

Summary of Public Meeting Comments

Chicago, Illinois Public Meeting

June 4, 2002

1:00 - 4:00 pm

7:00 - 10:00 pm

Rockville, Maryland Public Meeting

June 24, 2002

9:00 am - 5:00 pm

**Revisions to 10 CFR Part 71:
Compatibility With IAEA Transportation Safety Standards (TS-R-1) and
Other Transportation Safety Amendments**

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**United States Nuclear Regulatory Commission
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**Revisions to 10 CFR Part 71: Compatibility With IAEA Transportation
Safety Standards (TS-R-1) and Other Transportation Safety Amendments
Draft Comment Summary**

I. General Comments

Comment: One commenter complimented the fact that we worked with the U.S. Department of Transportation (DOT) while revising 10 CFR Part 71 (Commenter No. CA-003).

Comment: Three commenters requested an extension to the comment period (Commenter Nos. RM-005, RM-013, and RA-001).

Comment: One commenter suggested we separate the comment period for the Environmental Assessment (EA) and Regulatory Analysis (RA) from the comment period for the proposed rule (Commenter No. RM-005).

Comment: Several commenters questioned the credibility of the International Atomic Energy Agency (IAEA) and the International Commission on Radiological Protection (ICRP) because these organizations are not publicly accountable (Commenter Nos. CE-001, RA-002, and RM-002). They further questioned the process of simply accepting what the IAEA does, noting that agencies in Europe have challenged ICRP assumptions. One of these commenters stated that regulated or potentially regulated bodies should be allowed more involvement in the IAEA decision-making process (Commenter No. RA-002). Furthermore, the 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).

Comment: One commenter told us that U.S. agencies have not adequately represented public opinion with respect to transportation safety. The commenter was concerned that the number of irradiated fuel and plutonium shipments in the nation will increase as the proposed regulations weaken container safety standards (Commenter No. RM-002).

Comment: One commenter 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).

Comment: One commenter asked us if we were 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).

Comment: One commenter asked if there is any systematic process by which we have performed or will perform a cost-benefit analysis of these proposed regulations (Commenter No. CA-002).

Comment: One commenter said that changes in the scientific community's understanding of radiation injury will affect the risk assessments and other aspects of the proposed rules. The commenter said that both the Department of Energy (DOE) Biological Effects Division's and NASA's study of the impacts of low dose radiation impacts may require that we reconsider our current standards (Commenter No. RM-015).

Comment: Four commenters voiced their 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. The commenters questioned how our data was gathered and noted that a failure to keep accurate records constrains our ability to determine whether the proposed harmonization is economically justifiable. Furthermore, it undermines our claim that hundreds of thousands of radioactive material shipments are conducted safely every year (Commenter Nos. CA-002 and CA-004).

Comment: Two commenters said we should finish the package performance review study before we finalize our proposed rulemaking, as well as the rules governing irradiated fuel containers (Commenter Nos. CA-008 and RM-002).

Comment: We were cautioned by one commenter to ensure that the economic value of these regulations is not skewed. That is, the commenter does not want the needs of one particular industry to shape the regulations, when the regulations could have a greater impact on a different industry (Commenter No. CA-002).

Comment: Two commenters were concerned that many of the new regulations will make transported radioactive material more vulnerable to terrorist attacks and wanted to know how we anticipated responding to the threat of such attacks (Commenter Nos. CA-005 and RM-002).

Comment: The perception that we propose to shift the burden of proof onto the regulated entities concerned two commenters. They stated that these entities would need to justify any departure from IAEA standards. But in doing so, they would be handicapped because they don't understand the basis for originally adopting the IAEA proposals (Commenter Nos. RM-002 and RM-016).

Comment: One commenter stressed that when we have decisionmakers review public comments, they should look at primary documents instead of summary documents. The commenter cited NUREG/CR-6711 as an example where we run the risk of having decisionmakers read summaries of public comments without understanding the underlying context and content (Commenter No. RM-016).

Comment: One commenter said that data referenced in the proposed rule are too difficult to access (Commenter No. RM-005).

Comment: One commenter asked if currently licensed casks are undergoing a six-year review (Commenter No. CA-002).

Comment: One commenter expressed concern that the Nuclear Energy Institute used misleading information to demonstrate cask safety tests. And because we are the Nuclear Energy Institute's regulators, the commenter believed that the use of such misleading information undermined our credibility (Commenter No. CA-002).

Comment: One commenter asked which countries have already adopted the proposed guidelines (Commenter No. CA-001).

Comment: One commenter asked us if either our standards or IAEA's could protect the public from "real world" problems. The commenter inquired how we account for the fact that a cask might burn for longer than our standards require it to withstand fire. The commenter felt such rationales were particularly relevant in light of recent incidents, such as the Baltimore tunnel fire and the Arkansas River bridge accident (Commenter No. CA-002).

