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OFFICE OF SECRETARY
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July 29, 2002

Ms. Annette L. Vietti-Cook
 Secretary of the Commission
 U.S. Nuclear Regulatory Commission
 Washington, D.C. 20555-0001

ATTENTION: Rulemakings and Adjudication Staff

REFERENCE: Request for Comments on Proposed Rule "Compatibility With IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments" 10 CFR 71, RIN 3150-AG71, 67 *Fed. Reg.* 21390 (April 30, 2002)

Dear Ms. Vietti-Cook:

The Nuclear Energy Institute (NEI)¹ is submitting the following comments on the proposed rule, "Compatibility With IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments," that seeks to amend 10 CFR 71 and make NRC's regulations governing the shipments of radioactive materials compatible with international regulations. The proposed rule will also codify other requirements.

NEI commends the NRC for its outreach and solicitation of public involvement in this major rule making by means of the July 17, 2000, issues paper, three supporting "roundtable" workshops and through use of an interactive NRC web page. The staff kept the Commission informed by means of public briefings in early 2001 followed by two additional public meetings in April 2001. These outreach initiatives far exceeded

¹ NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

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most stakeholders' expectations in affording many opportunities to assess and comment upon the proposed regulatory changes.

NEI supports the overall intent of the proposed modifications. The nuclear industry is international and the ability to move radioactive materials among countries based on a common set of regulations is very important to the health of the industry. While we support the efforts of the NRC and the Department of Transportation (DOT), we are concerned with the slow actions of your agency. The international standards were prepared in 1996 and adopted by a majority of the IAEA member countries over one year ago. The NRC and DOT do not expect to have their rulemakings completed before next year and the implementation date may extend beyond into 2004. As you are aware, the IAEA has adopted a two-year review cycle for updating its transportation regulations. The first two-year cycle is coming to a close and the second cycle has already started. This two-year cycle will require both the NRC and DOT to expedite consideration of IAEA proposed revisions, without negatively impacting the opportunity for public input.

The NRC and DOT 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 USA domestic regulations. Therefore, while most of the IAEA standards should be incorporated into US regulations, the unique aspects of the US regulations need to be considered. The IAEA standards are appropriate for international shipments, but the NRC and DOT regulations should also provide allowance for domestic-only applications. This 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. Similarly, the A_2 value for molybdenum-99 and the A_1 and A_2 values for californium-252 should be retained for domestic-only use packages, but shippers would need to comply with the A_1 and A_2 values in TS-R-1 for international shipments.

In addition to adoption of the IAEA standards, the rulemaking proposes several changes to other sections of Part 71. For the most part the industry supports and encourages these changes. However, in the case of exemption values for fissile material the proposed rule is overly conservative and places increased costs and unnecessary burdens on the industry, specifically, in the case of bulk shipments of contaminated materials, such as soil or building rubble. The industry brought this concern to the staff's attention during the June 24, 2002, public meeting. Since that meeting, interactions with the staff and additional study by the industry have facilitated a more thorough understanding of, and identification of additional concerns with, the proposed rule. Industry now understands that the proposed rule addresses exemptions from criticality control by combining mass limits and concentration limits of fissile

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material. From the aspect of criticality safety either a mass limit or a concentration limit will assure that a criticality could not occur. The open issue is how to assure that the concentration limit or mass limit is not exceeded under upset conditions. The industry believes through additional work with the staff, mass limits or concentration limits with appropriate operational conditions can be established. The industry would like the rulemaking to go forward while it works with the staff to arrive at these operational limits that will assure the mass or concentration limit is maintained under accident conditions. The NRC must re-evaluate this aspect of the proposed rule.

The attachment to this letter provides information in support of our contention that the proposed limitations on domestic shipments of bulk materials are not required from a criticality safety perspective. It also provides NEI's comments on other aspects of the proposed rulemaking.

In summary, we encourage the NRC and the DOT to complete in a timely fashion their comprehensive assessments of TS-R-1 and future IAEA standards and adopt them as appropriate. We do not support the IAEA grandfathering provision for packages designed in accordance with the 1967 standard when such package(s) are limited to domestic-only shipments. Likewise, we do not support the IAEA's A_2 value for molybdenum-99 or the A_1 and A_2 values for californium-252 for domestic-only shipments of such isotopes. Finally, the NRC needs to re-evaluate the provisions for criticality exemption for fissile materials and establish a reasoned and defensible approach.

We would be pleased to discuss these comments with the NRC and to respond to any questions that you may have.

Sincerely,



Felix M. Killar, Jr.

