
Summary and Categorization of Public Comments on the Major Revision of 10 CFR Part 71

Manuscript Completed: July 28, 2003

Prepared by:
D. Hammer, K. Blake, E. Earle

ICF Consulting, Inc.
9300 Lee Highway
Fairfax, Va 22031-1207

N. Tanious, NRC Project Manager

Prepared for
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
NRC Job Code



ABSTRACT

This report presents a summary and analysis of comments the Nuclear Regulatory Commission (NRC) received on its proposal to modify 10 CFR Part 71 requirements pertaining to the packaging and transport of radioactive materials, including fissile materials. Specifically, the NRC has amended its regulations on packaging and transporting radioactive material to make them compatible with the International Atomic Energy Agency (IAEA) standards and to codify other applicable requirements. These changes will be compatible with TS-R-1, the latest revision of the IAEA transportation standards. This rulemaking 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). Finally, this rule makes a decision on a petition for rulemaking submitted by International Energy Consultants, Inc. (PRM-71-12: February 19, 1998; 63 FR 8362). The NRC has granted, in part, the requested action of PRM-71-12 by removing the double containment requirement of § 71.63(b); however, the NRC has retained the package contents requirements of § 71.63(a).

TABLE OF CONTENTS

ABSTRACT	iii
1. Introduction	1
1.1 Background	1
1.2 Organization	1
2. General Issues	3
2.1 Compatibility with IAEA and DOT standards	3
2.2 Regulatory Analysis (RA) and Environmental Assessment (EA)	9
2.3 State Regulations	11
2.4 Terrorism Concerns	12
2.5 Adequacy of NRC Regulations and Rulemaking Process	13
2.6 Proposed Yucca Mountain Facility	21
2.7 Miscellaneous (including comments to DOT)	22
3. TS-R-1 Compatibility Issues	29
3.1 Issue 1. Changing Part 71 to the International System of Units (SI) Only	29
3.2 Issue 2. Radionuclide Exemption Values	29
3.3 Issue 3. Revision of A_1 and A_2	47
3.4 Issue 4. Uranium Hexafluoride (UF_6) Package Requirements	53
3.5 Issue 5. Introduction of the Criticality Safety Index Requirements	55
3.6 Issue 6. Type C Packages and Low Dispersible Material	57
3.7 Issue 7. Deep Immersion Test	59
3.8 Issue 8. Grandfathering Previously Approved Packages	62
3.9 Issue 9. Changes to Various Definitions	80
3.10 Issue 10. Crush Test for Fissile Material Package Design	82
3.11 Issue 11. Fissile Material Package Design for Transport by Aircraft	85
4. NRC-Initiated Issues	87
4.1 Issue 12. Special Package Authorizations	87
4.2 Issue 13. Expansion of Part 71 Quality Assurance Requirements to Certificate of Compliance (CoC) Holders	90
4.3 Issue 14. Adoption of American Society of Mechanical Engineers (ASME) Code	90
4.4 Issue 15. Change Authority for Dual-Purpose Package Certificate Holders	90
4.5 Issue 16. Fissile Material Exemptions and General License Provisions	94
4.6 Issue 17. Decision on Petition for Rulemaking on Double Containment of Plutonium (PRM-71-12)	100
4.7 Issue 18. Contamination Limits as Applied to Spent Fuel and High-Level Waste (HLW) Packages	108
4.8 Issue 19. Modifications of Event Reporting Requirements	109

APPENDICES

A. List of Commenters A-1

1. Introduction

The purpose of this document is to summarize and analyze the comments received by the NRC during its rulemaking to revise Part 71. These include comments received during the public meetings held by NRC, comments the general public submitted to NRC, and comments Agreement States submitted to NRC. In total, NRC received comments from 200 individuals, organizations, and or agencies.

1.1 Background

The NRC published the Part 71 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 staff to continue the enhanced public participation process. The NRC staff held two public meetings to discuss the proposed rule requirements with members of the public. 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. Transcripts of these meetings were posted on the NRC website. The Department of Transportation (DOT) staff participated in these meetings. The public comment period closed on July 29, 2002. A total of 192 comments were received. Many of these comments were received after the closing date; however, all comments were analyzed and considered in this final rule.

Prior to the publication of the proposed rule, the NRC published the Part 71 issues paper in the Federal Register (65 FR 44360; July 17, 2000) for public comment. The issues paper presented the NRC's plan to revise Part 71 and provided a summary of all changes being considered, both IAEA-related changes and NRC-initiated changes. The NRC published the issues paper to begin an enhanced public-participation process designed to solicit public input on the Part 71 rulemaking. This process included establishing an interactive website and holding three facilitated public meetings: a "roundtable" workshop at the 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.

1.2 Organization

The contents of each submission have been carefully reviewed and binned into one of the 19 issue areas defined by NRC. However, commenters often included questions or comments not directly related to a particular issue area. These general comments are binned into a number of general topic areas.

A number of commenters submitted materials and or attended multiple public meeting(s). The comments NRC received from these individuals are not distilled to a single list of comments attributed to the commenter. Instead, if the commenter attended the Chicago meeting and submitted a comment letter to NRC later, for example, then this individual will appear twice in this comment summary analysis. Appendix A includes a table, Table A-2, where the commenters are mapped to their submissions.

In addition, NRC also received a number of form letters. These form letters have been included in this analysis but for presentation purposes, they have been lumped together. For example, Commenter No. 1090-0028 represents four commenter letters while Commenter No.

1090-0029 represents 112 comment letters.^{1,2} To reiterate, these submissions have been accounted for in both the summary as well as this analysis. The comments were consolidated solely for presentation purposes.

¹ Commenter No. 1090-0028 represents a form letter that was submitted by four people (Commenter Nos. 1090-0028, 1090-0036, 1090-0146, and 1090-0148).

² Commenter No. 1090-0029 represents a form letter that was submitted by 112 people (Commenter Nos. 1090-0029, 1090-0031, 1090-0047, 1090-0048, 1090-0055, 1090-0060:1090-0065, 1090-0067, 1090-0068:1090-0075, 1090-0077:1090-0079, 1090-0081:1090-0084, 1090-0086:1090-0096, 1090-0098, 1090-0101:1090-0105, 1090-0107:1090-0124, 1090-0126, 1090-0127, 1090-0131:1090-0135, 1090-0140, 1090-0149:1090-0170, 1090-0173:1090-0179, 1090-0181:1090-0185, 1090-0187:1090-0193, 1090-0195, 1090-0196).

2. General Issues

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 International Atomic Energy Agency (IAEA) and Department of Transportation (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).

2.1 Compatibility with IAEA and DOT standards

Comment. Several commenters generally supported NRC's efforts to be consistent with IAEA regulations (Commenter Nos. 1090-0034, 1090-0040, 1090-0041, 1090-0173, 1090-0052, 1090-0143, and CA-003). The particular reasons for this support varied among commenters but included such issues as approving of harmonization and encouraging NRC's coordination with DOT (Commenter No. 1090-0034). 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 (Commenter No. 1090-0034). Two commenters urged the NRC to move swiftly to complete this rulemaking effort and to remain consistent with DOT regulations (Commenter Nos. CA-009 and 1090-0143). One commenter stated that uniform international regulations were in the public's best interest for the safe movement of nuclear materials (Commenter No. 1090-0143). 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 (Commenter No. 1090-0041). 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 (Commenter No. 1090-0052). 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 (Commenter No. CA-003).

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 (Commenter No. 1090-0039).

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 (Commenter Nos. CE-001, RA-002, RM-002, and 1090-0097). 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 (Commenter Nos. CE-001, RA-002, and RM-002). One of these commenters stated that regulated or potentially regulated bodies should be allowed more involvement in the IAEA decisionmaking process (Commenter No. RA-002). 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 (Commenter No. CE-001). 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” (Commenter No. 1090-0097).

Response. The United States is represented at the IAEA 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) seek to amend their 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 (Commenter No. RM-016). Another commenter suggested that the burden of proof for rejecting the proposed regulatory changes is being shifted to citizens and stakeholders (Commenter No. RM-002).

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 (Commenter No. CA-002). 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 (Commenter No. 1090-0041). 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 (Commenter No. 1090-0128).

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 (Commenter No. 1090-0059).

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 (Commenter No. 1090-0046).

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 (Commenter No. RM-006). 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 (Commenter No. RM-008).

Response. The comments are acknowledged.

Comment. One commenter stated that harmonization is a “value neutral process” and isn’t necessarily good or bad (Commenter No. RM-008).

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 (Commenter Nos. 1090-0128, RM-002, RM-005, and RM-013). 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 (Commenter No. 1090-0128). Another commenter noted that the primary objective of these changes should be to protect public health, safety, and the environment (Commenter No. RM-005). 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 (Commenter No. RM-002). 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 our 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 (Commenter Nos. CA-001 and CA-002). 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 (Commenter No. CA-002).

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 (Commenter No. CA-001). 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 based 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 (Commenter Nos. 1090-0028, 1090-0038, and 1090-0058). 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 (Commenters Nos. 1090-0028 and 1090-0058). 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 (Commenter No. 1090-0028). 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 (Commenter Nos. 1090-0028, 1090-0046, 1090-0049, 1090-0050, 1090-0059, and 1090-0128). 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” (Commenter No. 1090-0128). 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 (Commenter No. 1090-0049).

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 (Commenters Nos. 1090-0028, 1090-0039, 1090-0044, 1090-0046, 1090-0050, 1090-0053, 1090-0058, 1090-0059, and 1090-0129). Two commenters

stated that IAEA does not necessarily consider the risk-informed, performance-based standards that are important to rulemaking in the U.S. (Commenters Nos. 1090-0053 and 1090-0058). 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 (Commenter Nos. RM-006, RM-008, RM-009, and RM-014). One commenter spoke for Agreement States and expressed support for harmonizing regulations (Commenter No. RM-009). 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 (Commenter Nos. RM-006 and RM-008). 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 (Commenter No. RM-014).

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.

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

Comment. Several commenters found the RA to be deficient in various aspects (Commenter Nos. RM-005, RM-013, RM-016, 1092-0002, and 1092-0003). 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 (Commenter No. RM-005). 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 (Commenter Nos. RM-005 and RM-016). The first 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 (Commenter No. RM-005). 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) (Commenter No. 1090-0128). 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 (Commenter No. RM-013). The commenter said that this fact precludes NRC from actually finding an environmental impact from the rules.

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 (Commenter Nos. RM-005 and RM-013). 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 (Commenter No. RM-005).

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 (Commenter No. RM-005). 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 (Commenter No. RM-013).

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 (Commenter No. RM-005). 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 (Commenter No. 1090-0128). 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.

2.3 State Regulations

Comment. One commenter asked if these new regulations would threaten a State's right to regulate radioactive materials that NRC has deregulated (Commenter No. CA-001). Two commenters stated opposition to the proposed rule due to their belief that it would lower standards (Commenter Nos. 1090-0027 and 1090-0032). The first commenter stated that the proposed rule would override State and local laws that are stricter than Federal regulations (Commenter No. 1090-0027) while the second commenter stated that the proposed rule would reduce environmental protection (Commenter No. 1090-0032). Four commenters added that "harmonization" with international law was a poor and ultimately insufficient justification to weaken U.S. regulations (Commenter Nos. 1090-0003, 1090-0039, 1090-0129, and 1090-0142).

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, Compatibility Category B. 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.