Comment: One commenter asked how the proposed changes would affect the safety of transporting radioactive materials across Lake Michigan (Commenter No. CA-008).

Comment: One commenter requested clarification on our assumptions for future radioactive materials transportation. Specifically, they wanted to know whether we are assuming the amounts will increase or remain consistent with past levels (Commenter No. CA-009).

Comment: One commenter did not want our regulations to treat radioactive materials like non-radioactive materials (Commenter No. CA-001).

Comment: One commenter asked if these new regulations would threaten a state's right to regulate radioactive materials that we have deregulated (Commenter No. CA-001).

Comment: One commenter expressed concern about the use of the millirem in these regulations. The commenter believed that we used the concept of the millirem too imprecisely. That is, the commenter believed that the millirem was a very fluid, unenforceable, and unverifiable term. The commenter believes that the IAEA created its millirem guidelines to justify letting nuclear materials be unregulated and released into commerce and recycled (Commenter No. CA-001).

Harmonization

Comment: The effort to harmonize regulations was supported by several commenters (Commenter Nos. RM-006, RM-008, RM-010, and RM-014). One commenter spoke for Agreement States and agreed with our decision to harmonize regulations (Commenter No. RM-010). 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 two-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).

Comment: On behalf of the nuclear industry, one commenter said that harmonization is logical in terms of cost and safety. Harmonized rules and uniform standards and criteria allow members of the nuclear industry to know how safe a package is, regardless of where it comes from. Because many other nations have already adopted many of these proposed rules, U.S. transporters are already required to meet these standards in many cases. The commenter also voiced support for exempting certain domestic shipments from these international regulations (Commenter No. RM-006).

Comment: One commenter told us there has already been a lot of deliberation over the proposed regulations. He stated that his organization, and the industry at large, has been looking at these proposed changes for well over ten years (Commenter No. RM-008).

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

Comment: Three commenters opposed harmonizing rules (Commenter Nos. RM-005, RM-006, and RM-013). One commenter noted that the primary objective of these changes should be to protect public health, safety, and the environment (Commenter No. RM-005). One commenter argued that harmonization should not be used as a justification for violating a country’s sovereignty or a state’s right to maintain stringent standards. The commenter said that U.S. rules were already harmonized before these proposed changes and that the authors of international regulations should not dictate U.S. regulations. The fact that other countries have adopted the IAEA regulations is not sufficient justification for the U.S. to adopt these regulations. The commenter agreed that some degree of harmonization makes sense, but emphasized that the U.S. needs to maintain control over its own rules (Commenter No. RM-006).

Request for Information on the IAEA-Related Issues

Comment: Two commenters asked us if we could quantifiably prove that harmonization is necessary (Commenter Nos. CA-001 and CA-002). One asked if our 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).

Comment: One commenter wanted to know how the IAEA drafted its regulations and statistics (Commenter No. CA-001). They questioned who the IAEA is and why we should accept their 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.

Yucca Mountain

Comment: One commenter worried that the proposed rule's July 29, 2002 deadline for receipt of public comments will prevent it from accounting for the impact of Yucca Mountain. The commenter thought that a one- or two-month rulemaking extension would be beneficial (Commenter No. RM-013).

Comment: Two commenters raised issues related to the possible approval of the Yucca Mountain site (Commenter Nos. CA-004 and CA-008). One commenter was concerned about the safety of dry casks. The commenter asked if we were 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 we bury a dry cask, we cannot change it – therefore, we have to be sure that we use a safe cask (Commenter No. CA-004). The second commenter urged us to consider the transportation issues associated with the possible approval of the Yucca Mountain site as we make rules pertaining to the packaging and transportation of radioactive materials (Commenter No. CA-008).

Comment: One commenter stated that these regulations could have important implications for the shipment of high-level radioactive waste. The commenter asked if we had considered the financial impact of the opening of the Yucca Mountain facility before proposing the regulations (Commenter No. CA-002).

Comment: Two commenters asked us how we factored the possible approval of the Yucca Mountain repository into our rulemaking (Commenter Nos. CA-008 and CA-009). One of the commenters urged us 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. They also provided data from DOE's Yucca Mountain Environmental Impact Statement on projected transportation volume through Illinois (Commenter No. CA-009).

II. Issue-by-Issue Comments

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

i. Overall Impact (including cost-benefit data)

No comments were received.

ii. NRC Proposed Position

Comment: One commenter said they appreciated our decision to maintain both the international and the familiar system of becquerels and curies and sieverts and rem (Comment No. RA-005).

B. Issue 2 - Radionuclide Exemption Values

i. Overall Impact (including cost-benefit data)

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).

Comment: Another commenter asked if it is really necessary for us to adopt the entire IAEA rule to accomplish our goals (Commenter No. CA-001).