Enclosure

c: Rick Boyle – DOT
NEI Transportation Task Force Members

ENCLOSURE

Comments on Proposed Rule "Compatibility With IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments"

This attachment presents NEI's comments on the 19 IAEA compatibility and NRC-initiated issues discussed in the *Federal Register* notice. It also provides responses to the NRC's requests for cost-benefit and exposure information as detailed in Section III of the *Federal Register* notice (pp. 21393-21395).

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

NRC Proposed Position: The NRC does not intend to change Part 71 to use SI units only, nor does it intend to impose on Part 71 licensees, certificate holders, or applicants for a CoC the use of SI units only.

Industry Position: Industry supports the NRC position.

Issue 2. Radionuclide Exemption Values

NRC Proposed Position: The NRC is proposing to adopt the radionuclide exemption values in TS-R-1 to assure continued consistency between domestic and international regulations for the basic definition of radioactive material.

Industry Position: Industry supports the NRC position.

NRC Request for Information: What impacts, if any, would result for industries that possess, use, or transport materials currently exempt from regulatory control (e.g., unimportant quantities of source material under 10 CFR 40.13) if adoption of the radionuclide exemption values were to occur in Part 71?

Industry Response: Adoption of the exemption values in TS-R-1 could result in the licensing of certain materials that are currently exempt from NRC regulation under 10 CFR 40.13. However, 10 CFR 71 shipping regulations would impose some packaging and labeling requirements. The NRC currently has an Interagency Task Force that is reviewing regulation of unimportant quantities of source material under the 10 CFR 40.13 definition. NEI understands that the Interagency Task Force has prepared and submitted recommendations to the Commission. Industry has recommended to the Interagency Task Force that unimportant quantities of source material currently exempt from regulations under 10 CFR 40.13 remain as such. Industrial and mineral beneficiation processes that concentrate radionuclides in excess of the 0.05% "unimportant quantity" limit and whose purpose is not the recovery of the source material should not be subject to NRC licensing and regulatory requirements.

NRC Request for Information: What impacts, if any, would result for industries that transport natural material and ores containing naturally occurring radionuclides which are not intended for processing for economic use of their isotopes (e.g., phosphate mining, waste products from the oil and gas industry), if the TS-R-1 exemption values are adopted, but without the "10 times the applicable exemption values" provision?

Industry Response: Even with the "10 times the applicable exemption values" natural material and ores containing naturally occurring radionuclides that are not to be processed for recovery of their radionuclides could still be transported, but not be exempt from the regulations. As discussed above, the industry does not want this to occur. As the Interagency Task Force learned, the regulations of other agencies, such as OSHA, afford adequate protection for workers and the public; the NRC does not need to enter into this regulatory arena. Therefore, we recommend that the exemption apply to the domestic transport of unimportant quantities of source material subject to the 10 CFR 40.13 exemption provided that the material and ores are not to be processed for economic recovery of their source material content.

The proposed radionuclide exemption values may impact waste disposal sites that are regulated by EPA under the Resource Conservation and Recovery Act (RCRA). The acceptance limit at these sites for materials containing radioactive residuals is the existing 70 Bq/g (0.002 Ci/g) standard which is used by DOT, NRC, and EPA. As only the NRC and DOT are proposing to adopt the exemption values, situations may arise whereby DOT regulations and the new exemption values would allow the transportation of materials with residual radioactivity, but the RCRA sites could not legally accept the materials for disposal.

NRC Request for Information: What cost impacts or other problems, if any, would result from adoption of the exemption values, in Part 71 and DOT regulations, for industries or entities involved in the shipment and disposal of materials with residual activity to RCRA sites?

Industry Response: Adoption will raise some questions from the operators of RCRA disposal facilities and the public about the safety of the materials that were previously exempt from transportation labeling and that are not exempt under the new regulations. This could cause a perception of a change in risk. In practice, nothing will change for the RCRA facility accepting (or not accepting) the materials for disposal, as the regulations for those facilities do not change. The exposure to the facility workers and public will not change, as the material must still be within the 70 Bq/g (0.002 Ci/g) standard.

Issue 3. Revision of A_1 and A_2

NRC Proposed Position: The NRC is proposing to make a conforming change to Part 71 to adopt the new A_1 and A_2 values from TS-R-1 in Part 71, with the differences as discussed for molybdenum-99 and californium-252. The NRC is also proposing not to

include A_1 and A_2 values for the 16 radionuclides that are currently listed in Part 71, but which do not appear in TS-R-1.

Industry Position: Industry supports the NRC position.

NRC Request for Information: What impacts, if any, would result for the radiopharmaceutical industry in terms of cost and worker dose by adopting the lower international A_2 value, rather than retaining the current A_2 value for domestic shipment of molybdenum-99?