2.4 Terrorism Concerns

Comment. Six commenters expressed concern with the increased threat of terrorism and its impact on radioactive material transport (Commenter Nos. CA-005, RM-002, 1090-0033, 1090-0130, 1090-0128, and 1092-0004). 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 (Commenter No. 1090-0033). 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 (Commenter Nos. CA-005 and RM-002). 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 (Commenter Nos. RM-002, 1090-0128, and 1092-0004). 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” (Commenter No. 1090-0128). 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 (Commenter No. 1090-0100). One commenter opposed the adoption of new transport regulations that reduce the protection to the public from transporting nuclear wastes (Commenter No. 1090-0028).

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 (Commenters Nos. 1090-0008, 1090-0039, 1090-0044, 1090-0129, 1090-0142, and CA-005). A commenter believes that labeling radioactive materials could aid terrorists by identifying the packages as radioactive (Commenter No. CA-005), while another commenter stated that shipments with or without labels provided potential terrorists with the materials for a dirty bomb (Commenter No. 1090-0044). Another commenter requested that NRC put protective measures into place at ports (Commenter No. 1090-0039) and to guard all nuclear shipments with U.S. military forces (Commenter No. 1090-0059). 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 (Commenter No. 1090-0039). 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 (Commenter Nos. 1090-0008 and 1090-0039).

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 licensees instead of initiating rulemaking which takes a longer time, and initiating shipment vulnerability studies. Also, the NRC will make the necessary rule changes.

2.5 Adequacy of NRC Regulations and Rulemaking Process

Comment. Four commenters believe that the NRC should better account for low-level radiation (Commenter Nos. 1090-0039, 1090-0050, 1090-0106, and 1090-0128). 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 (Commenter No. 1090-0039). The second commenter stated that the cumulative effects of trivial amounts of radioactivity can be devastating (Commenter No. 1090-0050). Another commenter stated that low-level radiation could cause cell death, cancer, genetic mutations, cancers, leukemia, birth defects, and reproductive, immune, and endocrine system disorders (Commenter No. 1090-0106). 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” (Commenter No. 1090-0106). 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 have been observed among the children born to atomic bomb survivors from Hiroshima and Nagasaki. 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 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 2.4 mSv (240 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 DOE and the National Aeronautics and Space Administration (NASA). These research projects are designed to better understand the biological responses of molecules, cells, tissues, organs, and organisms to low doses of radiation. NRC also is partially funding a review of the Biological Effects of Ionizing Radiation (BEIR) by the National Research Council. 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.

Finally, existing regulatory guidance suggests that protection of individuals (humans) is also protective of the environment. IAEA Technical Reports 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 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 (Commenter Nos. 1090-0003, 1090-0004, 1090-0027, 1090-0128, 1090-0030, 1090-0032, and 1090-0147).

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.

Comment. One commenter stated that U.S. agencies have not adequately represented public opinion regarding transportation safety (Commenter No. RM-002). 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 is 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 (Commenter 1090-0128).

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 (Commenter No. 1090-0128). 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 (Commenter Nos. RM-005, RM-013, RA-001, 1090-0039, 1090-0051, 1090-0128, 1090-129, 1090-0130, 1090-0141, 1090-0142, and 1092-0003). One commenter said that the proposed rule is written in a manner difficult for the public and even watchdog groups to understand

(Commenter No. 1090-0051). 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 (Commenter Nos. 1090-0128 and 1090-0142). Commenters added that the proposed rule was not urgent (Commenter No. 1090-0129) and required further analysis and research (Commenter No. 1090-0141). 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 (Commenter No. RM-013). The commenter suggested that a one- or two-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 web site 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 (Commenter No. RM-005).

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 (Commenter No. CA-002).

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 (Commenter No. RM-005 and 1092-0003).

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 NRC staff uses the ongoing processes and information described in former Chairman Meserve's letter as guidance when making any changes in 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 (Commenter No. CA-004). 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 ADAMS System (Agency Wide Document Access and Management System), no record was found for this letter; however, the NRC 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 (Commenter No. RM-015). 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 effects 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 (Commenter Nos. 1090-0008, 1090-00028, 1090-0030, 1090-0033, 1090-0039, 1090-0040, 1090-0129, 1090-0141, 1090-0142, and RM-005). One commenter urged NRC to ensure that the adopted rule represents a risk-informed, performance-based approach (Commenter No. 1090-0040). Two commenters criticized the proposed rule for not accounting for an expected increase in radioactive shipments (Commenter Nos. 1090-0008 and 1090-0129). Given such

an increase, one commenter criticized the NRC for using 20-year old data to justify rule changes that will reduce public safety (Commenter No. 1090-0008). 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, otherwise known as the "bystander effect." 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 (Commenter No. 1090-0028). 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 (Commenter No. 1090-0030). 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 (Commenter No. 1090-0033).

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 statement of considerations for this rulemaking. The commenter did not provide sufficient detail on which data was 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 (Commenter Nos. CA-002, CA-004, RM-005, and RM-013). Two commenters were specifically concerned that DOE and some commercial nuclear facilities are negligent in keeping radiation exposure and release records (Commenter Nos. CA-002 and CA-004). These commenters questioned how NRC data were 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 (Commenter Nos. RM-005, 1090-0128, and 1090-0142). One commenter requested improved public access to “sources of codes and IAEA documents that were cited by reference in the draft” rule (Commenter No. 1090-0128).

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.. Therefore, the NRC disagrees with the commenters.

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 (Commenter Nos. CA-008, RM-002, 1090-0028, and 1090-0142). 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 (Commenter No. 1090-0142).

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 has 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 Package Performance Study (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 (Commenters Nos. 1090-0043, 1090-0129, and 1090-0142).

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 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 (Commenter No. CA-002). 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 (Commenter No. RM-016). 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 (Commenter No. CA-001).

Response. The IAEA conducted a survey in September 2002, in which they 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-rasnet.iaea.org/downloads/radiation-safety/MSResponses2002.pdf>.

Comment. One commenter requested clarification on NRC assumptions for future radioactive materials transportation (Commenter No. CA-009). 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. Three commenters opposed weakening regulations that would reduce the public safety and health through new definitions or accepted concentration values (Commenters Nos. 1090-0028, 1090-0044, and 1092-0002). 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" (Commenter No. 1090-0128).

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 (Commenter No. 1090-0180). 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 (Commenter Nos. 1090-0106 and 1090-0145).

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 (Commenter No. 1090-0049).

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" (Commenter No. 1090-0128).

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

2.6 Proposed Yucca Mountain Facility

Comment. One commenter expressed opposition to sending shipments of nuclear materials to the proposed Yucca Mountain facility (Commenter No. 1090-0059).

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 (Commenter Nos. CA-004 and CA-008). One commenter expressed concern about the safety of dry casks (Commenter No. CA-004). 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. 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 (Commenter No. CA-008).

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 , 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 (Commenter Nos. CA-002, 1090-0028, and 1092-0003). The first commenter stated that these regulations could have important implications for the shipment of high-level radioactive waste (Commenter No. CA-002). 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 (Commenter Nos. CA-008 and CA-009). 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 (Commenter No. CA-009). 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.

2.7 Miscellaneous (including comments to DOT)

Comment. One commenter opposed any use of radioactive materials entirely (Commenter No. 1090-0059).

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 (Commenter No. 1090-0042). 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 (Commenter No. 1090-0008).

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 (Commenter No. 1090-0129).

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 (Commenter No. 1090-0129).

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 (Commenter No. 1090-0059).

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 (Commenter Nos. 1090-0039, 1090-0043, 1090-0059, and 1090-0129). Two commenters believe that NRC should publicly report all radioactive shipments (Commenter Nos. 1090-0039 and 1090-0059).

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 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 (Commenter Nos. 1090-0039, 1090-0043, 1090-0059, and 1090-0129). Two commenters urged the NRC to track, label, and publicly report all radioactive shipments (Commenter Nos. 1090-0039 and 1090-0059). 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 (Commenter No. 1090-0043). 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 (Commenter No. 1090-0039).

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 (Commenter No. CA-009).

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 (Commenter No. CA-001).

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 (Commenter No. RM-002). 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)” (Commenter No. 1090-0008). 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 (Commenter No. 1090-0049).

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” (Commenter No. 1090-0128).

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 (Commenter Nos. RM-0039, 1090-0039, and 1090-0128). One commenter believes that certain States are already burdened with unusually high concentrations of hazardous and radioactive materials transport (Commenter No. RM-015). 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” (Commenter No. 1090-0128). 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 (Commenter No. 1090-0039).

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 (Commenter Nos. CA-001, CA-005, 1090-0028, and 1090-0044).

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 (Commenter Nos. CA-005 and 1090-0039). These commenters asked if workers would be protected from and informed of leaks and whether there is sufficient money to pay lawsuit damages (Commenter No. CA-005). 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 (Commenter No. 1090-0039). One commenter then asserted that workers should be trained to handle radioactive materials and informed of the risks involved (Commenter No. 1090-0039).

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 (Commenter Nos. CA-006, 1090-0002, 1090-0039, and 1090-0044). 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 (Commenter No. 1090-0039). 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 (Commenter No. 1090-0039).

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 are 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 (Commenter No. 1090-0039). 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 (Commenter No. 1090-0039).

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 (Commenter No. 1090-0129).

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 (Commenter No. CA-007).

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 (Commenter No. RM-006). 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 (Commenter Nos. 1090-0028, 1090-0039, and 1090-0058). 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 (Commenters Nos. 1090-0028 and 1090-0058).

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.

3. TS-R-1 Compatibility Issues

This section summarizes comments related to TS-R-1 compatibility issues. As directed by the Commission, 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, NRC staff identified 11 areas in Part 71 that needed to be addressed in this rulemaking process as a result of the changes to the IAEA regulations. The staff grouped the Part 71 IAEA compatibility changes into the following issues: (1) Changing Part 71 to the International System of Units (SI) (also known as the metric system) exclusively; (2) Radionuclide specific exemption values; (3) Revision of A1 and A2 values; (4) Uranium hexafluoride (UF6) package requirements; (5) Introduction of criticality safety index requirements; (6) Type C packages and low dispersible material; (7) Deep immersion test; (8) Grandfathering previously approved packages; (9) Adding and modifying Part 71 definitions; (10) Crush test for fissile material package design; and (11) Fissile material package design for transport by aircraft.

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

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 (Comment Nos. RA-005, 1090-0039, 1090-0052, 1090-0053, 1090-0128, 1090-0138, 1090-0186, and 1092-0002).

Response. No response is necessary.

3.2 Issue 2. Radionuclide Exemption Values

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 (Commenter No. 1090-0044). 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 (Commenters Nos. CA-001, CE-001, 1090-0003, 1090-0008, 1090-0028, 1090-0039, 1090-0044, 1090-0050, 1090-0097, 1090-0129, 1090-0142, and 1090-0143). 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 (Commenter Nos. CA-001, 1090-0008, 1090-0028, 1090-0039, 1090-0044, 1090-0129, and 1090-0142).

Another commenter stated that the exempted levels could potentially provide a back door to recycle and release of radioactive material (Commenter No. RA-012).

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 (Commenter No. 1090-0008). 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 (Commenter No. CA-001). Two other commenters criticized the proposed regulations for treating radioactive substances as if they were not radioactively contaminated (Commenter Nos. CA-001 and 1090-0097).

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 [10 CFR 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 (Commenter No. 1090-0141). 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 (Commenter No. RM-002).

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 (Commenter No. CA-001).

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 (Commenter No. CA-002). 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 (Commenter No. CE-001). 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 (Commenter No. RM-002). 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 decision making. 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 (Commenter No. 1090-0141). The commenter notes that no cost-benefit analysis had been done on this issue and that the NRC chose it subjectively.

Response. NRC disagrees with the commenter's assertion that the exemption values were chosen subjectively (i.e., without good reasoning and without input 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). Moreover, 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.