Comment: We were asked by one commenter if we told DOT that the American public has rejected these proposed standards three times in the past decade, and if DOT has advised IAEA of these objections. The commenter said that if the IAEA has not been informed of the American public's resistance to these regulations, we need to inform the agency immediately (Commenter No. CA-002).

Comment: One commenter wanted to know if DOT, in its participation in the IAEA meetings on the exemption issue, reflected the 1992 U.S. rejection of NRC's BRC policies to the working groups. The commenter also asked what happened to that request, if such a request was made (Commenter No. RM-002).

Comment: One commenter inquired how much money is being spent regulating levels below the exemption values. The commenter questioned 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 (Commenter No. CE-001).

Comment: One commenter stated that we could not determine costs or savings from the proposed radionuclide exemption values, in part because we do not know what amounts will be exempted. The commenter also explained that although we could attempt to do projections based on the current industry, we could not know what amounts would be exempted in the future (Commenter No. RM-002).

ii. Issue-Specific Discussion

Comment: Four commenters expressed opposition to the exemption value changes (Commenter Nos. CA-001, RM-002, RA-001, and RA-012). One commenter stated that the exempted levels could potentially provide a back door to recycle and release radioactive material (Commenter No. RA-012). 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. The commenter also expressed

concern that we had not actively participated in determining the exemption values (Commenter Nos. RM-002 and RM-005).

Comment: One commenter requested information on calculations for dose impacts to members of the public, particularly with regards to recycling and the possibility of exempting materials that pose a radiation hazard to the public (Commenter No. RM-005).

Comment: One commenter requested the risk and biokinetic data supporting the proposed exemption values. The commenter also wanted to know more about who determines what data we use, including the physiological data used to justify the change in dose models (Commenter No. CE-001)

Comment: Two commenters said that it is unclear how or why the risk decreases for 222 of the 382 listed radioisotopes, when the allowable concentrations for those radioisotopes increase to above 70 becquerels. The commenters did not understand how the “risk or dose goes down” as some exempt quantities could lead to more than the “worker doses to the public from unregulated amounts of exempt quantities of radioisotopes” (Commenter Nos. RM-002 and RM-005).

Comment: 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). One stated that we 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 noted that there are synergistic effects and other types of uncertainties in radiation health effects.

Comment: One commenter noted that ICRP and IAEA risk models only look at fatal cancers and ignore non-fatal cancers, years of lost life, and the bystander effect. The commenter asserted that these agencies’ reports do not accurately reflect risk and that low levels of radiation are more damaging than the models are predicting (Commenter No. CE-001).

Comment: One commenter urged us to either make exemption values more stringent or not adopt any new values at all (Commenter No. CA-001).

Comment: One commenter inquired about the proposed mechanism for approving non-default exemption values. The commenter wondered whether A_1 and A_2 values could be used to create these exemption values under the proposed legislation (Commenter No. RA-001).

Comment: One commenter pointed out that the landfill disposal of naturally occurring radioactive materials (NORM) is outside our jurisdiction when technologically advanced NORM is involved with RCRA-regulated hazardous constituents. The commenter explained that numerous RCRA C landfills around the country have adopted 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 (Commenter No. RM-002).

Comment: One commenter stated that this rule has taken the focus off of more important issues in place of issues that are of less concern, such as the regulation of NORM. The commenter stated that lowering exemption values could distract attention from materials that would otherwise be of concern to law enforcement, particularly with regards to transportation across U.S. borders (Commenter No. RM-012).

Comment: One commenter indicated that, should the exemption values be adopted in a way which 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. They 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 (Commenter No. RM-002).

Comment: One commenter asked us if states whose regulations are more protective than the proposed regulations will have to abandon those regulations if we adopt these new regulations (Commenter No. CA-001).

Comment: One commenter stated that, because there is no limit on the number of negligible doses from exemptions, there is no way to know how much is being exempted in terms of curies or becquerels (Commenter No. RM-002).

Comment: 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. Their 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 (Commenter No. RM-005).

Comment: One commenter expressed concern that, for some members of the public, exposure could be over 100 millirem per year. The commenter understood from page 21396 of the Federal Register Notice 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 (Commenter No. RM-005).

Comment: One commenter questioned the composition of a list of 20 representative nuclides used to estimate the average annual dose per radionuclide. The commenter asserted that, among the 20 representative nuclides, a minority of nuclides whose doses decrease in the proposed regulations were over-represented. The commenter stated that most of the dose concentrations increase, some of them dramatically (Commenter No. CE-001).

Comment: One commenter noted that the current and proposed regulations have 50 and 23 millirem being average doses, respectively. In order to adequately protect public health, the average dose should be no more than one millirem (Commenter No. CE-001).

