC include and/or improve various definitions in the proposed rule. One commenter stated that improved definitions were necessary to categorize the ratio calculations.

Three commenters added that NRC should not exclude the definition of “shipment” from the rule. Another suggested that the proposed rule was ambiguous as to whether iron in the

packaging (e.g. internal structure) can be used to meet the 200:1 ratio requirement in the 15-g exception.

Two commenters noted that the proposed rule did not include a definition for “insoluble in water,” one of whom stated that the proposed rule fails to clarify the issue in part because of the rulemaking’s lack of clarity. This same commenter questioned NRC’s decision to omit definitions for “consignment” and “shipment” and urged NRC to adopt the TS-R-1 definition for these terms.

Response. The NRC staff believes the terms “ratio” and “calculations” are sufficiently clear without corresponding definitions. The terms “iron in the packaging” and “insoluble in water” have been deleted from the rule. Because of its bearing upon the fissile exemptions rule, a definition of “consignment” that is consistent with the definition in DOT’s corresponding rulemaking has been added to the final rule language. The NRC staff does not believe a definition of the common-usage term shipment is warranted.

Comment. One commenter noted that § 71.15(b) does not identify what standard is to be used in applying either the term “noncombustible” or the term “insoluble-in-water.” The commenter stated that if this section is kept as proposed, there is a need to clarify the terms and specify an appropriate standard.

Response. The text from the proposed rule has changed. Rather than clarify the words “noncombustible” and “insoluble-in-water,” the new text indicates only the need for the nonfissile material to be a “solid.” The NRC believes that new definitions are not necessary.

Comment 13. One commenter requested that NRC delete the proposed exemptions for plutonium-244 in proposed § 71.14(b)(1) because there are no special form plutonium-244 sources available.

Response: Section 71.14(b)(1) was changed to provide clarification and simplification of the language that existed in the current regulation (§ 71.10), while retaining the substance of the exemption. The current § 71.10 (b)(1) exempts shipments that contain no more than a Type A quantity of radioactive material from all of the requirements of Part 71, except for §§ 71.5 and 71.88. Similarly, § 71.10(b)(3) exempts domestic shipments that contain less than an aggregate 20 Curies (Ci) of special form americium or plutonium from all of the requirements of Part 71, except for §§ 71.5 and 71.88. The current Type A (A_1) limit for plutonium-244 is 8 Ci. The rule raises the A_1 limit for plutonium-244 to 11 Ci — still less than the 20-Ci exemption of the current § 71.10(b)(3). Consequently, for plutonium-244, the two exemption criteria of the current § 71.10(b)(1) and (b)(3) were in conflict. The NRC's proposed rule resolved that conflict. The commenter's proposed solution would retain that conflict. Accordingly, absent a substantive basis for changing the proposed rule, the NRC is retaining the existing 20-Ci exemption for domestic shipments of special form americium or plutonium in § 71.14(b)(1) in this final rule. Furthermore, because the A_1 limits for all other nuclides of plutonium are greater than 20 Ci, only plutonium-244 is mentioned in paragraph (b)(1).

Comment. Two commenters asserted that the regulations are overly complex and inconsistent with international regulations. One commenter agreed with NRC's proposal to change the requirements for fissile material shipments, but did have several objections. The three primary objections were that NRC hadn't adequately defined the terms to categorize the ratio calculations; information on the materials, necessary to perform calculations, is difficult to obtain; and the proposal is overly complex and inconsistent with international regulations. This same commenter stated that the proposed rule does not adequately account for both packages of large volume and packages of small volume. The proposed changes do not provide for the ability to ship large volumes of decommissioning waste in an effective manner and will

complicate international trade of fissile exempt materials. Furthermore, the proposed ratio control is inadequate, and NRC should define "insoluble in water." The commenter recommended inclusion of the TS-R-1 provisions for fissile exempt materials. Lastly, the commenter stated that, while NRC should go forward with the rulemaking, it should work with industry to determine operational limits that will assure that the mass or concentration limit is maintained under accident conditions.

Response. The staff has reviewed the proposed rule language and has determined that section §71.15(d) was not consistent with the language in TS-R-1 and has been revised. The commenter should note, that the intent for this rule change is to provide greater flexibility in transportation with a concomitant improvement of a shipper's knowledge about the contents of materials in the package. The rule has been revised to address the concerns about shipments of very small quantities of fissile material in small packages and shipment of low concentrations of fissile material where the large volume of the container and mass of nonfissile material might enable one to exceed the fissile limit in the proposed rule. The IAEA is currently considering changes to the current international regulations in the area of the fissile material exemptions. The concept put forward in the current rule is one of those under consideration. The other option proposed to the IAEA to provide safety in the event of uncontrolled accumulation of fissile exempt packages is to implement a CSI for all packages containing fissile material. The NRC considered both options and chose to implement the option that did not require a CSI on fissile exempt packages.

Comment. One commenter expressed concern that NRC's proposal to add atomic ratio criteria to the previously used 15-g ²³⁵U mass criterion may restrict exemption of fissile materials, not containing special moderators, that are currently acceptable. Another commenter expressed support for the concept of exemptions for fissile material shipments

under specific conditions. However, the commenter said that NRC's proposal in § 71.15 was overly conservative and resulted in a reduction in the limits of fissile material content without justification.

Response. The NRC staff agrees, in part, with these comments. Proposed § 71.15(c)(1) has been modified by removing the limit of 350 g in a package and instead specifies criteria for commingling of the material such that, within any selected 360 kg of nonfissile solid material, there can be no more than 180 g of fissile material. Thus, a large rail car with a homogenized distribution of fissile material within a nonfissile waste matrix might exceed the 180-g limit but would be effectively mixed at low enough concentration to enable safe shipment. In the case of small sample shipments, a limit of 2 g per package has been added to § 71.15(a) and applies without regard to any mass ratios.

Comment. One commenter stated that the proposed fissile material exemptions do not agree with the TS-R-1 exemptions and appear to contain requirements that are not necessary for nuclear criticality safety. This commenter also expressed concern about the discontinuance of the exemption for material containing less than 5 grams of uranium-235 per 10-liter volume and its impact on shipments related to decommissioning activities. The commenter also voiced support for the proposed new limit of 350g of fissile material with a 2000:1 ratio to noncombustible and insoluble-in-water material.

Response. The NRC staff acknowledges the comment of support for one of the proposed changes. Regarding the comment about the exemption discontinuance, the commenter did not provide any detailed justification for this concern; thus, no change has been made to the rule language. As stated above, the NRC has determined for a number of issues that it does not harmonize completely with all changes made in the IAEA guidance documents based on safety and other technical reasons.

Issue 17. Decision on Petition for Rulemaking on Double Containment of Plutonium (PRM-71-12).

Summary of Decision on PRM-71-12. The final rule grants petitioner's request to remove the double containment requirement of § 71.63(b). However, the requirement of § 71.63(a) that shipments whose contents contain greater than 0.74 TBq (20 Ci) of plutonium must be made with the contents in solid form is retained. Thus, the petitioner's alternative proposal is denied. This completes action on PRM-71-12.

The NRC has decided to remove the double containment requirement because this regulation is neither risk-informed nor performance-based. There are many nuclides with A_2 values the same or lower than plutonium's for which double containment has never been required. Thus, requiring double containment for plutonium alone is not consistent with the relative hazard rankings in Table A-1. The Type B packaging standards, which the outer containment of plutonium shipments must meet, in and of themselves, provide reasonable assurance that public health and safety and the environment are protected during the transportation of radioactive material. This position is supported by an excellent safety record in which no fatalities or injuries have been attributed to material transported in a Type B package. The imposition of an additional packaging requirement (in the form of a separate inner container) is fundamentally inconsistent with this position and is technically unnecessary to assure safe transport. Further, removal of this requirement will reduce an unnecessary regulatory burden on licensees, will likely result in reduced risk to radiation workers, and will serve to harmonize Part 71 with TS-R-1.

On the other hand, the imposition of the requirement that plutonium in excess of 0.74 TBq (20 Ci) per package be shipped as a solid does not create a regulatory inconsistency with the Type B package standards. The NRC considers the contents of a package when it is

evaluating the adequacy of a packaging's design. The approved content limits and the approved packaging design together define the CoC for a package. However, other than criticality controls and the solid form requirement of § 71.63(a), Subparts E and F do not contain any restrictions on the contents of a package. Thus, while the inner containment requirement in § 71.63(b) can be seen as conflicting with the Type B package standard because the inner containment affects the packaging's design, the solid form requirement of § 71.63(a) does not conflict with the packaging requirements of the Type B package standard because the solid form requirement affects only the contents of the package, not the packaging itself.

Affected Sections. Section 71.63.

Discussion of PRM-71-12: The NRC received a petition for rulemaking from International Energy Consultants, Inc. (IEC), dated September 25, 1997. The petition was docketed as PRM-71-12 and was published for public comment (63 FR 8362; February 19, 1998). Based on a request from General Atomic, the comment period was extended to July 31, 1998 (see 63 FR 34335; June 24, 1998). Nine public comments were received on the petition. Four commenters supported the petition, and five commenters opposed the petition.

The petitioner requested that § 71.63(b) be removed. The petitioner argued that the double containment provisions of § 71.63(b) cannot be supported technically or logically. The petitioner stated that based on the "Q-system for the Calculation of A_1 and A_2 Values," an A_2 quantity of any radionuclide has the same potential for damaging the environment and the human species as an A_2 quantity of any other radionuclide.

The NRC believes that the Q-values are based upon radiological exposure hazard models which calculate the allowable quantity limit (the A_1 or A_2 value) necessary to produce a known exposure (i.e., one A_2 of plutonium-239 or one A_2 of cobalt-60 will both yield the same radiation dose under the Q-system models, even though the A_2 values for these nuclides are

different (e.g., one A_2 of plutonium-239 = 2×10^{-4} TBq, and one A_2 of cobalt-60 = 1 TBq). The Q-system models take into account the exposure pathways of the various radionuclides, typical chemical forms of the radionuclide, methods for uptake into the body, methods for removal from the body, the type of radiation the radionuclide emits, and the bodily organs the radionuclide preferentially affects. The specific A_1 and A_2 values for each nuclide are developed using radiation dosimetry approaches recommended by the World Health Organization and the ICRP. The models are periodically reviewed by international health physics experts (including representatives from the United States), and the A_1 and A_2 values are updated during the IAEA revision process, based upon the best available data. (Note that changes to the A_1 and A_2 values as a result of changes to the models in TS-R-1 are also discussed in Issue 3 of this rule.) These values are then issued by the IAEA in safety standards such as TS-R-1. When the IAEA has revised the A_1 and A_2 values in previous revisions of its transport regulations, these revised values have been adopted by the NRC and DOT into the transportation regulations in 10 CFR Part 71 and 49 CFR Part 173, respectively.

NRC's review of the current A_1 and A_2 values in Appendix A to Part 71, Table A-1, reveals that 5 radionuclides have an A_2 value lower than plutonium (i.e., plutonium-239), and 11 radionuclides have an A_2 value that is equal to plutonium-239. Because the models used to determine the A_1 and A_2 values all result in the same radiation exposure (i.e., hazard), a smaller A_1 and A_2 value for one radionuclide would indicate a greater potential hazard to humans than a radionuclide with a larger A_1 and A_2 value. Thus, overall, Table A-1 can also be viewed as a relative hazard ranking (for transportation purposes) of the listed radionuclides. In that light, requiring double containment for plutonium alone is not consistent with the relative hazard rankings in Table A-1.

The petitioner also argued that the Type B package requirements should be applied consistently for any radionuclide, whenever a package's contents exceed an A_2 limit. However, Part 71 is not consistent by imposing the double containment requirement for plutonium. The petitioner believes that if Type B package standards are sufficient for a quantity of a particular radionuclide which exceeds the A_2 limit, then Type B package standards should also be sufficient for any other radionuclide which also exceeds the A_2 limit. The petitioner stated that:

While, for the most part, Part 71 regulations embrace this simple logical congruence, the congruence fails under 10 CFR 71.63(b) wherein packages containing plutonium must include a separate inner container for quantities of plutonium having a radioactivity exceeding 20 curies [0.74 TBq] (with certain exceptions).

The petitioner further stated that:

If the NRC allows this failure of congruence to persist, the regulations will be vulnerable to the following challenges: (1) the logical foundation of the adequacy of A_2 values as a proper measure of the potential for damaging the environment and the human species, as set forth under the Q-System, is compromised; (2) the absence of a limit for every other radionuclide which, if exceeded, would require a separate inner container, is an inherently inconsistent safety practice; and (3) the performance requirements for Type B packages, as called for by 10 CFR Part 71, establish containment conditions under different levels of package trauma. The satisfaction of these Type B package standards should be a matter of proper design work by the package designer and proper evaluation of the design through regulatory review. The imposition of any specific package design feature such as that contained in 10 CFR 71.63(b) is gratuitous. The

regulations are not formulated as package design specifications, nor should they be.

The NRC agrees that the Part 71 regulations are not formulated as package design specifications; rather, the Part 71 regulations establish performance standards for a package's design. The NRC reviews the application to evaluate whether the package's design meets the performance requirements of Part 71. Consequently, the NRC can then conclude that the design of the package provides reasonable assurance that public health and safety and the environment are adequately protected.

The petitioner also believes that the continuing presence of § 71.63(b) engenders excessively high costs in the transport of some radioactive materials without a clearly measurable net safety benefit. The petitioner stated that this is so, in part, because the ultimate release limits allowed under Part 71 package performance requirements are identical with or without a "separate inner container," and because the presence of a "separate inner container" promotes additional exposures to radiation through the additional handling required for the "separate inner container." Consequently, the petitioner asserted that the presence or absence of a separate inner container barrier does not affect the standard to which the outer container barrier must perform in protecting public health and safety and the environment. Therefore, the petitioner concluded that given that the outer containment barrier provides an acceptable level of safety, the separate inner container is superfluous and results in unnecessary cost and radiation exposure. According to the petitioner, these unnecessary costs involve both the design, review, and fabrication of a package, as well as the costs of transporting the package. And the unnecessary radiation exposure involves workers having to handle (i.e., seal, inspect, or move) the "separate inner container."

As an alternative to the primary petition, the petitioner believes that an option to eliminate both § 71.63(a) and (b) should also be considered. Section 71.63(a) requires that plutonium in quantities greater than 0.74 TBq (20 Ci) be shipped in solid form. This option would have the effect of removing § 71.63 entirely. The petitioner believes that the arguments set forth to support the elimination of § 71.63(b) also support the elimination of § 71.63(a). The petitioner did not provide a separate regulatory or cost analysis supporting the request to remove § 71.63(a).

History of the Double Containment Requirement: On June 17, 1974 (39 FR 20960), the AEC issued a final rule which imposed special requirements on the shipment of plutonium. These requirements are located in § 71.63 and apply to shipments of radioactive material containing quantities of plutonium in excess of 0.74 TBq (20 curies). Section 71.63 contains two principal requirements. First, the plutonium contents of the package must be in solid form [§ 71.63(a)]. Second, the packaging containing the plutonium must provide a separate inner containment (i.e., the "double containment" requirement) [§ 71.63(b)]. In addition, the AEC specifically excluded from the double containment requirement of § 71.63(b) plutonium in the form of reactor fuel elements, metal or metal alloys, and other plutonium-bearing solids that the Commission (AEC or NRC) may determine, on a case-by-case basis, do not require double containment. This regulation remained essentially unchanged from 1974 until 1998, when vitrified high-level waste in sealed canisters was added to the list of exempt forms of plutonium in § 71.63(b) (63 FR 32600; June 15, 1998). The double containment requirement is in addition to the existing 10 CFR Part 71 Subparts E and F requirements imposed on Type B packagings (e.g., the normal conditions of transport and hypothetical accident conditions of §§ 71.71 and 71.73, respectively, and the fissile package requirements of §§ 71.55 and 71.59). Part 71 does not impose a double containment requirement for any radionuclide other than plutonium.

Additionally, IAEA standard TS-R-1 does not provide for a double containment requirement (in lieu of the single containment Type B package standards) for any radionuclide.

The AEC issued this regulation at a time when AEC staff anticipated widespread reprocessing of commercial spent fuel, and existing shipments of plutonium were made in the form of liquid plutonium nitrate. Because of physical changes to the plutonium that was expected to be reprocessed (i.e., higher levels of burnup in commercial reactors for spent fuel, which would then be reprocessed), and regulatory concerns with the possibility of package leakage, the AEC issued a regulation that imposed the double containment requirement when the package contained more than 0.74 TBq (20 Ci) of plutonium. This double containment was in addition to the existing Type B package standards on packages intended for the shipment of greater than an A_1 or A_2 quantity of plutonium.

The NRC staff has reviewed the available regulatory history for § 71.63, and has provided a recapitulation of the supporting information which led to the issuance of this regulation. The NRC staff has extracted the following information from several SECY papers the AEC staff submitted to the Commission on this regulation. The NRC staff believes this information is relevant and will provide stakeholders with perspective in understanding the bases for this regulation, and thereby assist stakeholders in evaluating the staff's proposed changes to this regulation.

In SECY-R-702,⁶ the AEC staff identified two considerations that were the genesis of the rulemaking that led to § 71.63. AEC staff stated:

First, increasingly larger quantities of plutonium will be recovered from power reactor spent fuel. Second, the specific activity of the plutonium will increase with higher reactor fuel burnup resulting in greater pressure generation potential

⁶ SECY-R-702, "Consideration of Form for Shipping Plutonium," June 1, 1973.

from plutonium nitrate solutions in shipping containers, greater heat generation, and higher gamma and neutron radiation levels. These changes will make the present nitrate packages obsolete. Thus, from both safety and economic considerations, the transportation of plutonium as [liquid] nitrate will soon require substantial redesign of packages to handle larger quantities as well as to deal with the higher levels of gas evolution (pressurization), heat generation, and gamma and neutron radiation.

There is little doubt that larger plutonium nitrate packages could be designed to meet regulatory standards. The increased potential for human error and the consequences of such error in the shipment of plutonium nitrate are not so easily controlled by regulation. Even though such packages may be adequately designed, their loading and closure requires high operation performance by personnel on a continuing basis. As the number of packages to be shipped increases, the probability of leakage through improperly assembled and closed packages also increases.... More refined or stringent regulatory requirements, such as double containment, would not sufficiently lessen this concern because of the necessary dependence on people to affect engineered safeguards.

In SECY-R-74-5,⁷ AEC staff summarized the factors relevant to consideration of a proposed rule following a June 14, 1973, meeting to discuss SECY-R-702, between the Regulatory and General Manager's staffs (i.e., the rulemaking and operational sides of the AEC). The AEC stated:

⁷ SECY-R-74-5, "Consideration of Form for Shipping Plutonium," dated July 6, 1973.

As a result of this meeting [on June 14, 1973], the [Regulatory and General Manager's] staffs have agreed that the basic factors pertinent to the consideration of form for shipment of plutonium are:

1. The experience with shipping plutonium as an aqueous nitrate solution in packages meeting current regulatory criteria has been satisfactory to date.
2. The changing characteristic of plutonium recovered from power reactors will make the existing packaging obsolete for plutonium nitrate solutions and possibly for solid form. Economic factors will probably dictate considerably larger shipments (and larger packages) than currently used.
3. It is expected that packages can be designed to meet regulatory standards for either aqueous solutions or solid plutonium compounds. Just as in any situation involving the packaging of radioactive materials, a high level of human performance is necessary to assure against leakage caused by human error in packaging. As the number of plutonium shipments increases, as it will, and packages become larger and more complex in design, the probability of such human error increases.
4. The probability of human error with the packaging for liquid, anticipated to be more complex in design, is probably greater than with the packaging for solid. Furthermore, should a human error occur in package preparation or closure, the probability of liquid escaping from the improperly prepared package is greater than for most solids and particularly for solid plutonium materials expected to be shipped.

5. Staff studies reported in SECY-R-62 and SECY-R-509⁸ conclude that the consequences of release of solid or aqueous solutions do not differ appreciably. Therefore, this paper (SECY-R-702) does not deal with the consequences of releases.
6. It is, therefore, concluded that safety would be enhanced if plutonium were shipped as a solid rather than in solution.

The arguments for requiring a solid form of plutonium for shipment are largely subjective, in that there is no hard evidence on which to base statistical probabilities or to assess quantitatively the incremental increase in safety which is expected. The discussion in the regulatory paper, SECY-R-702, is not intended to be a technical argument which incontrovertibly leads to a conclusion. It is, rather, a presentation of the rationale which has led the Regulatory staff to its conclusion that a possible problem may develop and that the proposed action is a step towards increased assurance against the problem developing. In SECY-R-74-172,⁹ AEC staff submitted a final rule to the Commission for approval.

The proposed rule had contained a requirement that the plutonium be contained in a special form capsule. However, in response to comments from the AEC General Manager, the final rule changed this requirement to a separate inner container (i.e., the double containment requirement). The AEC staff indicated in a response to a public comment in Enclosure B (to SECY-R-74-172) that "[t]he need for the inner containment is based on the desire to provide a substitute for not requiring the plutonium to be in a 'nonrespirable' form."

⁸ SECY-R-62, "Shipment of Plutonium," and SECY-R-509, "Plutonium Handling and Storage," dated October 16, 1970. These papers concluded that there is no scientific or technical reason to prohibit shipment of plutonium nitrate and recommended that Commission (AEC) efforts be directed toward providing improved safety criteria for shipping containers.

⁹ SECY-R-74-172, "Consideration of Form for Shipping Plutonium," April 18, 1974.

The regulatory history of § 71.63 indicates that the AEC's decision to require a separate inner container for shipments of plutonium in excess of 0.74 TBq (20 Ci) was based on existing policy and regulatory concerns (i.e., "that a possible problem may develop and that the proposed action [in SECY-R-702] is a step towards increased assurance against the problem developing"). Because of the expectation of a significant increase in the number of liquid plutonium nitrate shipments, the AEC used a defense-in-depth philosophy (i.e., the double containment and solid form requirements), to ensure that respirable plutonium would not be released to the environment during a transportation accident. However, the regulatory history does indicate that the AEC's concerns did not involve the adequacy of existing liquid plutonium nitrate packages. Rather, the AEC's regulatory concern was on the increased possibility of human error combined with an expected increase in the number of shipments that would yield an increased probability of leakage during shipment. The AEC's policy concern was based on an economic decision on whether the AEC should require the reprocessing industry to build new, larger liquid plutonium-nitrate shipping containers, capable of handling higher burnup reactor spent fuel, or to build new, dry, powdered plutonium-dioxide shipping containers. The regulatory history indicates that the AEC staff judged that new, larger, higher burnup-capacity liquid plutonium-nitrate packages could be designed, approved, built, and safely used. However, one of the AEC's principal underlying assumptions for this rule was obviated in 1979 when the Carter administration decided that reprocessing of civilian spent fuel and reuse of plutonium was not desirable. Consequently, the expected plutonium reprocessing economy and widespread shipments of liquid plutonium nitrate within the U.S. never materialized.

On June 15, 1998 (63 FR 32600), in response to a petition for rulemaking submitted by DOE (PRM-71-11) (February 18, 1994; 59 FR 8143), the Commission issued a final rule revising § 71.63(b) to add vitrified high-level waste (HLW) contained in a sealed canister to the

list of forms of plutonium exempt from the double containment requirement (June 15, 1998; 63 FR 32600). In its original response to PRM-71-11, NRC proposed in SECY-96-215¹⁰ to make a "determination" under § 71.63(b)(3) that vitrified HLW contained in a sealed canister did not require double containment. However, the Commission in an SRM on SECY-96-215, dated October 31, 1996, disapproved the staff's approach and directed that resolution of this petition be addressed through rulemaking (the June 15, 1998, final rule was the culmination of this effort). In addition to disapproving the use of a "determination" process, the Commission also directed the staff to "... also address whether the technical basis for 10 CFR 71.63 remains valid, or whether a revision or elimination of portions of 10 CFR 71.63 is needed to provide flexibility for current and future technologies." In SECY-97-218¹¹, NRC responded to the SRM's direction and stated "[t]he technical basis remains valid and the provisions provide adequate flexibility for current and future technologies."

Summary of Comments Received on the Petition (PRM-71-12): Nine public comments were received on the petition (petition was published for public comment in 63 FR 8362; February 19, 1998). Four commenters supported the petition, and five commenters opposed the petition. The four commenters supporting the petition essentially stated that the IAEA's Q-system accurately reflects the dangers of radionuclides, including plutonium, and that elimination of § 71.63(a) and (b) would make the regulations more performance based, reduce costs and personnel exposures, and be consistent with the IAEA standards.

The five commenters opposing the petition essentially stated that: (1) Plutonium is very dangerous, especially in liquid form, and therefore additional regulatory requirements are

¹⁰ SECY-96-215, "Requirements for Shipping Packages Used to Transport Vitrified Waste Containing Plutonium," dated October 8, 1996.

¹¹ SECY-97-218, "Special Provisions for Transport of Large Quantities of Plutonium (Response to Staff Requirements Memorandum - SECY-96-215)," dated September 29, 1997.

warranted; (2) Existing regulations are not overly burdensome, especially in light of the total expected transportation cost; (3) TRUPACT-II packages meet current § 71.63(b) requirements (TRUPACT-II is a package developed by DOE to transport transuranic wastes (including plutonium) to the Waste Isolation Pilot Plant (WIPP) and has been issued a Part 71 CoC, No. 9218); (4) A commenter (the Western Governors' Association) has worked for over 10 years to ensure a safe transportation system for WIPP, including educating the public about the TRUPACT-II package; (5) Any change now would erode public confidence and be detrimental to the entire transportation system for WIPP shipments; and (6) Additional personnel exposure due to double containment is insignificant.

Analysis of Public Comments on the Issues Paper: The NRC has received 48 public comments on this issue in response to the issue paper, in subsequent public meetings, and the workshop (the issues paper was published at 65 FR 44360; July 17, 2000). Industry representatives and some members of the public support the petition. Public interest organizations, Agreement States and State representatives, and the Western Governors' Association, and other members of the public oppose the petition. Several commenters expressed their belief that Congress, in approving the Waste Isolation Pilot Plant Land Withdrawal Act (the Act), Pub. L. 102-579 (106 Stat. 4777), Section 16(a), which mandates that the NRC certify the design of packages used to transport transuranic waste to WIPP, expected those packages to have a double containment. The NRC researched this issue and found that Section 16(a) of the Act does not contain any explicit provisions mandating the use of a double containment in packages transporting transuranic waste to or from WIPP. Section 16(a) of the Act states, in part, "[n]o transuranic waste may be transported by or for the Secretary [of the DOE] to or from WIPP, except in packages the design of which has been certified by the Nuclear Regulatory Commission..." Furthermore, the NRC has reviewed the legislative

history¹² associated with the Act and has not identified any discussions on the use of double containment for the shipment of transuranic waste. The legislative history does mention that the design of these packages will be certified by the NRC; however, this language is identical to that contained in the Act itself. Therefore, the NRC believes the absence of specific language in Section 16(a) of the Act requiring double containment should be interpreted as requiring the NRC to apply its independent technical judgment in establishing standards for package designs and in evaluating applications for certification of package designs, to ensure that such packages would provide reasonable assurance that public health and safety and the environment would be adequately protected. In carrying out its mission, the courts have found that the NRC has broad latitude in establishing, maintaining, and revising technical performance criteria necessary to provide reasonable assurance that public health and safety and the environment are adequately protected. An example of these technical performance criteria is the Type B package design standards. Accordingly, the NRC believes that the proposed revision of a technical package standard (i.e., removal of the double containment requirement for plutonium from the Type B package standards) is not restricted by the mandate of Section 16(a) of the Act for the NRC to certify the design of packages intended to transport transuranic material to and from WIPP.

Other commenters stated that stakeholders' expectations were that packages intended to transport transuranic material to and from WIPP would include a double containment provision. Consequently, the commenters expressed a belief that removal of the double containment requirement would decrease public confidence in the NRC's accomplishment of its

¹² See Congressional Record Vol. 137, November 5, 1991, pages S15984 - 15997 (Senate approval of S. 1671); Cong. Rec. Vol. 138, July 21, 1992, pages H6301 - 6333 (House approval of H.R. 2637); Cong. Rec. Vol. 138, October 5, 1992, pages H11868 - 11870 (House approval of Conference Report on S. 1671); Cong. Rec. Vol. 138, October 8, 1992 (Senate approval of Conference Report on S. 1671); and Cong. Rec. Vol. 138, October 5, 1992, pages H12221 - 12226 (Conference Report on S. 1671 - H. Rpt. 102-1037).

mission in the approval of the design of packages for the transportation of transuranic waste to and from WIPP. The commenters stated that the public would view elimination of the double containment requirement as a relaxation in safety. The presence of a separate inner container provides defense-in-depth through an additional barrier to the release of plutonium during a transportation accident, according to commenters. In addition, the commenters stated that plutonium is so inherently deadly, that defense-in-depth is appropriate. The NRC agrees that a double containment does provide an additional barrier. However, the NRC believes that, for the reasons discussed below, double containment is unnecessary to protect public health and safety. The NRC and AEC have not required an additional containment barrier for Type B packages transporting any radionuclides other than plutonium and, before 1974, the AEC did not require double containment for plutonium.

In response to some of the comments opposed to the petition, the NRC believes that removal of § 71.63(b) would not invalidate the design of existing packages intended for the shipment of plutonium. These packages could continue to be used with a separate inner container. The NRC agrees with the commenters that a quantitative cost analysis was not provided by the petitioner.

The NRC has issued Part 71 CoC No. 9218 to DOE for the TRUPACT-II package (Docket No. 71-9218), for the transportation of transuranic waste (including plutonium) to and from the WIPP. The TRUPACT-II package complies with the current § 71.63(b) requirements and has a separate inner container. The TRUPACT-II SAR indicates that the weight of the inner container and its lid is approximately 2,620 lbs. Hypothetically, elimination of the separate inner container would increase the available payload for the TRUPACT-II package from the current 7,265 to 9,885 lbs. Thus, removal of the double containment requirement would potentially increase the TRUPACT-II's available payload by 36 percent. Further, the removal of

the inner container from the TRUPACT-II would also potentially increase the available volume. The NRC believes that the proposed rule would not invalidate the existing TRUPACT-II design (i.e., it would still meet all remaining applicable requirements of Part 71). Thus, DOE could continue to use the TRUPACT-II to ship transuranic waste to and from WIPP, or DOE could consider an alternate Type B package.