Industry Response: Impacts on worker dose are difficult to quantify. Intuitively, we believe the dose to workers will increase due to their need to handle more packages. As the limits per package transported will remain constant as far as contamination and direct exposure are concerned, regardless of the contents, occupational exposures will likely increase as workers will be handling a larger number of packages. Molybdenum-99 is the principal isotope used in medical imaging. As demand for this product can only increase with an aging population, by not retaining the current A_2 value a greater number of shipments will be required and this will result in higher per-treatment costs and higher costs for the industry.

NRC Request for Information: What impacts, if any, would result for industry in terms of cost and worker dose by retaining the current A_1 and A_2 values for californium-252, rather than adopting the international A_1 and A_2 values?

Industry Response: DOE is the principal shipper of californium-252 under the current exemption value and therefore we cannot assess the impact(s).

NRC Request for Information: What impacts, if any, would result for industry in terms of cost and worker dose by not including in Table A-1 (A_1 and A_2 Values for Radionuclides) the 16 radionuclides that are listed in the current Part 71 but not in TS-R-1?

Industry Response: Appendix A to Part 71 now contains A_1 and A_2 data for sixteen radionuclides that are not included in Table A-1 in TS-R-1. Commission approval is required to set A_1 and A_2 values for a radionuclide, although in the absence of data for a specific radionuclide, a licensee may use the *General Values for A_1 and A_2* presented in Table A-2. By omitting from Appendix A the A_1 and A_2 values for the sixteen radionuclides that are not in TS-R-1, the Commission is exposing itself the likelihood—almost certainty—of having to set such radionuclide values upon the future request of a licensee. As we know of no challenges to the health and safety bases for the sixteen radionuclides, we recommend that the NRC not delete them from Part 71, Appendix A. The NRC will save itself the cost and staff resources of establishing appropriate A_1 and A_2 values in the future and industry will be saved from another unnecessary regulatory burden.

Issue 4. Uranium Hexafluoride Package Requirements

NRC Proposed Position: The NRC is proposing to adopt §71.55(g) to address TS-R-1, paragraph 677(b), to exempt certain UF₆ packages from the requirements of §71.55(b).

Industry Position: Industry supports the NRC position, but with the following caveat. As drafted, the proposed §71.55(g) would restrict a UF₆ package contents to a maximum enrichment level of 5% ²³⁵U. This is problematic, as the NRC would be codifying an enrichment level that will likely be exceeded in fuels for new generation reactors or for higher burn-up levels. For higher enrichments, any UF₆ packages would, therefore, need to meet the requirements of §71.55(b). This would likely necessitate fairly significant changes to (and costs for) the type of UF₆ packages currently used by the industry.

NRC Request for Information: Should the current practice of excluding moderators in criticality evaluations for UF₆ packages be continued?

Industry Response: The current practice of excluding moderators in criticality evaluations for UF₆ packages should be continued. The justification for excluding it has not changed and there have not been any experiences to indicate that it should be changed. Therefore, it should be retained.

Issue 5. Introduction of the Criticality Safety Index Requirements

NRC Proposed Position: The NRC proposes to adopt the TS-R-1 (paragraph 218) which incorporates a CSI in Part 71 that would be determined in the same manner as the current Part 71 "TI for criticality control purposes." The NRC also proposes to adopt TS-R-1 (paragraph 530) which increases the CSI per package limit from 10 to 50 for fissile material packages in nonexclusive use shipments.

Industry Position: Industry supports the NRC position to add a CSI to 10 CFR 71. However, adoption of a CSI and the 50 limit will dramatically impact international transports of fissile material. §71.22(d)(3) and §71.59(c)(1) would limit the sum of the CSIs to less than or equal to 50 when the material is stored incident to transport. This would mean that a shipment resting at a port after being unloaded from an ocean vessel and awaiting loading on a truck for onward shipment would be limited to a combined CSI = 50. This change would effectively remove the exclusive use authorization for multi-modal shipments.

NRC's proposed changes to §71.59(b) and (c) constitute an overly conservative application of the CSI. The CSI is determined by dividing 50 by "N," where "N" refers to the number of packages used in the 5N/2N-criticality safety array size demonstration of

safety. In this demonstration "N" already represents a safe and acceptable array of packages and establishes an appropriate safety limit. The CSI is appropriate for use in demonstrating safety, but it should not be used in a manner that would further limit the array size of packages, overpacks or freight containers.

The proposed revision of §71.59(b) includes the sentence: "Any CSI greater than zero must be rounded up to the first decimal place." As TS-R-1 does not require such rounding, the proposed §71.59(b) is inconsistent with the IAEA guidance and the rounding-up requirement should be deleted. The requirement to round-up the CSI value, in effect, places additional limits on the array size and further limits shipments unnecessarily. For example, for the case in which the 2N value for a package equals 150 (N=75) as the limiting safety case, the CSI equals 0.6666. An array of packages would have a total CSI value of 50. If the CSI were rounded-up to the nearest tenth, then 75 packages would have a total CSI of 52.5 and the array would have to be limited to 71 packages to keep the CSI value equal to 50. This rounding-up causes an unnecessary 5% reduction in number of packages required to ship a given quantity of material. It unnecessarily increases the number of shipments required without any improvement in safety.