Comment: One commenter noted that there is no precedent for exempt quantities in our regulations and that this will create a new category. The commenter questioned the logic of creating such a category (Commenter No. CE-001).

Comment: One commenter discussed the impact that these proposed rules would have on the pharmaceutical industry. Many sectors of the pharmaceutical industry are heavily dependent on their ability to ship by air. This commenter estimated that air shipments account for about 80 percent of the materials the commenter's particular business ships. However, if the commenter wanted to ship radio-pharmaceuticals before July 1, 2002 within the U.S. on a carrier abiding by ICAO IATA, then the commenter would be unable to do so and remain in compliance with both American and IATA regulations. The commenter, therefore, concluded that the business would have been prohibited from legally shipping legal radio-pharmaceuticals by air (Commenter No. CA-003).

Comment: One commenter mentioned that the threat of terrorism should be taken into account when exempting radionuclides from transport regulations and changing container regulations (Commenter No. RM-002).

Comment: One commenter objected to the redefinition of the word "contamination" because assigning a special technical meaning to a common word that is contrary to its normal meaning is poor practice. The commenter objected to using exemption amounts as part of the definition of "contamination" (Commenter No. RM-002).

iii. NRC Proposed Position

Comment: One commenter supported lower concentrations for the radioactive isotopes because the proposed rulemaking increases public risk (Commenter No. RM-005).

Comment: One commenter asked if there is any possibility that we could simply decline to adopt the sections of the proposed rules that relate to radionuclide exemption values (Commenter No. CA-001).

Comment: Two commenters urged us not to adopt the proposed radionuclide exemption values (Commenter Nos. CA-001 and CE-001). One commenter said that these new exemption values allow radioactive materials and waste to be treated as if they are not radioactive. The commenter also said that these exemption values allow radioactive waste and materials to be recycled into everyday consumer items, such as hip replacements, braces, and toothbrushes. The commenter said that if we needed to adopt risk-based standards, we should just adopt ones that would reduce the allowable exemptions. The commenter criticized the proposed rules for increasing the allowable contamination in materials. The commenter was displeased with the current 70 bequerels-per-gram exemption level, and urged us to only change the exemption levels to make them more protective for isotopes whose exempt concentrations go down. The commenter believed that the proposed exemption values were too complex because it is too complicated to maintain more than half of all exemption values at 70 and to reduce those that are more

protective. The commenter did not want our transportation regulations to treat radioactive materials as if they were not radioactive (Commenter No. CA-001).

Comment: One commenter did not understand the concept of the "millirem." To this end, the commenter said that "millirem" is a fluid, unenforceable, and unverifiable term. The commenter said that the public is told not to worry about the proposed exemption values because it will only be exposed to one millirem of radioactive material. However, the commenter noted that the 20 most commonly shipped materials with the new exemption values are at 23 millirem. Therefore, the commenter was confused about what it meant to only be exposed to one millirem of radioactive material (Commenter No. CA-001).

C. Issue 3 - Revision of A_1 and A_2

i. Overall Impact (including cost-benefit data)

No comments received.

ii. Issue-Specific Discussion

Comment: One commenter indicated that the proposed A_1 and A_2 values were "far reaching." The commenter was concerned by the lack of data supporting these significant changes, but generally supported the changes (Commenter No. RM-10).

Comment: One commenter inquired about the proposed mechanism for approving non-default exemption values (Commenter No. RA-001).

Comment: Two commenters requested further information on how default exemption values can be calculated from the A_1 and A_2 values (Commenter Nos. RM-002 and RA-001).

Comment: One commenter requested more explanation of the implications of revision of the A_1 and A_2 values. The commenter requested simple summaries for both special form and normal materials (Commenter No. CE-001).

Comment: A commenter questioned the credibility of ICRP and IAEA, noting that these organizations are not accountable to the public. The commenter expressed a lack of trust for these organizations and questioned the credibility of their scientific conclusions regarding the proposed A_1 and A_2 values (Commenter No. CE-001).

Comment: One commenter asked if the justification for the change is the shift in accepted dose models from ICRP 26 and 30 to 60 and 66. The commenter requested data supporting the shift in dose models (Commenter No. CE-001).

Comment: One commenter noted that ICRP and IAEA risk models only look at fatal cancers and ignore non-fatal cancers, years of lost life, and the bystander effect. The commenter asserted

that the ICRP and IAEA reports do not accurately reflect risk and that low levels of radiation are more damaging than the models are predicting (Commenter No. CE-001).

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).

Comment: One commenter wanted to know if these revisions would actually expand the number of containers that have to meet test standards (Commenter No. CA-001).

iii. NRC Proposed Position

Comment: One commenter asked that we not adopt the exemption values contained in Table 2 of TS-R-1 (Commenter No. CA-001).