Comment. Another commenter stated that the technical benefits of the proposed rule do not outweigh the associated costs and efforts (Commenter No. 1090-0030).

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 (Commenter No. 1090-0030).

Response. NRC disagrees. 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 (Commenter No. 1090-0035). 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. On balance, the NRC believes the benefit of achieving international compatibility by adopting these values outweighs their associated costs.

Comment. Two commenters stated that the proposed rule would increase industry's regulatory burden (Commenter Nos. 1090-0030 and 1090-0052). 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 (Commenter No. 1090-0052). The proposed exemption thresholds would increase worker exposure to radioactive materials (Commenter No. 1090-0030).

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 (Commenter No. 1090-0141).

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 (Commenter Nos. 1090-0049 and 1090-0053). 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 (Commenter No. 1090-0053). 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 (Commenter No. 1090-0049). 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. If this exemption multiple was not included in the DOT and NRC regulations, substantial quantities of ores and natural materials that are not licensed as radioactive material might be subject to regulation as a radioactive material only during transportation.

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 (Commenter No. 1090-0053). 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. Ten commenters expressed opposition to the exemption values (Commenter Nos. CA-001, RM-002, RA-001, RM-005, RA-012, 1090-0039, 1090-0050, 1090-0059, 1090-0129, and 1090-0143). Two commenter argued that the proposed guidelines should allow no exemptions (Commenter Nos. 1090-0039 and 1090-0050). Two commenters stated that the proposed exemptions would negatively impact public health (Commenter Nos. 1090-0129 and 1090-0143). Two commenters argued that the redefinition would pose a threat to public health (Commenters Nos. 1090-0039 and 1090-0059). Two commenters opposed weakening regulations that would reduce the public safety and health through new definitions or accepted concentration values (Commenters Nos. 1090-0028 and 1090-0044). 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 (Commenter Nos. RM-002 and RM-005). Two commenters criticized the proposed rule for increasing the allowable contamination in materials. Two commenters 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.

Two commenters 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 disagrees that there is no justification for increasing allowable concentrations. 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 (Commenter No. RM-005).

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 this rulemaking has no impact on that activity.

Comment. A commenter requested the risk and biokinetic data supporting the proposed exemption values (Commenter No. CE-001). 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 (Commenter Nos. RM-002 and RM-005). 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 (Commenter No. CA-001).

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 are unavailable (Commenter No. 1092-0001). 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 are 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 (Commenter No. 1092-0001). They 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 are available. They then asked NRC 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 (Commenter No. RA-001). 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 (Commenter No. RM-012). The commenter explained that numerous RCRA landfills around the country have adopted the Environmental Protection Agency (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 they do not include appropriate exemptions and will result in unjustified increased costs and transportation burdens and liabilities (Commenters Nos. 1090-0049 and 1092-0002).

Response. This rule does not extend NRC 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 (Commenter No. 1090-0052).

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 (Commenter No. RM-012). 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 (Commenter No. 1090-0043). 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 (Commenter No. 1090-0052). 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 were 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 (Commenter No. RM-002). 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 (Commenter No. CA-001).

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 (Commenter No. RM-002).

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 (Commenter No. RM-005). 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 (Commenter No. CE-001). 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 (Commenter No. CE-001). 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 (Commenter No. RM-002).

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 (Commenter No. 1090-0052).

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 (Commenters Nos. RM-005, 1090-0052, 1090-0053, 1090-0138, and 1090-0186). One of these commenters supported lower concentrations for the radioactive isotopes because the proposed rulemaking increases public risk (Commenter No. RM-005). 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 (Commenter No. 1090-0138). 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 (Commenter No. 1090-0052). Another commenter expressed general support for ensuring consistency between domestic and international regulations (Commenter No. 1090-0186).

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 (Commenter No. CA-001).

One commenter said that there are no comparable exemptions in existing regulations (Commenter No. 1090-0097).

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 (Commenter Nos. 1090-0008, 1090-0028, and 1090-0030). One commenter opposed reliance on the International Commission on Radiological Protection (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 (Commenter No. 1090-0028). 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 (Commenter No. RM-005). 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 (Commenter Nos. 1090-0028, 1090-0046, and 1090-0129). One commenter stated that NRC radiation standards are outdated and should be subject to rigorous review, including independent outside experts (Commenter No. 1090-0129). 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 (Commenter No. 1090-0028). 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 (Commenter No. CE-001). 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. Any reconsideration of these ICRP baseline documents is also outside the scope of this effort.

Comment. The NRC was criticized by commenters for not having developed and pursued actual transport exposure scenarios for every radionuclide to justify the exemptions (Commenter Nos. 1090-008 and 1090-0141). 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 (Commenter No. 1090-0008). 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 (Commenter No. 1090-0141). 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 (Commenter No. 1090-0044).

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 (Commenter No. 1090-0028).

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 (Commenter No. CA-001).

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" (Commenter No. 1090-0141). 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 (Commenter No. 1090-0043). 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 (Commenter No. CE-001). 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 (Commenter No. 1090-0008).

One commenter stated that the proposed exemption values are based on unrealistic models (Commenter No. 1090-0008). 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 (Commenter No. 1090-0129). 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 (Commenter Nos. RM-002 and RM-005). 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 (Commenter No. 1090-0128). 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 (Commenter No. RM-005). 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 (Commenter No. 1090-0030). 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 (Commenter No. 1090-0008). 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 (Commenter No. CA-001). 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 (Commenter No. 1090-0141). Four other commenters opposed the proposed definition of "radioactive materials" (Commenter Nos. 1090-0028, 1090-0045, 1090-0059, and 1090-0129), one doing so in the name of national security (Commenter No. 1090-0059). This commenter argued that there are no low-level nuclear wastes and that there is no safe threshold for exposure to radioactive materials (Commenter No. 1090-0059).

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" (Commenter No. 1090-0141).

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" (Commenter No. CA-001). 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 (Commenter No. 1090-0059). 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 (Commenter No. 1090-0186). 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 (Commenter No. RM-002).

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 (Commenter No. 1090-0059).

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 (Commenter No. 1090-0049).

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 radiology (Commenter No. CA-007).

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'" (Commenter No. 1090-0128). 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.

3.3 Issue 3. Revision of A₁ and A₂

Comment. One commenter stated that the NRC should not reduce the numbers and types of material subject to shipping regulations (Commenter No. 1090-0033). 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 (Commenter No. 1090-0038).

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" (Commenter No. 1090-0128). 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 creates an inconsistency with other Federal standards.

The NRC disagrees with the second commenter that the final rule weaken the regulations. Conforming NRC regulations to the IAEA regulations is not the sole justification, it is also adopting good science. Also the increased A_1 or the A_2 values does not increase the level of exposure (i.e., it gives the same dose).

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 (Commenter No. 1090-0172). 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 (Commenter No. 1090-0053). 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" (Commenter No. RM-10). 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 (Commenter No. CE-001). 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 ($A_1 = 9E-1$ TBq (2.4E1 Ci); $A_2 = 9E-5$ TBq (2.4E-3 Ci)). Notice the tremendous difference from 24 Ci (A_1) to 0.0024 Ci (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 (Commenter No. CE-001). 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 (Commenter No. CE-001). 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 (Commenter No. CA-001).

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 (Commenter No. 1090-0041). 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 as well as 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 (Commenter No. 1090-0057). 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 (Commenter No. 1090-0053).

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 (Commenter No. 1090-0053). 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 (Commenter Nos. 1090-0052, 1090-0053, 1090-0138, and 1090-0186).

Response. The NRC acknowledges these comments.

Comment. Several commenters disagreed with the NRC staff's position (Commenters Nos. CA-001, 1090-0043, 1090-0044, 1090-0050, and 1090-0128). One commenter opposed weakening the present standard of radiation protection during transportation, particularly because NRC is proposing to ship radioactive wastes to a repository (Commenter No. 1090-0043). 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 (Commenter No. 1090-0044). Another commenter stated that any additional costs "must be borne by licensees and beneficiaries of use of materials" (Commenter No. 1090-0128). Another commenter asked the NRC not to adopt the exemption values contained in Table 2 of TS-R-1 (Commenter No. CA-001).

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 (Commenters Nos. 1090-0052 and 1090-0186). The first commenter noted that Footnote 2 to Table A-1 is incorrect and should instead read, "See Table A-4" (Commenter No. 1090-0052). 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 (Commenter No. 1090-0186).

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 (Commenter No. 1090-0001). 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 A₁ (TBq) in IAEA TS-R-1 is 9; A₂ (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 A₂ (TBq) in 49 CFR 173.435 should be 0.6; A₂ (Ci) in 49 CFR 173.435 should be 16. The radionuclide Pu-239 value for A₂ (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 A₂ (Ci) in 10 CFR 71, Table A-1, should be 0.11. The radionuclide Ra-228 value for A₂ (TBq) in 10 CFR 71, Table A-1, should be 0.02. The radionuclide Rh-105 value for A₂ (Ci) in 10 CFR 71, Table A-1, is in error. The radionuclide Sc-46 value for A₁ (TBq) in 10 CFR 71, Table A-1, should be 0.5. The radionuclide Sn-119m value for A₂ (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 A₂ (TBq) in 10 CFR 71, Table A-1, should be 40. The radionuclide Ta-179 value for A₁ (TBq) in 10 CFR 71, Table A-1, should be 30. The radionuclide Tb-157 value for A₁ (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 A₂ (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 A₁ (Ci) in 10 CFR 71, Table A-1, should be 27. The radionuclide Tc-96 value for A₁ (TBq) in 10 CFR 71, Table A-1, should be 0.4. The radionuclide Tb-96m value for A₁ (TBq) in 10 CFR 71, Table A-1, should be 0.4; value for A₂ (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 A₂ (Ci) in 10 CFR 71, Table A-1, should be 24. The radionuclide Te-129 value for A₁ (TBq) in 10 CFR 71, Table A-1, should be 0.7; value for A₂ (TBq) in 10 CFR 71, Table A-1, should be 0.6. The radionuclide Te-132 value for A₁ (TBq) in 10 CFR 71, Table A-1, should be 0.5. The radionuclide Th-227 value for A₂ (Ci) in 10 CFR 71, Table A-1, should be 0.14. The radionuclide Th-231 value for A₂ (TBq) in 10 CFR 71, Table A-1, should be 0.02. The radionuclide Th-234 value for A₁ (TBq) in 10 CFR 71, Table A-1, should be 0.3. The radionuclide Ti-44 value for A₁ (TBq) in 10 CFR 71, Table A-1, should be 0.5; value for A₂ (TBq) in 10 CFR 71, Table A-1, should be 0.4, value for A₂ (Ci) in 10 CFR 71, Table A-1, should be 10. The radionuclide TI-200 value for A₁ (TBq) in 10 CFR 71, Table A-1, should be 0.9. The radionuclide TI-204 value for A₂ (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. NRC accepts the comment and has updated the values in the final rule, Table A-1 to be consistent with TS-R-1.

Response. Appropriate changes have been made in the final rule.

Comment. Three commenters stated that the A₂ value for molybdenum-99 and the A₁ and A₂ values for californium-252 should be retained for domestic use only packages (Commenters Nos. 1090-0053, 1090-0058, and 1092-0002).

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

3.4 Issue 4. Uranium Hexafluoride (UF₆) Package Requirements

Comment. Five commenters expressed support for the proposed changes to UF₆ package rules that continue the current practice of moderator exclusion for UF₆ (Commenter Nos. 1090-0052, 1090-0053, 1090-0054, 1090-0138, and 1090-0186). One commenter cited the strong safety record applying these rules as evidence that the practice is adequate (Commenter No. 1090-0054). Two commenters objected to the 5 percent enrichment limit provision in proposed § 71.55(g) (Commenter Nos. 1090-0052 and 1090-0053), and a third commenter expressed concern with the enrichment limit (Commenter No. 1090-0007). 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 (Commenter No. 1090-0052). 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 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 (Commenter No. 1090-0007).