Additionally, based on comments received in the public meetings, the NRC believes that a misperception exists with respect to TRUPACT-II shipments; removal of the § 71.63(b) double containment requirement would not result in loose plutonium waste being placed inside a TRUPACT-II package. Based upon information contained in the SAR, plutonium wastes (i.e., used gloves, anti-Cs, rags, etc.) are placed in plastic bags, and these bags are sealed inside lined 55-gallon steel drums. Plutonium residues are placed inside cans which are then sealed inside a pipe overpack (a 6-inch or 12-inch stainless steel cylinder with a bolted lid), and the pipe overpack is then sealed inside a lined 55-gallon steel drum. The 55-gallon drums are then sealed inside the TRUPACT-II inner containment vessel, and finally the inner containment vessel is sealed inside the TRUPACT-II package. Consequently, the TRUPACT-II shipping practices employ multiple barriers and would continue to do so. Removal of the inner containment vessel would not be expected to produce a significant incremental increase in the possibility of leakage during normal transportation. The NRC notes that some NRC regulations have established additional requirements for plutonium (e.g., the special nuclear material license application provisions of § 70.22(f)).

The NRC believes that the Type B packaging standards, in and of themselves, provide reasonable assurance that public health and safety and the environment would be adequately protected during the transportation of radioactive material. This belief is supported by an excellent safety record in which no fatalities or injuries have been attributed to material

transported in a Type B package. Type B packaging standards have been in existence for approximately 40 years and have been incorporated into the Part 71 regulations by both the NRC and its predecessor, the AEC. The NRC's Type B package standards are based on IAEA's Type B package standards. Moreover, IAEA's Type B package standards have never required a separate inner container for packages intended to transport plutonium, nor for any other radionuclide.

Therefore, the NRC believes that imposition of an additional packaging requirement (in the form of a separate inner container) is fundamentally inconsistent with the position that Type B packaging standards, in and of themselves, provide reasonable assurance that public health and safety and the environment would be adequately protected during the transportation of (any type of) radioactive material. Thus, the NRC believes that maintaining § 71.63(b) is not consistent with the other existing Type B packaging standards contained in Part 71.

The NRC also believes that the regulatory history of § 71.63 demonstrates that the AEC's decision to add this section was based on policy and regulatory concerns. However, the NRC also agrees that the use of a double containment does provide defense-in-depth and does decrease the absolute risk of the release of respirable plutonium to the environment during a transportation accident. Consequently, while the defense-in-depth afforded by a double containment does reduce risk, the NRC believes the question which should be focused on is whether the double containment requirement is risk-informed. The NRC is unaware of any risk studies that would provide either a qualitative or quantitative indication of the risk reduction associated with the use of double containment in transportation of plutonium. Rather, the NRC would look to the demonstrated performance record of existing Type B package standards to conclude that double containment is not necessary.

In summary, the AEC indicated (in SECY-R-702 and SECY-R-74-5) that liquid plutonium nitrate packages were safe, and new, larger packages to handle higher burnup reactor spent fuel could also be designed. NRC believes that the AEC's assumption for initiating this requirement was that large scale reprocessing of civilian reactor spent fuel and reuse of plutonium would occur. The decision of former President Carter's administration to forgo the reprocessing of civilian reactor spent fuel and reuse of plutonium obviated the AEC's assumption. Consequently, the AEC's supposition that a human error occurring while sealing a package of liquid plutonium nitrate was more likely to occur with the expected increase in shipments of plutonium nitrate was also obviated by the Government's decision to forgo the reprocessing of civilian reactor spent fuel. In SECY-97-218, NRC staff indicated that the separate inner container provided an additional barrier to the release of plutonium in an accident. NRC continues to believe that a separate inner container provides an additional barrier to the release of plutonium in an accident, just as a package with triple containment would provide an even greater barrier to the release of plutonium in an accident. However, this type of approach is neither risk informed nor performance based. Consequently, based upon review of the petition, comments on the petition, and research into the regulatory history of the double containment requirement, the NRC agrees that a separate inner container is not necessary for Type B packages containing solid plutonium. NRC believes that the worldwide performance record over 40 years of Type B packages demonstrates that a single containment barrier is adequate. Therefore, the NRC agrees with the petitioner and believes that § 71.63(b) is not technically necessary to provide a reasonable assurance that public health and safety and the environment will be adequately protected during the transportation of plutonium.

While the NRC believes a case can be made for elimination of the separate inner container requirement in § 71.63(b), elimination of the solid form requirement in § 71.63(a) is

not as clear. While the same arguments can be made on the obviation of the AEC's basis for originally issuing § 71.63(a) (i.e., the elimination of reprocessing of plutonium), the same regulatory inconsistency between Type B package standards and the inner containment requirement does not exist for the liquid versus solid form argument. The NRC considers the contents of a package when it is evaluating the adequacy of a packaging's design. The approved content limits and the approved packaging design together define the CoC for a package. However, other than criticality controls and the liquid form requirement of § 71.63(a), 10 CFR Part 71 Subparts E and F do not contain any restrictions on the contents of a package. Thus, while the inner containment requirement in § 71.63(b) can be seen as conflicting with the Type B package standard because the inner containment affects the packaging's design, the solid form requirement of § 71.63(a) does not conflict with the packaging requirements of the Type B package standard because the solid form requirement affects only the contents of the package, not the packaging itself.

The NRC expects that cost and dose savings would accrue from the removal of § 71.63(b). However, because no shipments of liquid plutonium nitrate are contemplated in the U.S., NRC would not expect cost or dose savings to accrue from the removal of § 71.63(a), if that section were to be also removed. Further, the AEC's original bases have been obviated by former President Carter's administration's decision to not pursue a commercial fuel cycle involving the reprocessing of plutonium.

After weighing this information, the NRC continues to believe that the Type B package standards, when evaluated against 40 years of use worldwide, and millions of safe shipments of Type B packages, together provide reasonable assurance that public health and safety and the environment would be adequately protected during the transportation of radioactive material. The NRC believes that, in this case, the reasonable assurance standard, provided by the Type

B package requirements, provides an adequate basis for the public's confidence in the NRC's actions.

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC staff's responses for this issue follows:

Comment. Four commenters suggested that all radioactive materials should require double packaging. Two of these commenters stated double containment is a security and safety precaution. A third stated that existing container requirements are the minimum standards necessary for safety, security, and public acceptance. Another commenter simply objected to the removal of the requirement for double containment of plutonium.

Response. The NRC disagrees with these comments. The NRC has made a finding that single containment of radioactive material provides an adequate level of safety for all radioactive materials. The A₁ and A₂ value summary found at 67 FR 21422; April 30, 2002, under the heading Issue 3, provides information that supports the NRC's basis for this decision. The comments provided no justification for the double containment requirement for shipment of all nuclear materials.

Comment. Several commenters were concerned with NRC's proposal to eliminate double containment. The first of these commenters asked if there is any basis to eliminate the double containment requirement other than to harmonize our rules with the IAEA regulations. The second commenter expressed concern that the "only benefits from eliminating double containment . . . would accrue to the DOE, to contractors, licensees, and shippers in the form of cost savings." Furthermore, the commenter stated that the cost of maintaining transportation safety standards should be borne by those in the industry and that costs should not be "used as an excuse for deregulation or exemptions." A similar argument was made by another commenter who urged NRC not to remove § 71.63(b) reasoning that, as noted in the proposed

rulemaking, the petitioner did not provide a quantitative cost analysis; therefore, the contention that “presence of § 71.63(b) engenders excessively high costs” is unsubstantiated.

Response. The NRC has no technical justification or basis for maintaining double containment for plutonium or any other radionuclide. The NRC believes the arguments for removing double containment have been adequately addressed earlier in the proposed rule under this issue.

While NRC acknowledges that there may be monetary benefits associated with removing double containment, there are other reasons as well, including reduction in personnel exposure for those individuals involved in loading packages for transport. Moreover, NRC has been and remains committed to providing regulations that are not only risk informed, but also reduce unnecessary regulatory burden.

Comment. One commenter stated that removing the double containment requirement would reduce costs of packaging and associated hardware. The commenter asserted that double containment increases costs without measurable benefit. The commenter then provided cost information and discussed the design, certification, and fabrication of future packaging (e.g., TRUPACT III or the DPP-1 and DPP-2) needed to complete DOE’s Accelerated Cleanup strategy for resolution of the legacy wastes and materials from the Cold War.

Response. NRC acknowledges the comment.

Comment. Many commenters opposed the elimination of the double containment requirement because of possible public health and safety consequences.

Response. The commenters provided no basis for their assertions that removing the double-containment requirement would increase public exposure risks. The NRC staff believes that the current Type B package requirements, as applied to all radionuclides, are adequate to protect public health and safety.

Comment. One commenter stated that the principal benefit of removing the double containment requirement would be a reduction in exposure to the workers. The commenter added that it would also result in lower costs.

Response. NRC acknowledges the comment.

Comment. One commenter expressed concern that the A_1 and A_2 values have been used as a justification for single-shell containers for plutonium.

Response: The NRC does not agree with this unsubstantiated statement that the A_1 and A_2 values have been used as justification for the elimination of the double containment requirement for plutonium. The justifications for elimination of the double containment requirement were detailed in the proposed rule on April 30, 2002 (67 FR 21421 through 21425), and focus more on the fact that the original AEC requirement for double containment of plutonium was based on existing policy and regulatory concerns and was not risk informed. While the A_1 and A_2 values are referenced in the discussion, they are referenced from the standpoint that there are other radionuclides with the same or lower A_1 and A_2 values than plutonium. Because these radionuclides have never required double containment, it cannot be argued from a risk standpoint that the shipment of plutonium should be treated any differently.

Comment. Three commenters expressed support for the proposed removal of the requirement for “double containment” of plutonium from § 71.63. One commenter asserted that a single containment barrier is adequate for Type B packages containing more than 20 curies of solid form plutonium. The commenter further stated that the former AEC’s rationale for requiring the double containment provision is now moot because the expectation for liquid plutonium nitrate shipments has never materialized. The commenter also expressed opposition to the double containment requirement because it presents continuing costs without commensurate benefits. The commenter stated that removing the double containment

requirement would result in a small and acceptable increase in public risk. Furthermore, the requirement removes flexibility in package designs that might be needed to meet DOE's mission.

Another commenter expressed concern that the double containment requirement was implemented in the 1970s without adequate justification.

The third commenter said that using double containment causes unnecessary worker radiation exposure. This commenter said this unnecessary worker radiation is estimated to be 1200 to 1700 person-rem over a 10-year period. The commenter also said the conditions that justified double containment during the early 1970s have disappeared. These include large numbers of shipments of nitrate solutions or other forms from reprocessing, compounded by crude containment requirements, and the absence of quality assurance requirements. This position was justified because France, Germany, and the United Kingdom, as well as other IAEA Member Nations, no longer require double containment for plutonium. The commenter believed that harmonization of Part 71 with IAEA TS-R-1 was an important goal of this rulemaking because to do so would allow for consistent regulation among the principal nations shipping nuclear materials. Furthermore, it was recommended that NRC eliminate the special requirements for plutonium shipments in § 71.63 for consistency with the use of prescriptive, performance-based safety standards.

Response. The comments are generally in line with statements in the proposed rule on April 30, 2002 (67 FR 21421 through 21425) that described the NRC's bases for elimination of the double containment requirement.

Comment. Three commenters stated that double containment provides more protection to the public than single containment. One of these commenters stated the belief that the commenter and a majority of the Western Governors are concerned with the proposal to

eliminate the double containment requirement for plutonium shipments. The commenter stated that “the regulatory analysis is defective in its failure to recognize likely impacts on the agreement among the Western Governors’ Association, the individual Western States, and DOE for a system of extra regulatory transportation safeguards, which we believe are at the heart of both government and public acceptance of the WIPP transportation program.”

Response. NRC acknowledges that agreements between DOE and States may be impacted by the removal of double containment. However, any change to NRC regulations that impact how DOE conducts its transportation operations is up to DOE and the States to negotiate and resolve.

Comment. One commenter stated that the proposed rule is not risk informed and does not use a common sense approach. Another commenter stated strong agreement with this first commenter.

Response. The NRC believes the decision to eliminate double containment is risk informed and reduces an unnecessary regulatory burden. In this context, there is adequate actual operating experience with Type B package shipments to support the Commission’s decision to remove the double containment requirement for plutonium packages. There are many nuclides with A_2 values the same or lower than plutonium’s that have never required double containment.

Further, current NRC regulations state that, in certain circumstances, plutonium in excess of 0.74 TBq (20 Ci) can be shipped as a normal form solid without requiring double containment. The shipment of reactor fuel elements containing plutonium is one example. Using the most conservative A_2 value of 0.00541 Ci, 0.74 TBq (20 Ci) of plutonium (Pu-238, Pu-239, Pu-240) equates to an A_2 multiple of roughly 3700. In contrast, using 19 risk-significant nuclides from a typical single boiling water reactor spent fuel assembly (reference NUREG/CR-

6672, "Reexamination of Spent Fuel Shipment Risk Estimates," page 7-17), one can calculate a curie content of 148,346 Ci with a cumulative A_2 multiple of just under 790,000 (the assembly also would contain an A_2 multiple of 455,000 of plutonium nuclides). If the A_2 multiple is viewed as a measure of potential health effect, then from a risk-informed standpoint, the shipment of one particular nuclide in a Type B package should not be treated differently from any other nuclide of comparable A_2 in a Type B package. It should be noted that for domestic shipments, there is a well established and excellent safety record associated with the shipment of spent fuel assemblies in single containment spent fuel packages.

Comment. Two commenters stated that removing the double containment requirement would provide health benefits for radiation workers. One commenter argued that the cost of reducing the exposure to workers to the required 1 mrem/yr would be very high. One commenter asserted that we need to balance public safety and the safety of radiation workers.

Response. As discussed in the draft EA, NRC agrees that the removal of the double containment requirement would result in reduced risk to radiation workers.

Comment. One commenter stated that worker exposure estimates are not supported by data.

Response. The commenter's remark about lack of data on worker exposure estimates was true at the time of the public meeting on June 24, 2002, where the comment was made. However, during the comment period, DOE, one of the major entities affected by the current double containment rule, submitted the results of a detailed study they performed to evaluate the impacts for elimination of the current requirement. In that study, they presented quantifiable data that indicates that over a 10-year period, they could expect to see a reduction of 1200 to 1700 person-rem if the double containment provision is eliminated. While the NRC does not endorse or dispute the study's conclusions, the results are in line with the NRC's contention that

elimination of the double containment requirement will likely result in a reduction in worker radiation exposure.

Comment. One commenter stated that the NRC has not fully evaluated the regulatory impact of the proposed change on the use of the TRUPACT II design.

Response. During the development of the proposed rule, NRC staff used all available data to evaluate the costs and benefits of the proposed change. NRC staff requested specific information on costs and benefits as part of the proposed rule, and the information received was considered during the development of a final position. NRC received a study from the commenter and, while the NRC does not endorse or dispute the study's conclusions, the results are in line with the NRC's contention that elimination of the double containment requirement will likely result in a reduction in worker radiation exposure.

Comment. One commenter asked if NRC considers powder a solid form.

Response. Yes, the NRC has always considered powder as a solid form when implementing § 71.63(a). However, powders, under the eliciting rule, were not considered as a solid form that was exempt from the double containment requirements of § 71.63(b).

Comment. One commenter endorsed NRC's proposal to retain the requirement that shipments whose contents exceed 20 curies of plutonium must be made in a solid form as provided under § 71.63(a).

Response. The comment is acknowledged.

Comment. One commenter expressed support for the NRC position.

Response. The comment is acknowledged.

Comment. Two commenters expressed concern that removing the double containment requirement would erode public confidence in the Waste Isolation Pilot Plant (WIPP) in southeastern New Mexico. One of the commenters noted that NRC's decision is not supported

by any studies to demonstrate that the change is minimal and that NRC should only relax the double containment provisions when NRC receives scientific evidence that demonstrates beyond a reasonable doubt that single containment is as safe as double containment for shipments to WIPP.

Response. The comment is acknowledged; also the reader is referred to a related discussion earlier in this issue, under the heading: Analysis of Public Comments on the Issues Paper.

Comment. One commenter discussed an incident involving the shipment of plutonium-containing transuranic waste to DOE's Waste Isolation Pilot Plant in New Mexico. A truck carrying TRU waste was involved in a traffic accident. While no radiation was released, the inner container was discovered to be contaminated with radiation to the extent that it could not be unloaded. The commenter pointed out that the double-walled container provided a margin of safety that would not have existed under the proposed rule. The commenter stated that the incident underscores the importance of maintaining the double containment requirement, as it has been a crucial element in the success of the WIPP TRU waste shipping campaign to date.

Response. In the cited case, NRC staff understands that neither containment was compromised due to the accident.

Comment. One commenter stated that all shipping requirement revisions should be more, rather than less, protective of public health. Two other commenter stated that the AEC's original 1974 reasoning for imposing the double containment requirements was still valid, including the possibility for human error and expected increases in the number of shipments. The commenter also responded to the claim that adopting a single containment requirement

would be safer for personnel who handle the inner container by stating that this may simply be a shifting of risk from personnel to the public.

Response. The comment that shipping requirement revisions should all be more, rather than less, protective of public health, is acknowledged. The NRC's transportation regulations are designed to provide adequate protection to the public health and safety from radioactive material transportation activities. In doing so, NRC seeks to balance its regulations by ensuring public health and safety while at the same time not creating unnecessary regulatory burden.

Regarding the comment that the AEC's original 1974 reasoning for imposing double containment is still valid, the NRC notes that the AEC's original reasoning was based on the fact of transporting liquids; that is no longer the case. The justifications for elimination of the double containment requirement detailed in the proposed rule on April 30, 2002 (67 FR 21421 through 21425) is based on technical arguments and focus on the confidence in Type B packages. While there is an increase in the number of shipments to WIPP, the vast majority of these shipments do not involve liquids.

The NRC disagrees with the comment that while the adoption of a single containment requirement would be safer for personnel who handle the inner container, this constitutes a shifting of the risk from personnel to the public. The NRC believes that the risk of shipping plutonium in a single containment Type B package is no different than that of shipping other radionuclides with the same or lower A_1 and A_2 values than plutonium.

Comment. One commenter stated that although spent fuel that is damaged to the extent that the rod cladding's integrity is in question may be subject to the requirements of § 71.63, it is not clear that all damaged fuel will require double containment.

Response. NRC has previously published guidance (ISG-1, Rev. 1, dated October 25, 2002) on when the double containment provision is required for damaged spent fuel. Basically, canning (double containment) is required if the spent fuel contains known or suspected cladding defects greater than a pinhole leak or hairline crack that have the potential for release of significant amounts of fuel into the cask.

Comment. One commenter stated that additional procedures (e.g., closures and testing) are required to implement § 71.63, which leads to added worker exposures. The commenter provided quantitative and monetized data detailing the extra time and amount of money that the double containment requirement imposes on TRU Waste, Plutonium Oxides, and Damaged Spent Nuclear Fuel Operations.

Response. NRC acknowledges this comment.

Comment. One commenter stated that additional containment systems reduce cask capacities and consequently require more shipments to move the same material. This commenter also said that the double containment represents extra weight that must be moved and then provided estimates of the cost for moving the extra weight in the double-containment structure in the cases of TRU Waste, Plutonium Oxides, and Damaged Spent Nuclear Fuel operations.

Response. The comment is acknowledged.

Comment. One commenter stated that design costs and costs for NRC certification services are incurred by increased design complexity relating to the provision of the double-containment barrier. The commenter noted that the alternative to the design and certification cost penalty is to petition for an exemption under § 71.63(b)(4); however, preparing this petition is time-consuming and probably similar in cost to getting a separate containment boundary designed and certified. The commenter estimated certification and capital cost penalties for the

cases of CH-TRU and RH-TRU Wastes, Plutonium Oxides, DHLW Glass Exemption, and Damaged Spent Nuclear Fuel.

Response. The comment is acknowledged.

Comment. One commenter stated that while the restrictions of § 71.63 remain in effect, it must continue to expend funds unnecessarily for double-containment packaging. This commenter provided tables of monetized breakdowns of these estimates. The commenter estimated that the net result from all three areas (TRU wastes, plutonium oxides and residues, and damaged spent nuclear fuel) is that double-containment requirements will produce an avoidable cost of approximately \$12 million in capital cost, \$20 million in operational cost, and \$26 million to \$40 million in shipping and receiving costs. In addition, the commenter estimated that the double containment requirement will result in additional worker radiation exposure amounting to 1250 to 1770 person-rem.

Response. The commenter has provided information that appears to support the NRC's contention that removal of double containment would provide for cost savings and decreased personnel exposure.

Comment. One commenter stated that double containment provides some additional protection to the public in both normal and accident situations. The commenter stated that most of this additional protection relates to a potential reduction in population exposure. However, the commenter estimated that the total radiation exposure reduction in most cases amounts to a maximum of about 30 person-rem/year distributed among a potentially exposed population of tens of millions of persons. The commenter stated that such an effect would not be perceptible.

Response. NRC acknowledges the comment.

Comment. One commenter stated that, although double containment reduces the risk incurred by the public of exposure to radiation from the package in incident-free transport, the reduction is likely to be relatively small. The dose rate is already small enough at distances where the public is likely to be exposed that the impact of single- or double-contained material will not be consequential. This commenter also noted that one effective containment boundary is sufficient to meet containment requirements implicit in Type B design approvals, but the materials shipped are already within one or more inner containers. The commenter believes the presence of these redundant containers effectively rules out any problems that might result from human errors in achieving a required level of leak-tightness for single contained Type B packages.

Response. NRC acknowledges the comment.

Comment. One commenter stated that doubly contained packages pose lower risks and is not, by itself, sufficient justification for using doubly contained packages. The commenter stated that, in general, the likelihood of achieving an accident sufficient to compromise containment of a singly contained Type B package has been estimated to be fewer than 1 in 200 in the event of a severe accident. Achieving damage to two redundant containments could be expected to be as much as a factor of 10 lower risk relative to the single containment case. The commenter stated that this is not as large a benefit as it may seem; the decrease in absolute risk will be very small because the risk of shipping singly contained plutonium is exceedingly small to start. The commenter provided monetized and quantified estimates of the cost/risk tradeoffs associated with double-containment versus single-containment for the handling of Contact-Handled TRU Waste, Plutonium Oxide and Plutonium-Bearing Wastes, Remote-Handled TRU Waste, and Failed Fuel.

Response. NRC acknowledges the comment.

Comment. Two commenters stated that if the NRC continues to pursue the proposal to relax the plutonium shipment double containment standards, then it should conduct a series of hearings on the rulemaking, with at least one of those hearings held in the western U.S. Another commenter objected to the lack of public education regarding the “numerous, confusing, and complicated” proposed rule changes, which, when presented as they were, encourage nonengagement. The commenter requested that an extension be placed on the comment period and that “ordinary” language be used to explain the actual proposals, how they will impact public health, what agencies and rules are involved, and how one can easily reply to all agencies involved in these proposals by mail, email, or fax.

Response. The rulemaking process does not include the opportunity for formal hearings because the proposed rulemaking is not a licensing action, which does require hearings. The NRC staff thinks that the commenter meant holding public meetings to discuss the issue. Hearings were held in this rulemaking in the form of public meetings. Two meetings were held in June 2002, in Chicago, IL, and the NRC TWFN Auditorium, and 3 meetings were held in NRC Headquarters, Atlanta, GA, and Oakland, CA, during August and September 2000. The NRC did not extend the 90-day public comment period, because the public had ample opportunity to comment on this rule during the 1-year period following March 2001, when the proposed rule was posted on the Secretary of the Commission website.

Issue 18. Contamination Limits as Applied to Spent Fuel and High-Level Waste (HLW) Packages.

Summary of NRC Final Rule. The final rule does not adopt any changes to Part 71 for this issue because experience with regulations requiring that licensees monitor the external surfaces of labeled radioactive material packages for contamination upon receipt and opening

indicates the rate of packages exceeding allowable levels en route is low, and therefore, in transit decontamination of packages is not warranted. Further, requiring such decontamination of packages could result in a significant increase in worker doses without a commensurate increase in public health and safety.

Affected Sections. None (not adopted).

Background. In the period of December 1997 through April 1998, the French Nuclear Installations Safety Directorate inspected a French nuclear power plant and railway terminal used by La Hague reprocessing plant. The inspectors noticed that, since the beginning of the 1990's, a high percentage of spent fuel packages and/or railcars had a level of removable surface contamination that exceeded IAEA regulatory limits by as much as a factor of 1000. Subsequent investigations found that the contamination incidents involved shipments from other European countries, and the French transport authorities notified their counterparts of their findings. Subsequently, French, German, Swiss, Belgian, and Dutch spent fuel shipments were temporarily suspended.

After estimating the occupational and public doses from the contamination incidents, the European transport authorities concluded that these incidents did not have any radiological consequence. The contamination was believed to be caused by contact of the spent fuel package surface with contaminated water from the spent fuel storage pool during package handling operations. The authorities concluded that there were deficiencies in the contamination measurement procedures and the distribution of that information.

Media reports on these incidents focused attention on IAEA's regulations for removable contamination on package surfaces. TS-R-1 contains contamination limits for all packages of 4.0 Bq/cm² for beta and gamma and low toxicity alpha emitting radionuclides, and 0.4 Bq/cm² for all other alpha emitting radionuclides. Although TS-R-1 uses the term "limit," IAEA

considers these "limits" to be guidance values, or derived values, above which appropriate action should be considered. In cases of contamination above the limit, that action is to decontaminate to below the limits.

TS-R-1 further provides that in transport, "...the magnitude of individual doses, the number of persons exposed, and the likelihood of incurring exposure shall be kept as low as reasonable, economic and social factors being taken into account..." The IAEA contamination regulations have been applied to radioactive material packages in international commerce for almost 40 years, and practical experience demonstrates that the regulations can be applied successfully. With respect to contamination limits, TS-R-1 contains no changes from previous versions of IAEA's regulations.

Part 71 does not contain contamination limits, but § 71.87(i) requires that licensees determine that the level of removable contamination on the external surface of each package offered for transport is as low as is reasonably achievable, and within the limits specified in DOT regulations in 49 CFR 173.443.

The IAEA established a Coordinated Research Project (CRP) to review contamination models, approaches to reduce package contamination, strategies to address cask-weeping, and possible recommendations for revisions to the contamination standard that consider risks, costs, and practical experience. The IAEA CRP facilitates the investigation of radioactive material transportation issues by key IAEA Member States. IAEA is considering the CRP report, and any further actions or remedies that may be warranted are being addressed by the IAEA Transportation Safety Standards Committee (TRANSSC). NRC supported the IAEA initiative to establish the CRP, and NRC would participate in the IAEA review of surface contamination standards.

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC staff's responses for this issue follows:

Comment. One commenter expressed support of the NRC position not to change from current standards.

Response. The NRC acknowledges these comments. No further response necessary.

Comment. One commenter requested that the NRC keep "removable contamination of external 'spent' fuel shipping packages" to the "absolute minimum attainable, even if extra cost is incurred in doing so." The commenter added that "full data on container surface contamination must be kept and submitted to the regulatory agency as part of required manifest records."

Response. Keeping contamination to an absolute minimum could result in a significant increase in worker dose, due to the additional exposures required to achieve that low level of contamination, without a commensurate increase in public health and safety. Current DOT regulations require that shippers be able to provide to inspectors upon request documentation that supports the shipper's certification that radioactive material shipments were made in compliance with applicable requirements, including contamination limits. This practice has worked well, and NRC has no basis to change it.

Comment. One commenter stated that the NRC's measures should allow for decontamination of nuclear waste shipments during transport if they begin to exceed allowable radiation levels en route. The commenter stated that this would reduce exposure to the public and prevent shipments from having to return to the point of origin.

Response. Current NRC regulations require that licensees monitor the external surfaces of labeled radioactive material packages for contamination upon receipt and opening

[see details at § 20.1906(b)(1)]. Based on its experience with these regulations, the rate of packages exceeding allowable levels en route is low, and NRC does not believe that in transit decontamination of packages is warranted.

Comment. One commenter asserted that there is no reason to seek any special dose consideration or reduction in the handling and transport of spent fuel or storage casks. The commenter added that industry has not attributed any problems with decontamination and dose to the handling and transport of spent fuel or storage casks. The commenter did note that although industry did experience some of the weeping issues in the early 1990's, industry has taken steps to eliminate this condition.

Response. NRC agrees that incidents of cask weeping have subsided in recent years. However, NRC notes that considerable occupational dose is expended to achieve compliance with current regulatory limits that do not appear to be risk-informed, and that occupational and public doses associated with spent fuel cask surface contamination limits do not appear to be optimized.

Comment. One commenter requested that the NRC not relax “radiation protection in any shipments, especially high-level wastes and intensely irradiated ‘spent’ fuel,” the reason being that, in the near future, shipments of high-level wastes and spent fuel may increase in number, and this would justify NRC staff’s maintaining “maximum control ... as a principal goal of the NRC.” The commenter also stated that while “Europeans may dismiss contamination ‘incidents’ as having no radiological consequences ... that is not convincing, in view of recent research findings concerning adverse impacts of low-level radiation at the cellular and molecular levels.”

Response. No change to the contamination limit is being adopted in the final rule, and no relaxation of radiation protection has been proposed.

Comment. Two commenters expressed opposition to allowing greater contamination on surfaces of irradiated fuel and high-level radioactive waste containers and supported NRC's decision to refuse this. Two other commenters supported the NRC's proposal to make no changes in the contamination levels for these packages.

Response. No response is necessary.

Comment. One commenter expressed opposition to allowing greater contamination on surfaces of irradiated fuel and high level radioactive waste containers.

Response: The NRC acknowledges these comments. No response is necessary.

Issue 19. Modifications of Event Reporting Requirements.

Summary of NRC Final Rule. The final rule revises, in § 71.95, the event reporting submission period to provide a written report from 30 to 60 days. Other regulatory requirements to orally notify the NRC Operations Center promptly of an event and for licensees to report instances of failure to follow the conditions of the CoC while packaging was in use remain unchanged. The revision lengthening the time for submission of the written report is consistent with changes to similar requirements in Part 50.

Affected Sections. Section 71.95.

Background. The Commission recently issued a final rule to revise the event reporting requirements in Part 50 (see 65 FR 63769; October 20, 2000). This final rule revised the verbal and written event notification requirements for power reactor licensees in §§ 50.72 and 50.73. In SECY-99-181,¹³ NRC staff informed the Commission that public comments on the proposed Part 50 rule had suggested that conforming changes also be made to the event notification

¹³ SECY-99-181, "Proposed Plans and Schedules to Modify Reporting Requirements Other than 10 CFR 50.72 and 50.73 for Power Reactors and Material Licensees," dated July 9, 1999.

requirements in Part 72 (Licensing Requirements for the Independent Storage of Spent Fuel) and Part 73 (Physical Protection of Plants and Materials). In response, the Commission directed the NRC staff to study whether conforming changes should be made to Parts 72 and 73. During this study, the NRC also reviewed the Part 71 event reporting requirements in § 71.95 and concluded that similar changes could be made to the Part 71 event reporting requirements.