D. Issue 4 - Uranium Hexafluoride UF_6 Package Requirements

No comments received.

E. Issue 5 - Introduction of the Criticality Safety Index Requirements

i. Overall Impact (including cost-benefit data)

Comment: One commenter requested a basic explanation of the criticality safety index and transport index. The commenter wondered if the proposed changes would increase public risk (Commenter No. CE-001).

ii. Issue-Specific Discussion

Comment: One commenter expressed concern about the proposed changes to § 71.59 that are outlined in the proposed rule with regard to storage incident to transport. The commenter was particularly concerned with how the proposed changes will affect the exclusive use conditions (Commenter No. RA-007).

iii. NRC Proposed Position

No comments received.

F. Issue 6 - Type C Packages and Low Dispersible Material

i. Overall Impact (including cost-benefit data)

No comments received.

ii. Issue-Specific Discussion

Comment: One commenter mentioned that the threat of terrorism should be taken into account when exempting radionuclides from transport regulations and changing container regulations (Commenter No. RM-002).

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).

iii. NRC Proposed Position

No comments received.

G. Issue 7 - Deep Immersion Test

i. Overall Impact (including cost-benefit data)

Comment: One commenter suggested that the deep immersion test should consider the possibility that the cask could already be damaged or ruptured at the time of immersion. The commenter asked if there has been an analysis of the dissemination of radionuclides at high pressures for partially or completely ruptured casks. The commenter said that such an 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 (Commenter No. CA-002).

ii. Issue-Specific Discussion

Comment: One commenter noted that the proposed changes to Type C and double-containment regulations could result in a slight increase in the probability and consequences of an accidental release (Commenter No. CA-005).

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).

Comment: We heard from one commenter that the proposed rule's deep immersion test provisions would increase cask safety (Commenter No. RA-005).

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

Comment: One commenter requested we change our 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).

Comment: One commenter asked if the deep immersion test would apply to all packages shipped across Lake Michigan (Commenter No. CA-008).

Comment: One commenter asked if the deep immersion test actually requires a physical test. If the deep immersion test did not actually require a physical test, the commenter asked us to clarify what we mean by “test.” The commenter also wanted us to clarify to what the test specifically applies (Commenter No. CA-001).

iii. NRC Proposed Position

Comment: One commenter expressed concern that the deep immersion test only requires that packages be submerged for one hour. The concern is based on the belief that it is unlikely a package could be recovered within an hour following a real accident (Commenter No. CA-001).

Comment: One commenter asked us to clarify our assertion that our immersion test is stricter than the IAEA’s test because our language does not allow collapse, buckling, or any leakage of water (Commenter No. CA-001).

H. Issue 8 - Grandfathering Previously Approved Packages

i. Overall Impact (including cost-benefit data)

Comment: One commenter encouraged us to solicit cost-benefit information from the regulated community rather than providing it ourselves. The commenter added that there is no discernable safety benefit to adopting TS-R-1 on this issue and that no economic data have been used to support this proposal (Commenter No. RA-003).

Comment: One commenter stated that phasing out the 1967-approved packages, as specified in the proposed legislation, 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).

Comment: One commenter stated that certain containers excluded by the proposed legislation cannot be easily replaced because no alternative packaging currently exists at comparable prices. The commenter explained that designing, testing, and licensing a new package is expensive (approximately \$500,000) and usually takes over a year to accomplish (Commenter No. RA-003).

ii. Issue-Specific Discussion

Comment: One commenter was concerned that, in departing from IAEA grandfathering standards, we are placing the burden entirely on the regulated industry to develop the justification for such a departure. The commenter asserted that this is a problem because there was no basis for having adopted the IAEA grandfathering standards in the first place (Commenter No. RM-016).

Comment: One commenter requested specific information on the types and numbers of packages that would be effected and the timetable under which packages would be excluded (Commenter No. RA-005).

Comment: One commenter stated that regular two-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).

Comment: One commenter disagreed with the proposed grandfathering rule, stating that 1967-approved packages have operated successfully for years and that there is no health or safety reason for phasing them out. The commenter stated that extending the transition period beyond three 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-approved packages from international sources (Commenter No. RA-004).

Comment: One commenter expressed concern about the backfitting issue, and indicated that NRC should demonstrate that the basis for IAEA's position is tenable in the U.S., or develop an independent satisfactory basis for their position. The commenter stated that this is particularly important with regards to grandfathering packages when there may be different environments for international and domestic shipments (Commenter No. RM-016).

Comment: One commenter said that the proposed three-year transition period is too long (Commenter No. CA-005).

iii. NRC Proposed Position

No comments received.

I. Issue 9 - Changed to Various Definitions

i. Overall Impact (including cost-benefit data)

No comments received.

ii. NRC Proposed Position

Comment: One commenter stated opposition to the changes in definitions that could include changing exemption values, particularly because this is not subject to an environmental assessment (Commenter No. RM-002).