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 U-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 U-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 five 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 (Commenter No. 1090-0039).

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 (Commenter No. 1090-0038). 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 (Commenter Nos. 1090-0043 and 1090-0128). 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 (Commenter No. 1090-0043). One commenter cited both the Baltimore tunnel fire and the Arkansas bridge incident as justifications for not allowing any exemptions (Commenter No. 1090-0128).

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.

3.5 Issue 5. Introduction of the Criticality Safety Index Requirements

Comment 1. One commenter requested a basic explanation of the CSI and TI (Commenter No. CE-001). 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 (Commenter No. RA-007).

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 (Comment No. 1090-0138). 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 (Commenter No. 1090-0143).

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 (Commenter No. 1090-0143).

Response. The commenter correctly observes that § 71.59(b) requires all non-zero 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 (Commenter Nos. 1090-0052, 1090-0054, and 1090-0186). 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 (Commenter No. 1090-0138). 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." (Commenter No. 1090-0186)

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" (Commenter No. 1090-0128). 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.

3.6 Issue 6. Type C Packages and Low Dispersible Material

Comment. Four commenters expressed support for NRC's proposal to not adopt the requirements for Type C packages and LDM (Commenter Nos. 1090-0034, 1090-0041, 1090-0053, and 1090-0138). One commenter also expressed support for the NRC's decision to ensure that there is a mechanism for reviewing validations of foreign approvals (Commenter No. 1090-0138). 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 (Commenter No. 1090-0053).

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 (Commenters Nos. 1090-0034 and 1090-0041). One commenter stated that many parties are asking IAEA to modify the Type C requirements (Commenter No. 1090-0034). 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 (Commenter Nos. RM-002 and 1090-0128). 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 (Commenter No. 1090-0128). 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 (Commenter No. CA-005).

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” (Commenter No. 1090-0186). 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 (Commenter No. 1090-0043). 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.

3.7 Issue 7. Deep Immersion Test

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 be moved transcontinentally on highways and railroads” (Commenter No. 1090-0128). 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 leakage of water" is preferable. Type B package designs that are capable of withstanding a 1-hour test without "collapse, buckling, or leakage 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 (Commenter No. CA-002). 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 leakage 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/transport/safety/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 (Commenter No. 1090-0035).

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 (Commenter Nos. RA-005, 1090-0052 and 1090-0138). One commenter stated that the proposed rule's deep immersion test provisions would increase cask safety (1090-0138).

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) (Commenter No. 1090-

0129). 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 (Commenter No. RA-005).

Response. The NRC acknowledges this comment, but believes that s 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 (Commenter No. RA-001).

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 Certificate of Compliance remain unaffected.

Comment. One commenter stated that the cost of compliance was grossly underestimated, particularly for demonstrating cask integrity at 200 meters (Commenter No. RA-005).

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 (Commenter No. CA-008).

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 (Commenter No. CA-001). 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 (Commenter No. 1090-0053).

Response. The comment is acknowledged.

Comment. One commenter expressed concern that the deep immersion test only requires that packages be submerged for 1 hour (Commenter No. CA-001). 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 (Commenter No. CA-001).

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.

3.8 Issue 8. Grandfathering Previously Approved Packages

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, with the implementation of the new rule, NRC will continue with its position on grandfathering and phase out of 1967-approved package designs over the specified 4-year time period. A review of the specific comments and the NRC staff's responses for this issue follows.

Comment. Two commenters 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 (Commenter Nos. 1090-0053 and 1090-0058). 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 adoption 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) (Commenter No. 1090-0129). 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 (Commenter No. 1090-0128).

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 (Commenter No. 1090-0128). 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 (Commenter No. 1090-0053). 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 (Commenter No. 1090-0042). 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 adoption of a 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 are 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) Quality assurance requirements were applied to this type of package, whereas other package types were not subjected to the same level of quality assurance 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 exemptions 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 non-spent 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 (Commenter No. 1090-0186). 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 3 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 (Commenter No. RA-003).

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 3-year period (after adoption of a 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 (Commenter Nos. RA-003, 1090-0005, and 1090-0042). 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 (Commenter No. 1090-0042). 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 (Commenter No. RA-003). 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 (Commenter No. 1090-0042). 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 (Commenter No. 1090-0144). 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 3-year phase out of the 1967-approved packages, industry will have had at least 10 years (i.e., until 2007) 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 (Commenter No. 1090-0042). 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 (Commenter No. RA-003). 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 (Commenter No. 1090-0042). 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 (Commenter No. 1090-0042).

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 these 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 (Commenter No. 1090-0005). 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 adoption of a 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 (Commenter No. 1090-0058).

Response. NRC will retain the current A_2 value for molybdenum-99 (7.4E-1 TBq; 2.0E1 Ci) and the A_1 value for californium-252 (0.1 TBq; 2.7 Ci) (see Table A-1). 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 (Commenter No. 1090-0058). 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 (Commenter No. 1090-0035). 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 we consider allowing certified containers with satisfactory safety records 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.

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 (Commenter No. RM-016). The commenter asserted that this 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 adoption 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 (Commenter No. RA-005).

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 certificate of compliance.

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 (Commenter No. RA-003).

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 (Commenter No. RA-004). 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 phaseout 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 (Commenter No. RM-016). 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 (Commenter No. CA-005).

Response. NRC has used the 3-year time line in previous rulemakings, however the NRC believes that 4-year 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 (Commenter No. 1090-0005).

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 (Commenter Nos. 1090-0042 and 1090-0053). 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 (Commenter No. 1090-0042). 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 (Commenter No. 1090-0053).

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 standard. 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 adoption of a 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 (see response to comment 4 in this issue), 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 (Commenter No. 1090-0042). 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 quality assurance 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 standard.

Comment. One commenter said that currently approved DOT specification packages should continue to be approved for domestic shipments (Commenter No. 1090-0005). 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 (Commenter No. 1090-0005). 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 (Commenter No. 1090-0011). 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 at 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 (Commenter No. 1090-0042).

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 (Commenter No. 1090-0042).

Response. Packagings constructed to designs approved under the 1967 regulations were, in general, not subject to quality assurance 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. Quality assurance requirements in Subpart H of Part 71 include provisions for existing packagings with respect to quality assurance.

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 (Commenter No. 1090-0042).

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 (Commenter Nos. 1090-0041 and 1090-0052). 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 (Commenter No. 1090-0041). 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 (Commenter No. 1090-0138).

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 (Commenter No. 1090-0139). 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 (Commenter No. 1090-0042). 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 (Commenter No. 1090-0042). 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 their 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 (Commenter No. 1090-0042). 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 (Commenter No. 1090-0042). 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 quality assurance requirements, and that fabrication documents may not be available. NRC does not agree that this fact (lack of quality assurance 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 (Commenter No. 1090-0042). 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 3-year period after adoption of the final rule. Thus, should orphan sources result as consequence of this rule, industry will have a minimum of 4 years to establish a program and a means to eliminate them from their 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 (Commenter No. 1090-0042). The commenter warns that the device would become, overnight, an "orphan source."

Response. Applicability of NRC quality assurance 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 quality assurance 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 4-year phase-out period.

Comment. One commenter stated that the U.S. is not bound to IAEA requirements for domestic shipping (Commenter No. 1090-0042). 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 (Commenter No. 1090-0042). 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 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 (Commenter No. 1090-0042). 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 (Commenter No. 1090-0042). 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 (Commenter No. 1090-0042). 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 10 years that industry has had the opportunity to evaluate their 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 (Commenter No. 1090-0042). 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 (Commenter No. 1090-0042). 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 4-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 4-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 (Commenter No. 1090-0058). 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 be fabricated.

Response. The NRC acknowledges the comments about grandfathering and A_1 and A_2 values for domestic shipping. For the comment about 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 (Commenter No. 1090-0053). 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 re-qualifying 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 (Commenter No. 1090-0058).

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) 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.

3.9 Issue 9. Changes to Various Definitions

Comment. Four commenters generally supported the proposal (Commenter Nos. 1090-0052, 1090-0053, 1090-0138, and 1090-0186). One commenter specifically asked that NRC and DOT agree on the definition of "common terms" before issuance of the final rules (Commenter No. 1090-0186).

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" (Commenter No. 1090-0129). Another commenter expressed concern over the omission of a definition for "contamination" (Commenter No. 1090-0138).

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 a 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) (Commenter No. 1090-0040).

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 (Commenter Nos. 1090-0040, 1090-0052, and 1090-0053). One commenter provided specific information in objection to the proposed definitions of LSA-I and LSA-II (Commenter No. 1090-0052).

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 (Commenter No. 1090-0052).

Response. NRC acknowledges the comment.

Comment. Three commenters were concerned about the omission of a definition for "consignment" (Commenters Nos. 1090-0052, 1090-0053, and 1090-0138). One commenter suggested that NRC use the definition provided in the DOT proposed rule (Commenter No. 1090-0052).

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" (Commenters Nos. 1090-0052 and 1090-0138).

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" (Commenter Nos. 1090-0052 and 1090-0053).

Response. NRC disagrees. Section 71.87(i) refers to the non-fixed (removable) contamination regarding the contamination levels found in DOT regulations in 49 CFR 173.443, Table 11. NRC notes that the definition of "non-fixed 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 non-fixed 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, non-fixed contamination, shipment, transport index (Commenter No. 1090-0053). 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.

3.10 Issue 10. Crush Test for Fissile Material Package Design

Comment. One commenter stated that the additional cost of the crush test for fissile material is estimated at about \$5,000,000 (Commenter No. 1090-0053). 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 their belief that "No vehicle or container could have withstood the impact of that boulder's fall from several hundred feet above" (Commenter No. 1090-0128). The commenter 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 (Commenters Nos. 1090-0051, 1090-0129, and 1090-0137). 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) (Commenter No. 1090-0051). 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." They 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 (Commenter No. RA-001).

Another commenter expressed concern that crush testing is not required for packages having a mass greater than 500kg, which includes rail SNF waste packages (Commenter No. 1090-0137). 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 Department of Energy (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 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) 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 (Commenter Nos. 1090-0052, 1090-0053, and 1090-0186). 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 (Commenter No. 1090-0052). 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 (Commenter Nos. 1090-0053 and 1090-0186). 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 (Commenter No. 1090-0053). 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" (Commenter No. 1090-0186).

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 the 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 m (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 (Commenter Nos. 1090-0051 and 1090-0138). 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 (Commenter No. 1090-0051).

Response. No response is necessary.

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

Comment. Four commenters supported the NRC's position on this issue (Commenter Nos. 1090-0052, 1090-0053, 1090-0138, and 1090-0186). One commenter supported NRC's proposal to ensure consistent review of package designs affected by the requirements of the International Civil Aviation Organization (Commenter No. 1090-0138). Another commenter said adoption of Type C packages should be scheduled for future harmonization with IAEA regulations (Commenter No. 1090-0186).

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

4. NRC-Initiated Issues

This section provides a summary of comments focused on eight additional NRC-initiated issues (numbers 12 through 19). These eight issues were identified by Commission direction, and through staff consideration, for incorporation in the Part 71 rulemaking process. These NRC-initiated changes include: (12) Special package approvals; (13) Expansion of Part 71 quality assurance (QA) requirements to holders of, and applicants for, a Certificate of Compliance (CoC); (14) Adoption of the requirements of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (B&PV) Code for fabrication of spent fuel transportation packages; (15) Adoption of change authority; (16) Revisions to the fissile-exempt and general license provisions to address the unintended economic impact of the emergency rule (SRM-SECY-99-200); (17) Decision on Petition for Rulemaking PRM-71-12, which requested deletion of the double containment requirements for plutonium; (18) Surface contamination limits as applied to spent fuel and high-level waste packages (SRM-SECY-00-0117); and (19) Part 71 event reporting requirements.