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC staff's responses for this issue follows:

Comment. Two commenters expressed support for the proposed modifications. One commenter stated that the proposed modifications to event reporting requirements will enhance safety. The other commenter noted that many States respond to incidents involving radioactive materials on a regular basis and would not want to wait until the full 60 days for reporting purposes.

Response. The NRC acknowledges the comments supporting the change to require a 60-day report instead of a 30-day report for a transportation event. The comment that States would need to respond to incidents and would need reports sooner than 60 days is not consistent with the fact that prompt reporting to the National Response Center, NRC Operations Center, and appropriate State Authorities occurs after an event. The written report to the NRC will not affect this practice. Therefore, the change in the time to provide a written report would have no effect on the emergency response and information exchange actions that would still be performed by licensees or the DOT National Response Center. Therefore, no changes in the proposed rule language are being made.

Comment. One commenter asked how this proposed change affects other parts of the proposed rulemaking and urged the NRC to ensure that it conforms with the rest of the proposed rulemaking.

Response. There are no other impacts on the regulations associated with adopting this specific change.

Comment. Two commenters opposed the proposed event reporting requirements. The first commenter stated that there should never be a 30- or 60-day “delay in filing a report on any event involving malperformance of a package or container,” but that a report should be filed immediately with the NRC when a problem occurs. The second commenter suggested that “reporting should serve the needs of the [NRC] staff—and public safety,” rather than the licensee. This commenter also claimed that an extra 30 days may be too long an extension if there is a serious safety problem.

Response. The NRC notes that if a serious safety problem resulted from an incident, it would be reported promptly to the NRC Operations Center. The NRC staff notes that a review of the regulatory analysis included in the proposed rule stated that: “In new paragraph (a)(3), [of Section 71.95] the NRC would retain the existing requirement for licensees to report instances of failure to follow the conditions of the CoC while a packaging was in use.” This section was inadvertently left out of the proposed rule language and was added to the final rule.

Comment. One commenter indicated concern about the lack of data to support NRC’s position on extending the reporting period from 30 to 60 days.

Response. There is sufficient rationale as reflected in other regulations for reducing the regulatory burden related to the time for submitting written reports. See the discussion in the proposed rule (April 30, 2002; 67 FR 21427) for additional detail on the justification for the change. Therefore, no change to the rule is proposed.

Comment. One commenter was concerned about difficulties in compiling a jointly written report by the certificate holder and the shipper if they are in different countries.

Response. The commenter's concern about coordination of a jointly written event report is valid; however, the longer time being proposed for submitting an event report should accommodate delays in the communication interface and help ensure completion within the 60-day reporting period. Therefore, no changes have been made to the proposed rule language.

Comment. One commenter found the event reporting requirements unclear in two places. The proposed rule would direct the licensee to request information from certificate holders; however, neither the supporting discussion nor regulatory text addresses a situation in which a certificate holder declines to provide comments. The commenter asked whether the licensee's obligation would be satisfied at the point that a request is made to CoC holders. The commenter also found it unclear whether NRC intended to exempt DOT specification and foreign package designs holding U.S. validations from the reporting requirements. The commenter asserted that if NRC intends to make a distinction between NRC-approved packages and other authorized packages, it may be necessary to develop separate QA procedures and related instructions. The impacts on resources associated with such development may require further investigation.

Response. Regarding the first question about what would happen if a licensee did not receive supporting information in its process to issue an event report to the NRC to comply with the requirements of § 71.95, the NRC notes that the licensee should make an earnest attempt to obtain relevant information from the CoC holder. In the case where the CoC holder refused to provide input to the report, the licensee would still need to submit the report to the NRC within the 60-day time period. NRC technical staff would determine if CoC staff input should

have been included in the report and would obtain it directly from the CoC holder as necessary. Further, if the NRC determined that the CoC holder's lack of support resulted in a report that was incorrect or incomplete, then the NRC would pursue appropriate regulatory action against the CoC holder.

Regarding the second question about the reporting requirement being applicable to DOT specification and foreign package designs with U.S. validation, the NRC notes that its regulations only apply directly to its licensees or CoC holders. NRC will, however, forward this comment to DOT for appropriate consideration. No change to NRC rule language is being made.

Comment. One commenter stated that the requirement of the CoC holder to rely on other licensees or registered users, over whom the holder has no authority or control, to identify problems or package deficiencies, is inappropriate and must be modified. Another commenter stated that the authorized package user should be making the required report.

Response. Both comments deal with the original language in the existing § 71.95 which states that licensees are responsible for providing event reports to the NRC.

IV. Section-By-Section Analysis

Several sections In Part 71 are redesignated in this rulemaking to improve consistency and ease of use. For some sections, only the section number is changed. However, for other sections, revisions are being made to the regulatory language. The following table is provided to aid the public in understanding the numerical changes to sections of Part 71.

Redesignation Table	
New section number	Existing section number
§ 71.8	§ 71.11
§ 71.9	New section
§ 71.10	New section
§ 71.11 (Reserved)	NA
§ 71.12	§ 71.8
§ 71.13	§ 71.9
§ 71.14	§ 71.10
§ 71.15	§ 71. 53
§ 71.16 (Reserved)	NA
§ 71.17	§ 71.12
§ 71.18 (Reserved)	NA
§ 71.19	§ 71.13
§ 71.20	§ 71.14
§ 71.21	§ 71.16
§ 71.22	§ 71.18
§ 71.23	§ 71.20
§ 71.24 (Reserved)	§ 71.22 (Section removed)
§ 71.25 (Reserved)	§ 71.24 (Section removed)
§ 71.53 (Reserved)	§ 71.53 (Section redesignated)

Subpart A—General Provisions

Section 71.0 Purpose and scope.

Paragraph (d) has been reformatted into three paragraphs to simplify this regulation and to better use plain language. Paragraph (d)(1) indicates that general licenses, for which no NRC package approval is required, are issued in new §§ 71.20 through 71.23. This change reflects the removal of existing §§ 71.22 and 71.24 [redesignated §§ 71.24 and 71.25 (Reserved)]. Paragraph (d)(2) indicates that an application for package approval must be completed in accordance with Subpart D. Paragraph (d)(3) continues to require a licensee transporting, or delivering material to a carrier for transport, to meet the requirements of the applicable portions of Subparts A, G, and H.

New paragraph (e) has been added to indicate that persons who hold, or apply for, a Part 71 CoC for Type AF, Type B, Type BF, Type B(U)F, or Type B(M)F packages are within the scope of Part 71 regulations.

Existing paragraphs (e) and (f) have been redesignated as new paragraphs (f) and (g), respectively. The rule text in new paragraph (f) is the same as existing paragraph (e) text. New paragraph (g) has been revised to reflect the redesignation of existing § 71.11 as new § 71.8.

Section 71.1 Communications and records.

In § 71.1, paragraph (a) has been revised to indicate that documents submitted to the NRC should be addressed to the attention of the "Document Control Desk," not the "Director of the Office of Nuclear Material Safety and Safeguards." Provisions have also been added to provide requirements when a due date for a document falls on a Saturday, Sunday, or Federal holiday. In that case, the document would be due the next Federal workday. This change is identical to a change made to § 72.4 in a recent Part 72 final rule (see 64 FR 33178; June 22, 1999).

Section 71.2 Interpretations.

No changes were made to the text of this section; however, it has been retained in the revision of this subpart for completeness.

Section 71.3 Requirement for license.

No changes were made to the text of this section; however, it has been retained in the revision of this subpart for completeness.

Section 71.4 Definitions.

The existing definitions for “A₁,” “Fissile material,” “Low Specific Activity (LSA) material,” “Package,” and “Transport index (TI)” are revised as conforming changes. New definitions for “A₂,” “Certificate of Compliance,” “Consignment,” “Criticality Safety Index (CSI),” “Deuterium,” “U.S. Department of Transportation (DOT),” “Graphite,” “Spent fuel,” and “unirradiated uranium” have been added as conforming changes.

The definition of “A₁” has been revised to split the previous combined definition for “A₁” and “A₂” into two individual definitions. This approach is consistent with the standard in TS-R-1. Furthermore, no change has been made to the current technical content of the definition for “A₁”; however, the text is revised to improve readability.

A definition for “A₂” has been added, because the previous joint definition for “A₁” and “A₂” has been split into two definitions. (See also definition for “A₁.”)

A definition for “Certificate of Compliance” has been added. This definition is similar to the definition for the same term found in § 72.3.

A definition for “Consignment” has been added.

A definition of “Criticality Safety Index (CSI)” has been added.

A definition of “Deuterium” has been added that applies to new §§ 71.15 and 71.22.

A definition of “U.S. Department of Transportation (DOT)” has been added.

The definition of “Fissile material” has been revised by removing ²³⁸Pu from the list of fissile nuclides; clarifying that “fissile material” means the fissile nuclides themselves, not materials containing fissile nuclides; and redesignating the reference to exclusions from fissile material controls from § 71.53 to new § 71.15.

A definition of “Graphite” has been added that applies to new §§ 71.15 and 71.22.

The definition of “Low Specific Activity (LSA)” material (LSA-I, LSA-II, and LSA-III) has been revised to be consistent with DOT, and to reflect the existence of § 71.77 (§ 71.77 provides requirements on the qualification of LSA-III material).

A definition for “Optimum interspersed hydrogenous moderation” has been added (the definition itself was included in the proposed rule § 71.4, but, inadvertently, no mention of that fact was made in this Section).

The definition of “Package” has been revised by clarifying in subparagraph (1) that Fissile material package also means a Type AF, Type BF, Type B(U)F, or Type B(M)F package. New paragraph (2) has been added defining Type A packages in accordance with DOT regulations contained in 49 CFR Part 173. Existing subparagraph (2) defining Type B packages has been redesignated as subparagraph (3). No changes have been made to the redesignated text.

A definition of “Spent nuclear fuel” or “Spent fuel” has been added. This definition is the same as that currently found in § 72.3.

The definition for “Transport index (TI)” has been revised to reflect the new definition of Criticality Safety Index; however, the method for determining the TI of a package, based on the package's radiation dose rate, remains unchanged.

A definition for “unirradiated uranium” has been added as it is part of the LSA-I definition.

Section 71.5 Transportation of licensed material.

No changes were made to the text of this section; however, it has been included in the revision of this subpart for completeness.

Section 71.6 Information collection requirements: OMB approval.

This section has been redesignated from Subpart B, Exemptions, to Subpart A, General Provisions. Paragraph (b) of this section has been revised as a conforming change to reflect the addition of new information collection requirements in §§ 71.151, 71.153, 71.155, 71.157, 71.159, 71.161, 71.165, 71.167, 71.171, 71.173, 71.175, and 71.177. Additionally, the existing information collection requirement in Appendix A to Part 71, Paragraph II, was inadvertently omitted from the list of approved information collection requirements in a previous rulemaking; consequently, NRC staff has added Appendix A, Paragraph II, to paragraph (b) to correct this error. Furthermore, the reference to § 71.6a has been removed, because no such section currently exists in Part 71.

Section 71.7 Completeness and accuracy of information.

This section has been redesignated from Subpart B, Exemptions, to Subpart A, General Provisions. Further, paragraphs (a) and (b) have been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.8 Deliberate misconduct.

This section has been redesignated from Subpart B, Exemptions, to Subpart A, General Provisions. Further, in Subpart A, § 71.11 has been redesignated as § 71.8. However, the current text of § 71.11 has not changed in the redesignated § 71.8.

Section 71.9 Employee protection.

New § 71.9 has been added to provide requirements on employee protection. Currently, requirements relating to the protection of employees against firing or other discrimination when the employee engages in certain "protected activities" are provided under the Parts of Title 10 for which a specific license was issued to possess radioactive material. However, no provisions were provided in Part 71 relating to the protection of employees against firing or other discrimination when employees engage in certain "protected activities" when they are the employees of a certificate holder or applicant for a CoC. The NRC believes these employees should also be afforded the same rights and protection as are currently afforded employees of licensees. The new section is identical to the existing § 72.10, "Employee protection." In including licensees in the new § 71.9, the NRC recognizes that the potential for duplication occurs for licensees regulated under multiple Title 10 Parts. However, the NRC believes that by including licensees along with certificate holders and applicants for a CoC, improved regulatory clarity would be achieved, and any potential confusion would be minimized.

Section 71.10 Public inspection of application.

A new section has been added indicating that applications and documents submitted to the Commission, in connection with an application for a package approval, shall be available for public review in accordance with the provisions of Parts 2 and 9. This new section is similar to

existing § 72.20. Existing § 71.10 has been redesignated § 71.14 with changes to the text as discussed under § 71.14, below.

Section 71.11 (Reserved)

This section has been redesignated from Subpart B, Exemptions, to Subpart A, General Provisions, and is reserved. Existing § 71.11 has been redesignated as § 71.8.

Subpart B - Exemptions

Section 71.12 Specific exemptions.

Existing § 71.8 has been redesignated as § 71.12. No changes have been made to the contents of this section. Existing § 71.12 has been redesignated as § 71.17, with changes to the text as discussed under § 71.17, below.

Section 71.13 Exemption of physicians.

Existing § 71.9 has been redesignated as § 71.13. No changes have been made to the contents of this section. Existing § 71.13 has been redesignated as § 71.19, with changes to the text as discussed under § 71.19, below.

Section 71.14 Exemption for low-level materials.

Existing § 71.10 has been redesignated as § 71.14. Existing § 71.14 has been redesignated as § 71.20, with no changes to the text.

In new § 71.14, paragraph (a) has been revised by removing the existing single 70 Bq/g (0.002 $\mu\text{Ci/g}$) specific activity value. Additionally, paragraph (a) has been reformatted by

adding two new paragraphs. Subparagraph (a)(1) provides an increased exemption for natural radioactive materials and ores. Subparagraph (a)(2) provides an exemption for radioactive material based on the “Activity Concentration for Exempt Material” and the “Activity Limit for Exempt Consignment” found in Table A-2 in Appendix A to Part 71.

Paragraph (b) has been revised to consolidate the exemption provisions for LSA and SCO material. The LSA and SCO exemptions contained in existing paragraphs (b)(2) and (c) of this section have been consolidated into a revised paragraph (b)(3). The reference to material exempt from classification as fissile material has been revised from § 71.53 to § 71.15, because of the redesignation of the section.

Existing paragraph (b)(3) has been removed. The 0.74-TBq (20-Ci) exemption for special form americium and special form plutonium has been removed. However, the 0.74-TBq (20-Ci) exemption for special form plutonium-244, transported in domestic commerce, has been retained as new paragraph (b)(2). For international shipments, the A_1 quantity limit for special form plutonium-244 continues to apply.

Section 71.15 Exemption from classification as fissile material.

Existing § 71.11 has been redesignated as § 71.8. Existing § 71.53 has been redesignated as § 71.15, and relocated to Subpart B with the other Part 71 exemptions. This section has been revised by providing mass-ratio based limits in classifying fissile-exempt material. This approach removes the concentration- and consignment-based limits of the current § 71.53 and returns to package-based mass limits, with required minimum ratios of nonfissile-to-fissile mass.

The title has been changed to "Exemption from classification as fissile material."

New paragraph (a) has been added and allows for small samples of fissile material to be shipped. In paragraph (b), the fissile mass per package is limited to 15 grams with a nonfissile-to-fissile mass ratio of 200:1. In paragraph (c), the allowed provided there is less than 150 g of fissile material per 360 Kg ratio of nonfissile-to-fissile material is also raised to 2000:1. The mass of any lead, graphite, beryllium, and deuterium in the package cannot be included in determining the nonfissile material mass.

In current § 71.53, paragraph (c) has been redesignated as paragraph (e), and has been reformatted and revised to clarify that the nitrogen to uranium atomic ratio, for shipments of liquid uranyl nitrate, must be greater than or equal to 2.0. A new requirement has been added specifying the use of DOT Type A packaging.

In current § 71.53, paragraph (d) has been redesignated as paragraph (e), and has been reformatted and revised to clarify the mass limits for plutonium. No substantive changes have been made to this paragraph.

Section 71.16 (Reserved)

This section has been redesignated from Subpart C, General Licenses, to Subpart B, Exemptions, and is reserved. Further, existing § 71.16 has been redesignated as § 71.21. However, the current text of § 71.16 has not been changed in the redesignated § 71.21.

Subpart C—General Licenses

Section 71.17 General license: NRC-approved package.

Existing § 71.12 has been redesignated as § 71.17. The text of paragraphs (a) and paragraph (b) has not been changed.

Paragraph (c)(3) has been revised using plain language and to reflect the NRC's requirement to address information submitted to the NRC to the attention of the NRC's Document Control Desk, in accordance with § 71.1.

Paragraph (d) has not been changed.

Paragraph (e) has been revised to reflect the redesignation of § 71.13 to § 71.19. No other change was made for this paragraph.

Section 71.18 Reserved

Section 71.19 Previously approved package.

Existing § 71.13 has been redesignated as § 71.19. Paragraph (a) has been revised to reflect the current package designators [e.g., B(U)F, B(M)F, AF] and to reflect the redesignation of § 71.12 to § 71.17. Additionally, the contents of paragraph (a)(2) have been removed to reflect that these packages are no longer recognized internationally. Existing paragraph (a)(3) has been redesignated as (a)(2) with no change to the contents. Also, an expiration date for grandfathering these packages has been established in new paragraph (a)(3). Paragraph (b) has been updated to remove the LSA packages, as these packages no longer exist, and to reflect the redesignation of § 71.12 to § 71.17. No other changes were made. A new paragraph (c) has been added to reflect the type B(U) and B(M) packages that have met the requirements of IAEA Safety Series 6 1985 (as amended 1990) and to correct a typographical error. Additionally, a date by which fabrication of these packages must be complete has been added. Existing paragraph (c) has been redesignated as paragraph (d). Existing paragraph (d) has been redesignated as paragraph (e) and updated to reflect the identification number suffix of "-96" for previously approved package designs that have been resubmitted for review by the

NRC and have been approved, and to remove the package designated as Type A from this paragraph.

Section 71.20 General license: DOT specification container.

Existing § 71.14 has been redesignated as § 71.20. No changes have been made to the contents of paragraphs (a) through (d). New paragraph (e) has been added to indicate that these types of packages will be phased out 3 years after the effective date of this final rule.

Section 71.21 General license: Use of foreign approved package.

Existing § 71.16 has been redesignated as § 71.21. No changes have been made to the contents of this section.

Section 71.22 General license: Fissile material.

Existing § 71.18 has been redesignated as § 71.22. The current § 71.22 has been removed. This section has been amended by consolidating and simplifying the current fissile general license provisions contained in existing §§ 71.18, 71.20, 71.22, and 71.24 into a new § 71.22. The new § 71.22, while retaining some of the provisions of the existing general licenses, principally uses mass-based limits and a CSI. Concentration-based limits have been removed. Exceptions relating to plutonium-beryllium sealed sources in existing §§ 71.18 and 71.22 have been relocated to new § 71.23. The values contained in new Tables 71-1 and 71-2 have been revised from the values contained in the table in existing § 71.22 and in Table 1 in existing § 71.20, respectively; and are based on new minimum critical mass calculations described in NUREG/CR-5342. In some instances, the allowable mass limit has been increased from the current limits in existing §§ 71.18, 71.20, 71.22, and 71.24; in other

instances, the allowable mass limit has been reduced. The values contained in new Tables 71-1 and 71-2 are used as the variables X, Y, and Z in the equation in paragraph (e).

The title has been revised to indicate that this general license is not restricted to a specific type of fissile material shipment.

Paragraph (a) has been revised to require that fissile material shipped under this general license be contained in a DOT Type A package. Additionally, while the existing exception from Subparts E and F requirements has been maintained, the DOT Type A package regulations of 49 CFR Part 173 has also been specified.

Paragraph (b) remains unchanged.

Paragraph (c) has been revised to remove the specific gram limits for uranium and plutonium but retains the existing Type A quantity limit. Revised gram limits have been relocated to new Table 71-1, which is associated with new paragraphs (d) and (e). A requirement has also been added to limit the amount of special moderating materials beryllium, graphite, and hydrogenous material enriched in deuterium present in a package to less than 500 g.

Existing paragraph (d) has been removed. Revised gram limits for fissile material mixed with material having a hydrogen density greater than water (i.e., a moderating effectiveness greater than H_2O) have been placed in new Table 71-1. A note has been added to new Table 71-1 to indicate that reduced mass limits apply when more than 15 percent of a mixture of moderating materials contains moderating material with a hydrogen density greater than H_2O .

New paragraph (d) has been added to require that shipments of packages containing fissile material be labeled with a CSI, that the CSI per package be less than or equal to 10.0, and that the sum of the CSIs in a shipment of multiple fissile material packages be limited to

less than or equal to 50.0 for a nonexclusive use conveyance, and to less than or equal to 100.0 for an exclusive use conveyance.

Existing paragraphs (e) and (f) have been removed.

New paragraph (e) has been added to require that the CSI be calculated via a new equation for any of the fissile nuclides. Guidance on applying the equation and the mass limit input values of Tables 71-1 and 71-2 is also contained in this paragraph.

Section 71.23 General license: Plutonium-beryllium special form material.

The existing § 71.20, "General license: Fissile material, limited moderator per package," has been removed. A new section on the shipment of plutonium-beryllium (Pu-Be) special-form fissile material (i.e., sealed sources) has been added as a new § 71.23. New § 71.23 consolidates regulations on shipment of Pu-Be sealed sources contained in existing §§ 71.18 and 71.22 into one location in Part 71. The new § 71.23 reduces the maximum quantity of fissile plutonium Pu-Be sealed sources that could be shipped on a single conveyance through changes in the mass limits and calculation of the CSI. Currently, a Pu-Be sealed source package can contain up to 400 g of fissile plutonium with a CSI equal to 10.0. Consequently, the current conveyance limits are 4,000 g per shipment for an exclusive-use vehicle and 2000 g per shipment for a nonexclusive use vehicle. The new § 71.23 increases the maximum CSI per package from 10 to 100; however, the maximum quantity of plutonium per conveyance (i.e., shipment) would be reduced to 1000 g. The 1000-g per shipment limit and 240 g of fissile plutonium limit are equivalent to those in new § 71.22(f) (1000 g per shipment and 200 g of fissile plutonium). The 240 g versus 200 g of fissile plutonium per package is due to the increased confidence that the fissile plutonium, within a sealed source capsule, would not

escape from the capsule during an accident and reconfigure itself into an unfavorable geometry.

New § 71.23 has been titled: "General license: Plutonium-beryllium special form material." Paragraph (a) describes the applicability of this section, exceptions to the requirements of Subparts E and F, and the requirement to ship Pu-Be sealed sources in DOT Type A packages.

Paragraph (b) requires that shipments of Pu-Be sealed sources be made under an NRC-approved QA program.

Paragraph (c) requires a 1000 g per package limit. In addition, plutonium-239 and plutonium-241 constitute only 240 g of the 1000 g limit.

Paragraph (d) requires that a CSI be calculated per paragraph (e), and the CSI must be less than or equal to 100.0. For shipments of multiple packages, the sum of the CSIs is limited to less than or equal to 50.0 for a nonexclusive use conveyance and to less than or equal to 100.0 for an exclusive use conveyance.

Paragraph (e) provides an equation to calculate the CSI for Pu-Be sources. This equation is based upon the 240-g mass limit for fissile nuclide plutonium-239 and plutonium-241 in paragraph (c).

Section 71.24 (Reserved)

Section 71.25 (Reserved)

Existing §§ 71.22 and 71.24 have been redesignated as §§ 71.24 and 71.25. New §§ 71.24 and 71.25 have been removed and reserved.

Subpart D—Application for Package Approval

Section 71.41 Demonstration of compliance.

Paragraph (a) has been revised to require that a Type B package which contains radioactive contents with activity greater than $10^5 A_2$ of any radionuclide must meet the enhanced deep immersion test found in § 71.61. A new paragraph (d) has been added to provide special package authorizations.

Section 71.51 Additional requirements for Type B packages.

Paragraph (a) has been revised to remove the reference to § 71.52, because the requirements of § 71.52 have expired. Paragraph (d) has been added to require that a package which contains radioactive contents with activity greater than $10^5 A_2$ of any radionuclide must also meet the enhanced deep immersion test found in § 71.61.

Section 71.53 Fissile material exemptions (Reserved).

This section has been removed and reserved; its contents have been moved to § 71.15.

Section 71.55 General requirements for fissile material packages.

New paragraphs (f) and (g) have been added. Paragraph (f) specifies design and testing for fissile material package designs for transport by aircraft, and paragraph (g) addresses UF_6 criticality exception from § 71.55(b). Additionally, as a conforming change, paragraph (b) has been updated to support new paragraph (g).

Section 71.59 Standards for arrays of fissile material packages.

Paragraphs (b) and (c) have been revised to use the term CSI (criticality safety index).

Paragraph (b) has been revised to refer to a CSI rather than a TI for nuclear criticality control. The method for calculating a CSI is the same as the existing method for a TI for nuclear criticality control.

Paragraph (c) has been revised to provide direction to licensees when the CSI is exactly equal to 50 and to use plain language. Subparagraph (1) has been revised by replacing the term "[n]ot in excess of 10," with the term "[l]ess than or equal to 50." New paragraph (c)(2) has been added to provide for shipment of packages with a CSI of less than 50 on an exclusive use conveyance. The current conveyance limit of 100 has been retained. Existing paragraph (c)(2) has been redesignated as new paragraph (c)(3) and has been revised by replacing the term "[i]n excess of 10," with the term "[g]reater than 50." These three changes: (1) provide greater clarity and mathematical consistency among paragraphs (c)(1), (c)(2), and (c)(3); (2) clarify the CSI limits for storage incident to transport; and (3) increase the CSI limit per package from 10 to 50 for shipments made with nonexclusive use conveyances.

Section 71.61 Special requirements for Type B packages containing more than $10^5 A_2$.

This section has been revised to require an enhanced water immersion test for packages used for radioactive contents with activity greater than $10^5 A_2$. The title of this section has also been revised to reflect that the scope has been broadened beyond irradiated nuclear fuel.

Section 71.63 Special requirement for plutonium shipments.

The title has been revised to reflect only a single "requirement" rather than multiple requirements.

Paragraph (b) has been removed.

The designation of the remaining text as paragraph (a) has been removed, because only one paragraph remains. The text of former paragraph (a) has been revised to use plain language. The 0.74-TBq (20-Ci) limit and solid form requirement have been retained.

Section 71.73 Hypothetical accident conditions.

A new paragraph (c)(2) has been added to require a crush test for fissile material packages.

Section 71.88 Air transport of plutonium.

Paragraph (a)(2) has been revised to remove the 70-Bq/g (0.002- μ Ci/g) specific activity value and substitute activity concentration values for plutonium found in Appendix A, Table A-2, of this part. This revision is a conforming change to the revision to new § 71.14 to ensure consistent treatment of plutonium between these two sections.

Subpart G—Operating Controls and Procedures

Section 71.91 Records.

As a conforming change to Subpart H, paragraphs (b) and (c) have been redesignated as paragraphs (c) and (d), respectively, and are revised by adding the terms "certificate holder" and "applicant for a CoC." New paragraph (b) has been added to require a certificate holder to

keep records on the model, serial number, and date of manufacture of a packaging. These requirements are similar to the requirements in paragraph (a), though less information is required. No change has been made to paragraph (a).

Section 71.93 Inspection and tests.

As a conforming change to Subpart H, paragraphs (a) and (b) have been revised by adding the terms “certificate holder” and “applicant for a CoC.” Paragraph (c) has been revised to require the certificate holder to notify the NRC before it begins fabrication of a packaging that can contain material having a decay heat load in excess of 5 kW or a maximum normal operating pressure of 103 kPa [kilo Pascals] (15 lbf/in²) gauge. This notification could be for either fabricating a single packaging or the beginning of a campaign for fabricating multiple packagings. This notification is in accordance with the requirements of § 71.1, rather than an NRC Regional Administrator. This change in notification location reduces confusion in identifying the appropriate Regional Administrator when the certificate holder and fabrication location are overseas. Licensees have been removed from this paragraph because the NRC believes that requiring a licensee, who does not own the packaging, to notify the NRC in advance of a packaging fabrication, when the licensee may not use the packaging for years, is inappropriate and an unreasonable burden. The NRC believes that requiring certificate holders and applicants for a CoC to notify the NRC in advance of fabricating a packaging(s) would allow the NRC adequate opportunity to inspect these activities. This change is similar to the current requirement in § 72.232(d) for Part 72 certificate holders or applicants for a CoC to notify the NRC 45 days before starting the fabrication of the first storage cask under a Part 72 CoC. This action improves the harmonization between these two regulations in Parts 71 and 72,

particularly regarding dual-purpose casks (i.e., casks intended to both store and transport spent fuel).

Section 71.95 Reports.

The existing introductory text and paragraphs (a), (b), and (c) have been combined into a new paragraph (a) which requires a licensee, after requesting the certificate holder's input, to submit a written report to the NRC in certain circumstances. The requirement for the licensee to request input from the certificate holder during development of the written event report will ensure that design deficiency issues have been thoroughly considered. The licensee will also be required to provide the certificate holder with a copy of the written event report, after the report is submitted to the NRC. This will permit the certificate holder to monitor and trend the package performance information, arising from package use by multiple licensees. Additionally, requirements on timing and submission location for the written reports have been relocated to new paragraph (c). Furthermore, the 30-day reporting requirement has been lengthened to a 60-day reporting requirement.

The existing paragraph (c) has been redesignated as paragraph (b) and revised for clarity.

New paragraphs (c) and (d) have been added to provide requirements on the timing, submission location, form, and content of the written reports.

Section 71.100 Criminal penalties.

Section 223 of the Atomic Energy Act of 1954, as amended, [the Act] provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. The Commission stated in a

final rule on "Clarification of Statutory Authority for Purposes of Criminal Enforcement" (57 FR 55082; November, 24, 1992), that substantive rules under sections 161b, 161i, or 161o of the Act include those rules that create "duties, obligations, conditions, restrictions, limitations, and prohibitions." For the NRC to consider the possibility of criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any substantive regulations, the NRC must have clearly identified to affected parties which regulations in Part 71 are substantive rules. Accordingly, paragraph (b) of this section identifies those Part 71 regulations that the NRC does not consider as substantive regulations. Thus, willful violation of, attempted violation of, or conspiracy to violate any of the regulations listed in paragraph (b) is not subject to possible criminal sanctions.

Paragraph (b) of this section has been revised as a conforming change. The NRC has reviewed new §§ 71.10, 71.151, 71.153, 71.155, 71.157, 71.159, 71.161, 71.163, 71.165, 71.167, and 71.169 and considers that these regulations are not substantive rules. Therefore, new §§ 71.10 and 71.151 through 71.169 have been added to the list of sections in paragraph (b). The NRC reviewed new §§ 71.9, 71.18, 71.23, 71.171, 71.173, 71.175, and 71.177 and considers that these regulations are substantive rules. Therefore, these sections have not been added to paragraph (b). Additionally, the NRC has reviewed the existing §§ 71.9, 71.10, and 71.53 and concluded these sections should be recharacterized as substantive rules. Therefore, new §§ 71.13, 71.14, and 71.18 have not been included in paragraph (b). Additionally, existing §§ 71.52 and 71.53 have been removed from paragraph (b), because these section numbers have been removed from Part 71.