In §§71.59 (c)(1), (2) and (3) and in §71.55 (f)(3) the values of 50.0 and 100.0 should be changed to 50 and 100 to be consistent with TS-R-1's recommended application of the CSI.

NRC requests information: What cost or benefit impacts would result if the per package Criticality Safety Index (CSI) were to change from 10 to 50?

Industry Response: The increase of the CSI from 10 to 50 would have a major detrimental impact in shipping and intermodal storage areas. This could increase the number of shipments to avoid the staging of the packages at a storage facility incident to transport. The NRC is proposing changes to Part 71 that would dramatically impact international transports of fissile material. §71.22(d)(3) and §71.59(c)(1) would limit the sum of the CSIs to less than or equal to 50 when the material is stored incident to transport. This would mean that a shipment resting at a port after being unloaded from an ocean vessel and awaiting loading on a truck for onward shipment would be limited to a combined CSI of 50. As noted earlier, this change would effectively remove the exclusive use authorization for multi-modal shipments. Cost increases would be incurred in the documentation and scheduling areas. It would also increase the cost in customs handling and applications for import or export. It would increase the actual shipping cost, as higher rates would be charged due to smaller shipments. Demurrage fees would increase as less than fully loaded seapacks would be employed. Specific numbers are hard to identify, but it is clear this change would have a major detriment to shipping costs.

Issue 6. Type C Packages and Low Dispersible Material

NRC Proposed Position: The NRC would not adopt Type C or LDM requirements at this time.

Industry Position: Industry supports the NRC position as the IAEA specification is too broad. The industry supports the use of Type C packages and LDM for fissile oxides of plutonium, but there is no need for this package to transport other Class 7 materials. The industry would encourage the NRC and DOT to work with the IAEA to reduce the scope of the Type C package to these few materials.

NRC Request for Information on the need for Type C packages, specifically on the number of package designs and the timing of future requests for Type C package design approvals.

Industry Response: Currently the industry is not using any packages that would be replaced by a Type C package. As the program for the use of mixed oxide fuel advances, Type C packages may be required for shipment of some of these materials in the oxide form. Additionally, as international non-proliferation programs grow and expand with weapons grade materials being shipped and down-blended for commercial applications, Type C packages may be required to ship high enriched uranium oxide. Therefore, the industry recommends that the NRC and DOT work with the IAEA to limit the scope of Type C packages now, rather than later, when Type C package shipments are scheduled to occur and when package approvals may be more controversial.

Issue 7. Deep Immersion Test

NRC Proposed Position: The NRC proposes to adopt the requirement for enhanced water immersion test for packages used for radioactive contents with activity greater than $10^5 A_2$. The NRC intends to retain the current test requirements in §71.61 of "one hour without collapse, buckling, or inleakage of water."

Industry Position: Industry supports the NRC position.

Issue 8. Grandfathering Previously Approved Packages

NRC Proposed Position: NRC supports the update to grandfathering in TS-R-1 and is proposing to revise Part 71 to discontinue authorization to use packages approved under the provisions of the 1967 edition of Safety Series No. 6. Specifically, NRC is proposing to make modifications to existing §71.13 to phase out these types of packages. NRC realizes the impact this proposal may have on shipments using existing NRC-approved packages. Therefore, NRC proposes a 3-year transition period for the grandfathering provision on packages approved under the provisions of the 1967 edition of Safety Series No. 6. This period would provide industry the opportunity to

phase out old packages and phase in new ones, or demonstrate that current requirements are met.

Industry Position: Industry supports the phasing out of older packages and agrees that the use of packages certified to the 1967 edition of Safety Series No. 6 should be discontinued. However, there are a limited number of unique packages currently in use that were approved under the provisions of the 1967 edition of Safety Series No. 6 and whose continued use should be permitted. The NRC and DOT have the ability to disallow the use of any package for which they have any safety concerns, but in the absence of demonstrable safety deficiencies, older packages should be allowed to continue in domestic commerce.

One company has two NRC CoC containers and about a dozen DOT-specification containers, all built to the 1967 specifications that are used to make a couple of hundred shipments of Type B materials per year, mostly within the US. Were use of 1967-specification containers phased out, this company will either have to requalify all of its containers or leave the business. This would necessitate re-qualification for two CoCs (the current CoC and one for its DOT-specification containers). As the re-qualification costs approach \$500,000 per CoC, having to do so would be punitive, if not ruinous, to them (their annual revenues are on the order of \$5M/yr) even in this "best case" scenario.