4.1 Issue 12. Special Package Authorizations

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 (Commenter No. 1090-0035). 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 (Commenter No. 1090-0128). 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 (Commenter No. RA-005). 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 (Commenter No. RA-004). 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 (Commenter No. 1090-0186).

One commenter suggested that NRC establish general criteria for the special package authorization process (Commenter No. 1090-0053).

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 (Commenter No. 1090-0035).

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 an a case-by-case basis.

Comment. One commenter requested the NRC to view every shipment of a reactor vessel as a significant process requiring NEPA review (Commenter No. RA-005). 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 (Commenter No. RA-005).

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 (Commenter No. 1090-0053). 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 (Commenter Nos. 1090-0040, 1090-0052, 1090-0138, 1090-0171, and 1090-0186). 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 (Commenter Nos. 1090-0040 and 1090-0171). Two other

commenters supported corresponding with DOT to eliminate duplicities exemptions, but urged the NRC to work closely to ensure the clear implementation of this proposal (Commenter Nos. 1090-0052 and 1090-0138).

Response. No response necessary.

4.2 Issue 13. Expansion of Part 71 Quality Assurance Requirements to Certificate of Compliance (CoC) Holders

Comment. Five commenters supported the NRC's proposed position on this issue (Commenter Nos. 1090-0052, 1090-0053, 1090-0138, 1090-0186, and 1092-0001). One commenter recommended that NRC establish and apply a uniform set of QA requirements (Commenter No. 1090-0053). Another commenter added that it would like to see the consistent application of QA requirements throughout the regulations (Commenter No. 1090-0186).

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.

4.3 Issue 14. Adoption of American Society of Mechanical Engineers (ASME) Code

Comment. Four commenters expressed support for the decision not to adopt the ASME code (Commenter Nos. 1090-0052, 1090-0053, 1090-0138, and 1090-0186). One commenter said that these are voluntary standards and should not be made into requirements (Commenter No. 1090-0186).

Response. No response is required.

4.4 Issue 15. Change Authority for Dual-Purpose Package Certificate Holders

Comment. One commenter urged NRC to require more stringent testing procedures (drop tests, crash impacts, leakage, etc.) for both new and old shipping containers (Commenter No. 1090-0129).

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 our proposal to "harmonize" transport and storage of spent nuclear fuel and fissile materials with "a watered down international standard" (Commenter No. 1090-0043). 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 (Commenter No. RA-004). 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 (Commenter No. 1090-011, 1090-0053, 1090-0057, 1090-0058, 1090-0186). Two of these commenters suggested reasons why licensees should be allowed to make minor changes independent of the CoC holders (Commenters Nos. 1090-0011 and 1090-0058).

Another commenter stated that the changes allowed for shipping packages licensed under Part 72 should also be allowed for those under Part 71 (Commenter No. 1090-0186).

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 (Commenter Nos. RA-001, RA-005, 1090-008, 1090-0028, 1090-0045, 1090-0128, and 1090-0129). 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 (Commenter 1090-0128). The second commenter suggested that there would not be sufficient experience based on the part of the CoC holders to implement the responsibility effectively (Commenter No. RA-001), 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 (Commenter No. RA-005). One commenter asserted that the public has a right to know if design changes are being made (Commenter No. 1090-0008).

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 (Commenter No. RA-005).

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 (Commenter Nos. CE-001, RA-005, and 1092-0001). The first of these commenters asked for clarification on what is meant by "minimal changes" with potential safety consequences (Commenter No. 1092-0001). 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 (Commenter No. RA-005). 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 (Commenter No. CE-001). 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 (Commenter No. 1092-0001). 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 certificate of compliance 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 (Commenter No. RA-006). 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 (Commenter No. RA-005). 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 (Commenter No. RA-006). 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 (Commenter No. 1090-0139).

Response. The proposed change process is not being implemented as previously described.

Comment. Three commenters expressed support for the change authority (Commenters Nos. RA-006, 1090-0052, and 1090-0138). One of these commenters asserted that allowing the change authority would allow for more attention to more significant safety issues (Commenter No. RA-006).

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 (Commenter Nos. 1090-0011 and 1090-0057). One stated that the 2-year submittal date for application renewal is too long and instead suggested a 30-day requirement (Commenter No. 1090-0057). 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 (Commenter No. 1090-0011). 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 (Commenter Nos. 1090-0011 and 1090-0057). 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 (Commenter No. 1090-0011).

Response. The NRC has chosen not to include the proposed change process in the final rule.

Comment. One commenter discussed 71/72 SAR's (Safety Analysis Reports) for the change authority (Commenter No. 1090-0011). 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 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 certificate of compliance is not applicable.

Comment. One commenter expressed a number of concerns about the proposed change process for dual purpose casks (Commenter No. 1090-0053). 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 (Commenter No. 1090-0053). 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.

4.5 Issue 16. Fissile Material Exemptions and General License Provisions

Comment. One commenter noted that this is a significant deviation from the TS-R-1 requirement, which now has a 15-g ²³⁵U limit as well as a mass consignment limit (Commenter No. RA-007).

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 (Commenter Nos. RA-007, 1090-0052, and 1090-0138). 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 (Commenter No. RA-007). 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 (Commenter No. 1090-0138). 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 (Commenter Nos. RA-007, 1090-0052, and 1090-0138), with one commenter noting that the definition of iron is unclear (Commenter No. 1090-0138). 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 (Commenter No. RA-007). Another stated that it is difficult to obtain information on materials to carry out the calculations under the proposed regulations (Commenter No. 1090-0052).

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 (Commenter No. RA-007). 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 (Commenter Nos. 1090-0040 and 1090-0171). 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 ²³⁵U 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 ²³⁵U enrichments greater than 24 percent.

Comment. Several commenters discussed the economic impact of the proposed regulation (Commenters Nos. RA-007, 1090-0040, and 1090-0052). Two commenters asserted that the regulation will cause an increase in the number of shipments required with an associated increase in costs (Commenters Nos. RA-007 and 1090-0052), with one predicting required transports to increase two- to three-fold (Commenter No. 1090-0052). 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 (Commenter No. 1090-0040).

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)” (Commenter No. 1090-0128). 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 concerned about the use of the Part 110 definitions of “deuterium” and “graphite” in the proposed rule (Commenter Nos. 1090-0052 and 1090-0138). 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 ?? 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 (Commenter No. RM-002).

Response. No response is necessary.

Comment. Two commenters expressed general support for the fissile material exemptions (Commenter Nos. 1090-0052 and 1092-0001). 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 (Commenter No. 1092-0001). 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 (Commenter Nos. 1090-0035, 1090-0052, 1090-0053, and

1090-0138). One commenter stated that improved definitions were necessary to categorize the ratio calculations (Commenter No. 1090-0052).

Three commenters added that NRC should not exclude the definition of “shipment” from the rule (Commenter Nos. 1090-0052, 1090-0053, and 1090-0138). 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 (Commenter No. 1090-0035).

Two commenters noted that the proposed rule did not include a definition for “insoluble in water” (Commenters Nos. 1090-0052 and 1090-0138), one of whom stated that the proposed rule fails to clarify the issue in part because of the rulemaking’s lack of clarity (Commenter No. 1090-0138). 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 (Commenter No. 1090-0138).

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” (Commenter No. 1090-0171). 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. 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 (Commenter No. 1090-0052).

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 (Commenter Nos. 1090-0052 and 1090-0138). One commenter agreed with NRC's proposal to change the requirements for fissile material shipments, but did have several objections (Commenter No. 1090-0052). 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, 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 (Commenter No. 1090-0052).

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 ^{235}U mass criterion may restrict exemption of fissile materials, not containing special moderators, that are currently acceptable (Commenter No. 1090-0054). Another commenter expressed support for the concept of exemptions for fissile material shipments under specific conditions (Commenter No. 1090-0053). 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 (Commenter No. 1090-0186). 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.

4.6 Issue 17. Decision on Petition for Rulemaking on Double Containment of Plutonium (PRM-71-12)

Comment. Four commenters suggested that all radioactive materials should require double packaging (Commenter Nos. RA-001, 1090-0039, 1090-0128, and 1092-0004). Two of these commenters stated double containment is a security and safety precaution (Commenter Nos. RA-001 and 1090-0039). A third stated that existing container requirements are the minimum standards necessary for safety, security, and public acceptance (Commenter No. 1092-0004). Another commenter simply objected to the removal of the requirement for double containment of plutonium (Commenter 1090-0128).

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 FR21422; 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 (Commenter Nos. CA-008, 1090-0128, and 1090-0136). 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 (Commenter No. CA-008). 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" (Commenter No. 1090-0128). 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 (Commenter No. 1090-0136).

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 (Commenter No. 1090-0040). 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 (Commenter Nos. 1090-0003, 1090-0008, 1090-0028, 1090-0032, 1090-0033, 1090-0038, 1090-0039, 1090-0043, 1090-0045, 1090-0046, 1090-0051, 1090-0129, 1090-0130, 1090-0136, 1090-0141, and 1090-0142).

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 (Commenter No. 1090-0053). 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 (Commenter No. CE-001).

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 (Commenter Nos. 1090-0040, 1090-0186, and 1090-0194). One commenter asserted that a single containment barrier is adequate for Type B packages containing more than 20 Curies of solid form plutonium (Commenter No. 1090-0040). 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 (Commenter No. 1090-0186).

The third commenter said that using double containment causes unnecessary worker radiation exposure (Commenter No. 1090-0194). 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. Four commenters stated that double containment provides more protection to the public than single containment (Commenter Nos. RM-005, RA-001, RA-005, and 1092-0003). One of these commenters stated their belief that they and a majority of the Western Governors are concerned with the proposal to eliminate the double containment requirement for plutonium shipments (Commenter No. RM-005). 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 (Commenter No. RA-005). Another commenter stated strong agreement with this first commenter (Commenter No. RM-015).

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 (Commenters Nos. RA-008 and 1090-0040). One commenter argued that the cost of reducing the exposure to workers to the required 1 mrem/yr would be very high (Commenter No. 1090-0040). One commenter asserted that we need to balance public safety and the safety of radiation workers (Commenter No. RA-009).

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 (Commenter No. RA-005).

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 (Commenter No. RA-005).

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 (Commenter No. RA-001).

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) (Commenter No. 1090-0130).

Response. The comment is acknowledged.

Comment. One commenter expressed support for the NRC position (Commenter No. 1090-0053).

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 (Commenter Nos. 1090-0130 and 1092-0004). One of whom 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 receive scientific evidence that demonstrates beyond a reasonable doubt that single containment is as safe as double containment for shipments to WIPP (Commenter No. 1092-0004).

Response. The comment is acknowledged, also the reader is referred to 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 (Commenter No. 1092-0005). 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 (Commenter No. 1090-0039). 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 (Commenter No. 1090-0130 and 1092-0004). The commenters 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 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 package. 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 (Commenter No. 1090-0194).

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 (Commenter No. 1090-0194). 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 (Commenter No. 1090-0194). 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 (Commenter No. 1090-0194). 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 (Commenter No. 1090-0194). 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 (Commenter No. 1090-0194).