Subpart H—Quality Assurance

Section 71.101 Quality assurance requirements.

Paragraph (a) has been revised by adding two new sentences to the end of the paragraph specifying responsibilities for certificate holders and applicants for a CoC.

Paragraph (b) has been revised to add the terms "certificate holder" and "applicant for a CoC." The second sentence has been revised to provide greater clarity and consistency within Subpart H by referring to "the QA requirement's importance to safety."

Paragraph (c) has been revised by redesignating the existing text as paragraph (c)(1), and new text has been added on submitting QA programs in accordance with the requirements of § 71.1. New paragraph (c)(2) has been added to provide equivalent requirements on the submission of QA programs for certificate holders and applicants for a CoC.

Paragraph (f) has been revised to allow the use of existing NRC-approved Part 71 and Part 72 QA programs, in lieu of submitting a new QA program. Additionally, the terms "certificate holder" and "applicant for a CoC" have been added.

Paragraph (g) has been revised by making a minor change to clarify that § 34.31(b) is located in Chapter I of Title 10 of the Code of Federal Regulations. Additionally, as a conforming change, § 71.12(b) has been redesignated as § 71.17(b).

Section 71.103 Quality assurance organization.

Paragraph (a) has been revised by adding the terms "certificate holder" and "applicant for a CoC." Further, the fourth sentence has been revised to improve clarity and consistency within Subpart H and with Part 72, Subpart G, by referring to "the functions of structures, systems, and components that are important to safety."

Section 71.105 Quality assurance program.

Paragraphs (a) through (d) have been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.107 Package design control.

Paragraph (a) has been revised by adding the terms "certificate holder" and "applicant for a CoC." Further, the last sentence has been revised to improve clarity and consistency within Subpart H by referring to "processes that are essential to the functions of the materials, parts, and components that are important to safety."

Paragraph (b) has been revised by adding the terms "certificate holder" and "applicant for a CoC." Additionally, the last sentence of paragraph (c) has been revised by replacing the text "[c]hanges in the conditions specified in the package approval require NRC approval...." with "[c]hanges in the conditions specified in the CoC require NRC prior approval...."

Section 71.109 Procurement document control.

This section has been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.111 Instructions, procedures, and drawings.

This section has been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.113 Document control.

This section has been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.115 Control of purchased material, equipment, and services.

Paragraphs (a) through (c) have been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.117 Identification and control of materials, parts, and components.

This section has been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.119 Control of special processes.

This section has been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.121 Internal inspection.

This section has been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.123 Test control.

This section has been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.125 Control of measuring and test equipment.

This section has been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.127 Handling, storage, and shipping control.

This section has been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.129 Inspection, test, and operating status.

Paragraph (a) has been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.131 Nonconforming materials, parts, or components.

This section has been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.133 Corrective action.

This section has been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.135 Quality assurance records.

This section has been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.137 Audits.

This section has been revised by adding the terms "certificate holder" and "applicant for a CoC."

Appendix A to Part 71 — Determination of A_1 and A_2

No changes have been made in Paragraphs I, III, and V; however, these paragraphs have been included due to revising Appendix A, in its entirety.

Paragraph II has been revised to use plain language and has been redesignated as subparagraph II(a). The intent of existing paragraph II has not been changed; however, the reference to existing Table A-2 has been revised as a conforming change to the new Table A-3. New paragraph II(b) has been added to provide direction on determining exempt material activity concentration and exempt consignment activity values when a radionuclide has been identified as a constituent of a proposed shipment, but the individual radionuclide is not listed in Table A-2. Consequently, the structure of paragraphs II(a) and II(b) is the same. New paragraph II(c) has been added to provide direction to licensees on how to submit requests for Commission prior approval of either A_1 and A_2 values or exempt material activity concentration and exempt consignment activity values, for radionuclides that are not listed in Tables A-1 and A-2, respectively.

Paragraph IV has been revised by adding new paragraphs (e) and (f) to provide equations to use in determining a consolidated exempt material activity concentration and exempt consignment activity value when a shipment contains multiple radionuclides. The existing text describing an alternative method for calculating the A_1 or A_2 value of a mixture has been redesignated as paragraphs (c) and (d). No changes have been made from the existing equations.

Appendix A, Table A-1 - A_1 and A_2 Values for Radionuclides

This Table has been revised to reflect the values from TS-R-1.

Appendix A, Table A-2 - Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides

A new Table A-2 has been added to Appendix A of Part 71. This table contains the values of Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for selected radionuclides. Table A-2 is referenced in new § 71.14(a)(2) and is used in § 71.14 to determine when concentrations of material are not considered radioactive material, for the purposes of transportation.

Appendix A, Table A-3 — General Values for A_1 and A_2

The existing Table A-2 has been redesignated as new Table A-3, and the values have been revised to reflect the changes from TS-R-1.

Appendix A, Table A-4 — Activity Mass Relationships for Uranium

The existing Table A-3 has been redesignated as new Table A-4. No changes have been made to the values contained in new Table A-4.

V. Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act (AEA), the Commission is amending 10 CFR Part 71 under one or more of sections 161b, 161i, or 161o of the AEA.

Willful violations of the rule will be subject to criminal enforcement.

The following is a list of substantive rule sections being revised or added in this rulemaking: §§ 71.1, 71.3, 71.5, 71.8, 71.9, 71.12, 71.13, 71.14, 71.15, 71.17, , 71.19, 71.20, 71.21, 71.22, 71.23, 71.61, 71.63, 71.88, 71.91, 71.93, 71.95, 71.101, 71.103, 71.105, 71.107,

71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, 71.125, 71.127, 71.129, 71.131, 71.133, 71.135, 71.137, 71.171, 71.173, 71.175, and 71.177.

VI. Issues of Compatibility for Agreement States

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" which became effective on September 3, 1997 (62 FR 46517), NRC program elements (including regulations) are placed into four compatibility categories. In addition, NRC program elements also are identified as having particular health and safety significance or as being reserved solely to the NRC. Compatibility Category A are those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D are those program elements that do not meet any of the criteria of Category A, B, or C, and thus do not need to be adopted by Agreement States for purposes of compatibility. A bracket around a category means that the section may have been adopted elsewhere, and it is not necessary to

adopt it again. Health and Safety (H&S) are program elements that are not required for compatibility (i.e., Category D) but are identified as having a particular health and safety role (i.e., adequacy) in the regulation of agreement material within the State. Although not required for compatibility, the State should adopt program elements in this category based on those of NRC that embody the essential objectives of the NRC program elements because of particular health and safety considerations. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to Agreement States pursuant to the Atomic Energy Act, as amended, or provisions of Title 10 of the Code of Federal Regulations. These program elements should not be adopted by Agreement States. The following table lists the Part 71 revisions and their corresponding categorization under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs." This table has been revised to incorporate comments received from the States of California and Wisconsin during the 30-day Agreement States comment period which began on June 3, 2003.

Part 71 - PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.0	Purpose and Scope	D, except paragraph C is [B]	This requirement is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this requirement in another portion of its regulations, such as the State's DOT regulations, then the adoption of this provision is not necessary.
§71.1	Communications and Records	D	
§71.2	Interpretations	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.3	Requirements for license	[B]	This requirement is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions since it assures authorization for the transport of licensed material. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this requirement in another portion of its regulations, such as the State's DOT regulations, then the adoption of this provision is not necessary.
§71.4	Definitions		
	A ₁	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.
	A ₂	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Carrier	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.
	Certificate holder	D- for those States which have no licensees that use Type B packages. or [B]- for those States which have licensees that use Type B packages.	This term is used in the sections concerning quality assurance programs for Type B packages. Those States which have no licensees that use Type B packages are not required to adopt this definition. This definition is designated Compatibility Category B for those States which have licensees that use Type B packages because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement States should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Certificate of compliance	D- for those States which have no licensees that use Type B packages. or [B]- for those States which have licensees that use Type B packages.	This term is used in the sections concerning quality assurance programs for Type B packages. Those States which have no licensees that use Type B packages are not required to adopt this definition. This definition is designated Compatibility Category B for those States which have licensees that use Type B packages because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement States should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.
	Close reflection by water	D	This definition is not required for compatibility since it defines a term which pertains to an area reserved to NRC. A State may adopt this definition for purposes of clarity or communication. This definition can be adopted by Agreement States since it in and of itself does not convey any authority whereby a State can regulate in an exclusive NRC jurisdiction. However, if a State chooses to define the term then the definition should be essentially identical.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Consignment	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.
	Containment System	D	This term is not used in any section requiring Agreement State adoption.
	Conveyance	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.
	Criticality safety Index	B	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. In addition, this definition is needed for a common understanding beyond a plain dictionary meaning of the term in order to implement 10 CFR 71.22, 71.23 and 71.59.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Deuterium	B	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. In addition, this definition is needed for a common understanding beyond a plain dictionary meaning of the term in order to implement §71.15.
	DOT	D	This term does not meet any of the criteria of Category A, B, C, or H&S because it is a widely accepted abbreviation for the U. S. Department of Transportation.
	Exclusive use	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.
	Fissile material	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Graphite	B	This definition is needed for a common understanding beyond a plain dictionary meaning of the term in order to implement §71.15, which has direct and significant transboundary effects.
	Licensed material	[D]	This term does not meet any of the criteria of Category A, B, C, or H&S because it is widely accepted and understood. This definition also appears in 10 CFR 20.1003. For purposes of compatibility, the language of the Part 20 definition should be used and is assigned to Compatibility Category D.
	Low Specific Activity (LSA) material	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.
	Low toxicity alpha emitters	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Maximum normal operating pressure	D	The definition of the term “maximum normal operating pressure” was changed from a compatibility category “B” to a category “D.” This term is not used in any section requiring Agreement State adoption; it relates to the heat conditions in §71.71(c)(1), which is designated a category “NRC.” This definition is not required for compatibility since it defines a term which pertains to an area reserved to the NRC. A State may adopt this definition for purposes of clarity or communication. This definition can be adopted by Agreement States since it is and of itself does not convey any authority whereby a State can regulate in an exclusive NRC jurisdiction. However, if a State chooses to define this term then the definition should be essentially identical.
	Natural thorium	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, “B,” indicates that if a State has adopted this definition in another portion of its regulations, such as the State’s DOT regulations, then the adoption of this definition is not necessary.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Normal form radioactive material	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.
	Optimum interspersed hydrogenous moderation	D	This definition is not required for compatibility since it defines a term which pertains to an area reserved to NRC. A State may adopt this definition for purposes of clarity or communication. This definition can be adopted by Agreement States since it in and of itself does not convey any authority whereby a State can regulate in an exclusive NRC jurisdiction. However, if a State chooses to define the term then the definition should be essentially identical.
	Package	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Fissile material package or Type AF package, Type BF, Type B(U)F package, or Type B(M)F	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.
	Type A package	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.
	Type B package	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Packaging	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.
	Special form radioactive material	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.
	Specific activity	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Spent Nuclear Fuel or Spent Fuel	D	This definition is not required for compatibility since it defines a term which pertains to an area reserved to NRC. A State may adopt this definition for purposes of clarity or communication. This definition can be adopted by Agreement States since it in and of itself does not convey any authority whereby a State can regulate in an exclusive NRC jurisdiction. However, if a State chooses to define the term then the definition should be essentially identical.
	State	D	
	Surface Contaminated Object (SCO)	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.
	Transport Index	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Type A quantity	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.
	Type B quantity	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.
	Unirradiated uranium	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this definition in another portion of its regulations, such as the State's DOT regulations, then the adoption of this definition is not necessary.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Uranium—natural, depleted and enriched	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, “B,” indicates that if a State has adopted this definition in another portion of its regulations, such as the State’s DOT regulations, then the adoption of this definition is not necessary.
§71.5	Transportation of Licensed Material	[B]	This requirement is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, “B,” indicates that if a State has adopted this provision in another portion of its regulations, such as the State’s DOT regulations, then the adoption of this requirement is not necessary.
§71.6	Information collection requirements: OMB approval	D	
§71.7	Completeness and accuracy of Information	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.8	Deliberate misconduct	C	The Commission determined in response to SECY-97-156 that Agreement States should adopt the essential objectives of this provision. The essential objectives of this provision are provided in paragraphs (a), (b), (c), and (d). If deliberate misconduct and wrongdoing issues involving Agreement State licensees were not pursued and closed by Agreement States, then a potential gap may be created between NRC and Agreement State programs.
§71.9	Employee Protection	D	This provision does not meet any of the criteria for designations Category A, B, C, or health and safety. Thus, it does not need to be adopted by Agreement States.
§71.10	Public Inspection of Application	D	This provision does not meet any of the criteria for designations Category A, B, C, or health and safety. Thus, it does not need to be adopted by Agreement States.
§71.11	[RESERVED]		
§71.12	Specific exemptions	D	
§71.13	Exemption for physicians	[B]	This provision is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this provision in another portion of its regulations, such as the State's DOT regulations, then the adoption of this requirement is not necessary.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.14	Exemptions for low level material	[B]- paragraph (a) NRC- paragraph (b)	<p>Paragraph (a) is designated as a Compatibility Category B because of its significant transboundary impacts with respect to the establishment of exempt materials in the area of transportation. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this requirement in another portion of its regulations, such as the State's DOT regulations, then the adoption of this requirement is not necessary.</p> <p>Paragraph (b) is designated Compatibility Category "NRC." This provision is reserved to the NRC because it delineates NRC's authority from that of DOT's in the area of transportation of radioactive materials. These provisions relinquish to DOT the control of types of shipment that are of low risk both from radiation and criticality standpoints. Further, to ensure that only low criticality risk shipments are included in the area of DOT authority, these provisions restrict the exemption to Type A and low-specific-activity (LSA) or surface contaminated objects (SCOs) that either contain no fissile material or satisfy the fissile material exemption requirements in §71.11. Finally, this provision is reserved to the NRC because this exemption does not relieve licensees from DOT requirements by reason of NRC's authority. Thus, Agreement States should not adopt this provision in order to retain their ability to implement all of 49 CFR as directed by DOT.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.15	Exemptions from classification as fissile material	[B]	<p>This provision is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this provision in another portion of its regulations, such as the State's DOT regulations, then the adoption of this requirement is not necessary. Note: This provision was previously designated "NRC." It was changed to "B" to ensure compatibility between NRC and Agreement States in an area that has significant and direct transboundary implications. During further staff review, it was noted that the requirements in this section "Fissile material exemptions" is the same as those of DOT in 49 CFR 173.453, "Fissile materials exceptions." Staff noted that States adopt these DOT regulations as a part of their transportation regulations. Staff also noted that in accordance with § 150.11, an Agreement State can regulate the following fissile materials: U-235 in quantities not exceeding 350 grams, U-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams, or any combination of these materials that would be sufficient to form a critical mass. These requirements would apply to the materials Agreement States regulate. Thus, the compatibility of this requirement was changed to a "[B]," which indicates that if a State has adopted this provision as a part of the State's DOT regulations, then the adoption of this provision is not necessary.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.16	[RESERVED]		
§71.17	General license: NRC-approved package	[B]	This provision is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this provision in another portion of its regulations, such as the State's DOT regulations, then the adoption of this provision is not necessary.
§71.19	Previously approved package	NRC	This provision is reserved to the NRC because it addresses packages intended for both the storage and transportation of spent fuel.
§71.20	General license: DOT specification container material	[B]	This provision is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this provision in another portion of its regulations, such as the State's DOT regulations, then the adoption of this provision is not necessary.
§71.21	General license: Use of foreign approved package	[B]	This provision is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this provision in another portion of its regulations, such as the State's DOT regulations, then the adoption of this provision is not necessary.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.22	General license: Fissile material	[B]	<p>This provision is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this provision in another portion of its regulations, such as the State's DOT regulations, then the adoption of this provision is not necessary.</p> <p>Note: A similar provision was previously designated "NRC." It was changed to "B" to ensure compatibility between NRC and Agreement States in an area that has significant and direct transboundary implications. During further staff review, it was noted that in accordance with 10 CFR 150.11, an Agreement State can regulate the following fissile materials: U-235 in quantities not exceeding 350 grams, U-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams, or any combination of these materials that would be sufficient to form a critical mass. These requirements would apply to the materials Agreement States regulate. Thus, the compatibility of this requirement was changed to a "[B]," which indicates that if a State has adopted this provision as a part of the State's DOT regulations, then the adoption of this provision is not necessary.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.23	General license: Plutonium-beryllium special form material	[B]	This provision is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this provision in another portion of its regulations, such as the State's DOT regulations, then the adoption of this requirement is not necessary.
§71.24	[RESERVED]		
§71.25	[RESERVED]		
§71.31	Contents of Application	NRC	
§71.33.	Package description	NRC	
§71.35	Package evaluation	NRC	
§71.37	Quality Assurance	NRC	
§71.38	Renewal of a certificate of compliance or quality assurance program approval	NRC	
§71.39	Requirements for additional information	NRC	
§71.41	Demonstration of Compliance	NRC	This provision is designated NRC because it addresses an area reserved to NRC's regulatory authority.
§71.43	General Standards for all packages	NRC	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.45	Lifting and tie-down Standards for all packages	NRC	
§71.47	External radiation Standards for all packages	[B]	This requirement was changed from a compatibility category "NRC" to "[B]." This provision was changed because it establishes the external radiation standards for all transportation packages. It is essential that the Agreement States adopt this provision in an essentially identical manner because they have direct and significant transboundary effects. The bracket, "B," indicates that a State should adopt this provision in an essentially identical manner because of its direct and significant transboundary effects; however, if a State has adopted this provision as a part of its DOT regulations, then the adoption of this section is not necessary.
§71.51	Additional Requirements for Type B packages	NRC	This provision is designated NRC because it addresses an area reserved to NRC's regulatory authority.
§71.53	[RESERVED]		
§71.55	General Requirements for fissile material packages	NRC	This provision is designated NRC because it addresses an area reserved to NRC's regulatory authority.
§71.57	[RESERVED]		
§71.59	Standards for arrays of fissile material packages	NRC	This provision is designated NRC because it addresses an area reserved to NRC's regulatory authority.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.61	Special requirements for Type B packages containing more than $10^5 A_2$	NRC	This provision is designated NRC because it addresses an area reserved to NRC's regulatory authority.
§71.63	Special requirements for plutonium shipments	NRC	This provision is designated NRC because it addresses an area reserved to NRC's regulatory authority.
§71.64	Special requirements for plutonium air shipments	NRC	This provision is designated NRC because it addresses an area reserved to NRC's regulatory authority.
§71.65	Additional Requirements	NRC	This provision is designated NRC because it addresses an area reserved to NRC's regulatory authority.
§71.71	Normal conditions of transport	NRC	This provision is designated NRC because it addresses an area reserved to NRC's regulatory authority.
§71.73	Hypothetical accident conditions	NRC	This provision is designated NRC because it addresses an area reserved to NRC's regulatory authority.
§71.74	Accident conditions for air transport of plutonium	NRC	This provision is designated NRC because it addresses an area reserved to NRC's regulatory authority.
§71.75	Qualification of special form radioactive material	NRC	This provision is designated NRC because it addresses an area reserved to NRC's regulatory authority.
§71.77	Qualification of LSA-III material	NRC	This provision is designated NRC because it addresses an area reserved to NRC's regulatory authority.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.81	Applicability of operating controls	D	This requirement was changed from a compatibility category “B” to “D.” This designation was changed because it does not meet any of the criteria for designation as Category A, B, C or Health and Safety and is not required for the purposes of compatibility.
§71.83	Assumptions as to unknown properties	[B]	This requirement was changed from a compatibility category “NRC” to “[B].” Agreement States can regulate fissile material below 350g. This provision is needed to address fissile material regulated by the States and to assure that a regulatory gap in the regulations of these materials is not created. The bracket, “b,” indicates that a State should adopt this provision in an essentially identical manner because of its direct and significant transboundary effects; however, if a State has adopted this provision as a part of its DOT regulations, then the adoption of this section is not necessary.
§71.85	Preliminary determinations	[B]	This provision is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, “B,” indicates that if a State has adopted this provision in another portion of its regulations, such as the State’s DOT regulations, then the adoption of this provision is not necessary.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.87	Routine determinations	[B]	This provision is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this provision in another portion of its regulations, such as the State's DOT regulations, then the adoption of this provision is not necessary.
§71.88	Air transport of plutonium	[B]	This provision is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this provision in another portion of its regulations, such as the State's DOT regulations, then the adoption of this regulation is not necessary.
§71.89	Opening instructions	[B]	This provision is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this provision in another portion of its regulations, such as the State's DOT regulations, then the adoption of this regulation is not necessary.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.91	Records	D	This provision does not meet any of the criteria for designations Category A, B, C, or health and safety. Thus, it does not need to be adopted by Agreement States.
§71.93	Inspection and tests	D	This provision does not meet any of the criteria for designations Category A, B, C, or health and safety. Thus, it does not need to be adopted by Agreement States.
§71.95	Reports	D	This provision does not meet any of the criteria for designations Category A, B, C, or health and safety. Thus, it does not need to be adopted by Agreement States.
§71.97	Advance notification of shipment of irradiated reactor fuel and nuclear waste	B	This provision is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner.
§71.99	Violations	D	
§71.100	Criminal penalties	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.101	Quality assurance requirements	<p>D- Paragraphs (a), (b), and (c)(1) are designated D for those States which have no users of Type B packages-other than Industrial Radiography**</p> <p>C- Paragraphs (a), (b) and (c)(1) are designated C for those States which have users of Type B packages-other than Industrial Radiography.**</p> <p>D- paragraph (f)</p> <p>C- paragraph (g) NRC- paragraphs (c)(2), (d) and (e)</p> <p>**Note: 10 CFR 71.101(g) indicates that QA programs for industrial radiography Type B package users are covered by 10 CFR 34.31 (b). It also indicated that this section satisfies §71.12 (b) and thus would satisfy those sections referenced in this provision (§§ 71.101 through 71.137).</p>	<p>Paragraphs (a), (b), and (c)(1) are designated Category C and the essential objectives of these provisions should be adopted by those Agreement States which have licensees who use Type B packages. These provisions are designated Category C because the quality assurance of Type B packages is an activity that is needed in order to avoid a nationwide gap in the regulation of the transportation of radioactive materials. If these provisions are not adopted, this could result in undesirable consequences in multiple jurisdictions. The essential objective of paragraph (a) is that each licensee who uses a Type B package is responsible for the quality assurance requirements which apply to the use of a package. The essential objective of paragraph (b) is that each licensee who uses a Type B package shall establish, maintain, and execute a quality assurance program. The essential objective of paragraph (c)(1) is that each licensee who uses a Type B package shall, prior to the use of any package for the shipment of any material subject to this part, obtain approval of its quality assurance program by the regulatory agency.</p> <p>Paragraph (f) is not required for compatibility because the States have the flexibility to determine whether they wish to accept a previously approved quality assurance program.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.103	Quality assurance organization	<p>D- for those States which have no users of Type B packages-other than Industrial Radiography**</p> <p>[C]- Paragraph (a) is designated [C] for those States which have users of Type B packages-other than Industrial Radiography**</p> <p>C-Paragraph (b) is designated C for those States which have users of Type B packages-other than Industrial Radiography**</p> <p>D- paragraphs (d), (e), and (f)</p> <p>**Note: § 71.101 (g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31 (b). It also indicated that this section satisfies § 71.12 (b) and thus would satisfy those sections referenced in this provision (§§71.101 through 71.137).</p>	<p>For paragraph (a), those States which have licenses that use Type B packages, and have adopted the essential objectives of §71.101(a), it is not necessary for them to adopt this provision again.</p> <p>Paragraph (b) is designated as a Category C, and the essential objectives of these provisions should be adopted by those Agreement States which have licensees who use Type B packages. This provision is designated Category C because the quality assurance of Type B packages is an activity that is needed in order to avoid a nationwide gap in the regulation of the transportation of radioactive materials. If these provisions are not adopted, this could result in undesirable consequences in multiple jurisdictions. The essential objective of paragraph (b) is that each licensee who uses a Type B package should verify by procedures such as checking, auditing, and inspection, that activities affecting the safety-related functions have been performed correctly.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.105	Quality assurance program	<p>D- for those States which have no users of Type B packages-other than Industrial Radiography** or C- Paragraphs (a), (c), and (d) and [C] - paragraph b for those States which have users of Type B packages-other than Industrial Radiography**</p> <p>**Note: 10 CFR 71.101(g) indicates that QA programs for industrial radiography Type B package users are covered by 10 CFR 34.31(b). It also indicated that this section satisfies § 71.12(b) and thus would satisfy those sections referenced in this provision (§§ 71.101 through 71.137).</p>	<p>Para. (a) is designated [C] and para. (b) is designated C for those Agreement States with licensees that use Type B packages and the essential objectives of these provisions should be adopted by those Agreement States. These provisions are designated Category C because the QA of Type B packages is an activity that is needed in order to avoid a nationwide regulatory gap in the regulation of the transportation of radioactive materials. If these provisions are not adopted, this could result in undesirable consequences in multiple jurisdictions. The essential objective of para. (a) is that each licensee who uses a Type B package 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, and shall identify the material and components covered by the quality assurance program. The essential objective of para. (b) is that each licensee who uses a Type B package shall control activities affecting the safety-related functions of the Type B package. Para. (b) is a bracketed "C", because the essential objective of this provision is captured by § 71.103(b); if an Agreement State adopts the essential objectives of § 71.103(b), it is not necessary to adopt this provision again. The essential objective of para. (c) is that the licensee and certificate holder shall base its QA program on items listed in (1) through (5). The essential objective of para. (d) is that the licensee and certificate holder shall provide training of personnel performing activities affecting the quality of the package to assure proficiency in their knowledge of the QA program; review the status and adequacy of the QA program at established intervals; and regular management review of the QA program by all cognizant organizations participating in the program.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.107	Package design control	NRC	This provision is reserved to the NRC because it addresses the design, fabrication, modification, and approval of Type B packages.
§71.109	Procurement document control	NRC	This provision is reserved to the NRC because it addresses the design, fabrication, modification, and approval of Type B packages.
§71.111	Instructions, procedures, and drawings	NRC	This provision is reserved to the NRC because it addresses the design, fabrication, modification, and approval of Type B packages.
§71.113	Document control	NRC	This provision is reserved to the NRC because it addresses the design, fabrication, modification, and approval of Type B packages.
§71.115	Control of purchased material, equipment, and services	NRC	This provision is reserved to the NRC because it addresses the design, fabrication, modification, and approval of Type B packages.
§71.117	Identification and control of materials, parts, and components	NRC	This provision is reserved to the NRC because it addresses the design, fabrication, modification, and approval of Type B packages.
§71.119	Control of special processes	NRC	This provision is reserved to the NRC because it addresses the design, fabrication, modification, and approval of Type B packages.
§71.121	Internal Inspection	NRC	This provision is reserved to the NRC because it addresses the design, fabrication, modification, and approval of Type B packages.
§71.123	Test control	NRC	This provision is reserved to the NRC because it addresses the design, fabrication, modification, and approval of Type B packages.
§71.125	Control of measuring and test equipment	NRC	This provision is reserved to the NRC because it addresses the design, fabrication, modification, and approval of Type B packages.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.127	Handling, storage, and shipping control	<p>D- for those States which have no users of Type B packages-other than Industrial Radiography**</p> <p>[C]- for those States which have users of Type B packages-other than Industrial Radiography**</p> <p>**Note: 10 CFR 71.101 (g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.12(b) and thus would satisfy those sections referenced in this provision (§§ 71.101 through 71.137).</p>	<p>This provision is designated Category C for those States which have licensees that use Type B packages. This provision is designated Category C because the quality assurance of Type B packages is an activity that is needed in order to avoid a nationwide gap in the regulation of the transportation of radioactive materials. If this provision is not adopted, this could result in undesirable consequences in multiple jurisdictions. For those States which have licensees that use Type B packages, and have adopted the essential objectives of § 71.105, it is not necessary for them to adopt this provision again.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.129	Inspection, test, and operating status	<p>D- for those States which have no users of Type B packages-other than Industrial Radiography**</p> <p>[C]- for those States which have users of Type B packages-other than Industrial Radiography**</p> <p>**Note: 10 CFR 71.101 (g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.12(b) and thus would satisfy those sections referenced in this provision (§§ 71.101 through 71.137)..</p>	<p>This provision is designated Category C because the quality assurance of Type B packages is an activity that is needed in order to avoid a nationwide gap in the regulation of the transportation of radioactive materials. If this provision is not adopted, this could result in undesirable consequences in multiple jurisdictions. For those States which have licensees that use Type B packages, and have adopted the essential objectives of § 71.105, it is not necessary for them to adopt this provision again.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.131	Nonconforming materials, parts, or components	<p>D- for those States which have no users of Type B packages-other than Industrial Radiography**</p> <p>[C]- for those States which have users of Type B packages-other than Industrial Radiography**</p> <p>**Note: 10 CFR 71.101 (g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.12(b) and thus would satisfy those sections referenced in this provision (§§ 71.101 through 71.137).</p>	<p>This provision is designated Category C because the quality assurance of Type B packages is an activity that is needed in order to avoid a nationwide gap in the regulation of the transportation of radioactive materials. If this provision is not adopted, this could result in undesirable consequences in multiple jurisdictions. For those States which have licensees that use Type B packages, and have adopted the essential objectives of § 71.105, it is not necessary for them to adopt this provision again.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
71.133	Corrective action	<p>D- for those States which have no users of Type B packages-other than Industrial Radiography**</p> <p>C- for those States which have users of Type B packages-other than Industrial Radiography**</p> <p>**Note: 10 CFR 71.101 (g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.12(b) and thus would satisfy those sections referenced in this provision (§§ 71.101 through 71.137).</p>	<p>This provision is designated Category C for those States which have licensees that use Type B packages. This provision is designated Category C because the quality assurance of Type B packages is an activity that is needed in order to avoid a nationwide gap in the regulation of the transportation of radioactive materials. If this provision is not adopted, this could result in undesirable consequences in multiple jurisdictions. The essential objective of this provision is that each licensee who uses a Type B package 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.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.135	Quality assurance records	<p>D- for those States which have no users of Type B packages-other than Industrial Radiography**</p> <p>C- for those States which have users of Type B packages-other than Industrial Radiography**</p> <p>**Note: 10 CFR 71.101 (g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.12(b) and thus would satisfy those sections referenced in this provision (§§ 71.101 through 71.137).</p>	<p>This provision is designated a Category C for those States which have licensees that use Type B packages. This provision is designated Category C because the quality assurance of Type B packages is an activity that is needed in order to avoid a nationwide gap in the regulation of the transportation of radioactive materials. If this provision is not adopted, this could result in undesirable consequences in multiple jurisdictions. The essential objective of this provision is that each licensee who uses a Type B package shall maintain sufficient written records to demonstrate compliance with the quality assurance program.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.137	Audits	<p>D- for those States which have no users of Type B packages-other than Industrial Radiography**</p> <p>C - for those States which have users of Type B packages-other than Industrial Radiography**</p> <p>**Note: 10 CFR 71.101 (g) indicates that QA programs for industrial radiography Type B package users are covered by § 34.31(b). It also indicated that this section satisfies § 71.12(b) and thus would satisfy those sections referenced in this provision (§§ 71.101 through 71.137)..</p>	<p>This provision is designated a Category C for those States which have licensees that use Type B packages. This provision is designated Category C because the quality assurance of Type B packages is an activity that is needed in order to avoid a nationwide gap in the regulation of the transportation of radioactive materials. If this provision is not adopted, this could result in undesirable consequences in multiple jurisdictions. The essential objectives of this provision are that each licensee who uses a Type B package shall carry out a system of planned and periodic audits to: (1) verify compliance with all aspects of the quality assurance program, (2) determine the effectiveness of the program, (3) verify that the audits are performed by appropriately trained personnel, (4) audits performed in accordance with procedures; (5) audit results documented and reviewed by appropriate management; and (6) follow-up actions are taken as necessary.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
Appendix A	Determination of A ₁ and A ₂	[B]	This definition is designated Compatibility Category B because it applies to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. The bracket, "B," indicates that if a State has adopted this provision in another portion of its regulations, such as the State's DOT regulations, then the adoption of this requirement is not necessary.