Adding to the complexity, this company's devices — mostly irradiators and calibrators — come in a variety of models that contain integral shielding which is part of the "packaging." If the NRC were not to permit flexible descriptions in its CoCs so as to account for variations in size, dimensions, weight etc. of the shielding on the devices, this company would find itself having to requalify its 1967-specification containers for not just two CoCs but literally dozens of them. They simply cannot afford this and would go out of business. One result would be that several hundreds of Type B sources would become, for all practical purposes, stranded and immovable from their current locations. Most of them -- the ones that are now shipped in DOT-specification containers -- could be transported, very expensively, in other existing containers; but for some, the only licensed containers capable of carrying them are the company's containers, which would no longer be usable.

A review of stakeholder comments posted on the NRC's web site and of the NRC's summary of them (NUREG/CR-6712, "*Summary and Categorization of Public Comments on the Major Revision of 10 CFR Part 71*") reveals two facts: (1) the breadth and vehemence of a large number of commenters from industry, state governments, and federal agencies, about the harm that would result from ending the use of 1967-specification containers even to transport existing sources, and (2) the dilution, misunderstanding and even mischaracterization of these comments in the NRC's summary document. If the staff is basing its perception of the nature of comments on NUREG/CR-6712, it will never appreciate public concerns.

Finally, the DOT proposal with respect to containers manufactured under the 1967 standards appears even more limiting than that of the NRC. There is an inconsistency between the two agencies.

NRC Request for Information: Under what conditions should packagings be removed from service?

Industry Response: Packages should be removed from service if they cannot meet the safety requirements to which they were designed or if new safety issues are recognized that would prevent the package from meeting its safety function. Packages should remain in service indefinitely unless either of the above two conditions were to exist. Industry does support the phase-out of older packages by not manufacturing new packages to the old specifications; however, packages currently in use should be allowed to continue in use. The industry currently projects that it will cost approximately \$500,000 to re-certify a 1967 package. We have identified five packages in this category; therefore, the re-certification case is a minimum of \$2,500,000. In lieu of re-certification it would cost about the same for the certification of a new design, following the design work plus the cost to manufacture the replacement packages. Therefore, the replacement design cost would be \$2,500,000 for certification plus about \$2,500,000 for the design work and \$10,000,000 for the manufacture of the replacement packages. These cost estimates are based on the family of the five known packages. We have reason to believe that there are additional packages in use by small companies that have not been tracking the potential changes and impacts.

NRC Request for Information: What are the cost or benefit impacts associated with the proposal to remove B() packages from service?

Industry Response: Accurate data are not currently available to forecast cost-benefit impacts. There are only a few B() packages in use. The NRC needs to work with each holder of B() packages to determine if they wish to maintain this package.

Issue 9. Changes to Various Definitions

NRC Proposed Position: The NRC is proposing to adopt the TS-R-1 definition of Criticality Safety Index (CSI). Additionally, the following definitions would be revised to improve their clarity: A₁, A₂, and LSA-III.

Industry Position: Industry supports the NRC's proposed adoption of the specified definitions. The NRC should additionally adopt the following TS-R-1 definitions:

- Confinement system: we note the NRC's comments regarding confinement system, but nonetheless urge the NRC to adopt the definition as it could impact the review of designs intended for use in a broad range of countries

- Consignment
- Contamination
- Fixed contamination
- Non-fixed contamination
- Shipment
- Transport Index

The NRC's proposed rule does not make a significant change to the definitions of LSA and SCO. However the DOT proposes a major change in the definition of LSA-I material. This introduces an issue of compatibility between the two rules. The NRC and DOT need to assure that there is compatibility between the rules.

Issue 10. Crush Test for Fissile Material Package Design

NRC Proposed Position: The NRC proposes to adopt the requirement for a crush test for fissile material packages, and eliminate the 1000 A₂ criterion for fissile material packages. However, because there is no new information that addresses concerns from the previous rulemaking regarding the difference in test requirements between Part 71 and Safety Series No. 6, the NRC proposes not to change the testing sequence nor to change the drop and crush test requirements in this revision

Industry Position: Industry supports the NRC position. However, the rule needs to clarify that a package must pass either the drop test or the crush test, but not necessarily both. If computer modeling is inadequate to demonstrate a package's integrity and drop and crush tests are performed, the rule should state that separate packages are to be used for each test. The same package should not be used to pass both tests in sequence.

NRC Request for Information: What are the cost or benefit impacts of imposing the crush test requirement on fissile material package designs?

Industry Response: The additional cost of the crush test for fissile materials is estimated at about \$5,000,000. This is to design, certify and manufacture replacement packages for those currently in use for the shipment of uranium oxide. There are currently three to five packages currently in use that the industry believes will need to be slightly modified to assure they pass the crush test. Due to the limits on changes to these packages, re-certifications of the current CoCs will be required.