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 (Commenter No. 1090-0194). 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 (Commenter No. 1090-0194). 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. (Commenter Nos. 1090-0130 and 1092-0004). 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 (Commenter No. 1090-0039). 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-days public comment period, because the public had ample opportunity to comment on this rule during the one-year period following March 2001, when the proposed rule was posted on the Secretary of the Commission website.

4.7 Issue 18. Contamination Limits as Applied to Spent Fuel and High-Level Waste (HLW) Packages

Comment. One commenter expressed support of the NRC position not to change from current standards (Commenter No. 1092-0001).

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” (Commenter No. 1090-0128). 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 (Commenter No. 1090-0039). 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 (Commenter No. 1090-0053). 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" (Commenter No. 1090-0128). 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 (Commenter Nos. 1090-0142 and 1090-0129). Two other commenters supported the NRC's proposal to make no changes in the contamination levels for these packages (Commenter Nos. 1090-0053 and 1090-0186).

Response. No response necessary.

Comment. One commenter expressed opposition to allowing greater contamination on surfaces of irradiated fuel and high level radioactive waste containers (Commenter No. 1090-0028).

Response. The NRC acknowledges these comments. No response necessary.

4.8 Issue 19. Modifications of Event Reporting Requirements

Comment. Two commenters expressed support for the proposed modifications (Commenter Nos. RA-005 and RA-009). One commenter stated that the proposed modifications to event reporting requirements will enhance safety (Commenter No. RA-005). 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 (Commenter No. RM-009).

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 (Commenter No. RM-010).

Response. There are no other impacts on the regulations associated with adopting this specific change.

Comment. Two commenters opposed the proposed event reporting requirements (Commenter Nos. RA-005 and 1090-0128). 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 (Commenter No. 1090-0128). The second commenter suggested that “reporting should serve the needs of the [NRC] staff—and public safety,” rather than the licensee (Commenter No. RA-005). 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 (Commenter No. RM-009).

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 (Commenter No. RA-011).

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 (Commenter No. 1090-0138). The proposed rule would direct the licensee to request

information from certificate holders; however, neither the supporting discussion nor regulatory test 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 (Commenter Nos. 1090-0053 and 1090-0186). Another commenter stated that the authorized package user should be making the required report (Commenter No. 1090-0186).

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.

APPENDIX A

APPENDIX A

List of Public Commenters

Appendix A contains two tables listing the public commenters who submitted comments to NRC during public meetings, through the mail, via facsimile machine and or through NRC web site. The first table, Table A1, is a simple commenter list whereas the second table, Table A2, identifies which commenters submitted more than one commenter – e.g., during a public meeting and via the web site.

Table A1. List of Commenters

Commenter Number	Commenter Name	Affiliation
Chicago, Illinois Public Meeting (Afternoon Session; June 4, 2002)		
CA-001	Ms. Diane D'Arrigo	Nuclear Information and Resource Service
CA-002	Mr. David Kraft	Nuclear Energy Information Service
CA-003	Mr. Mark Doruff	Council on Radionuclides and Radio-pharmaceuticals
CA-004	Ms. Sidney Baiman	Nuclear Energy Information Service
CA-005	Ms. Joy Reese	N/A
CA-006	Ms. Margaret Nagel	Variety of Chicago organizations including Chicago Media Watch and Chicago Peace Response
CA-007	Mr. Manny Tuazon	Consumers Energy
CA-008	Ms. Debbie Musiker	Lake Michigan Federation
CA-009	Mr. Paul Gaynor	Environmental Law and Policy Center of the Midwest
Chicago, Illinois Public Meeting (Evening Session; June 4, 2002)		
CE-001	Ms. Diane D'Arrigo	Nuclear Information and Resource Service
Rockville, Maryland Public Meeting (Morning Session; June 24, 2002)		
RM-001	Mr. Marc-Andre Charette	MDS Nordion
RM-002	Ms. Diane D'Arrigo	Nuclear Information and Resource Service
RM-003	Dr. M. Elizabeth Darrough	United States Enrichment Corporation
RM-004	Ms. Elizabeth Goldwasser	United States Enrichment Corporation

Table A1. List of Commenters (Continued)

Commenter Number	Commenter Name	Affiliation
RM-005	Mr. Robert Halstead	Nevada Agency for Nuclear Projects
RM-006	Mr. Felix Killar	Nuclear Energy Institute
RM-007	Mr. William Lake	U.S. Department of Energy
RM-008	Ms. Melissa Mann	Transport Logistics International
RM-009	Mr. Robert Owen	Ohio Department of Health
RM-010	Mr. David Ritter	Public Citizen
RM-011	Mr. Mark Rogers	Airline Pilots Association
RM-012	Mr. Charles Simmons	Kilpatrick Stockton
RM-013	Mr. Fred Dilger	Clark County, Nevada
RM-014	Ms. Eileen Supko	Energy Resource International
RM-015	Dr. Judith Johnsrud	Sierra Club Environment Coalition
RM-016	Mr. Don Erwin	Hunton & Williams (Representing J.L. Shepherd)
Rockville, Maryland Public Meeting (Afternoon Session; June 24, 2002)		
RA-001	Ms. Diane D'Arrigo	Nuclear Information and Resource Service
RA-002	Mr. Charles Simmons	Kilpatrick Stockton
RA-003	Mr. Don Erwin	Hunton & Williams (Representing J.L. Shepherd)
RA-004	Mr. Felix Killar	Nuclear Energy Institute
RA-005	Mr. Robert Halstead	Nevada Agency for Nuclear Projects

Table A1. List of Commenters (Continued)

Commenter Number	Commenter Name	Affiliation
RA-006	Mr. Brian Gutherman	Holtech International
RA-007	Ms. Melissa Mann	Transport Logistics International
RA-008	Mr. William Lake	U.S. Department of Energy
RA-009	Mr. Robert Owen	Ohio Department of Health
RA-010	Ms. Eileen Supko	Energy Resource International
RA-011	Mr. Marvin Turkanis	Neutron Products
RA-012	Mr. David Ritter	Public Citizen's Critical Mass Energy and Environment Program
Public Comments Posted to NRC Web Site		
1090-0001	Mr. Stephen A. Thompson	U.S. Department of Energy
1090-0002	Mr. Jack Hovingh	N/A
1090-0003		Global Resource Action Center for the Environment
1090-0004	Mr. Jay Reese	N/A
1090-0005	Mr. John J. Miller	International Isotopes, Inc.
1090-0006	Mr. Robert Goettler et al.	N/A
1090-0007	Mr. Thomas Dougherty	Columbiana Hi Tech Front End, LLC
1090-0008	Mr. Mark Donham and Ms. Kristi Hanson	Coalition for Nuclear Justice
1090-0011	Mr. Brian Gutherman	N/A
1090-0027	Ms. Jody Lanier	N/A

Table A1. List of Commenters (Continued)

Commenter Number	Commenter Name	Affiliation
1090-0028	Mr. Robert E. Rutkowski	N/A
1090-0029	Mr. B. Geary	N/A
1090-0030	Ms. Roberta Chase and Mr. Mike Schade	Citizens' Environmental Coalition
1090-0031	Mr. Richard Geary	N/A
1090-0032	Ms. Linda Novenski	N/A
1090-0033	Mr. Gerry Welch	St. Louis County Municipal League
1090-0034	Mr. Marc-Andre Charette	MDS Nordion
1090-0035	Mr. B.K. Miles	U.S. Department of Energy
1090-0036	Ms. Diane D'Arrigo et al.	Nuclear Information and Resource Service et al.
1090-0037	Ms. Diane D'Arrigo	Nuclear Information and Resource Service
1090-0038	Mr. Peter N. Skinner, P.E.	State of New York, Office of the Attorney General
1090-0039	Ms. Sara Barczak	Georgians for Clean Energy
1090-0040	Mr. Kent Hancock	Department of Energy
1090-0041	Mr. Mark A. Doruff	Council on Radionuclides and Radiopharmaceuticals
1090-0042	Mr. Donald P. Irwin	Hunton & Williams, on behalf of J.L. Shepard & Associates
1090-0043	Mr. Louis Zeller	Blue Ridge Environmental Defense League
1090-0044	Ms. Kay Drey	N/A
1090-0045	Ms. Barbara Bailine	N/A

Table A1. List of Commenters (Continued)

Commenter Number	Commenter Name	Affiliation
1090-0046	Ms. Eileen Greene	N/A
1090-0047	Mr. Coffie C. Wortham	N/A
1090-0048	Ms. Sheila England	N/A
1090-0049	Mr. Charles T. Simmons	Kilpatrick Stockton, on behalf of Zirconium Environmental Committee
1090-0050	Ms. Pamel Blockey-O'Brian	N/A
1090-0051	Ms. Susan R. Gordon	Alliance for Nuclear Accountability
1090-0052	Mr. A. Joseph Nardi	Westinghouse Electric Company
1090-0053	Mr. Felix M. Killar, Jr.	Nuclear Energy Institute
1090-0054	Mr. Steven A. Toelle	United States Enrichment Corporation
1090-0055	Ms. Nisha Dawson	N/A
1090-0056	Mr. Donald P. Irwin	Hunton & Williams, on behalf of J.L. Shepherd and Associates
1090-0057	Mr. Patrick R. Simpson	Exelon Generation Company, LLC
1090-0058	Mr. Terry C. Morton	Carolina Power & Light and Florida Power Corporation
1090-0059	Mr. John Jay Ulloth	N/A
1090-0060	Ms. Erin Rogers	N/A
1090-0061	Mr. David Bedell	N/A
1090-0062	Ms. Elaine Gedige	N/A
1090-0063	Ms. Auna T. Rand	N/A

Table A1. List of Commenters (Continued)

Commenter Number	Commenter Name	Affiliation
1090-0064	Ms. Julia Butera	N/A
1090-0065	Mr. Gary A. Karch	N/A
1090-0066	Mr. Billy Ponard	N/A
1090-0067	Mr. Mark M. Giese	N/A
1090-0068	Ms. Valerie Wyman	N/A
1090-0069	Ms. Brianna Knoffer	N/A
1090-0070	Ms. Estelle Lit	N/A
1090-0071	Ms. Estelle Lit	N/A
1090-0072	Ms. Patricia Christian	N/A
1090-0073	Mr. Julius Sippen	N/A
1090-0074	Mr. Tom Ferguson	Physicians for Social Responsibility
1090-0075	Ms. Rebecca Troon	N/A
1090-0077	Mr. Thomas Reilly	N/A
1090-0078	Ms. Fawn L. Shillinglaw	N/A
1090-0079	Ms. Lynne Brock	N/A
1090-0081	Ms. Lucille Salitan	N/A
1090-0082	Mr. F.L. Holdridge	N/A
1090-0083	Mr. Joseph Pastorelli	N/A

Table A1. List of Commenters (Continued)

Commenter Number	Commenter Name	Affiliation
1090-0084	Mr. J. Weiss	N/A
1090-0086	Ms. Joan Carroll	N/A
1090-0087	Mr. Victor Skorapa	N/A
1090-0088	Mr. Bruce Grower	N/A
1090-0089	Mr. Lloyd Anderson	N/A
1090-0090	Mr. Steve Matthews	N/A
1090-0091	Mr. Thomas LaBarr	N/A
1090-0092	Ms. Gladys Mehrmann	N/A
1090-0093	Mr. Glenn R. Lee	N/A
1090-0094	Mr. Cris Cooley and Ms. Catherine Cooley	N/A
1090-0095	Mr. Paul Z. Wright	N/A
1090-0096	Ms. Elisabeth Nolan	N/A
1090-0097	Ms. Marjory M. Donn	N/A
1090-0098	Ms. Margaret Ayers	N/A
1090-0100	Ms. Emily B. Calhoun	N/A
1090-0101	Mr. Tera Freese	N/A
1090-0102	Mr. Chris Ilderton	N/A
1090-0103	Ms. Ruth Allen Miner	N/A