VII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standard bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this rule, the NRC considered but decided not to adopt the ASME Code, Section III, Division 3, as described in Issue 14. However, NRC has amended its transportation regulations to make them compatible with the IAEA transportation standards. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

VIII. Environmental Assessment: Finding of No Significant Environmental Impact

The Commission has prepared an environmental assessment entitled Final Environmental Assessment (EA) of Major Revision of 10 CFR Part 71 (NUREG/CR-6711, **Insert New Date**), on this regulation. The EA is available on the NRC rulemaking website (<http://ruleforum.llnl.gov>) and is also available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Room O-1F21, Rockville, MD. The following is a brief summary of the EA.

The EA grouped the proposed action into 19 different changes to Part 71, which could be adopted either all together as one list or independently in a partial list. Of these 19 changes, the following 4 meet the NRC's categorical exclusion criteria:

- Changes to Various Definitions (Issue 9);
- Expansion of Part 71 Quality Assurance Requirements to Certificate of Compliance (CoC) Holders (Issue 13);
- Change Authority for Dual-Purpose Package Certificate Holders (Issue 15); and
- Modifications of Event Reporting Requirements (Issue 19).

None of the remaining 15 changes are expected to cause a significant impact to human health, safety, or the environment, whether issued altogether or individually. In fact, most of the changes would have negligible effects or result in slight improvements in health, safety, and environmental protection. In particular, the following changes are primarily administrative in nature, would not cause any new negative impacts, and would result in the beneficial effect of simplifying and/or harmonizing the NRC's regulations with TS-R-1:

- Changing Part 71 to the International System of Units (SI) Only (Issue 1);
- Revision of A_1 and A_2 (Issue 3);

- A new requirement to display the Criticality Safety Index on shipping packages of fissile material (Issue 5);
- A provision to “grandfather” older shipping packages under the Part 71 requirements in existence when their Certificates of Compliance were issued (Issue 8); and
- Procedures for approval of special arrangements for shipment of special packages (Issue 12).

The following changes would result in slight net improvements in health, safety, and environmental protection:

- Addition of uranium hexafluoride package requirements (Issue 4);
- Strengthening the requirements in § 71.61 to ensure package containment in deep submersion scenarios (Issue 7);
- Adoption of the crush test for fissile material package design (Issue 10);
- Adoption of fissile material package design requirements for transport by aircraft (Issue 11); and
- Adoption of the ASME Code for spent fuel transportation casks (Issue 14).

The proposal to change the existing 70-Bq/g (0.002- μ Ci/g) level to radionuclide-specific activity limits (Issue 2) is expected to have mixed, although overall minor, effects. For radionuclides with new exemption values that are lower than the current limit, there could be a decrease in the number of exempted shipments and a commensurate slight increase in the level of protection. For radionuclides with new exemption values that are higher than the current limit, there could be an increase in the number of exempted shipments and a commensurate slight increase in associated radiation exposures. However, IAEA and the NRC have determined that this change would not significantly increase the risk to individuals.

The addition of the Type C package and low level dispersible material concepts (Issue 6) would result in mixed, although overall minor, effects. If the same number of packages are handled, the radiation doses to workers loading and unloading Type C packages shipped by air will be slightly higher than the doses to workers loading and unloading other kinds of packages shipped by other means. At the same time, "incident-free" doses during the shipping of Type C packages are expected to be slightly reduced compared to baseline conditions, while the risks associated with accidents during shipping could be slightly increased or decreased depending on the shipping scenario.

Changes to transportation regulations for fissile materials actually consist of 17 individual recommendations for revisions to Part 71 (Issue 16). Ten of these recommendations are expected to result in no impact, as they simply clarify definitions, consolidate related requirements into single sections, or streamline the regulations. Four of the recommendations will result in small improvements to health, safety, and environmental protection by eliminating confusion among licensees and/or providing added assurance for critical safety. The last two recommendations, which would revise exemptions for low-level material and remove or modify provisions related to the shipment of Pu-Be neutron sources, are expected to significantly improve criticality safety.

Changes to the requirements for plutonium shipments in § 71.63 (PRM-71-12) could result in a slight increase in the probability and consequences of accidental releases, primarily when and if plutonium is shipped in liquid form. However, most plutonium shipments are either related to the disposition of plutonium wastes or to the production of mixed oxides, neither of which involve the shipment of a liquid solution of plutonium.

No changes have been identified for the issue related to surface contamination limits as applied to spent fuel and high level waste (Issue 18). The issue was included in the proposed

rule in response to Commission direction in SRM-SECY-00-0117. NRC is seeking input on whether the NRC should address this issue in future rulemaking activities. As a result, no regulatory options were developed, and therefore no environmental assessment conducted.

The Commission has determined, under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule is not a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement (EIS) is not required.

The Commission's "Final Environmental Statement on the Transportation of Radioactive Material by Air and Other Modes," NUREG-0170¹⁴, dated December 1977, is NRC's generic EIS, covering all types of radioactive material transportation by all modes (road, rail, air, and water). From the Commission's latest survey of radioactive material shipments and their characteristics, "Transport of Radioactive Material in the United States," SAND 84-7174, April 1985, the NRC concluded that current radioactive material shipments are not so different from those evaluated in NUREG-0170 as to invalidate the results or conclusions of that EIS. The environmental assessment of the impacts associated with this rulemaking is evaluated in Final Environmental Assessment (EA) of Major Revision of 10 CFR Part 71 (NUREG/CR-6711, **Insert New Date**).

NUREG-0170 established the nonaccident related radiation exposures associated with transportation of radioactive material in the United States as 98 person-Sv (9800 person-rem) which, based on the conservative linear radiation dose hypothesis, resulted in a maximum of

¹⁴ Copies of NUREG-0170 may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is also available for inspection and copying for a fee in the NRC Public Document Room, 11555 Rockville Pike, Room O-1F21, Rockville, MD.

1.7 genetic effects and 1.2 latent cancer effects per year. More than half this impact resulted from shipment of medical-use radioactive materials. Accident related impacts were established at a maximum of one genetic effect and one latent cancer fatality for 200 years of transporting radioactive materials. The principal nonradiological impacts were found to be two injuries per year and less than one accidental death per 4 years. In contrast, nonaccident related radiation exposures and accident related impacts associated with this rulemaking would not change from the impact of the current Part 71 requirements (i.e., no increase or decrease). Nonradiological traffic injuries and nonradiological traffic deaths would not change. These impacts are judged to be insignificant compared with the baseline impacts established in NUREG-0170.

IX. Paperwork Reduction Act Statement

The rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

The burden to the public for these information collections is estimated to average 16.3 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

X. Regulatory Analysis

The Commission has prepared a regulatory analysis entitled "Final Regulatory Analysis of Major Revision of 10 CFR Part 71 - NUREG/CR-6713, **Insert New Date.** " To support the discussions of the proposed changes, selected material from this regulatory analysis has been included earlier under each issue. The analysis examines the costs and benefits of the alternatives considered by the Commission. The regulatory analysis is available on the NRC rulemaking website, and is also available for inspection at the NRC Public Document Room, 11555 Rockville Pike, Room O-1F21, Rockville, MD.

XI. Regulatory Flexibility Act Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule affects NRC licensees, including operators of nuclear power plants, who transport or deliver to a carrier for transport, relatively large quantities of radioactive material in a single package. These companies do not generally fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards adopted by the NRC (10 CFR 2.810).

Only one small entity commented on the proposed changes suggesting that small entities would be negatively affected by the rule. Reviewing records of licensed QA programs, NRC found that only 15 of the 127 NRC-licensed QA programs were small entities. Furthermore, of these 15 companies, NRC staff expects that only two or three would be negatively affected by the final rule, given these companies' lines of business and day-to-day

operations. Based on these data, it is believed there will not be significant economic impacts for a substantial number of small entities.

XII. Backfit Analysis

The NRC has determined that the backfit rule does not apply to this rule; therefore, a backfit analysis is not required for this rule because these amendments do not involve any provisions that would require backfits as defined in 10 CFR Chapter I.

List of Subjects in 10 CFR Part 71

Criminal penalties, Hazardous materials transportation, Nuclear materials, Packaging and containers, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the Commission is adopting the following amendments to 10 CFR Part 71.

PART 71 -- PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

1. The authority citation for Part 71 continues to read as follows:

AUTHORITY: Secs. 53, 57, 62, 63, 81, 161, 182, 183, 234 68 Stat. 930, 932, 933, 935, 948, 953, 954, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C.2073,2077,2092,

2093, 2111, 2201, 2232, 2233, 2297f); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846);

Section 71.97 also issued under sec. 301, Pub. L. 96-295, 94 Stat. 789-790.

2. Subparts A, B, and C to Part 71 are revised to read as follows:

Subpart A - General Provisions

Sec.

71.0 Purpose and scope.

71.1 Communications and records.

71.2 Interpretations.

71.3 Requirement for license.

71.4 Definitions.

71.5 Transportation of licensed material.

71.6 Information collection requirements: OMB approval.

71.7 Completeness and accuracy of information.

71.8 Deliberate misconduct.

71.9 Employee protection.

71.10 Public inspection of application.

71.11 [Reserved]

Subpart B - Exemptions

Sec.

71.12 Specific exemptions.

71.13 Exemption of physicians.

71.14 Exemption for low-level materials.

71.15 Exemption from classification as fissile material.

71.16 [Reserved]

Subpart C - General Licenses

Sec.

71.17 General license: NRC-approved package.

71.18 Reserved.

71.19 Previously approved package.

71.20 General license: DOT specification container.

71.21 General license: Use of foreign approved package.

71.22 General license: Fissile material.

71.23 General license: Plutonium-beryllium special form material.

71.24 [Reserved]

71.25 [Reserved]

Subpart A - General Provisions

§ 71.0 Purpose and scope.

(a) This part establishes --

(1) Requirements for packaging, preparation for shipment, and transportation of licensed material; and

(2) Procedures and standards for NRC approval of packaging and shipping procedures for fissile material and for a quantity of other licensed material in excess of a Type A quantity.

(b) The packaging and transport of licensed material are also subject to other parts of this chapter (e.g., 10 CFR parts 20, 21, 30, 40, 70, and 73) and to the regulations of other agencies (e.g., the U.S. Department of Transportation (DOT) and the U.S. Postal Service¹) having jurisdiction over means of transport. The requirements of this part are in addition to, and not in substitution for, other requirements.

(c) The regulations in this part apply to any licensee authorized by specific or general license issued by the Commission 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 NRC license, or transports that material on public highways. No provision of this part authorizes possession of licensed material.

(d)(1) Exemptions from the requirement for license in § 71.3 are specified in § 71.14. General licenses for which no NRC package approval is required are issued in §§ 71.20 through 71.23. The general license in § 71.17 requires that an NRC certificate of compliance or other package approval be issued for the package to be used under this general license.

(2) Application for package approval must be completed in accordance with subpart D of this part, demonstrating that the design of the package to be used satisfies the package approval standards contained in subpart E of this part, as related to the tests of subpart F of this part.

(3) A licensee transporting licensed material, or delivering licensed material to a carrier for transport, shall comply with the operating control requirements of subpart G of this part; the quality assurance requirements of subpart H of this part; and the general provisions of subpart A of this part, including DOT regulations referenced in § 71.5.

¹ Postal Service manual (Domestic Mail Manual), Section 124, which is incorporated by reference at 39 CFR 111.1.

(e) The regulations of this part apply to any person holding, or applying for, a certificate of compliance, issued pursuant to this part, for a package intended for the transportation of radioactive material, outside the confines of a licensee's facility or authorized place of use.

(f) The regulations in this part apply to any person required to obtain a certificate of compliance, or an approved compliance plan, pursuant to part 76 of this chapter, 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.

(g) This part also gives notice to all persons who knowingly provide to any licensee, certificate holder, quality assurance program approval holder, applicant for a license, certificate, or quality assurance program approval, or to a contractor, or subcontractor of any of them, components, equipment, materials, or other goods or services, that relate to a licensee's, certificate holder's, quality assurance program approval holder's, or applicant's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of § 71.8.

§ 71.1 Communications and records.

(a) Except where otherwise specified, all communications and records concerning the regulations in this part, and applications filed under them, should be addressed to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk. Written communications, reports, and applications may be delivered in person to the U.S. NRC, ATTN: Document Control Desk, at One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738 between 7:30 a.m. and 4:15 p.m., Federal workdays. If the submittal deadline date falls on a Saturday, Sunday, or a Federal holiday, the next Federal workday becomes the official due date.

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

§ 71.2 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission, other than a written interpretation by the General Counsel, will be recognized to be binding upon the Commission.

§ 71.3 Requirement for license.

Except as authorized in a general license or a specific license issued by the Commission, or as exempted in this part, no licensee may --

- (a) Deliver licensed material to a carrier for transport; or
- (b) Transport licensed material.

§ 71.4 Definitions.

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

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 this part, or may be derived in accordance with the procedures prescribed in Appendix A of this part.

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 this part, or may be derived in accordance with the procedures prescribed in Appendix A of this part.

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

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

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

Consignment means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

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

Conveyance means:

- (1) For transport by public highway or rail any transport vehicle or large freight container;
- (2) For transport by water any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and
- (3) For transport by any aircraft.

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

Fissile material means the radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, 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 § 71.15.

Graphite means, for the purposes of §§ 71.15 and 71.22, graphite with a boron equivalent content less than 5 parts per million and density greater than 1.5 grams per cubic centimeter.

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

Low Specific Activity (LSA) material means radioactive material with limited specific activity which is nonfissile or is excepted under § 71.15, 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 naturally occurring radioactive radionuclides which are not intended to be processed for the use of these radionuclides;

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

(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 Appendix A.

(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 $10^{-4} A_2/g$ 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 § 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.);

(ii) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for 7 days, would not exceed $0.1 A_2$; and

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

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 tailings; or alpha emitters with a half-life of less than 10 days.

Maximum normal operating pressure means the maximum gauge pressure that would develop in the containment system in a period of 1 year under the heat condition specified in

§ 71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport.

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

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

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

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

(1) *Fissile material package 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.

(3) *Type B package* means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC 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 § 71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT

regulations in 49 CFR Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in § 71.19.

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

Special form radioactive material means radioactive material that satisfies the following conditions:

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

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

(3) It satisfies the requirements of § 71.75. A special form encapsulation designed in accordance with the requirements of § 71.4 in effect on June 30, 1983 (see 10 CFR part 71, revised as of January 1, 1983), and constructed before July 1, 1985, and a special form encapsulation designed in accordance with the requirements of § 71.4 in effect on March 31, 1996 (see 10 CFR part 71, revised as of January 1, 1983), and constructed before April 1, 1998, may continue to be used. Any other special form encapsulation must meet the specifications of this definition.

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

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.

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

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

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

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

(ii) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $4 \times 10^4\text{ Bq/cm}^2$ (1.0 microcurie/ cm^2) for beta and gamma and low toxicity alpha emitters, or $4 \times 10^3\text{ Bq/cm}^2$ (0.1 microcurie/ cm^2) for all other alpha emitters; and

(iii) The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $4 \times 10^4\text{ Bq/cm}^2$ (1 microcurie/ cm^2) for beta and gamma and low toxicity alpha emitters, or $4 \times 10^3\text{ Bq/cm}^2$ (0.1 microcurie/ cm^2) for all other alpha emitters.

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

(i) The nonfixed contamination on the accessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 400 Bq/cm² (10⁻² microcurie/cm²) for beta and gamma and low toxicity alpha emitters or 40 Bq/cm² (10⁻³ microcurie/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 8x10⁵ Bq/cm² (20 microcuries/cm²) for beta and gamma and low toxicity alpha emitters, or 8x10⁴ Bq/cm² (2 microcuries/cm²) for all other alpha emitters; and

(iii) The 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 8x10⁵ Bq/cm² (20 microcuries/cm²) for beta and gamma and low toxicity alpha emitters, or 8x10⁴ Bq/cm² (2 microcuries/cm²) for all other alpha emitters.

Transport index (TI) means the dimensionless number (rounded up to the next tenth) placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at 1 meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at 1 meter (3.3 ft)).

Type A quantity means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A₁ for special form radioactive material, or A₂, for normal form radioactive material, where A₁ and A₂ are given in Table A - 1 of this part, or may be determined by procedures described in Appendix A of this part.

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

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.

§ 71.5 Transportation of licensed material.

(a) Each licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the DOT regulations in 49 CFR parts 170 through 189 appropriate to the mode of transport.

(1) The licensee shall particularly note DOT regulations in the following areas:

(i) Packaging -- 49 CFR part 173: Subparts A, B, and I.

(ii) Marking and labeling -- 49 CFR part 172: Subpart D, §§ 172.400 through 172.407, §§ 172.436 through 172.440, and Subpart E.

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

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

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

(vi) Hazardous material employee training -- 49 CFR part 172: Subpart H.

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

(2) The licensee shall also note DOT regulations pertaining to the following modes of transportation:

(i) Rail -- 49 CFR part 174: Subparts A through D and K.

(ii) Air -- 49 CFR part 175.

(iii) Vessel -- 49 CFR part 176: Subparts A through F and M.

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

(b) If DOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the DOT specified in paragraph (a) of this section to the same extent as if the shipment or transportation were subject to DOT regulations. A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

§ 71.6 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0008.

(b) The approved information collection requirements contained in this part appear in §§ 71.5, 71.7, 71.9, 71.12, 71.17, , 71.19, 71.20, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.47, 71.85, 71.87, 71.89, 71.91, 71.93, 71.95, 71.97, 71.101, 71 103, 71.105, 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, 71.125, 71.127, 71.129, 71.131, 71.133, 71.135, 71.137, and Appendix A.

§ 71.7 Completeness and accuracy of information.

(a) Information provided to the Commission by a licensee, certificate holder, or an applicant for a license or CoC; or information required by statute or by the Commission's regulations, orders, license or CoC conditions, to be maintained by the licensee or certificate holder, must be complete and accurate in all material respects.

(b) Each licensee, certificate holder, or applicant for a license or CoC must notify the Commission of information identified by the licensee, certificate holder, or applicant for a license or CoC as having, for the regulated activity, a significant implication for public health and safety or common defense and security. A licensee, certificate holder, or an applicant for a license or CoC violates this paragraph only if the licensee, certificate holder, or applicant for a license or CoC fails to notify the Commission of information that the licensee, certificate holder, or applicant for a license or CoC has identified as having a significant implication for public health and safety or common defense and security. Notification must be provided to the Administrator of the appropriate Regional Office within 2 working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements.

§ 71.8 Deliberate misconduct.

(a) This section applies to any--

(1) Licensee;

(2) Certificate holder;

(3) Quality assurance program approval holder;

(4) Applicant for a license, certificate, or quality assurance program approval;

(5) Contractor (including a supplier or consultant) or subcontractor, to any person identified in paragraph (a)(4) of this section; or

(6) Employees of any person identified in paragraphs (a)(1) through (a)(5) of this section.

(b) A person identified in paragraph (a) of this section who knowingly provides to any entity, listed in paragraphs (a)(1) through (a)(5) of this section, any components, materials, or other goods or services that relate to a licensee's, certificate holder's, quality assurance program approval holder's, or applicant's activities subject to this part may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, 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, certificate, or approval issued by the Commission; or

(2) Deliberately submit to the NRC, a licensee, a certificate holder, quality assurance program approval holder, an applicant for a license, certificate or quality assurance program approval, or a licensee'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 NRC.

(c) A person who violates paragraph (b)(1) or (b)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.

(d) For the purposes of paragraph (b)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee, certificate holder, quality assurance program approval holder, or applicant for a license, 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 certificate issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate holder, quality assurance program approval holder, applicant, or the contractor or subcontractor of any of them.

§ 71.9 Employee protection.

(a) Discrimination by a Commission licensee, certificate holder, an applicant for a Commission license or a CoC, or a contractor or subcontractor of any of these, against an employee for engaging in certain protected activities, is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, as amended.

(1) The protected activities include, but are not limited to:

(i) Providing the Commission or his or her employer information about alleged violations of either of the statutes named in paragraph (a) of this section or possible violations of requirements imposed under either of those statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in paragraph (a) of this section or under these requirements if the employee has identified the alleged illegality to the employer;

(iii) Requesting the Commission to institute action against his or her employer for the administration or enforcement of these requirements;

(iv) Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in paragraph (a) of this section; and

(v) Assisting or participating in, or is about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee's assistance or participation.

(3) This section has no application to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraph (a), (e), or (f) of this section by a Commission licensee, certificate holder, applicant for a Commission license or a CoC, or a contractor or subcontractor of any of these may be grounds for:

- (1) Denial, revocation, or suspension of the license or the CoC;
- (2) Imposition of a civil penalty on the licensee or applicant; or
- (3) Other enforcement action.

(d) Actions taken by an employer, or others, which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e)(1) Each licensee, certificate holder, and applicant for a license or CoC must prominently post the current revision of NRC Form 3, "Notice to Employees," referenced in § 19.11(c) of this chapter. This form must be posted at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. The premises must be posted not later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license or CoC, and for 30 days following license or CoC termination.

(2) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in Appendix D to part 20 of this chapter or by calling the NRC Publishing Services Branch at 301-415-5877.

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the

Department of Labor pursuant to section 211 of the Energy Reorganization Act of 1974, as amended, may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in a protected activity as defined in paragraph (a)(1) of this section including, but not limited to, providing information to the NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

§ 71.10 Public inspection of application.

Applications for approval of a package design under this part, which are submitted to the Commission, may be made available for public inspection, in accordance with provisions of parts 2 and 9 of this chapter. This includes an application to amend or revise an existing package design, any associated documents and drawings submitted with the application, and any responses to NRC requests for additional information.

§ 71.11 [Reserved]

Subpart B - Exemptions

§ 71.12 Specific exemptions.

On application of any interested person or on its own initiative, the Commission may grant any exemption from the requirements of the regulations in this part that it determines is authorized by law and will not endanger life or property nor the common defense and security.

§ 71.13 Exemption of physicians.

Any physician licensed by a State to dispense drugs in the practice of medicine is exempt from § 71.5 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.

§ 71.14 Exemption for low-level materials.

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

(1) Natural material and ores containing naturally occurring radionuclides that are 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 this part.

(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 this part.

(b) A licensee is exempt from all the requirements of this part, other than §§ 71.5 and 71.88, with respect to shipment or carriage of the following packages, provided the packages do not contain any fissile material, or the material is exempt from classification as fissile material under § 71.15:

(1) A package that contains no more than a Type A quantity of radioactive material.

(2) A package transported within the United States that contains no more than 0.74 TBq (20 Ci) of special form plutonium-244; or

- (3) The package contains only LSA or SCO radioactive material, provided —
 - (i) That the LSA or SCO material has an external radiation dose of less than or equal to 10 mSv/h (1 rem/h), at a distance of 3 m from the unshielded material; or
 - (ii) That the package contains only LSA-I or SCO-I material.

§ 71.15 Exemption from classification as fissile material.

Fissile material meeting the requirements of at least one of the paragraphs (a) through (f) of this section are exempt from classification as fissile material and from the fissile material package standards of §§ 71.55 and 71.59, but are subject to all other requirements of this part, except as noted.

- (a) Individual package containing 2 grams or less fissile material.
- (b) 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.
- (c)(1) 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.

(2) 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.

(d) 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.

(e) 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.

(f) 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.

§ 71.16 [Reserved]

Subpart C - General Licenses

§ 71.17 General license: NRC-approved package.

(a) A general license is issued to any licensee of the Commission to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance (CoC), or other approval has been issued by the NRC.

(b) This 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 this part.

(c) This general license applies only to a licensee who --

(1) Has a copy of the CoC, 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 this part; and

(3) Submits in writing to the NRC, 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. A licensee shall submit this information in accordance with § 71.1.

(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 NRC before April 1, 1996, the general license is subject to the additional restrictions of § 71.19.

§ 71.18 [Reserved.]

§71.19 Previously approved package.

(a) A Type B package previously approved by NRC, but not designated as B(U), B(M), B(U)F, B(M)F, in the identification number of the NRC CoC, or Type AF packages approved by the NRC prior to September 6, 1983, may be used under the general license of § 71.17 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 § 71.85(c);

(2) A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging; and

(3) Paragraph (a) of this section expires (insert date 4 years after the effective date of this final rule). The effective date of this final rule is 1 year from the publication date in the Federal Register.

(b) A Type B(U) package, a Type B(M) package, or a fissile material package, previously approved by the NRC but without the designation "-85" in the identification number of the NRC CoC, may be used under the general license of § 71.17 with the following additional conditions:

(1) Fabrication of the package is satisfactorily completed by April 1, 1999, as demonstrated by application of its model number in accordance with § 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 DOT regulations at 49 CFR 173.403; and

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

(c) A Type B(U) package, a Type B(M) package, or a fissile material package previously approved by the NRC with the designation "-85" in the identification number of the NRC CoC, may be used under the general license of § 71.17 with the following additional conditions:

(1) Fabrication of the package must be satisfactorily completed by December 31, 2007, as demonstrated by application of its model number in accordance with § 71.85(c); and

(2) After December 31, 2003, a package used for a shipment to a location outside the United States is subject to multilateral approval as defined in DOT regulations at 49 CFR 173.403.

(d) NRC will approve modifications to the design and authorized contents of a Type B package, or a fissile material package, previously approved by NRC, provided --

(1) The modifications of a Type B package are not significant with respect to the design, operating characteristics, or safe performance of the containment system, when the package is subjected to the tests specified in §§ 71.71 and 71.73;

(2) The modifications of a fissile material package are not significant, with respect to the prevention of criticality, when the package is subjected to the tests specified in §§ 71.71 and 71.73; and

(3) The modifications to the package satisfy the requirements of this part.

(e) NRC will revise the package identification number to designate previously approved package designs as B, BF, AF, B(U), B(M), B(U)F, B(M)F, B(U)-85, B(U)F-85, B(M)-85, B(M)F-85, or AF-85 as appropriate, and with the identification number suffix "-96" after receipt of an application demonstrating that the design meets the requirements of this part.

§ 71.20 General license: DOT specification container.

(a) A general license is issued to any licensee of the Commission to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in DOT regulations at 49 CFR parts 173 and 178.

(b) This general license applies only to a licensee who has a quality assurance program approved by the Commission as satisfying the provisions of subpart H of this part.

(c) This general license applies only to a licensee who --

(1) Has a copy of the specification; and

(2) Complies with the terms and conditions of the specification and the applicable requirements of subparts A, G, and H of this part.

(d) This general license is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States, except by multilateral approval, as defined in DOT regulations at 49 CFR 173.403.

(e) This section expires (insert date 3 years after the effective date of this rule).

§ 71.21 General license: Use of foreign approved package.

(a) A general license is issued to any licensee of the Commission to transport, or to deliver to a carrier for transport, licensed material in a package, the design of which has been approved in a foreign national competent authority certificate, that has been revalidated by DOT as meeting the applicable requirements of 49 CFR 171.12.

(b) Except as otherwise provided in this section, the general license applies only to a licensee who has a quality assurance program approved by the Commission as satisfying the applicable provisions of subpart H of this part.

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

(d) This general license applies only to a licensee who --

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

(2) Complies with the terms and conditions of the certificate and revalidation, and with the applicable requirements of subparts A, G, and H of this part. With respect to the quality assurance provisions of subpart H of this part, the licensee is exempt from design, construction, and fabrication considerations.

§ 71.22 General license: Fissile material.

(a) A general license is issued to any licensee of the Commission to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section. The fissile material need not be contained in a package which meets the standards of subparts E and F of this part; 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 this part.

(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 paragraph (e) of this section;
- (2) Has a value less than or equal to 10; and

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

(e)(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 71-1 or 71-2, as appropriate;

(4) If Table 71-2 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 71-1 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 71-1. MASS LIMITS FOR GENERAL LICENSE PACKAGES CONTAINING MIXED QUANTITIES OF FISSILE MATERIAL OR URANIUM-235 OF UNKNOWN ENRICHMENT PER § 71.22(e)

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 71-2 — MASS LIMITS FOR GENERAL LICENSE PACKAGES CONTAINING URANIUM-235 OF KNOWN ENRICHMENT PER § 71.22(e)

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

§ 71.23 General license: Plutonium-beryllium special form material.

(a) A general license is issued to any licensee of the Commission to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with this section. This material need not be contained in a package which meets the standards of subparts E and F of this part; 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 this part.

(c) The general license applies only when a package's contents:

(1) Contain less than a Type A quantity of 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 paragraph (e) of this section;

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

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

(e)(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.

§ 71.24 [Reserved]

§ 71.25 [Reserved]

3. In § 71.41, paragraph (a) is revised, and a new paragraph (d) is added to read as follows:

§ 71.41 Demonstration of compliance.

(a) The effects on a package of the tests specified in § 71.71 ("Normal conditions of transport"), and the tests specified in § 71.73 ("Hypothetical accident conditions"), and § 71.61 ("Special requirements for Type B packages containing more than 10^5 A₂"), must be evaluated by subjecting a specimen or scale model to a specific test, or by another method of demonstration acceptable to the Commission, as appropriate for the particular feature being considered.