J. Issue 10 - Crush Test for Fissile Materials Package Design

i. Overall Impact (including cost-benefit data)

No comments received.

ii. Issue-Specific Discussion

No comments received.

iii. NRC Proposed Position

Comment: One 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 (Commenter No. RA-001).

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

No comments received.

L. Issue 12 - Special Package Approval

i. Overall Impact

No comments received

ii. Issue-Specific Discussion

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.

Comment: One commenter requested more information about how we are going approve special packages. The commenter explained that a better explanation of this process would aid regulated bodies in acquiring special package authorization (Commenter No. RA-004).

Comment: One commenter told us we should 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.

Comment: One commenter suggested that shipping retired reactor vessels should be a separate issue from the exception process (Commenter No. RA-005).

iii. NRC Proposed Position

No comments received.

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

i. Overall Impact

Comment: One commenter supported the change authority for CoC holders, and also recommended it for licensees as well noting that currently the Part 71 language doesn't include licensee changes. But, the licensees can make changes to these dual purpose casks under Part 72, and as it's "a common piece of hardware, the change doesn't get unchanged for Part 71" (Commenter No. RA-006).

ii. NRC Proposed Position

No comments received.

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

No comments received.

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

i. Overall Impact

Comment: One commenter supported the idea of applying the change authority to any cask that is licensed under Part 71. The commenter stated that appropriate minor changes should be allowed as long as they do not impact the safety envelope. The commenter noted that part of the argument in favor of limiting the change authority to dual-purpose containers is that the quality assurance program of Part 72 is superior to Part 71, but the commenter rebuffed this argument, stating that the two are comparable (Commenter No. RA-004).

Comment: One commenter noted that minor changes can be acceptable for some purposes but not for transportation (Commenter No. RA-001).

Comment: One commenter requested a more detailed explanation of what constitutes a minor design change with no safety significance (Commenter No. RA-005).

Comment: One commenter stated that regulated bodies that make minor modifications to packages without our prior approval are being hindered by regulations when safety is not an issue. The commenter noted that other laws pertaining to radioactive material have provisions

for minor modifications to hardware that involve evaluating safety levels, and these laws do not require prior approval (Commenter No. RA-004).

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).

Comment: One commenter wanted to know if a certificate holder proposing a minor change would still have to check with us to see if the change was permissible under the proposed change authority. The commenter wanted to know if we would be notified before the changes are made. The commenter requested clarification of the procedure for changes under the proposed change authority (Commenter No. RA-005).

Comment: One commenter requested that we be notified of any changes before a cask is moved offsite (Commenter No. RA-005).

Comment: One commenter noted that the eight criteria used to determine if changes require our prior approval were extracted verbatim from 10 CFR Parts 50 and 72 and placed into 10 CFR Part 71. The commenter suggested that these criteria be customized prior to inclusion in Part 71 (Commenter No. RA-006).

Comment: One commenter noted that a large number of highly radioactive shipments could take place in dual-purpose containers and that these shipments could be destined for a repository. The commenter explained that even minor design changes would affect waste acceptance at the repository (Commenter No. RA-005).

Comment: One commenter requested an explanation of the change authority, particularly information about what types of changes could be made to dual purpose spent nuclear fuel casks intended for domestic transport (Commenter No. CE-001).

ii. NRC Proposed Position

Comment: One commenter supported the change authority because it would allow us to focus on more significant safety issues (Commenter No. RA-006).

Comment: One commenter supported the change authority for COC holders and suggested extending the authority to licensees as well (Commenter No. RA-006).

P. Issue 16 - Fissile Material Exemptions and General License Provisions

i. Overall Impact

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

Comment: One commenter noted that the three-tiered system dramatically complicates 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).

Comment: One commenter stated that companies that ship internationally will have a difficult time complying with our proposed system as well as the international system. The commenter suggested that we simplify compliance for these companies (Commenter No. RA-007).

Comment: One commenter requested clarification of what constitutes iron with regard to Tier 1 or fissile exempt quantities. The commenter specifically asked if steel is considered iron (Commenter No. RA-007).

Comment: One commenter urged the our staff to explain why they propose changing the total shipment CSI in cases where there is storage incident to transport, effectively doing away with an exclusive use condition. The commenter considered this proposal a significant change in the method of calculating the CSI per consignment and wanted to remind us that the proposed rule maintains segregation and storage requirements (Commenter No. RA-007).

Comment: One commenter stated that the proposed rule favors a greater number of shipments, and that costs will increase with the number of shipments (Commenter No. RA-007).

ii. NRC Proposed Position

Comment: One commenter indicated opposition to the fissile material exemptions (Commenter No. RM-002).