Issue 11. Fissile Material Package Design for Transport by Aircraft

NRC Proposed Position: The NRC proposes to adopt TS-R-1, paragraph 680, criticality evaluation, in a new proposed §71.55(f) that only applies to air transport. Section 71.55 specifies the general package requirements for fissile materials, and the

existing paragraphs of §71.55 are unchanged. Because (1) the NRC is deferring adoption of the Type C packaging tests (see Issue 6); (2) TS- R-1, paragraph 680, references the Type C tests; and (3) paragraph 680 applies to more than Type C packages, only the salient text would be inserted into §71.55(f), and would apply to domestic shipments.

Industry Position: Industry supports the NRC position.

Issue 12. Special Package Authorizations

NRC Proposed Position: NRC proposes a special package authorization that would apply only in limited circumstances, and only to one-time shipments of large components. Further, any such special package authorization would be issued on a case-by-case basis, and would require the applicant to demonstrate that the proposed shipment would not endanger life or property nor the common defense and security, following the basic process used by applicants to obtain nonspecial package authorizations from NRC.

Industry Position: Industry would prefer that the NRC establish general criteria against which such packages can be evaluated. As currently proposed, the special package authorization is open-ended and the applicant does not have a common basis against which to prepare the application.

NRC Request for Information: What additional limitations, if any, should apply to the conditions under which an applicant could apply for a package authorization?

Industry Response: No additional limitations are required. The few packages that have been authorized have moved without incident and without undue risk to the public, workers or the environment. The special package approval process is working under the current requirements.

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

NRC Proposed Position: The NRC is proposing to expand the QA provisions of Part 71, Subpart H, to specifically include certificate holders and applicants for a CoC. In addition to the changes to Subpart H, conforming changes would also be made to: §71.0, "Purpose and scope"; §71.1, "Communications and records"; §71.6, "Information collection requirements: OMB approval"; §71.7, "Completeness and accuracy of information"; §71.91, "Records"; §71.93, "Inspection and tests"; and §71.100, "Criminal penalties." Additionally, §71.11 would be redesignated as §71.8; and a new §71.9, "Employee protection," would be added.

Industry Position: Industry supports the NRC position, but recommends that the NRC establish and apply a uniform set of QA requirements. QA is now required for 10 CFR Parts 50, 70, 71, 72 and 76 licensees, but there are differences in the way it is applied to each class of licensee. The industry has demonstrated, and the NRC has accepted, the grading of QA applications. Therefore, applications of QA should be consistent throughout the regulations and be based on risks.

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

NRC Proposed Position: The NRC staff recommends not incorporating the ASME Code, Section III, Division 3 requirements into Part 71.

Industry Position: Industry supports the NRC position.

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

NRC Proposed Position: The NRC proposes to add a new type of package (dual-purpose) to Part 71 [i.e., Type B(DP)]. Type B(DP) transportation packages would be certified for the storage of spent fuel under Part 72 and for transportation of spent fuel under Part 71. Type B(DP) packages would be restricted to use in domestic commerce. Requirements on the submission, review, amendment, and issuance of a CoC for a Type B(DP) package would be contained in a new Subpart I to Part 71. A new general license providing for the use of a Type B(DP) package would be added to Subpart C (§ 71.18). Certificate holders for Type B(DP) packages would also be required to submit, and periodically update, an FSAR describing the package's design. Additionally, only the certificate holder for a Type B(DP) package would be allowed under Subpart I to make changes to the package's design.

Industry Position: Industry supports the NRC proposed concept. However, the change authorization process should be extended to all packages licensed under Part 71.

NRC is proposing to amend 10 CFR 71 by addition of a new §71.175, 'Changes', which establishes a change process for Certificate holders analogous to 10 CFR 50.59, 10 CFR 70.72, and 10 CFR 72.48. Industry supports this initiative conceptually, but is concerned that the change authority does not extend to licensees, but is restricted only to the CoC holder. The change authority is limited to dual purpose (Storage and Shipment) spent fuel packages licensed under the provisions of 10 CFR 72 in addition to Certificates obtained under 10 CFR 71. These packages are to be designated as Type B(DP) and would be limited to shipment of spent fuel within the USA.

The major fault in the staff's 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. Industry agrees that the licensee would rarely initiate a design change. But the

proposed Part 71.175 (a)(5) also states:

Procedures as described in the FSAR (as updated) means those procedures that contain information described in the safety analysis report such as how SSCs are operated and controlled (including assumed operator actions and response times.)

The proposed Part 71.175 (c)(1) states:

A Certificate holder maymake changes in the procedures, as described in the FSAR (as updated) without obtaining a CoC amendment under 71.167....