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(d) Packages for which compliance with the other provisions of these regulations is impracticable shall not be transported except under special package authorization. Provided the applicant demonstrates that compliance with the other provisions of the regulations is impracticable and that the requisite standards of safety established by these regulations have been demonstrated through means alternative to the other provisions, a special package

authorization may be approved for one-time shipments. The applicant shall demonstrate that the overall level of safety in transport for these shipments is at least equivalent to that which would be provided if all the applicable requirements had been met.

4. In § 71.51, the introductory text of paragraph (a) is revised, and a new paragraph (d) is added to read as follows:

§ 71.51 Additional requirements for Type B packages.

(a) A Type B package, in addition to satisfying the requirements of §§ 71.41 through 71.47, must be designed, constructed, and prepared for shipment so that under the tests specified in:

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(d) For packages which contain radioactive contents with activity greater than $10^5 A_2$, the requirements of § 71.61 must be met.

§ 71.53 [Reserved]

5. Section 71.53 is removed and reserved.

6. In § 71.55, the introductory text of paragraph (b) is revised, and new paragraphs (f) and (g) are added to read as follows:

§ 71.55 General requirements for fissile material packages.

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(b) Except as provided in paragraph (c) or (g) of this section, a package used for the shipment of fissile material must be so designed and constructed and its contents so limited that it would be subcritical if water were to leak into the containment system, or liquid contents were to leak out of the containment system so that, under the following conditions, maximum reactivity of the fissile material would be attained:

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(f) For fissile material package designs to be transported by air:

(1) The package must be designed and constructed, and its contents limited so that it would be subcritical, assuming reflection by 20 cm (7.9 in) of water but no water inleakage, when subjected to sequential application of:

(i) The free drop test in § 71.73(c)(1);

(ii) The crush test in § 71.73(c)(2);

(iii) A puncture test, for packages of 250 kg or more, consisting of a free drop of the specimen through a distance of 3 m (120 in) in a position for which maximum damage is expected at the conclusion of the test sequence, onto the upper end of a solid, vertical, cylindrical, mild steel probe mounted on an essentially unyielding, horizontal surface. The probe must be 20 cm (7.9 in) in diameter, with the striking end forming the frustum of a right circular cone with the dimensions of 30 cm height, 2.5 cm top diameter, and a top edge rounded to a radius of not more than 6 mm (0.25 in). For packages less than 250 kg, the puncture test must be the same, except that a 250 kg probe must be dropped onto the specimen which must be placed on the surface; and

(iv) The thermal test in § 71.73(c)(4), except that the duration of the test must be 60 minutes.

(2) The package must be designed and constructed, and its contents limited, so that it would be subcritical, assuming reflection by 20 cm (7.9 in) of water but no water inleakage, when subjected to an impact on an unyielding surface at a velocity of 90 m/s normal to the surface, at such orientation so as to result in maximum damage. A separate, undamaged specimen can be used for this evaluation.

(3) Allowance may not be made for the special design features in paragraph (c) of this section, unless water leakage into or out of void spaces is prevented following application of the tests in paragraphs (f)(1) and (f)(2) of this section, and subsequent application of the immersion test in § 71.73(c)(5).

(g) Packages containing uranium hexafluoride only are excepted from the requirements of paragraph (b) of this section provided that:

(1) Following the tests specified in § 71.73 ("Hypothetical accident conditions"), there is no physical contact between the valve body and any other component of the packaging, other than at its original point of attachment, and the valve remains leak tight;

(2) There is an adequate quality control in the manufacture, maintenance, and repair of packagings;

(3) Each package is tested to demonstrate closure before each shipment; and

(4) The uranium is enriched to not more than 5 weight percent uranium-235.

7. In § 71.59, paragraphs (b) and (c) are revised to read as follows:

§ 71.59 Standards for arrays of fissile material packages.

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(b) The CSI must be determined by dividing the number 50 by the value of "N" derived using the procedures specified in paragraph (a) of this section. The value of the CSI may be zero provided that an unlimited number of packages are subcritical, such that the value of "N" is effectively equal to infinity under the procedures specified in paragraph (a) of this section. Any CSI greater than zero must be rounded up to the first decimal place.

(c) For a fissile material package which is assigned a CSI value —

(1) Less than or equal to 50, that package may be shipped by a carrier in a nonexclusive use conveyance, provided the sum of the CSIs is limited to less than or equal to 50.

(2) Less than or equal to 50, that package may be shipped by a carrier in an exclusive use conveyance, provided the sum of the CSIs is limited to less than or equal to 100.

(3) Greater than 50, that package must be shipped by a carrier in an exclusive use conveyance, provided the sum of the CSIs is limited to less than or equal to 100.

8. Section 71.61 is revised to read as follows:

§ 71.61 Special requirements for Type B packages containing more than $10^5 A_2$.

A Type B package containing more than $10^5 A_2$ must be designed so that its undamaged containment system can withstand an external water pressure of 2 MPa (290 psi) for a period of not less than 1 hour without collapse, buckling, or inleakage of water.

9. Section 71.63 is revised to read as follows:

§ 71.63 Special requirement for plutonium shipments.

Shipments containing plutonium must be made with the contents in solid form, if the contents contain greater than 0.74 TBq (20 Ci) of plutonium.

10. In § 71.73, paragraph (c)(2) is revised to read as follows:

§ 71.73 Hypothetical accident conditions.

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(c) ★ ★ ★

(2) *Crush.* Subjection of the specimen to a dynamic crush test by positioning the specimen on a flat, essentially unyielding horizontal surface so as to suffer maximum damage by the drop of a 500-kg (1100-lb) mass from 9 m (30 ft) onto the specimen. The mass must consist of a solid mild steel plate 1 m (40 in) by 1 m (40 in) and must fall in a horizontal attitude. The crush test is required only when the specimen has a mass not greater than 500 kg (1100 lb), an overall density not greater than 1000 kg/m³ (62.4 lb/ft³) based on external dimension, and radioactive contents greater than 1000 A₂ not as special form radioactive material. For packages containing fissile material, the radioactive contents greater than 1000 A₂ criterion does not apply.

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11. In § 71.88, paragraph (a)(2) is revised to read as follows:

§ 71.88 Air transport of plutonium.

(a) ★ ★ ★

(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 Appendix A, Table A-2, of this part, and in which the radioactivity is essentially uniformly distributed; or

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12. In § 71.91, paragraphs (b) and (c) are revised, and a new paragraph (d) is added to read as follows:

§ 71.91 Records.

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(b) Each certificate holder shall maintain, for a period of 3 years after the life of the packaging to which they apply, records identifying the packaging by model number, serial number, and date of manufacture.

(c) The licensee, certificate holder, and an applicant for a CoC, shall make available to the Commission for inspection, upon reasonable notice, all records required by this part. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.

(d) The licensee, certificate holder, and an applicant for a CoC 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 § 71.85; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any

deficiencies noted. These records must be retained for 3 years after the life of the packaging to which they apply.

13. Section 71.93 is revised to read as follows:

§ 71.93 Inspection and tests.

(a) The licensee, certificate holder, and applicant for a CoC shall permit the Commission, at all reasonable times, to inspect the licensed material, packaging, premises, and facilities in which the licensed material or packaging is used, provided, constructed, fabricated, tested, stored, or shipped.

(b) The licensee, certificate holder, and applicant for a CoC shall perform, and permit the Commission to perform, any tests the Commission deems necessary or appropriate for the administration of the regulations in this chapter.

(c) The certificate holder and applicant for a CoC shall notify the NRC, in accordance with § 71.1, 45 days in advance of starting fabrication of the first packaging under a CoC. This paragraph applies to any packaging used for the shipment of licensed material which has either—

- (1) A decay heat load in excess of 5 kW; or
- (2) A maximum normal operating pressure in excess of 103 kPa (15 lbf/in²) gauge.

14. Section 71.95 is revised to read as follows:

§ 71.95 Reports.

(a) The licensee, after requesting the certificate holder's input, shall submit a written report to the Commission of —

(1) Instances in which there is a significant reduction in the effectiveness of any NRC-approved Type B or Type AF packaging during use; or

(2) Details of any defects with safety significance in any NRC-approved Type B or fissile material packaging, after first use.

(3) Instances in which the conditions of approval in the Certificate of Compliance were not observed in making a shipment.

(b) The licensee shall submit a written report to the Commission of instances in which the conditions in the certificate of compliance were not followed during a shipment.

(c) Each licensee shall submit, in accordance with § 71.1, a written report required by paragraph (a) or (b) of this section within 60 days of the event or discovery of the event. The licensee shall also provide a copy of each report submitted to the NRC to the applicable certificate holder. Written reports prepared under other regulations may be submitted to fulfill this requirement if the reports contain all the necessary information, and the appropriate distribution is made. These written reports must include the following:

(1) A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.

(2) A clear, specific, narrative description of the event that occurred so that knowledgeable readers conversant with the requirements of Part 71, but not familiar with the design of the packaging, can understand the complete event. The narrative description must include the following specific information as appropriate for the particular event.

- (i) Status of components or systems that were inoperable at the start of the event and that contributed to the event;
 - (ii) Dates and approximate times of occurrences;
 - (iii) The cause of each component or system failure or personnel error, if known;
 - (iv) The failure mode, mechanism, and effect of each failed component, if known;
 - (v) A list of systems or secondary functions that were also affected for failures of components with multiple functions;
 - (vi) The method of discovery of each component or system failure or procedural error;
 - (vii) For each human performance-related root cause, a discussion of the cause(s) and circumstances;
 - (viii) The manufacturer and model number (or other identification) of each component that failed during the event; and
 - (ix) For events occurring during use of a packaging, the quantities and chemical and physical form(s) of the package contents.
- (3) An assessment of the safety consequences and implications of the event. This assessment must include the availability of other systems or components that could have performed the same function as the components and systems that failed during the event.
- (4) A description of any corrective actions planned as a result of the event, including the means employed to repair any defects, and actions taken to reduce the probability of similar events occurring in the future.
- (5) Reference to any previous similar events involving the same packaging that are known to the licensee or certificate holder.
- (6) The name and telephone number of a person within the licensee's organization who is knowledgeable about the event and can provide additional information.

(7) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

(d) Report legibility. The reports submitted by licensees and/or certificate holders under this section must be of sufficient quality to permit reproduction and micrographic processing.

15. In § 71.100, paragraph (b) is revised to read as follows:

§ 71.100 Criminal penalties.

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(b) The regulations in part 71 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 71.0, 71.2, 71.4, 71.6, 71.7, 71.10, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.40, 71.41, 71.43, 71.45, 71.47, 71.51, 71.55, 71.59, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99, 71.100, and 71.151 through 71.169.

16. Subpart H to Part 71 is revised to read as follows:

Subpart H - Quality Assurance

Sec.

71.101 Quality assurance requirements.

71.103 Quality assurance organization.

71.105 Quality assurance program.

71.107 Package design control.

71.109 Procurement document control.

71.111 Instructions, procedures, and drawings.

71.113 Document control.

71.115 Control of purchased material, equipment, and services.

71.117 Identification and control of materials, parts, and components.

71.119 Control of special processes.

71.121 Internal inspection.

71.123 Test control.

71.125 Control of measuring and test equipment.

71.127 Handling, storage, and shipping control.

71.129 Inspection, test, and operating status.

71.131 Nonconforming materials, parts, or components.

71.133 Corrective action.

71.135 Quality assurance records.

71.137 Audits.

Subpart H—Quality Assurance

§ 71.101 Quality assurance requirements.

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

quality of the material or component to predetermined requirements. 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 §§ 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.

(c) Approval of program.

(1) Before the use of any package for the shipment of licensed material subject to this subpart, each licensee shall obtain Commission approval of its quality assurance program. Each licensee shall, in accordance with § 71.1, file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied.

(2) Before the fabrication, testing, or modification of any package for the shipment of licensed material subject to this subpart, each licensee, certificate holder, or applicant for a CoC shall obtain Commission approval of its quality assurance program. Each certificate holder or applicant for a CoC shall, in accordance with § 71.1, file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied.

(d) Existing package designs. The provisions of this paragraph deal with packages that have been approved for use in accordance with this part before January 1, 1979, and which have been designed in accordance with the provisions of this part in effect at the time of application for package approval. Those packages will be accepted as having been designed in accordance with a quality assurance program that satisfies the provisions of paragraph (b) of this section.

(e) Existing packages. The provisions of this paragraph deal with packages that have been approved for use in accordance with this part before January 1, 1979, have been at least partially fabricated before that date, and for which the fabrication is in accordance with the provisions of this part in effect at the time of application for approval of package design. These packages will be accepted as having been fabricated and assembled in accordance with a quality assurance program that satisfies the provisions of paragraph (b) of this section.

(f) Previously approved programs. A Commission-approved quality assurance program that satisfies the applicable criteria of subpart H of this part, Appendix B of part 50 of this chapter, or subpart G of part 72 of this chapter, and that is established, maintained, and executed regarding transport packages, will be accepted as satisfying the requirements of paragraph (b) of this section. Before first use, the licensee, certificate holder, and applicant for a CoC shall notify the NRC, in accordance with § 71.1, of its intent to apply its previously approved subpart H, Appendix B, or subpart G quality assurance program to transportation activities. The licensee, certificate holder, and applicant for a CoC shall identify the program by date of submittal to the Commission, Docket Number, and date of Commission approval.

(g) Radiography containers. A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of § 34.31(b) of this chapter or

equivalent Agreement State requirement, is deemed to satisfy the requirements of §§ 71.17(b) and 71.101(b).

§ 71.103 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. The licensee, certificate holder, and applicant for a CoC shall clearly establish and delineate, in writing, the authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components that are important to safety. 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.

(c) The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom to—

(1) Identify quality problems;

(2) Initiate, recommend, or provide solutions; and

² 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.

(3) Verify implementation of solutions.

(d) The persons and organizations performing quality assurance functions shall report to a management level that assures that the required authority and organizational freedom, including sufficient independence from cost and schedule, when opposed to safety considerations, are provided.

(e) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom.

(f) Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform this function.

§ 71.105 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 §§ 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, through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee, 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.

(c) 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.

(d) 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.

§ 71.107 Package design control.

(a) The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that applicable regulatory requirements and the package design, as specified in the license or CoC for those materials and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the materials, parts, and components of the packaging that are important to safety.

(b) The licensee, certificate holder, and applicant for a CoC shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures, among participating design organizations, for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design, by methods such as design reviews, alternate

or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, the licensee, certificate holder, and applicant for a CoC shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. The licensee, certificate holder, and applicant for a CoC shall apply design control measures to the following:

(1) Criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses;

(2) Compatibility of materials;

(3) Accessibility for inservice inspection, maintenance, and repair;

(4) Features to facilitate decontamination; and

(5) Delineation of acceptance criteria for inspections and tests.

(c) The licensee, certificate holder, and applicant for a CoC shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the CoC require prior NRC approval.

§ 71.109 Procurement document control.

The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that adequate quality is required in the documents for procurement of material, equipment, and services, whether purchased by the licensee, certificate holder, and applicant for a CoC or by its contractors or subcontractors. To the extent necessary, the licensee,

certificate holder, and applicant for a CoC shall require contractors or subcontractors to provide a quality assurance program consistent with the applicable provisions of this part.

§ 71.111 Instructions, procedures, and drawings.

The licensee, certificate holder, and applicant for a CoC shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

§ 71.113 Document control.

The licensee, certificate holder, and applicant for a CoC shall establish measures to control the issuance of documents such as instructions, procedures, and drawings, including changes, that prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed.

§ 71.115 Control of purchased material, equipment, and services.

(a) The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection,

objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products on delivery.

(b) The licensee, certificate holder, and applicant for a CoC shall have available documentary evidence that material and equipment conform to the procurement specifications before installation or use of the material and equipment. The licensee, certificate holder, and applicant for a CoC shall retain, or have available, this documentary evidence for the life of the package to which it applies. The licensee, certificate holder, and applicant for a CoC shall assure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment.

(c) The licensee, certificate holder, and applicant for a CoC shall assess the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or services.

§ 71.117 Identification and control of materials, parts, and components.

The licensee, certificate holder, and applicant for a CoC shall establish measures for the identification and control of materials, parts, and components. These measures must assure that identification of the item is maintained by heat number, part number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, installation, and use of the item. These identification and control measures must be designed to prevent the use of incorrect or defective materials, parts, and components.

§ 71.119 Control of special processes.

The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that special processes, including welding, heat treating, and nondestructive testing are

controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

§ 71.121 Internal inspection.

The licensee, certificate holder, and applicant for a CoC shall establish and execute a program for inspection of activities affecting quality by or for the organization performing the activity, to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. The inspection must be performed by individuals other than those who performed the activity being inspected. Examination, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If direct inspection of processed material or products is not carried out, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when quality control is inadequate without both. If mandatory inspection hold points, which require witnessing or inspecting by the licensee's designated representative and beyond which work should not proceed without the consent of its designated representative, are required, the specific hold points must be indicated in appropriate documents.

§ 71.123 Test control.

The licensee, certificate holder, and applicant for a CoC shall establish a test program to assure that all testing required to demonstrate that the packaging components will perform satisfactorily in service is identified and performed in accordance with written test procedures that incorporate the requirements of this part and the requirements and acceptance limits contained in the package approval. The test procedures must include provisions for assuring

that all prerequisites for the given test are met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. The licensee, certificate holder, and applicant for a CoC shall document and evaluate the test results to assure that test requirements have been satisfied.

§ 71.125 Control of measuring and test equipment.

The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified times to maintain accuracy within necessary limits.

§ 71.127 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.

§ 71.129 Inspection, test, and operating status.

(a) 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.

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

§ 71.131 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.

§ 71.133 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.

§ 71.135 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 § 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.

§ 71.137 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. Followup action, including reaudit of deficient areas, must be taken where indicated.

17. Appendix A to Part 71 is revised to read as follows:

APPENDIX A TO PART 71 - DETERMINATION OF A_1 AND A_2

I. Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations, are given in Table A-1. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) figure. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is one tenth of one percent or less. Where values of A_1 and A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some 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 § 71.1 of this part.

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 radionuclide has a half-life either longer than 10 days, or longer than that of the parent radionuclide, 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 radionuclide of that chain. In the case of radioactive decay chains in which any daughter radionuclide has a half-life either longer than 10 days, or greater than that of the parent radionuclide, the parent and those daughter radionuclides shall be considered as mixtures of different radionuclides.

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 as follows:

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

where $B(i)$ is the activity of radionuclide i , and $A_2(i)$ is the A_2 value for radionuclide i .

(c) Alternatively, the A_1 value for mixtures of special form material may be determined as follows:

$$A_1 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where $f(i)$ is the fraction of activity for radionuclide I in the mixture, and $A_1(i)$ is the appropriate A_1 value for radionuclide I.

(d) Alternatively, the 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 for radionuclide I in the mixture, and $A_2(i)$ is the appropriate A_2 value for radionuclide 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 concentration 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 may be grouped, and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Ac-225 (a)	Actinium (89)	8.0X10 ⁻¹	2.2X10 ¹	6.0X10 ⁻³	1.6X10 ⁻¹	2.1X10 ³	5.8X10 ⁴
Ac-227 (a)		9.0X10 ⁻¹	2.4X10 ¹	9.0X10 ⁻⁵	2.4X10 ⁻³	2.7	7.2X10 ¹
Ac-228		6.0X10 ⁻¹	1.6X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	8.4X10 ⁴	2.2X10 ⁶
Ag-105	Silver (47)	2.0	5.4X10 ¹	2.0	5.4X10 ¹	1.1X10 ³	3.0X10 ⁴
Ag-108m (a)		7.0X10 ⁻¹	1.9X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	9.7X10 ⁻¹	2.6X10 ¹
Ag-110m (a)		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.8X10 ²	4.7X10 ³
Ag-111		2.0	5.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	5.8X10 ³	1.6X10 ⁵
Al-26	Aluminum (13)	1.0X10 ⁻¹	2.7	1.0X10 ⁻¹	2.7	7.0X10 ⁻⁴	1.9X10 ⁻²
Am-241	Americium (95)	1.0X10 ¹	2.7X10 ²	1.0X10 ⁻³	2.7X10 ⁻²	1.3X10 ⁻¹	3.4
Am-242m (a)		1.0X10 ¹	2.7X10 ²	1.0X10 ⁻³	2.7X10 ⁻²	3.6X10 ⁻¹	1.0X10 ¹
Am-243 (a)		5.0	1.4X10 ²	1.0X10 ⁻³	2.7X10 ⁻²	7.4X10 ⁻³	2.0X10 ⁻¹
Ar-37	Argon (18)	4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	3.7X10 ³	9.9X10 ⁴
Ar-39		2.0X10 ¹	5.4X10 ²	4.0X10 ¹	1.1X10 ³	1.3	3.4X10 ¹
Ar-41		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	1.5X10 ⁶	4.2X10 ⁷
As-72	Arsenic (33)	3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	6.2X10 ⁴	1.7X10 ⁶
As-73		4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	8.2X10 ²	2.2X10 ⁴
As-74		1.0	2.7X10 ¹	9.0X10 ⁻¹	2.4X10 ¹	3.7X10 ³	9.9X10 ⁴
As-76		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	5.8X10 ⁴	1.6X10 ⁶
As-77		2.0X10 ¹	5.4X10 ²	7.0X10 ⁻¹	1.9X10 ¹	3.9X10 ⁴	1.0X10 ⁶
At-211 (a)	Astatine (85)	2.0X10 ¹	5.4X10 ²	5.0X10 ⁻¹	1.4X10 ¹	7.6X10 ⁴	2.1X10 ⁶
Au-193	Gold (79)	7.0	1.9X10 ²	2.0	5.4X10 ¹	3.4X10 ⁴	9.2X10 ⁵
Au-194		1.0	2.7X10 ¹	1.0	2.7X10 ¹	1.5X10 ⁴	4.1X10 ⁵

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Au-195	Gold (79)	1.0X10 ¹	2.7X10 ²	6.0	1.6X10 ²	1.4X10 ²	3.7X10 ³
Au-198		1.0	2.7X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	9.0X10 ³	2.4X10 ⁵
Au-199		1.0X10 ¹	2.7X10 ²	6.0X10 ⁻¹	1.6X10 ¹	7.7X10 ³	2.1X10 ⁵
Ba-131 (a)	Barium (56)	2.0	5.4X10 ¹	2.0	5.4X10 ¹	3.1X10 ³	8.4X10 ⁴
Ba-133		3.0	8.1X10 ¹	3.0	8.1X10 ¹	9.4	2.6X10 ²
Ba-133m		2.0X10 ¹	5.4X10 ²	6.0X10 ⁻¹	1.6X10 ¹	2.2X10 ⁴	6.1X10 ⁵
Ba-140 (a)		5.0X10 ⁻¹	1.4X10 ¹	3.0X10 ⁻¹	8.1	2.7X10 ³	7.3X10 ⁴
Be-7	Beryllium (4)	2.0X10 ¹	5.4X10 ²	2.0X10 ¹	5.4X10 ²	1.3X10 ⁴	3.5X10 ⁵
Be-10		4.0X10 ¹	1.1X10 ³	6.0X10 ⁻¹	1.6X10 ¹	8.3X10 ⁻⁴	2.2X10 ⁻²
Bi-205	Bismuth (83)	7.0X10 ⁻¹	1.9X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	1.5X10 ⁻³	4.2X10 ⁴
Bi-206		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	3.8X10 ³	1.0X10 ⁵
Bi-207		7.0X10 ⁻¹	1.9X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	1.9	5.2X10 ¹
Bi-210		1.0	2.7X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	4.6X10 ³	1.2X10 ⁵
Bi-210m (a)		6.0X10 ⁻¹	1.6X10 ¹	2.0X10 ⁻²	5.4X10 ⁻¹	2.1X10 ⁻⁵	5.7X10 ⁻⁴
Bi-212 (a)		7.0X10 ⁻¹	1.9X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	5.4X10 ⁵	1.5X10 ⁷
Bk-247	Berkelium (97)	8.0	2.2X10 ²	8.0X10 ⁻⁴	2.2X10 ⁻²	3.8X10 ⁻²	1.0
Bk-249 (a)		4.0X10 ¹	1.1X10 ³	3.0X10 ⁻¹	8.1	6.1X10 ¹	1.6X10 ³
Br-76	Bromine (35)	4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	9.4X10 ⁴	2.5X10 ⁶
Br-77		3.0	8.1X10 ¹	3.0	8.1X10 ¹	2.6X10 ⁴	7.1X10 ⁵
Br-82		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁴	1.1X10 ⁶
C-11	Carbon (6)	1.0	2.7X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	3.1X10 ⁷	8.4X10 ⁸
C-14		4.0X10 ¹	1.1X10 ³	3.0	8.1X10 ¹	1.6X10 ⁻¹	4.5

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Ca-41	Calcium (20)	Unlimited	Unlimited	Unlimited	Unlimited	3.1X10 ⁻³	8.5X10 ⁻²
Ca-45		4.0X10 ¹	1.1X10 ³	1.0	2.7X10 ¹	6.6X10 ²	1.8X10 ⁴
Ca-47 (a)		3.0	8.1X10 ¹	3.0X10 ⁻¹	8.1	2.3X10 ⁴	6.1X10 ⁵
Cd-109	Cadmium (48)	3.0X10 ¹	8.1X10 ²	2.0	5.4X10 ¹	9.6X10 ¹	2.6X10 ³
Cd-113m		4.0X10 ¹	1.1X10 ³	5.0X10 ⁻¹	1.4X10 ¹	8.3	2.2X10 ²
Cd-115 (a)		3.0	8.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.9X10 ⁴	5.1X10 ⁵
Cd-115m		5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	9.4X10 ²	2.5X10 ⁴
Ce-139	Cerium (58)	7.0	1.9X10 ²	2.0	5.4X10 ¹	2.5X10 ²	6.8X10 ³
Ce-141		2.0X10 ¹	5.4X10 ²	6.0X10 ⁻¹	1.6X10 ¹	1.1X10 ³	2.8X10 ⁴
Ce-143		9.0X10 ⁻¹	2.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	2.5X10 ⁴	6.6X10 ⁵
Ce-144 (a)		2.0X10 ⁻¹	5.4	2.0X10 ⁻¹	5.4	1.2X10 ²	3.2X10 ³
Cf-248	Californium (98)	4.0X10 ¹	1.1X10 ³	6.0X10 ⁻³	1.6X10 ⁻¹	5.8X10 ¹	1.6X10 ³
Cf-249		3.0	8.1X10 ¹	8.0X10 ⁻⁴	2.2X10 ⁻²	1.5X10 ⁻¹	4.1
Cf-250		2.0X10 ¹	5.4X10 ²	2.0X10 ⁻³	5.4X10 ⁻²	4.0	1.1X10 ²
Cf-251		7.0	1.9X10 ²	7.0X10 ⁻⁴	1.9X10 ⁻²	5.9X10 ⁻²	1.6
Cf-252 (h)		1.0X10 ⁻¹	2.7	3.0X10 ⁻³	8.1X10 ⁻²	2.0X10 ¹	5.4X10 ²
Cf-253 (a)		4.0X10 ¹	1.1X10 ³	4.0X10 ⁻²	1.1	1.1X10 ³	2.9X10 ⁴
Cf-254		1.0X10 ⁻³	2.7X10 ⁻²	1.0X10 ⁻³	2.7X10 ⁻²	3.1X10 ²	8.5X10 ³
Cl-36	Chlorine (17)	1.0X10 ¹	2.7X10 ²	6.0X10 ⁻¹	1.6X10 ¹	1.2X10 ⁻³	3.3X10 ⁻²
Cl-38		2.0X10 ⁻¹	5.4	2.0X10 ⁻¹	5.4	4.9X10 ⁶	1.3X10 ⁸
Cm-240	Curium (96)	4.0X10 ¹	1.1X10 ³	2.0X10 ⁻²	5.4X10 ⁻¹	7.5X10 ²	2.0X10 ⁴
Cm-241		2.0	5.4X10 ¹	1.0	2.7X10 ¹	6.1X10 ²	1.7X10 ⁴

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Cm-242	Curium (96)	4.0X10 ¹	1.1X10 ³	1.0X10 ⁻²	2.7X10 ⁻¹	1.2X10 ²	3.3X10 ³
Cm-243		9.0	2.4X10 ²	1.0X10 ⁻³	2.7X10 ⁻²	1.9X10 ⁻³	5.2X10 ¹
Cm-244		2.0X10 ¹	5.4X10 ²	2.0X10 ⁻³	5.4X10 ⁻²	3.0	8.1X10 ¹
Cm-245		9.0	2.4X10 ²	9.0X10 ⁻⁴	2.4X10 ⁻²	6.4X10 ⁻³	1.7X10 ⁻¹
Cm-246		9.0	2.4X10 ²	9.0X10 ⁻⁴	2.4X10 ⁻²	1.1X10 ⁻²	3.1X10 ⁻¹
Cm-247 (a)		3.0	8.1X10 ¹	1.0X10 ⁻³	2.7X10 ⁻²	3.4X10 ⁻⁶	9.3X10 ⁻⁵
Cm-248		2.0X10 ⁻²	5.4X10 ⁻¹	3.0X10 ⁻⁴	8.1X10 ⁻³	1.6X10 ⁻⁵	4.2X10 ⁻³
Co-55	Cobalt (27)	5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	1.1X10 ⁵	3.1X10 ⁶
Co-56		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	1.1X10 ³	3.0X10 ⁴
Co-57		1.0X10 ¹	2.7X10 ²	1.0X10 ¹	2.7X10 ²	3.1X10 ²	8.4X10 ³
Co-58		1.0	2.7X10 ¹	1.0	2.7X10 ¹	1.2X10 ³	3.2X10 ⁴
Co-58m		4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	2.2X10 ⁵	5.9X10 ⁶
Co-60		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	4.2X10 ¹	1.1X10 ³
Cr-51	Chromium (24)	3.0X10 ¹	8.1X10 ²	3.0X10 ¹	8.1X10 ²	3.4X10 ³	9.2X10 ⁴
Cs-129	Cesium (55)	4.0	1.1X10 ²	4.0	1.1X10 ²	2.8X10 ⁴	7.6X10 ⁵
Cs-131		3.0X10 ¹	8.1X10 ²	3.0X10 ¹	8.1X10 ²	3.8X10 ³	1.0X10 ⁵
Cs-132		1.0	2.7X10 ¹	1.0	2.7X10 ¹	5.7X10 ³	1.5X10 ⁵
Cs-134		7.0X10 ⁻¹	1.9X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	4.8X10 ¹	1.3X10 ³
Cs-134m		4.0X10 ¹	1.1X10 ³	6.0X10 ⁻¹	1.6X10 ¹	3.0X10 ⁵	8.0X10 ⁶
Cs-135		4.0X10 ¹	1.1X10 ³	1.0	2.7X10 ¹	4.3X10 ⁻⁵	1.2X10 ⁻³
Cs-136		5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	2.7X10 ³	7.3X10 ⁴
Cs-137 (a)		2.0	5.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	3.2	8.7X10 ¹