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

i. Overall Impact

Comment: One commenter 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).

ii. Issue-Specific Discussion

Comment: Two commenters argued that double containment is safer than single containment (Commenter Nos. RA-001 and RA-005). One suggested that withdrawing the requirement will decrease public confidence in our regulations (Commenter No. RA-005). They both stated we need to respond to the facts indicating the increased hazards of single containment, particularly in terms of risk and economic issues as well as more latent cancer fatalities result if a serious accident does occur involving a single containment vessel.

Comment: One commenter stated that actual, and not perceived, risk should be the basis of regulations. The commenter said that we should educate the public so that there is greater understanding of the actual risks (Commenter No. RA-010).

Comment: One commenter stated that the proposed rule is not risk-informed and does not use a common sense approach (Commenter No. RA-005).

Comment: One commenter stated that the increased cancer risk of single containment will be imperceptible from an epidemiological perspective (Commenter No. RA-010).

Comment: Another commenter believes that removing the double containment requirement will provide health benefits for radiation workers. The reason being that radiation workers now must confirm double containment, which requires increased exposure (Commenter No. RA-008).

Comment: One commenter stated that we need to balance public safety and the safety of radiation workers (Commenter RA-009).

Comment: One commenter stated that worker exposure estimates are not supported by data (Commenter No. RA-005).

Comment: One commenter mentioned that the threat of terrorism should be taken into account when exempting radionuclides from transport regulations and changing container regulations (Commenter No. RM-002).

Comment: One commenter argued that the NRC has not fully evaluated the regulatory impact of the proposed change on the use of the TRUPAC II design (Commenter No. RA-005).

Comment: One commenter asked for clarification on how the NRC calculates CSI for radiological shipments in order to ensure that a shipment is under limits (RA-006).

Comment: One commenter asked if we consider powder a solid form (Commenter No. RA-001).

iii. NRC Proposed Position

Comment: Two commenters expressed opposition to the proposal to eliminate the double containment requirement for plutonium shipments (Commenter Nos. RA-001 and RA-006).

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

No comments received.

S. Issue 19 - Modifications of Event Reporting Requirements

i. Overall Impact

Comment: One commenter felt that the proposed modifications to event reporting requirements will enhance safety (Commenter No. RA-005).

Comment: One commenter supported changing the reporting period from 30 days to 60 days. The reason being 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. However, the commenter was unsure how this proposed change affects other parts of the proposed rulemaking and urged us to ensure that it conforms with the rest of the proposed rulemaking (Commenter No. RM-10).

Comment: One commenter stated that an extra 30 days may be too long an extension if there is a serious safety problem (Commenter No. RA-005).

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-010).

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).

ii. NRC Proposed Position

No comments received.

III. Department of Transportation-Related Issues

Comment: One commenter was pleased that we are acknowledging DOT's responsibility to ensure the safe shipment of spent nuclear fuel (Commenter No. CA-009).

Comment: One commenter asked us to clarify the current status of DOT's regulations for international shipments with regard to exempt quantities and concentrations (Commenter No. CA-001).

Comment: One commenter urged us to work with DOT to develop a concurrent rulemaking if we want to enhance the security of radioactive materials transportation. The 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).

Comment: We heard from one commenter who was concerned with how the proposed regulations fit into the hierarchy of federal, State, and local regulations. The commenter noted that DOT regulations expressly preempt and supercede state and local regulations (Commenter No. RM-005).

IV. Other Issues

Comment: One commenter questioned how states' special concerns would be addressed with the proposed rulemaking. They believe the proposed regulations do not address the fact that certain states are already burdened with unusually high concentrations of hazardous and radioactive materials transport (Commenter No. RM-015).

Comment: One commenter urged us not to rush to adopt the proposed regulations simply because other countries were adopting similar regulations. The commenter agreed that there should be some amount of international unity concerning these regulations, but insisted that U.S. regulations should not be dictated by IAEA or ICRP changes, or issues other participants deemed important. We should be open to modifying the international regulations as appropriate to the U.S., even if U.S. regulations are more stringent than IAEA's (Commenter No. RM-002).

Comment: One commenter expressed concern that the nation's commercial needs would overshadow the nation's health and safety needs in developing and finalizing the proposed rulemaking. They said it was unfortunate we must transport anything radioactive because any accident would be dangerous, and it is impossible to guarantee no accidents will ever occur (Commenter No. CA-005).

Comment: One commenter asked if the public and workers will be protected from and informed of leaks. And in the instance of a massive accident resulting from a leak, they wondered if there is enough money to pay lawsuit damages (Commenter No. CA-005).

Comment: One commenter was concerned that transported radioactive materials could be vulnerable to terrorist attacks. They stated their belief that labeling radioactive materials could aid terrorists by identifying which packages are radioactive. They also asked if the public would be informed of a terrorist attack on radioactive materials (Commenter No. CA-005).