The Certificate holder will likely have little on-site involvement with the actual loading of a Type B(DP) package and will have little knowledge of the site-specific parameters affecting preparation, loading, and shipment of Type B(DP) packages. The NAC International FSAR, Section 7.0 even states that "The cask user is responsible for developing, preparing, and approving-site specific procedures in accordance with these procedures, the package certificate of compliance, and the user's quality assurance program." Unfortunately, the industry has been unable to convince the staff that the level of required detail in the FSAR, including Section 7 'Operating Procedures', and Section 8 'Acceptance Tests and Maintenance Program' is excessive. Consequently, virtually every procedure approval, including changes however minor, will require the CoC holder evaluation as the licensee is precluded from performing the evaluation under the proposed rule. Industry's experience with Part 72 storage procedures clearly demonstrates that the proposed limitation on procedure evaluation against the Part 71 FSAR by the licensee is unworkable.

In proposing the exclusion of the licensees from 10 CFR 71.175 the NRC offers the following justifications:

(1) The Commission has recently issued a final rule that authorized Part 72 certificate holders to make minor changes to a spent fuel storage cask design.

10 CFR 72.48 also authorizes the licensee (with either a site specific Part 72 license or a general license under the provisions of Subpart K for 10 CFR 50 licensees) to make minor changes. By limiting the change authority of §71.175 just to the Certificate holders, the NRC creates a disconnect between 10 CFR 71 and 10 CFR 72. For a dual-purpose container, the exclusion of the licensee from the Part 71 change process limits the capability of licensees to exercise their authority under Part 72. The proposed §71.175 effectively creates a "veto" situation to any changes acceptable under Part 72, but related to systems, structures, and components described in the 10 CFR 71 FSAR, regardless of how innocuous the change may be.

(2)a licensee is not required to understand the technical bases of the Part 71 regulations of the Part 71 regulations on normal conditions of transport, hypothetical accident conditions, and criticality control (i.e., Sections 71.71, 71.73, and 71.75, respectively), before the licensee can use the package to transport radioactive material.

This statement may have some merit when applied to a Type A shipping package, but this statement, when applied to a Part 50, Part 70, or a Part 72 licensee, indicates the staff is insensitive to the realities of radioactive materials shipment. Regardless of the regulations or the perception of the staff, the licensee bears full responsibility for all aspects of storage and shipment of radioactive materials and the safety of the public. The inference that a Part 50/70/72 licensee would remain ignorant of the normal conditions of transport, hypothetical accident conditions, and criticality control is not credible. We remind the staff that Part 50 licensees design, fabricate, analyze, and operate entire core reloads under 50.59 and the Part 50 as well as the Part 70 operate and make changes to such facilities under Part 50.59 or 70.72.

(3) ...under §72.48, a licensee is required to evaluate proposed changes....and to periodically incorporate those changes into the FSAR....

Licensees under Part 72 are required to forward changes per §72.48 (d)(6) to the Certificate Holder for evaluation to determine if the changes should be included in the generic Part 72 FSAR during the required periodic update. The licensee has no authority to amend the FSAR of the Part 72 Certificate holder. The Certificate holder shall provide a record of any changes to all users per §72.48(d)(6)(iii).

(4)the licensee is considered a "registered user" of the package. This second circumstance, when coupled with a Part 71 change authority, might create a situation in which one licensee could make an authorized change to a package, without prior NRC approval, transfer that package to another registered user, without forwarding all of the change summaries to the next user, who would be unable to verify or recognize that the package is in conformance with the CoC.

If the proposed §71.175 (d)(6) were expanded to include the provisions of §72.48(d)(6)(i) and (ii), this concern would be resolved. (It is not conceivable that a licensee could transfer a Part 71 Type B(DP) to another user without the active involvement, e. g., contractual arrangement of the CoC holder).

(5)...change to the CoC (or any drawings incorporated into the CoC by reference) would not be permitted. As a consequence, these referenced drawings limit the population of potential changes that a licensee of certificate holder could make under a Part 71 change authority equivalent to §72.48.

Industry agrees with this observation that in part also provides assurance that the concern of the staff expressed in item 4 above is groundless. This limitation, of course, does not apply to procedures that are described in various sections of the Part 71

FSAR.

Issue 16. Fissile Material Exemptions and General License Provisions

NRC Proposed Position: The NRC proposes revisions to the fissile material exemptions and the general license provisions in Part 71.

Industry Position: Industry supports the concept of exemptions for fissile material shipments under specific conditions. The NRC's proposal in §71.15 is overly conservative and results in a reduction in the limits of fissile material content without justification. As discussed in our covering letter, the proposed rule combines the use of a concentration limit with a mass limit. This approach is overly conservative, as either means of criticality control would assure the safety of the package.