Table A1. List of Commenters (Continued)

Commenter Number	Commenter Name	Affiliation
1090-0104	Mr. Martin Schulz	N/A
1090-0105	Mr. Fredric Sternberg	N/A
1090-0106	Mr. Gene Bernardi	N/A
1090-0107	Mr. Thomas J. Becker	N/A
1090-0108	Ms. Judith B. Evered	N/A
1090-0109	Ms. Lorraine Goid	N/A
1090-0110	Ms. Diana Holmes	N/A
1090-0111	Mr. James Holmes	N/A
1090-0112	Mr. Richard Knight	N/A
1090-0113	Ms. Kris Listoe	N/A
1090-0114	Mr. Joseph Michael	N/A
1090-0115	Ms. Frances V. Moulder	N/A
1090-0116	Ms. Carolyn Newhouse	N/A
1090-0117	Ms. Christine Puente	N/A
1090-0118	Mr. Richard Sampson	N/A
1090-0119	Ms. Vivian Tatem	N/A
1090-0120	Ms. MaryAnn Hannon	N/A
1090-0121	Ms. Maria J. Holt	N/A

Table A1. List of Commenters (Continued)

Commenter Number	Commenter Name	Affiliation
1090-0122	Mr. M.C. Jackson	N/A
1090-0123	Mr. Marley Kellar	N/A
1090-0124	Mr. Egan O'Connor	N/A
1090-0126	Ms. Maria Maia	N/A
1090-0127	Ms. Susan Mills	N/A
1090-0128	Ms. Judith H. Johnsrud	Environmental Coalition on Nuclear Power and New England Coalition on Nuclear Power
1090-0129		Sierra Club
1090-0130	Ms. Jane Dee Hull, Mr. Mike Johanns, Mr. Kenny Guinn, Mr. Gary E. Johnson, Dr. John A. Kitzhaber, Mr. Jim Geringer	States of Arizona, Nebraska, Nevada, New Mexico, Oregon and Wyoming
1090-0131	Ms. Joann Myers	N/A
1090-0132	Ms. Virginia Wilkins	N/A
1090-0133	Mr. Richard Lincoln	N/A
1090-0134	Ms. Janice M. Pierson	N/A
1090-0135	Ms. Ann Borden	N/A
1090-0136	Mr. Timothy A. Runyon	The Council of State Governments of Midwestern Radioactive Materials Transportation Committee
1090-0137	Mr. Robert E. Fronczak	Association of American Railroads

Table A1. List of Commenters (Continued)

Commenter Number	Commenter Name	Affiliation
1090-0138	Ms. Melissa Mann	Transport Logistics International, Inc.
1090-0139	Mr. David L. Larkin	Holtec Users Group
1090-0140	Ms. Deborah Kelly	N/A
1090-0141	Mr. Carl Rupert	N/A
1090-0142	Mr. David Ritter	Public Citizen - Critical Mass Energy and Environment Program
1090-0143	Mr. C.M. Vaughan	Global Nuclear Fuel
1090-0144	Mr. Carl R. Yates and Mr. David L. Spangler	BWX Technologies
1090-0145	Mr. Nabil Al-Hadithy	City of Berkeley
1090-0146	Ms. Diane D'Arrigo	Nuclear Information and Resource Service and Others
1090-0147	Mr. Thomas Baldino	N/A
1090-0148	Ms. Genevieve O'Hara and Ms. Dorothy Poor	St. Louis Section of Women's International League for Peace and Freedom
1090-0149	Ms. Victoria Fox	N/A
1090-0150	Ms. Cheryl Rudin	N/A
1090-0151	Ms. Patricia Weikert	N/A
1090-0152	Ms. Dori Burg	N/A
1090-0153	Ms. Beverly Dyckman	N/A
1090-0154	Ms. Kathleen Sullivan	N/A

Table A1. List of Commenters (Continued)

Commenter Number	Commenter Name	Affiliation
1090-0155	Ms. Christina Eliason	N/A
1090-0156	Mr. Mike Weintraub	N/A
1090-0157	Mr. P.H. Snyder	N/A
1090-0158	Ms. Maria Pendzich	N/A
1090-0159	Ms. Laura Drey	N/A
1090-0160	Mr. John LaFarge	Nukewatch
1090-0161	Ms. Grace Aaron	N/A
1090-0162	Mr. Neil Rudin	N/A
1090-0163	Mr. N. Black	N/A
1090-0164	Ms. Ellen Steinfeld	N/A
1090-0165	Ms. Deanna Donovan	N/A
1090-0166	Mr. William Hill	N/A
1090-0167	Ms. Candy Redley	N/A
1090-0168	Ms. Eileen Markzon	N/A
1090-0169	Mr. Harold Powell	N/A
1090-0170	Mr. Robert Campbell	N/A
1090-0171	Mr. Jessie Roberson	U.S. Department of Energy
1090-0172	Mr. P. Brochman	N/A

Table A1. List of Commenters (Continued)

Commenter Number	Commenter Name	Affiliation
1090-0173	Mr. K. DeSchane	N/A
1090-0174	Mr. Carl Milch	N/A
1090-0175	Ms. Susan Carrol	N/A
1090-0176	Ms. Susan Bergman	N/A
1090-0177	Ms. Sue Wallace	N/A
1090-0178	Ms. Katie Peck	N/A
1090-0179	Ms. Angela Graziano	N/A
1090-0180	Mr. Weldon Rucker	City of Berkeley, Office of the City Manager
1090-0181	Mr. Lee Renna	N/A
1090-0182	Ms. Pamela Rubin	N/A
1090-0183	Mr. Louise Lumeri	N/A
1090-0184	Mr. Kali Jamison and Mr. James Jamison	N/A
1090-0185	Ms. Julia Kirchen	N/A
1090-0186	Ms. Marie Moore	Nuclear Fuel Services, Inc.
1090-0187	Ms. Linda Thurston	N/A
1090-0188	Mr. Charles Benett	N/A
1090-0189	Ms. Julia Abatelli	N/A
1090-0190	J. Pearl	N/A

Table A1. List of Commenters (Continued)

Commenter Number	Commenter Name	Affiliation
1090-0191	Ms. Jennifer Trebenon	N/A
1090-0192	Ms. Sara McArdle	N/A
1090-0193	Y. T. Zeidlyn	N/A
1090-0194	Ms. Patrice M. Bubar	U.S. Department of Energy
1090-0195	Mr. Robert C. Anderson	N/A
1090-0196	Mr. Schuyler Watts	N/A
Agreement State Comments Posted to NRC Web Site		
1092-0001	Mr. Thomas W. Orciger	Illinois Department of Nuclear Safety
1092-0002	Ms. Lauren Palmer	Georgia Department of Natural Resources
1092-0003	Mr. Robert J. Halstead	State of Nevada, Agency for Nuclear Projects
1092-0004	Mr. Aubrey V. Godwin	Arizona Radiation Regulatory Agency
1092-0005	Mr. Robert R. Loux	State of Nevada, Agency for Nuclear Projects

Table A2. Condensed List of Commenters

New Commenter Number	Old Commenter Number	Commenter Name	Affiliation
Chicago, Illinois Public Meeting (Afternoon Session; June 4, 2002)			
1	CA-001, CE-001, RM-002, RA-001, 1090-0037, 1090-0146	Ms. Diane D'Arrigo	Nuclear Information and Resource Service
2	CA-002	Mr. David Kraft	Nuclear Energy Information Service
3	CA-003, 1090-0041	Mr. Mark Doruff	Council on Radionuclides and Radio-pharmaceuticals
4	CA-004	Ms. Sidney Baiman	Nuclear Energy Information Service
5	CA-005, 1090-0004	Ms. Joy Reese	N/A
6	CA-006	Ms. Margaret Nagel	Variety of Chicago organizations including Chicago Media Watch and Chicago Peace Response
7	CA-007	Mr. Manny Tuazon	Consumers Energy
8	CA-008	Ms. Debbie Musiker	Lake Michigan Federation
9	CA-009	Mr. Paul Gaynor	Environmental Law and Policy Center of the Midwest
Rockville, Maryland Public Meeting (Morning Session; June 24, 2002)			
10	RM-001, 1090-0034	Mr. Marc-Andre Charette	MDS Nordion
11	RM-003	Dr. M. Elizabeth Darrough	United States Enrichment Corporation
12	RM-004	Ms. Elizabeth Goldwasser	United States Enrichment Corporation
13	RM-005, RA-005	Mr. Robert Halstead	Nevada Agency for Nuclear Projects

Table A2. Condensed List of Commenters (Continued)

New Commenter Number	Old Commenter Number	Commenter Name	Affiliation
14	RM-006, RA-004, 1090-0053	Mr. Felix Killar, Jr.	Nuclear Energy Institute
15	RM-007, RA-008	Mr. William Lake	U.S. Department of Energy
16	RM-008, RA-007, 1090-0138	Ms. Melissa Mann	Transport Logistics International
17	RM-009, RA-009	Mr. Robert Owen	Ohio Department of Health
18	RM-010, RA-012, 1090-0142	Mr. David Ritter	Public Citizen - Critical Mass Energy and Environment Program
19	RM-011	Mr. Mark Rogers	Airline Pilots Association
20	RM-012, RA-002, 1090-0049	Mr. Charles Simmons	Kilpatrick Stockton
21	RM-013	Mr. Fred Dilger	Clark County, Nevada
22	RM-014, RA-010	Ms. Eileen Supko	Energy Resource International
23	RM-015	Dr. Judith Johnsrud	Sierra Club Environment Coalition
24	RM-016, RA-003	Mr. Don Erwin	Hunton & Williams (Representing J.L Shepherd)
Rockville, Maryland Public Meeting (Afternoon Session; June 24, 2002)			
25	RA-006, 1090-0011	Mr. Brian Gutherman	Holtech International
26	RA-011	Mr. Marvin Turkanis	Neutron Products
Public Comments Posted to NRC Web Site			
27	1090-0001	Mr. Stephen A. Thompson	U.S. Department of Energy
28	1090-0002	Mr. Jack Hovingh	N/A

Table A2. Condensed List of Commenters (Continued)

New Commenter Number	Old Commenter Number	Commenter Name	Affiliation
29	1090-0003		Global Resource Action Center for the Environment
30	1090-0004	Mr. Jay Reese	N/A
31	1090-0005	Mr. John J. Miller	International Isotopes, Inc.
32	1090-0006	Mr. Robert Goettler et al.	N/A
33	1090-0007	Mr. Thomas Dougherty	Columbiana Hi Tech Front End, LLC
34	1090-0008	Mr. Mark Donham and Ms. Kristi Hanson	Coalition for Nuclear Justice
35	1090-0027	Ms. Jody Lanier	N/A
37	1090-0028	Mr. Robert E. Rutkowski	N/A
38	1090-0029	Mr. B. Geary	N/A
39	1090-0030	Ms. Roberta Chase and Mr. Mike Schade	Citizens' Environmental Coalition
40	1090-0031	Mr. Richard Geary	N/A
41	1090-0032	Ms. Linda Novenski	N/A
42	1090-0033	Mr. Gerry Welch	St. Louis County Municipal League
43	1090-0035	Mr. B.K. Miles	U.S. Department of Energy
44	1090-0036	Ms. Diane D'Arrigo et al.	Nuclear Information and Resource Service et al.
45	1090-0038	Mr. Peter N. Skinner, P.E.	State of New York, Office of the Attorney General

Table A2. Condensed List of Commenters (Continued)