Comment: One commenter said we should impose more, not fewer, regulatory barriers to the transportation of radioactive materials. The commenter cited Iraq as a nation whose population has suffered the health consequences of radioactive material transportation. The commenter said that transportation of radioactive materials for the medical/pharmaceutical sector is the only type of radioactive materials transportation that should be facilitated (Commenter No. CA-006).

Comment: One commenter asked us to explain how our official proposal on the changes in packaging and transporting of radioactive materials would affect industrial radiology (Commenter No. CA-007).

Comment: One commenter said that we do not need to adopt all of the proposed regulations that would allow radioactive materials to move unlabeled or regulations that would affect Type B containers for irradiated fuel simply in order to please members of the radio-pharmaceutical industry (Commenter No. CA-001).

Issues of Compatibility for Agreement States

Comment: One commenter supported compatibility among the agreement states. This commenter indicated that it is appropriate for states to have the ability to develop materials necessary for intrastate shipments. However, for interstate shipments, the commenter stated that it is necessary for one state to be compatible with the rest of the country in order for the country to be compatible with the world (Commenter No. RM-006).

Environmental Assessment: Finding of No Significant Impact

Comment: 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).

Comment: One commenter said that the EA and the rulemaking are too carefully tied together. The commenter said that this fact precludes us from actually finding an environmental impact from the rules (Commenter No. RM-013).

Comment: We heard from one commenter on several issues related to the EA and RA. This commenter indicated that the draft EA and RA were deeply deficient. Specifically, the following information is lacking: 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).

Comment: One commenter raised several issues concerning the EA. The commenter did not believe that the EA contained sufficient information to draw the conclusion that there are no significant impacts. The commenter stated that we should revisit and improve the EA before proceeding with the rulemaking. The commenter stated that we need to provide more information (e.g., transportation scenarios) before the public can make an informed decision.

The commenter criticized page 43 of the EA, which first identifies information necessary to make a risk-informed decision on the proposed regulation and then discusses the lack of information in the EA. The commenter also criticized our rationale for performing a qualitative assessment, and the instances where data from 1982 are used but not identified as outdated. The commenter noted a discrepancy in our efforts, particularly the number of our staff and resources devoted to this rulemaking for the past two years versus the lack of resources devoted to updating the 1982 data (Commenter No. RM-013).

Comment: This commenter asserted that some industry, DOE, and U.S. Army concerns fell by the wayside in the proposed rulemaking. These concerns were related to their estimated \$6 to \$7 million per year impact from the Type C package changes are not included in the analysis.

The commenter added that specific quantitative information is missing from the analysis. According to the commenter, the Shephard Organization previously indicated that process irradiators are shipping sources equaling about 50 million curies by air alone. However, this is 15 to 25 times greater than the curie count for any of the numbers listed in the proposed rulemaking. The commenter stated that, although we asked for data during the public comment period, we should be responsible for including all of the relevant data and information in the proposed rule (Commenter No. RM-005).

Regulatory Analysis

Comment: One commenter indicated that the draft EA and RA are deficient. The commenter stated that the following information needs to be included in both analyses: the number of exempt and nonexempt packages, the number of exempt and nonexempt shipments, the average number of packages per shipment, and the detailed information on curie counts by shipment categories.

The commenter asserted that all stakeholders are affected by these deficiencies. In particular, public information groups are affected because they cannot determine with any specificity what the impact of the value exemptions in the A_1 and A_2 changes will be, and the Western states are affected by our risk assessment for eliminating double containment requirements for plutonium. The commenter stressed the importance of using quantitative data in the analysis, and stated that the deficiencies could not be corrected without data (Commenter No. RM-013).

Comment: We were told by one commenter we are making many of these changes without being entirely aware of the proposed rule's costs (Commenter No. RM-016).

Comment: One commenter 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).

Comment: One commenter stated that the RA is deficient because of its failure to recognize likely impacts of the changes to the double containment of plutonium regulations, particularly

with regards to the agreement between the Western Governors Association, the individual western states, and DOE for a system of additional transportation safeguards (Commenter No. RM-005).

ATTACHMENT 1

| List of Commenters - Public Meetings | | |
|--|---------------------------|---|
| 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 |
| RM-005 | Mr. Robert Halstead | Nevada Agency for Nuclear Projects |

| List of Commenters - Public Meetings | | |
|--|-----------------------|--|
| Commenter Number | Commenter Name | Affiliation |
| 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 |
| 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 |

| List of Commenters - Public Meetings | | |
|---|-----------------------|---|
| Commenter Number | Commenter Name | Affiliation |
| RA-011 | Mr. Marvin Turkanis | Neutron Products |
| RA-012 | Mr. David Ritter | Public Citizen's Critical Mass Energy and Environment Program |