§71.15 (a) 'Exemptions from classification as fissile material' provides a blanket exemption from fissile shipment requirements for less than 15 grams of fissile material if shipped in, or with, combustible materials. Our concern is the impact on a shipment of resin or other materials that has small quantities (>15g) of fissile material. Resin is combustible, and there may not be enough iron to meet the new requirements. Thus, there are no exemptions for material that obviously could not go critical. As 350 grams or less of fissile material is criticality safe regardless of the moderation or configuration, in lieu of 15 grams the limitation should be 350 grams per conveyance.

§71.15 (b) would make sense if it applied to soluble fissile material, but for insoluble material the limits should be based on a concentration limit. Previously the NRC had accepted the following exemption:

"There is no more than 5g of fissile material in any 10 liter volume of material and the material is packaged so as to maintain this limit of fissile radionuclide concentration during normal transport."

This was a reasoned position. Under the Envirocare license the fissile material exemption is 1900 pCi/g of ^{235}U . Additionally, from Table A.1, NUREG/CR-6505, Volume 2, reproduced below, only after one exceeds 0.00248 grams U/cm³ is a K_{eff} of 1 exceeded. The NRC needs to reconsider the exemption value from fissile material requirements to facilitate routine operations at nuclear power plants as well as for disposal of soil or building rubble during decommissioning of fuel cycle facilities and shipment of samples containing small amounts of fissile materials. Industry recommends that the NRC proceed with this rulemaking, but simultaneously work with the shippers to establish criticality control on either a mass or concentration basis. This is necessary due to the different types of shippers and the materials that they ship.

Maximum k-eff versus Uranium Density

Line #	g 235U/cc	g 235U/g S-S	g S-S/g 235U	k(max)
1	0.00050	0.000313	3200	0.430
9	0.00142	0.000886	1129	0.779
22	0.00163	0.001019	982	0.832
35	0.00180	0.001125	889	0.870
43	0.00187	0.001171	854	0.884
56	0.00215	0.001346	743	0.935
69	0.00248	0.001548	646	0.982
82	0.00285	0.001779	562	1.027

Issue 17. Double Containment of Plutonium (PRM-71-12)

NRC Proposed Position: The NRC would adopt, in part, the recommended action of PRM-71-12. Specifically, the NRC would remove the double containment requirement of §71.63(b). However, the NRC would retain the package contents requirement in §71.63(a). Shipments whose contents contain greater than 0.74 TBq (20 Ci) of plutonium must be made with the contents in solid form.

Industry Position: Industry supports the NRC position.

NRC Request for Information: What cost or benefit impacts would arise from removal of the double containment requirement for plutonium?

Industry Response: The principal benefit of removing the double containment requirement would be a reduction in exposure to the workers. Currently the double containment requires that the worker spend more time packaging, inspecting the loaded package and certifying it meets the double containment requirements. By removing this requirement workers will be less exposed and, therefore, more likely to receive lower doses. It would also result in a lower packing cost from the design, manufacturing and operational aspects compared to the current double containment package.

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

NRC Proposed Position: The NRC proposes no changes to Part 71 for this issue.

Industry Position: Industry supports the NRC position.

NRC Request for Information: The NRC seeks information regarding the application of the regulatory limits for removable contamination on the external surfaces of packages

used for spent fuel shipments. This information will be most helpful if respondents also indicate the cask design used and whether or not the cask is fitted with a protective cover prior to immersion in the spent fuel pool. Specifically, for previous spent fuel shipments, information is sought on: (1) the removable contamination level on the cask surface after the cask has been loaded, removed from the spent fuel pool, and dried; (2) the dose attributable to any decontamination efforts, including external dose from cask and facility radiation fields and internal dose from airborne radioactivity in the cask handling/loading areas; (3) the removable contamination level on the cask surface after decontamination efforts and before shipment; and (4) the removable contamination levels on the cask surface upon receipt at the destination facility.

Industry Response: Industry has not experienced problems with decontamination and dose attributable to the handling and transport of spent fuel or storage casks. There is no reason to seek any special dose consideration or reductions in this area. The industry did experience some of the weeping issues in the early 90's but through programs working with the manufacturers of casks and use of improved cleaning agents we have eliminated this condition.

Issue 19. Modifications of Event Reporting Requirements

NRC Proposed Position: The NRC proposes a reduction in regulatory burden for licensees by lengthening the §71.95 event reporting submission period from 30 to 60 days.

Industry Position: Industry supports the NRC position. However, we are concerned with the requirement that the holder of a CoC be cognizant of any problems related to a package. The requirement for the holder to rely on other licensees or registered users, over which the holder has no authority or control, to identify problems or package deficiencies is inappropriate and must be modified.