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Cu-64	Copper (29)	6.0	1.6X10 ²	1.0	2.7X10 ¹	1.4X10 ⁵	3.9X10 ⁶
Cu-67		1.0X10 ¹	2.7X10 ²	7.0X10 ⁻¹	1.9X10 ¹	2.8X10 ⁴	7.6X10 ⁵
Dy-159	Dysprosium (66)	2.0X10 ¹	5.4X10 ²	2.0X10 ¹	5.4X10 ²	2.1X10 ²	5.7X10 ³
Dy-165		9.0X10 ⁻¹	2.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	3.0X10 ⁵	8.2X10 ⁶
Dy-166 (a)		9.0X10 ⁻¹	2.4X10 ¹	3.0X10 ⁻¹	8.1	8.6X10 ³	2.3X10 ⁵
Er-169	Erbium (68)	4.0X10 ¹	1.1X10 ³	1.0	2.7X10 ¹	3.1X10 ³	8.3X10 ⁴
Er-171		8.0X10 ⁻¹	2.2X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	9.0X10 ⁴	2.4X10 ⁶
Eu-147	Europium (63)	2.0	5.4X10 ¹	2.0	5.4X10 ¹	1.4X10 ³	3.7X10 ⁴
Eu-148		5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	6.0X10 ²	1.6X10 ⁴
Eu-149		2.0X10 ¹	5.4X10 ²	2.0X10 ¹	5.4X10 ²	3.5X10 ²	9.4X10 ³
Eu-150 (short lived)		2.0	5.4X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	6.1X10 ⁴	1.6X10 ⁶
Eu-150 (long lived)		2.0	5.4X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	6.1X10 ⁴	1.6X10 ⁶
Eu-152		1.0	2.7X10 ¹	1.0	2.7X10 ¹	6.5	1.8X10 ²
Eu-152m		8.0X10 ⁻¹	2.2X10 ¹	8.0X10 ⁻¹	2.2X10 ¹	8.2X10 ⁴	2.2X10 ⁶
Eu-154		9.0X10 ⁻¹	2.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	9.8	2.6X10 ²
Eu-155		2.0X10 ¹	5.4X10 ²	3.0	8.1X10 ¹	1.8X10 ¹	4.9X10 ²
Eu-156		7.0X10 ⁻¹	1.9X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	2.0X10 ³	5.5X10 ⁴
F-18	Fluorine (9)	1.0	2.7X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	3.5X10 ⁶	9.5X10 ⁷
Fe-52 (a)	Iron (26)	3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	2.7X10 ⁵	7.3X10 ⁶
Fe-55		4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	8.8X10 ¹	2.4X10 ³
Fe-59		9.0X10 ⁻¹	2.4X10 ¹	9.0X10 ⁻¹	2.4X10 ¹	1.8X10 ³	5.0X10 ⁴
Fe-60 (a)		4.0X10 ¹	1.1X10 ³	2.0X10 ⁻¹	5.4	7.4X10 ⁻⁴	2.0X10 ⁻²

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Ga-67	Gallium (31)	7.0	1.9X10 ²	3.0	8.1X10 ¹	2.2X10 ⁴	6.0X10 ⁵
Ga-68		5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	1.5X10 ⁶	4.1X10 ⁷
Ga-72		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.1X10 ⁵	3.1X10 ⁶
Gd-146 (a)	Gadolinium (64)	5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	6.9X10 ²	1.9X10 ⁴
Gd-148		2.0X10 ¹	5.4X10 ²	2.0X10 ⁻³	5.4X10 ⁻²	1.2	3.2X10 ¹
Gd-153		1.0X10 ¹	2.7X10 ²	9.0	2.4X10 ²	1.3X10 ²	3.5X10 ³
Gd-159		3.0	8.1X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	3.9X10 ⁴	1.1X10 ⁶
Ge-68 (a)	Germanium (32)	5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	2.6X10 ²	7.1X10 ³
Ge-71		4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	5.8X10 ³	1.6X10 ⁵
Ge-77		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	1.3X10 ⁵	3.6X10 ⁶
Hf-172 (a)	Hafnium (72)	6.0X10 ⁻¹	1.6X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	4.1X10 ¹	1.1X10 ³
Hf-175		3.0	8.1X10 ¹	3.0	8.1X10 ¹	3.9X10 ²	1.1X10 ⁴
Hf-181		2.0	5.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	6.3X10 ²	1.7X10 ⁴
Hf-182		Unlimited	Unlimited	Unlimited	Unlimited	8.1X10 ⁻⁶	2.2X10 ⁻⁴
Hg-194 (a)	Mercury (80)	1.0	2.7X10 ¹	1.0	2.7X10 ¹	1.3X10 ⁻¹	3.5
Hg-195m (a)		3.0	8.1X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	1.5X10 ⁴	4.0X10 ⁵
Hg-197		2.0X10 ¹	5.4X10 ²	1.0X10 ¹	2.7X10 ²	9.2X10 ³	2.5X10 ⁵
Hg-197m		1.0X10 ¹	2.7X10 ²	4.0X10 ⁻¹	1.1X10 ¹	2.5X10 ⁴	6.7X10 ⁵
Hg-203		5.0	1.4X10 ²	1.0	2.7X10 ¹	5.1X10 ²	1.4X10 ⁴
Ho-166	Holmium (67)	4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	2.6X10 ⁴	7.0X10 ⁵
Ho-166m		6.0X10 ⁻¹	1.6X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	6.6X10 ⁻²	1.8

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
I-123	Iodine (53)	6.0	1.6X10 ²	3.0	8.1X10 ¹	7.1X10 ⁴	1.9X10 ⁶
I-124		1.0	2.7X10 ¹	1.0	2.7X10 ¹	9.3X10 ³	2.5X10 ⁵
I-125		2.0X10 ¹	5.4X10 ²	3.0	8.1X10 ¹	6.4X10 ²	1.7X10 ⁴
I-126		2.0	5.4X10 ¹	1.0	2.7X10 ¹	2.9X10 ³	8.0X10 ⁴
I-129		Unlimited	Unlimited	Unlimited	Unlimited	6.5X10 ⁻⁶	1.8X10 ⁻⁴
I-131		3.0	8.1X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	4.6X10 ³	1.2X10 ⁵
I-132		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	3.8X10 ⁵	1.0X10 ⁷
I-133		7.0X10 ⁻¹	1.9X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	4.2X10 ⁴	1.1X10 ⁶
I-134		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	9.9X10 ⁵	2.7X10 ⁷
I-135 (a)		6.0X10 ⁻¹	1.6X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	1.3X10 ⁵	3.5X10 ⁶
In-111	Indium (49)	3.0	8.1X10 ¹	3.0	8.1X10 ¹	1.5X10 ⁴	4.2X10 ⁵
In-113m		4.0	1.1X10 ²	2.0	5.4X10 ¹	6.2X10 ⁵	1.7X10 ⁷
In-114m (a)		1.0X10 ¹	2.7X10 ²	5.0X10 ⁻¹	1.4X10 ¹	8.6X10 ²	2.3X10 ⁴
In-115m		7.0	1.9X10 ²	1.0	2.7X10 ¹	2.2X10 ⁵	6.1X10 ⁶
Ir-189 (a)	Iridium (77)	1.0X10 ¹	2.7X10 ²	1.0X10 ¹	2.7X10 ²	1.9X10 ³	5.2X10 ⁴
Ir-190		7.0X10 ⁻¹	1.9X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	2.3X10 ³	6.2X10 ⁴
Ir-192		1.0	2.7X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	3.4X10 ²	9.2X10 ³
Ir-194		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	3.1X10 ⁴	8.4X10 ⁵
K-40	Potassium (19)	9.0X10 ⁻¹	2.4X10 ¹	9.0X10 ⁻¹	2.4X10 ¹	2.4X10 ⁻⁷	6.4X10 ⁻⁶
K-42		2.0X10 ⁻¹	5.4	2.0X10 ⁻¹	5.4	2.2X10 ⁵	6.0X10 ⁶
K-43		7.0X10 ⁻¹	1.9X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	1.2X10 ⁵	3.3X10 ⁶

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Kr-81	Krypton (36)	4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	7.8X10 ⁻⁴	2.1X10 ⁻²
Kr-85		1.0X10 ¹	2.7X10 ²	1.0X10 ¹	2.7X10 ²	1.5X10 ¹	3.9X10 ²
Kr-85m		8.0	2.2X10 ²	3.0	8.1X10 ¹	3.0X10 ⁵	8.2X10 ⁶
Kr-87		2.0X10 ⁻¹	5.4	2.0X10 ⁻¹	5.4	1.0X10 ⁶	2.8X10 ⁷
La-137	Lanthanum (57)	3.0X10 ¹	8.1X10 ²	6.0	1.6X10 ²	1.6X10 ⁻³	4.4X10 ⁻²
La-140		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	2.1X10 ⁴	5.6X10 ⁵
Lu-172	Lutetium (71)	6.0X10 ⁻¹	1.6X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	4.2X10 ³	1.1X10 ⁵
Lu-173		8.0	2.2X10 ²	8.0	2.2X10 ²	5.6X10 ¹	1.5X10 ³
Lu-174		9.0	2.4X10 ²	9.0	2.4X10 ²	2.3X10 ¹	6.2X10 ²
Lu-174m		2.0X10 ¹	5.4X10 ²	1.0X10 ¹	2.7X10 ²	2.0X10 ²	5.3X10 ³
Lu-177		3.0X10 ¹	8.1X10 ²	7.0X10 ⁻¹	1.9X10 ¹	4.1X10 ³	1.1X10 ⁵
Mg-28 (a)	Magnesium (12)	3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	2.0X10 ⁵	5.4X10 ⁶
Mn-52	Manganese (25)	3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	1.6X10 ⁴	4.4X10 ⁵
Mn-53		Unlimited	Unlimited	Unlimited	Unlimited	6.8X10 ⁻⁵	1.8X10 ⁻³
Mn-54		1.0	2.7X10 ¹	1.0	2.7X10 ¹	2.9X10 ²	7.7X10 ³
Mn-56		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	8.0X10 ⁵	2.2X10 ⁷
Mo-93	Molybdenum (42)	4.0X10 ¹	1.1X10 ³	2.0X10 ¹	5.4X10 ²	4.1X10 ⁻²	1.1
Mo-99 (a) (h)		1.0	2.7X10 ¹	7.4X10 ⁻¹	2.0X10 ¹	1.8X10 ⁴	4.8X10 ⁵
N-13	Nitrogen (7)	9.0X10 ⁻¹	2.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	5.4X10 ⁷	1.5X10 ⁹
Na-22	Sodium (11)	5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	2.3X10 ²	6.3X10 ³
Na-24		2.0X10 ⁻¹	5.4	2.0X10 ⁻¹	5.4	3.2X10 ⁵	8.7X10 ⁶

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Nb-93m	Niobium (41)	4.0X10 ¹	1.1X10 ³	3.0X10 ¹	8.1X10 ²	8.8	2.4X10 ²
Nb-94		7.0X10 ⁻¹	1.9X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	6.9X10 ⁻³	1.9X10 ⁻¹
Nb-95		1.0	2.7X10 ¹	1.0	2.7X10 ¹	1.5X10 ³	3.9X10 ⁴
Nb-97		9.0X10 ⁻¹	2.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	9.9X10 ⁵	2.7X10 ⁷
Nd-147	Neodymium (60)	6.0	1.6X10 ²	6.0X10 ⁻¹	1.6X10 ¹	3.0X10 ³	8.1X10 ⁴
Nd-149		6.0X10 ⁻¹	1.6X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	4.5X10 ⁵	1.2X10 ⁷
Ni-59	Nickel (28)	Unlimited	Unlimited	Unlimited	Unlimited	3.0X10 ⁻³	8.0X10 ⁻²
Ni-63		4.0X10 ¹	1.1X10 ³	3.0X10 ¹	8.1X10 ²	2.1	5.7X10 ¹
Ni-65		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	7.1X10 ⁵	1.9X10 ⁷
Np-235	Neptunium (93)	4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	5.2X10 ¹	1.4X10 ³
Np-236 (short-lived)		2.0X10 ¹	5.4X10 ²	2.0	5.4X10 ¹	4.7X10 ⁻⁴	1.3X10 ⁻²
Np-236 (long-lived)		2.0X10 ¹	5.4X10 ²	2.0	5.4X10 ¹	4.7X10 ⁻⁴	1.3X10 ⁻²
Np-237		2.0X10 ¹	5.4X10 ²	2.0X10 ⁻³	5.4X10 ⁻²	2.6X10 ⁻⁵	7.1X10 ⁻⁴
Np-239		7.0	1.9X10 ²	4.0X10 ⁻¹	1.1X10 ¹	8.6X10 ³	2.3X10 ⁵
Os-185	Osmium (76)	1.0	2.7X10 ¹	1.0	2.7X10 ¹	2.8X10 ²	7.5X10 ³
Os-191		1.0X10 ¹	2.7X10 ²	2.0	5.4X10 ¹	1.6X10 ³	4.4X10 ⁴
Os-191m		4.0X10 ¹	1.1X10 ³	3.0X10 ¹	8.1X10 ²	4.6X10 ⁴	1.3X10 ⁶
Os-193		2.0	5.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	2.0X10 ⁴	5.3X10 ⁵
Os-194 (a)		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	1.1X10 ¹	3.1X10 ²
P-32	Phosphorus (15)	5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	1.1X10 ⁴	2.9X10 ⁵
P-33		4.0X10 ¹	1.1X10 ³	1.0	2.7X10 ¹	5.8X10 ³	1.6X10 ⁵

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Pa-230 (a)	Protactinium (91)	2.0	5.4X10 ¹	7.0X10 ⁻²	1.9	1.2X10 ³	3.3X10 ⁴
Pa-231		4.0	1.1X10 ²	4.0X10 ⁻⁴	1.1X10 ⁻²	1.7X10 ⁻³	4.7X10 ⁻²
Pa-233		5.0	1.4X10 ²	7.0X10 ⁻¹	1.9X10 ¹	7.7X10 ²	2.1X10 ⁴
Pb-201	Lead (82)	1.0	2.7X10 ¹	1.0	2.7X10 ¹	6.2X10 ⁴	1.7X10 ⁶
Pb-202		4.0X10 ¹	1.1X10 ³	2.0X10 ¹	5.4X10 ²	1.2X10 ⁻⁴	3.4X10 ⁻³
Pb-203		4.0	1.1X10 ²	3.0	8.1X10 ¹	1.1X10 ⁴	3.0X10 ⁵
Pb-205		Unlimited	Unlimited	Unlimited	Unlimited	4.5X10 ⁻⁶	1.2X10 ⁻⁴
Pb-210 (a)		1.0	2.7X10 ¹	5.0X10 ⁻²	1.4	2.8	7.6X10 ¹
Pb-212 (a)		7.0X10 ⁻¹	1.9X10 ¹	2.0X10 ⁻¹	5.4	5.1X10 ⁴	1.4X10 ⁶
Pd-103 (a)	Palladium (46)	4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	2.8X10 ³	7.5X10 ⁴
Pd-107		Unlimited	Unlimited	Unlimited	Unlimited	1.9X10 ⁻⁵	5.1X10 ⁻⁴
Pd-109		2.0	5.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	7.9X10 ⁴	2.1X10 ⁶
Pm-143	Promethium (61)	3.0	8.1X10 ¹	3.0	8.1X10 ¹	1.3X10 ²	3.4X10 ³
Pm-144		7.0X10 ⁻¹	1.9X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	9.2X10 ¹	2.5X10 ³
Pm-145		3.0X10 ¹	8.1X10 ²	1.0X10 ¹	2.7X10 ²	5.2	1.4X10 ²
Pm-147		4.0X10 ¹	1.1X10 ³	2.0	5.4X10 ¹	3.4X10 ¹	9.3X10 ²
Pm-148m (a)		8.0X10 ⁻¹	2.2X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	7.9X10 ²	2.1X10 ⁴
Pm-149		2.0	5.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	1.5X10 ⁴	4.0X10 ⁵
Pm-151		2.0	5.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	2.7X10 ⁴	7.3X10 ⁵
Po-210	Polonium (84)	4.0X10 ¹	1.1X10 ³	2.0X10 ⁻²	5.4X10 ⁻¹	1.7X10 ²	4.5X10 ³
Pr-142	Praseodymium (59)	4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	4.3X10 ⁴	1.2X10 ⁶
Pr-143		3.0	8.1X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	2.5X10 ³	6.7X10 ⁴

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Pt-188 (a)	Platinum (78)	1.0	2.7X10 ¹	8.0X10 ⁻¹	2.2X10 ¹	2.5X10 ³	6.8X10 ⁴
Pt-191		4.0	1.1X10 ²	3.0	8.1X10 ¹	8.7X10 ³	2.4X10 ⁵
Pt-193		4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	1.4	3.7X10 ¹
Pt-193m		4.0X10 ¹	1.1X10 ³	5.0X10 ⁻¹	1.4X10 ¹	5.8X10 ³	1.6X10 ⁵
Pt-195m		1.0X10 ¹	2.7X10 ²	5.0X10 ⁻¹	1.4X10 ¹	6.2X10 ³	1.7X10 ⁵
Pt-197		2.0X10 ¹	5.4X10 ²	6.0X10 ⁻¹	1.6X10 ¹	3.2X10 ⁴	8.7X10 ⁵
Pt-197m		1.0X10 ¹	2.7X10 ²	6.0X10 ⁻¹	1.6X10 ¹	3.7X10 ⁵	1.0X10 ⁷
Pu-236	Plutonium (94)	3.0X10 ¹	8.1X10 ²	3.0X10 ⁻³	8.1X10 ⁻²	2.0X10 ¹	5.3X10 ²
Pu-237		2.0X10 ¹	5.4X10 ²	2.0X10 ¹	5.4X10 ²	4.5X10 ²	1.2X10 ⁴
Pu-238		1.0X10 ¹	2.7X10 ²	1.0X10 ⁻³	2.7X10 ⁻²	6.3X10 ⁻¹	1.7X10 ¹
Pu-239		1.0X10 ¹	2.7X10 ²	1.0X10 ⁻³	2.7X10 ⁻²	2.3X10 ⁻³	6.2X10 ⁻²
Pu-240		1.0X10 ¹	2.7X10 ²	1.0X10 ⁻³	2.7X10 ⁻²	8.4X10 ⁻³	2.3X10 ⁻¹
Pu-241 (a)		4.0X10 ¹	1.1X10 ³	6.0X10 ⁻²	1.6	3.8	1.0X10 ²
Pu-242		1.0X10 ¹	2.7X10 ²	1.0X10 ⁻³	2.7X10 ⁻²	1.5X10 ⁻⁴	3.9X10 ⁻³
Pu-244 (a)		4.0X10 ⁻¹	1.1X10 ¹	1.0X10 ⁻³	2.7X10 ⁻²	6.7X10 ⁻⁷	1.8X10 ⁻⁵
Ra-223 (a)	Radium (88)	4.0X10 ⁻¹	1.1X10 ¹	7.0X10 ⁻³	1.9X10 ⁻¹	1.9X10 ³	5.1X10 ⁴
Ra-224 (a)		4.0X10 ⁻¹	1.1X10 ¹	2.0X10 ⁻²	5.4X10 ⁻¹	5.9X10 ³	1.6X10 ⁵
Ra-225 (a)		2.0X10 ⁻¹	5.4	4.0X10 ⁻³	1.1X10 ⁻¹	1.5X10 ³	3.9X10 ⁴
Ra-226(a)		2.0X10 ⁻¹	5.4	3.0X10 ⁻³	8.1X10 ⁻²	3.7X10 ⁻²	1.0
Ra-228 (a)		6.0X10 ⁻¹	1.6X10 ¹	2.0X10 ⁻²	5.4X10 ⁻¹	1.0X10 ¹	2.7X10 ²

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Rb-81	Rubidium (37)	2.0	5.4X10 ¹	8.0X10 ⁻¹	2.2X10 ¹	3.1X10 ⁵	8.4X10 ⁶
Rb-83 (a)		2.0	5.4X10 ¹	2.0	5.4X10 ¹	6.8X10 ²	1.8X10 ⁴
Rb-84		1.0	2.7X10 ¹	1.0	2.7X10 ¹	1.8X10 ³	4.7X10 ⁴
Rb-86		5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	3.0X10 ³	8.1X10 ⁴
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	3.2X10 ⁻⁹	8.6X10 ⁻⁸
Rb(nat)		Unlimited	Unlimited	Unlimited	Unlimited	6.7X10 ⁶	1.8X10 ⁸
Re-184	Rhenium (75)	1.0	2.7X10 ¹	1.0	2.7X10 ¹	6.9X10 ²	1.9X10 ⁴
Re-184m		3.0	8.1X10 ¹	1.0	2.7X10 ¹	1.6X10 ²	4.3X10 ³
Re-186		2.0	5.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	6.9X10 ³	1.9X10 ⁵
Re-187		Unlimited	Unlimited	Unlimited	Unlimited	1.4X10 ⁻⁹	3.8X10 ⁻⁸
Re-188		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	3.6X10 ⁴	9.8X10 ⁵
Re-189 (a)		3.0	8.1X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	2.5X10 ⁴	6.8X10 ⁵
Re(nat)		Unlimited	Unlimited	Unlimited	Unlimited	0.0	2.4X10 ⁻⁸
Rh-99	Rhodium (45)	2.0	5.4X10 ¹	2.0	5.4X10 ¹	3.0X10 ³	8.2X10 ⁴
Rh-101		4.0	1.1X10 ²	3.0	8.1X10 ¹	4.1X10 ¹	1.1X10 ³
Rh-102		5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	4.5X10 ¹	1.2X10 ³
Rh-102m		2.0	5.4X10 ¹	2.0	5.4X10 ¹	2.3X10 ²	6.2X10 ³
Rh-103m		4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	1.2X10 ⁶	3.3X10 ⁷
Rh-105		1.0X10 ¹	2.7X10 ²	8.0X10 ⁻¹	2.2X10 ¹	3.1X10 ⁴	8.4X10 ⁵
Rn-222 (a)	Radon (86)	3.0X10 ⁻¹	8.1	4.0X10 ⁻³	1.1X10 ⁻¹	5.7X10 ³	1.5X10 ⁵

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Ru-97	Ruthenium (44)	5.0	1.4X10 ²	5.0	1.4X10 ²	1.7X10 ⁴	4.6X10 ⁵
Ru-103 (a)		2.0	5.4X10 ¹	2.0	5.4X10 ¹	1.2X10 ³	3.2X10 ⁴
Ru-105		1.0	2.7X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	2.5X10 ⁵	6.7X10 ⁶
Ru-106 (a)		2.0X10 ⁻¹	5.4	2.0X10 ⁻¹	5.4	1.2X10 ²	3.3X10 ³
S-35	Sulphur (16)	4.0X10 ¹	1.1X10 ³	3.0	8.1X10 ¹	1.6X10 ³	4.3X10 ⁴
Sb-122	Antimony (51)	4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.5X10 ⁴	4.0X10 ⁵
Sb-124		6.0X10 ⁻¹	1.6X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	6.5X10 ²	1.7X10 ⁴
Sb-125		2.0	5.4X10 ¹	1.0	2.7X10 ¹	3.9X10 ¹	1.0X10 ³
Sb-126		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	3.1X10 ³	8.4X10 ⁴
Sc-44	Scandium (21)	5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	6.7X10 ⁵	1.8X10 ⁷
Sc-46		5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	1.3X10 ³	3.4X10 ⁴
Sc-47		1.0X10 ¹	2.7X10 ²	7.0X10 ⁻¹	1.9X10 ¹	3.1X10 ⁴	8.3X10 ⁵
Sc-48		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	5.5X10 ⁴	1.5X10 ⁶
Se-75	Selenium (34)	3.0	8.1X10 ¹	3.0	8.1X10 ¹	5.4X10 ²	1.5X10 ⁴
Se-79		4.0X10 ¹	1.1X10 ³	2.0	5.4X10 ¹	2.6X10 ⁻³	7.0X10 ⁻²
Si-31	Silicon (14)	6.0X10 ⁻¹	1.6X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	1.4X10 ⁶	3.9X10 ⁷
Si-32		4.0X10 ¹	1.1X10 ³	5.0X10 ⁻¹	1.4X10 ¹	3.9	1.1X10 ²
Sm-145	Samarium (62)	1.0X10 ¹	2.7X10 ²	1.0X10 ¹	2.7X10 ²	9.8X10 ¹	2.6X10 ³
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	8.5X10 ⁻¹	2.3X10 ⁻⁸
Sm-151		4.0X10 ¹	1.1X10 ³	1.0X10 ¹	2.7X10 ²	9.7X10 ⁻¹	2.6X10 ¹
Sm-153		9.0	2.4X10 ²	6.0X10 ⁻¹	1.6X10 ¹	1.6X10 ⁴	4.4X10 ⁵

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Sn-113 (a)	Tin (50)	4.0	1.1X10 ²	2.0	5.4X10 ¹	3.7X10 ²	1.0X10 ⁴
Sn-117m		7.0	1.9X10 ²	4.0X10 ⁻¹	1.1X10 ¹	3.0X10 ³	8.2X10 ⁴
Sn-119m		4.0X10 ¹	1.1X10 ³	3.0X10 ¹	8.1X10 ²	1.4X10 ²	3.7X10 ³
Sn-121m (a)		4.0X10 ¹	1.1X10 ³	9.0X10 ⁻¹	2.4X10 ¹	2.0	5.4X10 ¹
Sn-123		8.0X10 ⁻¹	2.2X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	3.0X10 ²	8.2X10 ³
Sn-125		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ³	1.1X10 ⁵
Sn-126 (a)		6.0X10 ⁻¹	1.6X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.0X10 ⁻³	2.8X10 ⁻²
Sr-82 (a)	Strontium (38)	2.0X10 ⁻¹	5.4	2.0X10 ⁻¹	5.4	2.3X10 ³	6.2X10 ⁴
Sr-85		2.0	5.4X10 ¹	2.0	5.4X10 ¹	8.8X10 ²	2.4X10 ⁴
Sr-85m		5.0	1.4X10 ²	5.0	1.4X10 ²	1.2X10 ⁶	3.3X10 ⁷
Sr-87m		3.0	8.1X10 ¹	3.0	8.1X10 ¹	4.8X10 ⁵	1.3X10 ⁷
Sr-89		6.0X10 ⁻¹	1.6X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	1.1X10 ³	2.9X10 ⁴
Sr-90 (a)		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	5.1	1.4X10 ²
Sr-91 (a)		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	1.3X10 ⁵	3.6X10 ⁶
Sr-92 (a)		1.0	2.7X10 ¹	3.0X10 ⁻¹	8.1	4.7X10 ⁵	1.3X10 ⁷
T(H-3)	Tritium (1)	4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	3.6X10 ²	9.7X10 ³
Ta-178 (long-lived)	Tantalum (73)	1.0	2.7X10 ¹	8.0X10 ⁻¹	2.2X10 ¹	4.2X10 ⁶	1.1X10 ⁸
Ta-179		3.0X10 ¹	8.1X10 ²	3.0X10 ¹	8.1X10 ²	4.1X10 ¹	1.1X10 ³
Ta-182		9.0X10 ⁻¹	2.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	2.3X10 ²	6.2X10 ³
Tb-157	Terbium (65)	4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	5.6X10 ⁻¹	1.5X10 ¹
Tb-158		1.0	2.7X10 ¹	1.0	2.7X10 ¹	5.6X10 ⁻¹	1.5X10 ¹
Tb-160		1.0	2.7X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	4.2X10 ²	1.1X10 ⁴

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Tc-95m (a)	Technetium (43)	2.0	5.4X10 ¹	2.0	5.4X10 ¹	8.3X10 ²	2.2X10 ⁴
Tc-96		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.2X10 ⁴	3.2X10 ⁵
Tc-96m (a)		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.4X10 ⁶	3.8X10 ⁷
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	5.2X10 ⁻⁵	1.4X10 ⁻³
Tc-97m		4.0X10 ¹	1.1X10 ³	1.0	2.7X10 ¹	5.6X10 ²	1.5X10 ⁴
Tc-98		8.0X10 ⁻¹	2.2X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	3.2X10 ⁻⁵	8.7X10 ⁻⁴
Tc-99		4.0X10 ¹	1.1X10 ³	9.0X10 ⁻¹	2.4X10 ¹	6.3X10 ⁻⁴	1.7X10 ⁻²
Tc-99m		1.0X10 ¹	2.7X10 ²	4.0	1.1X10 ²	1.9X10 ⁵	5.3X10 ⁶
Te-121	Tellurium (52)	2.0	5.4X10 ¹	2.0	5.4X10 ¹	2.4X10 ³	6.4X10 ⁴
Te-121m		5.0	1.4X10 ²	3.0	8.1X10 ¹	2.6X10 ²	7.0X10 ³
Te-123m		8.0	2.2X10 ²	1.0	2.7X10 ¹	3.3X10 ²	8.9X10 ³
Te-125m		2.0X10 ¹	5.4X10 ²	9.0X10 ⁻¹	2.4X10 ¹	6.7X10 ²	1.8X10 ⁴
Te-127		2.0X10 ¹	5.4X10 ²	7.0X10 ⁻¹	1.9X10 ¹	9.8X10 ⁴	2.6X10 ⁶
Te-127m (a)		2.0X10 ¹	5.4X10 ²	5.0X10 ⁻¹	1.4X10 ¹	3.5X10 ²	9.4X10 ³
Te-129		7.0X10 ⁻¹	1.9X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	7.7X10 ⁵	2.1X10 ⁷
Te-129m (a)		8.0X10 ⁻¹	2.2X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.1X10 ³	3.0X10 ⁴
Te-131m (a)		7.0X10 ⁻¹	1.9X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	3.0X10 ⁴	8.0X10 ⁵
Te-132 (a)		5.0X10 ⁻¹	1.4X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.1X10 ⁴	8.0X10 ⁵
Th-227	Thorium (90)	1.0X10 ¹	2.7X10 ²	5.0X10 ⁻³	1.4X10 ⁻¹	1.1X10 ³	3.1X10 ⁴
Th-228 (a)		5.0X10 ⁻¹	1.4X10 ¹	1.0X10 ⁻³	2.7X10 ⁻²	3.0X10 ¹	8.2X10 ²
Th-229		5.0	1.4X10 ²	5.0X10 ⁻⁴	1.4X10 ⁻²	7.9X10 ⁻³	2.1X10 ⁻¹
Th-230		1.0X10 ¹	2.7X10 ²	1.0X10 ⁻³	2.7X10 ⁻²	7.6X10 ⁻⁴	2.1X10 ⁻²