New Commenter Number	Old Commenter Number	Commenter Name	Affiliation
46	1090-0039	Ms. Sara Barczak	Georgians for Clean Energy
47	1090-0040	Mr. Kent Hancock	Department of Energy

Table A2. Condensed List of Commenters (Continued)

New Commenter Number	Old Commenter Number	Commenter Name	Affiliation
48	1090-0042, 1090-0056	Mr. Donald P. Irwin	Hunton & Williams, on behalf of J.L. Shepard & Associates
50	1090-0043	Mr. Louis Zeller	Blue Ridge Environmental Defense League
51	1090-0044	Ms. Kay Drey	N/A
52	1090-0045	Ms. Barbara Bailine	N/A
53	1090-0046	Ms. Eileen Greene	N/A
54	1090-0047	Mr. Coffie C. Wortham	N/A
55	1090-0048	Ms. Sheila England	N/A
56	1090-0050	Ms. Pamel Blockey-O'Brian	N/A
58	1090-0051	Ms. Susan R. Gordon	Alliance for Nuclear Accountability
59	1090-0052	Mr. A. Joseph Nardi	Westinghouse Electric Company
60	1090-0054	Mr. Steven A. Toelle	United States Enrichment Corporation
61	1090-0055	Ms. Nisha Dawson	N/A
62	1090-0057	Mr. Patrick R. Simpson	Exelon Generation Company, LLC
64	1090-0058	Mr. Terry C. Morton	Carolina Power & Light and Florida Power Corporation
65	1090-0059	Mr. John Jay Ulloth	N/A
66	1090-0060	Ms. Erin Rogers	N/A
67	1090-0061	Mr. David Bedell	N/A

Table A2. Condensed List of Commenters (Continued)

New Commenter Number	Old Commenter Number	Commenter Name	Affiliation
68	1090-0062	Ms. Elaine Gedige	N/A
69	1090-0063	Ms. Auna T. Rand	N/A
70	1090-0064	Ms. Julia Butera	N/A
71	1090-0065	Mr. Gary A. Karch	N/A
72	1090-0066	Mr. Billy Ponard	N/A
73	1090-0067	Mr. Mark M. Giese	N/A
74	1090-0068	Ms. Valerie Wyman	N/A
75	1090-0069	Ms. Brianna Knoffer	N/A
76	1090-0070, 1090-0071	Ms. Estelle Lit	N/A
77	1090-0072	Ms. Patricia Christian	N/A
79	1090-0073	Mr. Julius Sippen	N/A
80	1090-0074	Mr. Tom Ferguson	Physicians for Social Responsibility
81	1090-0075	Ms. Rebecca Troon	N/A
82	1090-0077	Mr. Thomas Reilly	N/A
83	1090-0078	Ms. Fawn L. Shillinglaw	N/A
84	1090-0079	Ms. Lynne Brock	N/A
85	1090-0081	Ms. Lucille Salitan	N/A

Table A2. Condensed List of Commenters (Continued)

New Commenter Number	Old Commenter Number	Commenter Name	Affiliation
86	1090-0082	Mr. F.L. Holdridge	N/A
87	1090-0083	Mr. Joseph Pastorelli	N/A
88	1090-0084	Mr. J. Weiss	N/A
89	1090-0086	Ms. Joan Carroll	N/A
90	1090-0087	Mr. Victor Skorapa	N/A
91	1090-0088	Mr. Bruce Grower	N/A
92	1090-0089	Mr. Lloyd Anderson	N/A
93	1090-0090	Mr. Steve Matthews	N/A
94	1090-0091	Mr. Thomas LaBarr	N/A
95	1090-0092	Ms. Gladys Mehrmann	N/A
96	1090-0093	Mr. Glenn R. Lee	N/A
97	1090-0094	Mr. Cris Cooley and Ms. Catherine Cooley	N/A
98	1090-0095	Mr. Paul Z. Wright	N/A
99	1090-0096	Ms. Elisabeth Nolan	N/A
100	1090-0097	Ms. Marjory M. Donn	N/A
101	1090-0098	Ms. Margaret Ayers	N/A
102	1090-0100	Ms. Emily B. Calhoun	N/A

Table A2. Condensed List of Commenters (Continued)

New Commenter Number	Old Commenter Number	Commenter Name	Affiliation
103	1090-0101	Mr. Tera Freese	N/A
104	1090-0102	Mr. Chris Ilderton	N/A
105	1090-0103	Ms. Ruth Allen Miner	N/A
106	1090-0104	Mr. Martin Schulz	N/A
107	1090-0105	Mr. Fredric Sternberg	N/A
108	1090-0106	Mr. Gene Bernardi	N/A
109	1090-0107	Mr. Thomas J. Becker	N/A
110	1090-0108	Ms. Judith B. Evered	N/A
111	1090-0109	Ms. Lorraine Goid	N/A
112	1090-0110	Ms. Diana Holmes	N/A
113	1090-0111	Mr. James Holmes	N/A
114	1090-0112	Mr. Richard Knight	N/A
115	1090-0113	Ms. Kris Listoe	N/A
116	1090-0114	Mr. Joseph Michael	N/A
117	1090-0115	Ms. Frances V. Moulder	N/A
118	1090-0116	Ms. Carolyn Newhouse	N/A
119	1090-0117	Ms. Christine Puente	N/A

Table A2. Condensed List of Commenters (Continued)

New Commenter Number	Old Commenter Number	Commenter Name	Affiliation
120	1090-0118	Mr. Richard Sampson	N/A
121	1090-0119	Ms. Vivian Tatem	N/A
122	1090-0120	Ms. MaryAnn Hannon	N/A
123	1090-0121	Ms. Maria J. Holt	N/A
124	1090-0122	Mr. M.C. Jackson	N/A
125	1090-0123	Mr. Marley Kellar	N/A
126	1090-0124	Mr. Egan O'Connor	N/A
127	1090-0126	Ms. Maria Maia	N/A
128	1090-0127	Ms. Susan Mills	N/A
129	1090-0128	Ms. Judith H. Johnsrud	Environmental Coalition on Nuclear Power and New England Coalition on Nuclear Power
130	1090-0129		Sierra Club
131	1090-0130	Ms. Jane Dee Hull, Mr. Mike Johanns, Mr. Kenny Guinn, Mr. Gary E. Johnson, Dr. John A. Kitzhaber, Mr. Jim Geringer	States of Arizona, Nebraska, Nevada, New Mexico, Oregon and Wyoming
132	1090-0131	Ms. Joann Myers	N/A
133	1090-0132	Ms. Virginia Wilkins	N/A
134	1090-0133	Mr. Richard Lincoln	N/A

Table A2. Condensed List of Commenters (Continued)

New Commenter Number	Old Commenter Number	Commenter Name	Affiliation
135	1090-0134	Ms. Janice M. Pierson	N/A
136	1090-0135	Ms. Ann Borden	N/A

Table A2. Condensed List of Commenters (Continued)

New Commenter Number	Old Commenter Number	Commenter Name	Affiliation
137	1090-0136	Mr. Timothy A. Runyon	The Council of State Governments of Midwestern Radioactive Materials Transportation Committee
138	1090-0137	Mr. Robert E. Fronczak	Association of American Railroads
139	1090-0139	Mr. David L. Larkin	Holtec Users Group
140	1090-0140	Ms. Deborah Kelly	N/A
141	1090-0141	Mr. Carl Rupert	N/A
142	1090-0143	Mr. C.M. Vaughan	Global Nuclear Fuel
143	1090-0144	Mr. Carl R. Yates and Mr. David L. Spangler	BWX Technologies
144	1090-0145	Mr. Nabil Al-Hadithy	City of Berkeley
145	1090-0147	Mr. Thomas Baldino	N/A
147	1090-0148	Ms. Genevieve O'Hara and Ms. Dorothy Poor	St. Louis Section of Women's International League for Peace and Freedom
148	1090-0149	Ms. Victoria Fox	N/A
149	1090-0150	Ms. Cheryl Rudin	N/A
150	1090-0151	Ms. Patricia Weikert	N/A
151	1090-0152	Ms. Dori Burg	N/A
152	1090-0153	Ms. Beverly Dyckman	N/A

Table A2. Condensed List of Commenters (Continued)

New Commenter Number	Old Commenter Number	Commenter Name	Affiliation
153	1090-0154	Ms. Kathleen Sullivan	N/A
154	1090-0155	Ms. Christina Eliason	N/A
155	1090-0156	Mr. Mike Weintraub	N/A
156	1090-0157	Mr. P.H. Snyder	N/A
157	1090-0158	Ms. Maria Pendzich	N/A
158	1090-0159	Ms. Laura Drey	N/A
159	1090-0160	Mr. John LaFarge	Nukewatch
160	1090-0161	Ms. Grace Aaron	N/A
161	1090-0162	Mr. Neil Rudin	N/A
162	1090-0163	Mr. N. Black	N/A
163	1090-0164	Ms. Ellen Steinfeld	N/A
164	1090-0165	Ms. Deanna Donovan	N/A
165	1090-0166	Mr. William Hill	N/A
166	1090-0167	Ms. Candy Redley	N/A
167	1090-0168	Ms. Eileen Markzon	N/A
168	1090-0169	Mr. Harold Powell	N/A
169	1090-0170	Mr. Robert Campbell	N/A

Table A2. Condensed List of Commenters (Continued)

New Commenter Number	Old Commenter Number	Commenter Name	Affiliation
170	1090-0171	Mr. Jessie Roberson	U.S. Department of Energy
171	1090-0172	Mr. P. Brochman	N/A
172	1090-0173	Mr. K. DeSchane	N/A
173	1090-0174	Mr. Carl Milch	N/A
174	1090-0175	Ms. Susan Carrol	N/A
175	1090-0176	Ms. Susan Bergman	N/A
176	1090-0177	Ms. Sue Wallace	N/A
177	1090-0178	Ms. Katie Peck	N/A
178	1090-0179	Ms. Angela Graziano	N/A
179	1090-0180	Mr. Weldon Rucker	City of Berkeley, Office of the City Manager
180	1090-0181	Mr. Lee Renna	N/A
181	1090-0182	Ms. Pamela Rubin	N/A
182	1090-0183	Mr. Louise Lumeri	N/A
183	1090-0184	Mr. Kali Jamison and Mr. James Jamison	N/A
184	1090-0185	Ms. Julia Kirchen	N/A
185	1090-0186	Ms. Marie Moore	Nuclear Fuel Services, Inc.
186	1090-0187	Ms. Linda Thurston	N/A

Table A2. Condensed List of Commenters (Continued)

New Commenter Number	Old Commenter Number	Commenter Name	Affiliation
187	1090-0188	Mr. Charles Benett	N/A
188	1090-0189	Ms. Julia Abatelli	N/A
189	1090-0190	J. Pearl	N/A
190	1090-0191	Ms. Jennifer Trebenon	N/A
191	1090-0192	Ms. Sara McArdle	N/A
192	1090-0193	Y. T. Zeidlyn	N/A
193	1090-0194	Ms. Patrice M. Bubar	U.S. Department of Energy
194	1090-0195	Mr. Robert C. Anderson	N/A
195	1090-0196	Mr. Schuyler Watts	N/A
Agreement State Comments Posted to NRC Web Site			
196	1092-0001	Mr. Thomas W. Orciger	Illinois Department of Nuclear Safety
197	1092-0002	Ms. Lauren Palmer	Georgia Department of Natural Resources
198	1092-0003	Mr. Robert J. Halstead	State of Nevada, Agency for Nuclear Projects
199	1092-0004	Mr. Aubrey V. Godwin	Arizona Radiation Regulatory Agency
200	1092-0005	Mr. Robert R. Loux	State of Nevada, Agency for Nuclear Projects