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Th-231	Thorium (90)	4.0X10 ¹	1.1X10 ³	2.0X10 ⁻²	5.4X10 ⁻¹	2.0X10 ⁴	5.3X10 ⁵
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	4.0X10 ⁻⁹	1.1X10 ⁻⁷
Th-234 (a)		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	8.6X10 ²	2.3X10 ⁴
Th(nat)		Unlimited	Unlimited	Unlimited	Unlimited	8.1X10 ⁻⁹	2.2X10 ⁻⁷
Ti-44 (a)	Titanium (22)	5.0X10 ⁻¹	1.4X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	6.4	1.7X10 ²
Tl-200	Thallium (81)	9.0X10 ⁻¹	2.4X10 ¹	9.0X10 ⁻¹	2.4X10 ¹	2.2X10 ⁴	6.0X10 ⁵
Tl-201		1.0X10 ¹	2.7X10 ²	4.0	1.1X10 ²	7.9X10 ³	2.1X10 ⁵
Tl-202		2.0	5.4X10 ¹	2.0	5.4X10 ¹	2.0X10 ³	5.3X10 ⁴
Tl-204		1.0X10 ¹	2.7X10 ²	7.0X10 ⁻¹	1.9X10 ¹	1.7X10 ¹	4.6X10 ²
Tm-167	Thulium (69)	7.0	1.9X10 ²	8.0X10 ⁻¹	2.2X10 ¹	3.1X10 ³	8.5X10 ⁴
Tm-170		3.0	8.1X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	2.2X10 ²	6.0X10 ³
Tm-171		4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³
U-230 (fast lung absorption) (a)(d)	Uranium (92)	4.0X10 ¹	1.1X10 ³	1.0X10 ⁻¹	2.7	1.0X10 ³	2.7X10 ⁴
U-230 (medium lung absorption) (a)(e)		4.0X10 ¹	1.1X10 ³	1.0X10 ⁻¹	2.7	1.0X10 ³	2.7X10 ⁴
U-230 (slow lung absorption) (a)(f)		4.0X10 ¹	1.1X10 ³	1.0X10 ⁻¹	2.7	1.0X10 ³	2.7X10 ⁴
U-232 (fast lung absorption) (d)		4.0X10 ¹	1.1X10 ³	1.0X10 ⁻²	2.7X10 ⁻¹	8.3X10 ⁻¹	2.2X10 ¹
U-232 (medium lung absorption) (e)		4.0X10 ¹	1.1X10 ³	1.0X10 ⁻²	2.7X10 ⁻¹	8.3X10 ⁻¹	2.2X10 ¹

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
U-233 (fast lung absorption) (d)	Uranium (92)	4.0X10 ¹	1.1X10 ³	9.0X10 ⁻²	2.4	3.6X10 ⁻⁴	9.7X10 ⁻³
U-233 (medium lung absorption) (e)		4.0X10 ¹	1.1X10 ³	9.0X10 ⁻²	2.4	3.6X10 ⁻⁴	9.7X10 ⁻³
U-233 (slow lung absorption) (f)		4.0X10 ¹	1.1X10 ³	9.0X10 ⁻²	2.4	3.6X10 ⁻⁴	9.7X10 ⁻³
U-234 (fast lung absorption) (d)		4.0X10 ¹	1.1X10 ³	9.0X10 ⁻²	2.4	2.3X10 ⁻⁴	6.2X10 ⁻³
U-234 (medium lung absorption) (e)		4.0X10 ¹	1.1X10 ³	9.0X10 ⁻²	2.4	2.3X10 ⁻⁴	6.2X10 ⁻³
U-234 (slow lung absorption) (f)		4.0X10 ¹	1.1X10 ³	9.0X10 ⁻²	2.4	2.3X10 ⁻⁴	6.2X10 ⁻³
U-235 (all lung absorption types) (a),(d),(e),(f)		Unlimited	Unlimited	Unlimited	Unlimited	8.0X10 ⁻⁸	2.2X10 ⁻⁶
U-236 (fast lung absorption) (d)		Unlimited	Unlimited	Unlimited	Unlimited	2.4X10 ⁻⁶	6.5X10 ⁻⁵
U-236 (medium lung absorption) (e)		Unlimited	Unlimited	Unlimited	Unlimited	2.4X10 ⁻⁶	6.5X10 ⁻⁵
U-236 (slow lung absorption) (f)		Unlimited	Unlimited	Unlimited	Unlimited	2.4X10 ⁻⁶	6.5X10 ⁻⁵
U-238 (all lung absorption types) (d),(e),(f)		Unlimited	Unlimited	Unlimited	Unlimited	1.2X10 ⁻⁸	3.4X10 ⁻⁷
U (nat)		Unlimited	Unlimited	Unlimited	Unlimited	2.6X10 ⁻⁸	7.1X10 ⁻⁷
U (enriched to 20% or less)(g)		Unlimited	Unlimited	Unlimited	Unlimited	N/A	N/A
U (dep)		Unlimited	Unlimited	Unlimited	Unlimited	0.0	(See Table A-3)
V-48	Vanadium (23)	4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	6.3X10 ³	1.7X10 ⁵
V-49		4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	3.0X10 ²	8.1X10 ³

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
W-178 (a)	Tungsten (74)	9.0	2.4X10 ²	5.0	1.4X10 ²	1.3X10 ³	3.4X10 ⁴
W-181		3.0X10 ¹	8.1X10 ²	3.0X10 ¹	8.1X10 ²	2.2X10 ²	6.0X10 ³
W-185		4.0X10 ¹	1.1X10 ³	8.0X10 ⁻¹	2.2X10 ¹	3.5X10 ²	9.4X10 ³
W-187		2.0	5.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	2.6X10 ⁴	7.0X10 ⁵
W-188 (a)		4.0X10 ⁻¹	1.1X10 ¹	3.0X10 ⁻¹	8.1	3.7X10 ²	1.0X10 ⁴
Xe-122 (a)	Xenon (54)	4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	4.8X10 ⁴	1.3X10 ⁶
Xe-123		2.0	5.4X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	4.4X10 ⁵	1.2X10 ⁷
Xe-127		4.0	1.1X10 ²	2.0	5.4X10 ¹	1.0X10 ³	2.8X10 ⁴
Xe-131m		4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	3.1X10 ³	8.4X10 ⁴
Xe-133		2.0X10 ¹	5.4X10 ²	1.0X10 ¹	2.7X10 ²	6.9X10 ³	1.9X10 ⁵
Xe-135		3.0	8.1X10 ¹	2.0	5.4X10 ¹	9.5X10 ⁴	2.6X10 ⁶
Y-87 (a)	Yttrium (39)	1.0	2.7X10 ¹	1.0	2.7X10 ¹	1.7X10 ⁴	4.5X10 ⁵
Y-88		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	5.2X10 ²	1.4X10 ⁴
Y-90		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	2.0X10 ⁴	5.4X10 ⁵
Y-91		6.0X10 ⁻¹	1.6X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	9.1X10 ²	2.5X10 ⁴
Y-91m		2.0	5.4X10 ¹	2.0	5.4X10 ¹	1.5X10 ⁶	4.2X10 ⁷
Y-92		2.0X10 ⁻¹	5.4	2.0X10 ⁻¹	5.4	3.6X10 ⁵	9.6X10 ⁶
Y-93		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	1.2X10 ⁵	3.3X10 ⁶
Yb-169	Ytterbium (79)	4.0	1.1X10 ²	1.0	2.7X10 ¹	8.9X10 ²	2.4X10 ⁴
Yb-175		3.0X10 ¹	8.1X10 ²	9.0X10 ⁻¹	2.4X10 ¹	6.6X10 ³	1.8X10 ⁵
Zn-65	Zinc (30)	2.0	5.4X10 ¹	2.0	5.4X10 ¹	3.0X10 ²	8.2X10 ³
Zn-69		3.0	8.1X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	1.8X10 ⁶	4.9X10 ⁷
Zn-69m (a)		3.0	8.1X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	1.2X10 ⁵	3.3X10 ⁶

TABLE A - 1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Zr-88	Zirconium (40)	3.0	8.1X10 ¹	3.0	8.1X10 ¹	6.6X10 ⁻²	1.8X10 ⁴
Zr-93		Unlimited	Unlimited	Unlimited	Unlimited	9.3X10 ⁻⁵	2.5X10 ⁻³
Zr-95 (a)		2.0	5.4X10 ¹	8.0X10 ⁻¹	2.2X10 ¹	7.9X10 ⁻²	2.1X10 ⁴
Zr-97 (a)		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	7.1X10 ⁻⁴	1.9X10 ⁶

NOTES

- (a) A₁ and/or A₂ values include contributions from daughter nuclides with half-lives less than 10 days
- (b) Parent nuclides and their progeny included in secular equilibrium are listed in the following:
- | | |
|---------|--|
| Sr-90 | Y-90 |
| Zr-93 | Nb-93m |
| Zr-97 | Nb-97 |
| Ru-106 | Rh-106 |
| Cs-137 | Ba-137m |
| Ce-134 | La-134 |
| Ce-144 | Pr-144 |
| Ba-140 | La-140 |
| Bi-212 | Tl-208 (0.36), Po-212 (0.64) |
| Pb-210 | Bi-210, Po-210 |
| Pb-212 | Bi-212, Tl-208 (0.36), Po-212 (0.64) |
| Rn-220 | Po-216 |
| Rn-222 | Po-218, Pb-214, Bi-214, Po-214 |
| Ra-223 | Rn-219, Po-215, Pb-211, Bi-211, Tl-207 |
| Ra-224 | Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64) |
| Ra-226 | Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210 |
| Ra-228 | Ac-228 |
| Th-226 | Ra-222, Rn-218, Po-214 |
| Th-228 | Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64) |
| Th-229 | Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209 |
| Th-nat | Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64) |
| Th-234 | Pa-234m |
| U-230 | Th-226, Ra-222, Rn-218, Po-214 |
| U-232 | Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64) |
| U-235 | Th-231 |
| U-238 | Th-234, Pa-234m |
| U-nat | Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, |
| U-240 | Np-240m |
| Np-237 | Pa-233 |
| Am-242m | Am-242 |
| Am-243 | Np-239 |

- (c) The quantity may be determined from a measurement of the rate of decay or a measurement of the radiation level at a prescribed distance from the source.
- (d) These values apply only to compounds of uranium that take the chemical form of UF_6 , UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.
- (e) These values apply only to compounds of uranium that take the chemical form of UO_3 , UF_4 , UCl_4 , and hexavalent compounds in both normal and accident conditions of transport.
- (f) These values apply to all compounds of uranium other than those specified in (d) and (e), above.
- (g) These values apply to unirradiated uranium only.
- (h) These values apply to domestic transport only. For international transport, use the values in the table below.

TABLE A - 1 (SUPPLEMENT) A_1 AND A_2 VALUES FOR RADIONUCLIDES FOR INTERNATIONAL SHIPMENTS							
Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific activity (TBq/g)	Specific activity (Ci/g)
Cf-252	Californium (98)	5.0×10^{-2}	1.4	3.0×10^{-3}	8.1×10^{-2}	2.0×10^1	5.4×10^2
Mo-99 (a)	Molybdenum (42)	1.0	2.7×10^1	6.0×10^{-1}	1.6×10^1	1.8×10^4	4.8×10^5

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ac-225 (a)	Actinium (89)	1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
Ac-227 (a)		1.0×10^{-1}	2.7×10^{-12}	1.0×10^3	2.7×10^{-8}
Ac-228		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Ag-105	Silver (47)	1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Ag-108m (a)		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Ag-110m (a)		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Ag-111		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Al-26	Aluminum (13)	1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Am-241	Americium (95)	1.0	2.7×10^{-11}	1.0×10^4	2.7×10^{-7}
Am-242m (a)		1.0	2.7×10^{-11}	1.0×10^4	2.7×10^{-7}
Am-243 (a)		1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
Ar-37	Argon (18)	1.0×10^6	2.7×10^{-5}	1.0×10^8	2.7×10^{-3}
Ar-39		1.0×10^7	2.7×10^{-4}	1.0×10^4	2.7×10^{-7}
Ar-41		1.0×10^2	2.7×10^{-9}	1.0×10^9	2.7×10^{-2}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
As-72	Arsenic (33)	1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
As-73		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
As-74		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
As-76		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
As-77		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
At-211 (a)	Astatine (85)	1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Au-193	Gold (79)	1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Au-194		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Au-195		1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Au-198		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Au-199		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Ba-131 (a)	Barium (56)	1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Ba-133		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Ba-133m		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Ba-140 (a)		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Be-7	Beryllium (4)	1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Be-10		1.0×10^4	2.7×10^{-7}	1.0×10^6	2.7×10^{-5}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Bi-205	Bismuth (83)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Bi-206		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Bi-207		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Bi-210		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Bi-210m (a)		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Bi-212 (a)		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Bk-247	Berkelium (97)	1.0	2.7×10^{-11}	1.0×10^4	2.7×10^{-7}
Bk-249 (a)		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Br-76	Bromine (35)	1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Br-77		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Br-82		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
C-11	Carbon (6)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
C-14		1.0×10^4	2.7×10^{-7}	1.0×10^7	2.7×10^{-4}
Ca-41	Calcium (20)	1.0×10^5	2.7×10^{-6}	1.0×10^7	2.7×10^{-4}
Ca-45		1.0×10^4	2.7×10^{-7}	1.0×10^7	2.7×10^{-4}
Ca-47 (a)		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Cd-109	Cadmium (48)	1.0×10^4	2.7×10^{-7}	1.0×10^6	2.7×10^{-5}
Cd-113m		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Cd-115 (a)		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Cd-115m		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Ce-139	Cerium (58)	1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Ce-141		1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Ce-143		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Ce-144 (a)		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
Cf-248	Californium (98)	1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
Cf-249		1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
Cf-250		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
Cf-251		1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
Cf-252		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
Cf-253 (a)		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
Cf-254		1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
Cl-36	Chlorine (17)	1.0×10^4	2.7×10^{-7}	1.0×10^6	2.7×10^{-5}
Cl-38		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Cm-240	Curium (96)	1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
Cm-241		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Cm-242		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
Cm-243		1.0	2.7×10^{-11}	1.0×10^4	2.7×10^{-7}
Cm-244		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
Cm-245		1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
Cm-246		1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
Cm-247 (a)		1.0	2.7×10^{-11}	1.0×10^4	2.7×10^{-7}
Cm-248		1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
Co-55	Cobalt (27)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Co-56		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Co-57		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Co-58		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Co-58m		1.0×10^4	2.7×10^{-7}	1.0×10^7	2.7×10^{-4}
Co-60		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Cr-51	Chromium (24)	1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Cs-129	Cesium (55)	1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
Cs-131		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Cs-132		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Cs-134		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
Cs-134m		1.0×10^3	2.7×10^{-8}	1.0×10^5	2.7×10^{-6}
Cs-135		1.0×10^4	2.7×10^{-7}	1.0×10^7	2.7×10^{-4}
Cs-136		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Cs-137 (a)		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
Cu-64	Copper (29)	1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Cu-67		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Dy-159	Dysprosium (66)	1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Dy-165		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Dy-166 (a)		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Er-169	Erbium (68)	1.0×10^4	2.7×10^{-7}	1.0×10^7	2.7×10^{-4}
Er-171		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Eu-147	Europium (63)	1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Eu-148		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Eu-149		1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Eu-150 (short lived)		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Eu-150 (long lived)		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Eu-152		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Eu-152 m		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Eu-154		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Eu-155		1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Eu-156		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
F-18	Fluorine (9)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Fe-52 (a)	Iron (26)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Fe-55		1.0×10^4	2.7×10^{-7}	1.0×10^6	2.7×10^{-5}
Fe-59		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Fe-60 (a)		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ga-67	Gallium (31)	1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Ga-68		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Ga-72		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Gd-146 (a)	Gadolinium (64)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Gd-148		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
Gd-153		1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Gd-159		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Ge-68 (a)	Germanium (32)	1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Ge-71		1.0×10^4	2.7×10^{-7}	1.0×10^8	2.7×10^{-3}
Ge-77		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Hf-172 (a)	Hafnium (72)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Hf-175		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Hf-181		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Hf-182		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Hg-194 (a)	Mercury (80)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Hg-195m (a)		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Hg-197		1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Hg-197m		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Hg-203		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
Ho-166	Holmium (67)	1.0×10^3	2.7×10^{-8}	1.0×10^5	2.7×10^{-6}
Ho-166m		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
I-123	Iodine (53)	1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
I-124		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
I-125		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
I-126		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
I-129		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
I-131		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
I-132		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
I-133		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
I-134		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
I-135 (a)		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
In-111	Indium (49)	1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
In-113m		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
In-114m (a)		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
In-115m		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Ir-189 (a)	Iridium (77)	1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Ir-190		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Ir-192		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
Ir-194		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
K-40	Potassium (19)	1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
K-42		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
K-43		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Kr-81	Krypton (36)	1.0×10^4	2.7×10^{-7}	1.0×10^7	2.7×10^{-4}
Kr-85		1.0×10^5	2.7×10^{-6}	1.0×10^4	2.7×10^{-7}
Kr-85m		1.0×10^3	2.7×10^{-8}	1.0×10^{10}	2.7×10^{-1}
Kr-87		1.0×10^2	2.7×10^{-9}	1.0×10^9	2.7×10^{-2}
La-137	Lanthanum (57)	1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
La-140		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Lu-172	Lutetium (71)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Lu-173		1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Lu-174		1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Lu-174m		1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Lu-177		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Mg-28 (a)	Magnesium (12)	1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Mn-52	Manganese (25)	1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Mn-53		1.0×10^4	2.7×10^{-7}	1.0×10^9	2.7×10^{-2}
Mn-54		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Mn-56		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Mo-93	Molybdenum (42)	1.0×10^3	2.7×10^{-8}	1.0×10^8	2.7×10^{-3}
Mo-99 (a)		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
N-13	Nitrogen (7)	1.0×10^2	2.7×10^{-9}	1.0×10^9	2.7×10^{-2}
Na-22	Sodium (11)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Na-24		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Nb-93m	Niobium (41)	1.0×10^4	2.7×10^{-7}	1.0×10^7	2.7×10^{-4}
Nb-94		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Nb-95		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Nb-97		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Nd-147	Neodymium (60)	1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Nd-149		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Ni-59	Nickel (28)	1.0×10^4	2.7×10^{-7}	1.0×10^8	2.7×10^{-3}
Ni-63		1.0×10^5	2.7×10^{-6}	1.0×10^8	2.7×10^{-3}
Ni-65		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Np-235	Neptunium (93)	1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Np-236 (short-lived)		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Np-236 (long-lived)		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Np-237		1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
Np-239		1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Os-185	Osmium (76)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Os-191		1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Os-191m		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Os-193		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Os-194 (a)		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
P-32	Phosphorus (15)	1.0×10^3	2.7×10^{-8}	1.0×10^5	2.7×10^{-6}
P-33		1.0×10^5	2.7×10^{-6}	1.0×10^8	2.7×10^{-3}
Pa-230 (a)	Protactinium (91)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Pa-231		1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
Pa-233		1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Pb-201	Lead (82)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Pb-202		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Pb-203		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Pb-205		1.0×10^4	2.7×10^{-7}	1.0×10^7	2.7×10^{-4}
Pb-210 (a)		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
Pb-212 (a)		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Pd-103 (a)	Palladium (46)	1.0×10^3	2.7×10^{-8}	1.0×10^8	2.7×10^{-3}
Pd-107		1.0×10^5	2.7×10^{-6}	1.0×10^8	2.7×10^{-3}
Pd-109		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Pm-143	Promethium (61)	1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Pm-144		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Pm-145		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Pm-147		1.0×10^4	2.7×10^{-7}	1.0×10^7	2.7×10^{-4}
Pm-148m (a)		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Pm-149		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Pm-151		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Po-210	Polonium (84)	1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
Pr-142	Praseodymium (59)	1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
Pr-143		1.0×10^4	2.7×10^{-7}	1.0×10^6	2.7×10^{-5}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Pt-188 (a)	Platinum (78)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Pt-191		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Pt-193		1.0×10^4	2.7×10^{-7}	1.0×10^7	2.7×10^{-4}
Pt-193m		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Pt-195m		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Pt-197		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Pt-197m		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Pu-236	Plutonium (94)	1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
Pu-237		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Pu-238		1.0	2.7×10^{-11}	1.0×10^4	2.7×10^{-7}
Pu-239		1.0	2.7×10^{-11}	1.0×10^4	2.7×10^{-7}
Pu-240		1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
Pu-241 (a)		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
Pu-242		1.0	2.7×10^{-11}	1.0×10^4	2.7×10^{-7}
Pu-244 (a)		1.0	2.7×10^{-11}	1.0×10^4	2.7×10^{-7}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ra-223 (a)	Radium (88)	1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
Ra-224 (a)		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Ra-225 (a)		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
Ra-226 (a)		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
Ra-228 (a)		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Rb-81	Rubidium (37)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Rb-83 (a)		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Rb-84		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Rb-86		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
Rb-87		1.0×10^4	2.7×10^{-7}	1.0×10^7	2.7×10^{-4}
Rb(nat)		1.0×10^4	2.7×10^{-7}	1.0×10^7	2.7×10^{-4}
Re-184	Rhenium (75)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Re-184m		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Re-186		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Re-187		1.0×10^6	2.7×10^{-5}	1.0×10^9	2.7×10^{-2}
Re-188		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
Re-189 (a)		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Re(nat)		1.0×10^6	2.7×10^{-5}	1.0×10^9	2.7×10^{-2}

**TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT
CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES**

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Rh-99	Rhodium (45)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Rh-101		1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Rh-102		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Rh-102m		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Rh-103m		1.0×10^4	2.7×10^{-7}	1.0×10^8	2.7×10^{-3}
Rh-105		1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Rn-222 (a)	Radon (86)	1.0×10^1	2.7×10^{-10}	1.0×10^8	2.7×10^{-3}
Ru-97	Ruthenium (44)	1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Ru-103 (a)		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Ru-105		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Ru-106 (a)		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
S-35	Sulphur (16)	1.0×10^5	2.7×10^{-6}	1.0×10^8	2.7×10^{-3}
Sb-122	Antimony (51)	1.0×10^2	2.7×10^{-9}	1.0×10^4	2.7×10^{-7}
Sb-124		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Sb-125		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Sb-126		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Sc-44	Scandium (21)	1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Sc-46		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Sc-47		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Sc-48		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Se-75	Selenium (34)	1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Se-79		1.0×10^4	2.7×10^{-7}	1.0×10^7	2.7×10^{-4}
Si-31	Silicon (14)	1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Si-32		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Sm-145	Samarium (62)	1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Sm-147		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
Sm-151		1.0×10^4	2.7×10^{-7}	1.0×10^8	2.7×10^{-3}
Sm-153		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Sn-113 (a)	Tin (50)	1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Sn-117m		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Sn-119m		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Sn-121m (a)		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Sn-123		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Sn-125		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
Sn-126 (a)		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Sr-82 (a)	Strontium (38)	1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Sr-85		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Sr-85m		1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Sr-87m		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Sr-89		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Sr-90 (a)		1.0×10^2	2.7×10^{-9}	1.0×10^4	2.7×10^{-7}
Sr-91 (a)		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Sr-92 (a)		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
T(H-3)	Tritium (1)	1.0×10^6	2.7×10^{-5}	1.0×10^9	2.7×10^{-2}
Ta-178 (long-lived)	Tantalum (73)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Ta-179		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Ta-182		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
Tb-157	Terbium (65)	1.0×10^4	2.7×10^{-7}	1.0×10^7	2.7×10^{-4}
Tb-158		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Tb-160		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Tc-95m (a)	Technetium (43)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Tc-96		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Tc-96m (a)		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Tc-97		1.0×10^3	2.7×10^{-8}	1.0×10^8	2.7×10^{-3}
Tc-97m		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Tc-98		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Tc-99		1.0×10^4	2.7×10^{-7}	1.0×10^7	2.7×10^{-4}
Tc-99m		1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Te-121	Tellurium (52)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Te-121m		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
Te-123m		1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Te-125m		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Te-127		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Te-127m (a)		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Te-129		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Te-129m (a)		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Te-131m (a)		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Te-132 (a)		1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}

**TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT
CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES**

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Th-227	Thorium (90)	1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
Th-228 (a)		1.0	2.7×10^{-11}	1.0×10^4	2.7×10^{-7}
Th-229		1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
Th-230		1.0	2.7×10^{-11}	1.0×10^4	2.7×10^{-7}
Th-231		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Th-232		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
Th-234 (a)		1.0×10^3	2.7×10^{-8}	1.0×10^5	2.7×10^{-6}
Th (nat)		1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
Ti-44 (a)	Titanium (22)	1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Tl-200	Thallium (81)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Tl-201		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Tl-202		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Tl-204		1.0×10^4	2.7×10^{-7}	1.0×10^4	2.7×10^{-7}
Tm-167	Thulium (69)	1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Tm-170		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Tm-171		1.0×10^4	2.7×10^{-7}	1.0×10^8	2.7×10^{-3}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
U-230 (fast lung absorption) (a)(d)	Uranium (92)	1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
U-230 (medium lung absorption) (a)(e)		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
U-230 (slow lung absorption) (a)(f)		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
U-232 (fast lung absorption) (d)	Uranium (92)	1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
U-232 (medium lung absorption) (e)		1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
U-232 (slow lung absorption) (f)		1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
U-233 (fast lung absorption) (d)		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
U-233 (medium lung absorption) (e)		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
U-233 (slow lung absorption) (f)		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
U-234 (fast lung absorption) (d)		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
U-234 (medium lung absorption) (e)		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
U-234 (slow lung absorption) (f)		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
U-235 (all lung absorption types) (a),(d),(e),(f)		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
U-236 (fast lung absorption) (d)		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
U-236 (medium lung absorption) (e)	Uranium (92)	1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
U-236 (slow lung absorption) (f)		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
U-238 (all lung absorption types) (d),(e),(f)		1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
U (nat)		1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
U (enriched to 20% or less)(g)		1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
U (dep)		1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
V-48	Vanadium (23)	1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
V-49		1.0×10^4	2.7×10^{-7}	1.0×10^7	2.7×10^{-4}
W-178 (a)	Tungsten (74)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
W-181		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
W-185		1.0×10^4	2.7×10^{-7}	1.0×10^7	2.7×10^{-4}
W-187		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
W-188 (a)		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Xe-122 (a)	Xenon (54)	1.0×10^2	2.7×10^{-9}	1.0×10^9	2.7×10^{-2}
Xe-123		1.0×10^2	2.7×10^{-9}	1.0×10^9	2.7×10^{-2}
Xe-127		1.0×10^3	2.7×10^{-8}	1.0×10^5	2.7×10^{-6}
Xe-131m		1.0×10^4	2.7×10^{-7}	1.0×10^4	2.7×10^{-7}
Xe-133		1.0×10^3	2.7×10^{-8}	1.0×10^4	2.7×10^{-7}
Xe-135		1.0×10^3	2.7×10^{-8}	1.0×10^{10}	2.7×10^{-1}
Y-87 (a)	Yttrium (39)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Y-88		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Y-90		1.0×10^3	2.7×10^{-8}	1.0×10^5	2.7×10^{-6}
Y-91		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Y-91m		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Y-92		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
Y-93		1.0×10^2	2.7×10^{-9}	1.0×10^5	2.7×10^{-6}
Yb-169	Ytterbium (79)	1.0×10^2	2.7×10^{-9}	1.0×10^7	2.7×10^{-4}
Yb-175		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Zn-65	Zinc (30)	1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Zn-69		1.0×10^4	2.7×10^{-7}	1.0×10^6	2.7×10^{-5}
Zn-69m (a)		1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}

TABLE A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES					
Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Zr-88	Zirconium (40)	1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Zr-93		1.0×10^3	2.7×10^{-8}	1.0×10^7	2.7×10^{-4}
Zr-95 (a)		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Zr-97 (a)		1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}

NOTES

(a) A_1 and/or A_2 values include contributions from daughter nuclides w/half-lives less than 10 days.

(b) Parent nuclides and their progeny included in secular equilibrium are listed in the following:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Cs-137	Ba-137m
Ce-134	La-134
Ce-144	Pr-144
Ba-140	La-140
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-226	Ra-222, Rn-218, Po-214
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-nat	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-nat	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214,
U-240	Np-240m
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

- (c) The quantity may be determined from a measurement of the rate of decay or a measurement of the radiation level at a prescribed distance from the source.
- (d) These values apply only to compounds of uranium that take the chemical form of UF_6 , UO_2F_2 , and $\text{UO}_2(\text{NO}_3)_2$ in both normal and accident conditions of transport.
- (e) These values apply only to compounds of uranium that take the chemical form of UO_3 , UF_4 , UCl_4 , and hexavalent compounds in both normal and accident conditions of transport.
- (f) These values apply to all compounds of uranium other than those specified in (d) and (e), above.
- (g) These values apply to unirradiated uranium only.

TABLE A-3: GENERAL VALUES FOR A_1 AND A_2

Contents	A_1		A_2		Activity concentration for exempt material	Activity concentration for exempt material	Activity limits for exempt consignments	Activity limits for exempt consignments
	(TBq)	(Ci)	(TBq)	(Ci)	(Bq/g)	(Ci/g)	(Bq)	(Ci)
Only beta or gamma emitting radionuclides are known to be present	1×10^{-1}	2.7×10^0	2×10^{-2}	5.4×10^{-1}	1×10^1	2.7×10^{-10}	1×10^4	2.7×10^{-7}
Only alpha emitting radionuclides are known to be present	2×10^{-1}	5.4×10^0	9×10^{-5}	2.4×10^{-3}	1×10^{-1}	2.7×10^{-12}	1×10^3	2.7×10^{-8}
No relevant data are available	1×10^{-3}	2.7×10^{-2}	9×10^{-5}	2.4×10^{-3}	1×10^{-1}	2.7×10^{-12}	1×10^3	2.7×10^{-8}

TABLE A-4: ACTIVITY-MASS RELATIONSHIPS FOR URANIUM

Uranium Enrichment ¹ wt % U-235 present	Specific Activity	
	TBq/g	Ci/g
0.45	1.8×10^{-8}	5.0×10^{-7}
0.72	2.6×10^{-8}	7.1×10^{-7}
1	2.8×10^{-8}	7.6×10^{-7}
1.5	3.7×10^{-8}	1.0×10^{-6}
5	1.0×10^{-7}	2.7×10^{-6}
10	1.8×10^{-7}	4.8×10^{-6}
20	3.7×10^{-7}	1.0×10^{-5}
35	7.4×10^{-7}	2.0×10^{-5}
50	9.3×10^{-7}	2.5×10^{-5}
90	2.2×10^{-6}	2.8×10^{-5}
93	2.6×10^{-6}	7.0×10^{-5}
95	3.4×10^{-6}	9.1×10^{-5}

¹ The figures for uranium include representative values for the activity of the uranium-234 that is concentrated during the enrichment process.

Dated at Rockville, Maryland, this _____ day of _____, 2003.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary of the Commission.