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January 20, 2017

Secretary
U.S. Nuclear Regulatory Commission
ATTN: Rulemakings and Adjudications Staff
Washington, DC 20555-0001

Subject: Comments Concerning 10 CFR 71 Issues Paper - *"Revisions to Transportation Safety Requirements and Compatibility with International Atomic Energy Agency Transportation Standards"* (81FR83171, dated November 21, 2016, Docket ID NRC-2016-0179)

This letter is being submitted in response to the U.S. Nuclear Regulatory Commission's (NRC's) request for comments concerning the subject Issues Paper published in the *Federal Register* (i.e., 81FR83171, dated November 21, 2016).

The NRC is considering a potential amendment to its regulations that would revise the regulations on packaging and transporting radioactive material. The NRC is gathering information about potential changes that may be proposed in a subsequent rulemaking activity, and is requesting public comment on the subject Issues Paper about potential changes that are being considered.

As noted in the *Federal Register* notice, the NRC has initiated a rulemaking effort that addresses the need to make the regulations in 10 CFR 71, *"Packaging and Transportation of Radioactive Material,"* compatible with the most current revisions of the International Atomic Energy Agency (IAEA) Specific Safety Requirements (SSR) No. SSR-6, *"Regulations for the Safe Transport of Radioactive Material."* The regulations in 10 CFR 71 are based, in general, on the specific safety requirements developed by the IAEA. The IAEA has been revising its requirements on an approximate 10-year cycle, with the last edition of IAEA SSR-6 published in 2012 and the current draft of the new revision of SSR-6 expected to be published in 2018. The NRC is also considering other changes to 10 CFR 71 that are not related to SSR-6. The Issues Paper was developed in coordination with the U.S. Department of Transportation (DOT), since the DOT and the NRC co-regulate transportation of radioactive materials. Therefore, to further facilitate NRC's efforts, the subject Issues Paper has been developed which describes the potential rulemaking issues (i.e., IAEA and non-IAEA-related) for the next revision to 10 CFR 71.

Exelon Generation Company, LLC (Exelon) appreciates the opportunity to comment on the subject Issues Paper and offers the attached comments for consideration by the NRC.

If you have any questions or require additional information, please contact Richard Gropp at (610) 765-5557.

Respectfully,

David P. Helker
Manager, Licensing and Regulatory Affairs
Exelon Generation Company, LLC

Attachment

ATTACHMENT

Response to Request for Comments Concerning 10 CFR 71 Issues Paper, *"Revisions to Transportation Safety Requirements and Compatibility with International Atomic Energy Agency Transportation Standards"*

Response to U.S. Nuclear Regulatory Commission (NRC) Request for Comments for Issues Paper on Potential Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements

Exelon Generation Company, LLC (Exelon) appreciates the opportunity to comment on this subject and offers the comments described below for consideration by the NRC. These comments provide feedback on NRC questions identified in the Issues Paper related to the potential impacts of International Atomic Energy Agency (IAEA) Specific Safety Requirements (SSR) No. SSR-6, *"Regulations for the Safe Transport of Radioactive Material,"* on 10 CFR 71 requirements. Each specific issue from the Issues Paper is restated below followed by Exelon's response, where applicable.

Issue No. 1: Fissile Materials

In 10 CFR Part 71, there are requirements for packaging that is certified by the NRC to transport fissile material. These provisions include the criteria for exemptions from classification as fissile material (§ 71.15; also in 49 CFR 173.453) and provide general licenses for limited quantities of fissile material and plutonium-beryllium special form sources (§§ 71.22, 71.23, respectively).

The fissile material exemptions in § 71.15 and the fissile material general licenses in §§ 71.22 and 71.23 facilitate the safe transport of low-risk (e.g., small quantities or low concentrations) fissile material by relieving shipments of these materials from the fissile material packaging requirements and criticality safety assessments required for fissile material transportation, and to allow the shipments to take place without specific NRC approval. There is less regulatory oversight for these low-risk fissile material shipments, because the fissile exemptions and general licenses are established to ensure safety under normal conditions of transport and hypothetical accident conditions.

The NRC staff contracted with Oak Ridge National Laboratory (ORNL) to review 10 CFR Part 71 regulations on the transportation of fissile material, including exemption and general license provisions, study the regulatory and technical bases associated with these regulations, and perform criticality calculations for different mixtures of fissile materials and moderators. The results of the ORNL study were documented in NUREG/CR-5342, "Assessment and Recommendations for Fissile-Material Packaging Exemptions and General Licenses within 10 CFR Part 71" (Ref. 16). Based in part on the recommendations in NUREG/CR-5342, the NRC revised the fissile material exemptions and general license provisions in 10 CFR Part 71, in a final rule that was published on January 26, 2004 (69 FR 3698, Ref. 11). The revisions to the fissile exemption and general license provisions included in this final rule were: 1) consolidating fissile exemption and general license requirements in a more appropriate part of the regulations; 2) providing a nonfissile-to-fissile mass ratio approach for some exemptions; 3) limiting low-absorption moderators consistently across the exemption and general license provisions; 4) requiring Type A package standards for the low-enriched uranyl nitrate provision; 5) separating the Plutonium-Beryllium general license requirements from the consolidated fissile material general license requirements; and 6) revising the general license mass limits to provide similar safety equivalence provided by certified packages per the criteria of §§ 71.55 and 71.59.

In 2012, the IAEA updated its fissile "exception" provisions (similar to 10 CFR Part 71 fissile exemptions) in SSR-6. Additionally, the IAEA updated its provisions for fissile material packages that do not require criticality analysis, where accumulation control is provided through the use of a criticality safety index (CSI) label (analogous to 10 CFR Part 71 fissile material general license

provisions). The NRC is considering the differences between the fissile material exemptions and general licenses in 10 CFR Part 71, and similar provisions in IAEA SSR-6, as part of its effort to harmonize its regulations with the IAEA's requirements, as appropriate. The following subsections describe the differences between the fissile material exemption and general license provisions in 10 CFR Part 71 and the IAEA's SSR-6, provide factors for consideration, and propose actions related to each item.

Issue No. 1a: New Fissile Exceptions in IAEA SSR-6, Paragraph 417

The IAEA revised the fissile exceptions in SSR-6 paragraph 417 to include three new provisions, each with package or mass accumulation controls from paragraph 570:

- *417(c) – uranium with enrichment up to 5.0 weight percent ^{235}U, up to 3.5 grams ^{235}U per package, with up to 45 grams ^{235}U per consignment,*
- *417(d) – up to 2.0 grams fissile nuclides (^{233}U, ^{235}U, 239Pu, or ^{241}Pu) per package, with up to 15 grams fissile nuclides per consignment, and*
- *417(e) – up to 45 grams fissile nuclides, packaged or unpackaged, shipped exclusive use.*

The exception in paragraph 417(c) is comparable to the § 71.15(a) exemption limit of up to 2 grams of fissile material per package. The additional neutron absorption provided by ^{238}U in 5.0 weight percent enriched uranium in paragraph 417(c) compensates for the additional 1.5 grams of ^{235}U mass (i.e., up to 3.5 grams ^{235}U per package), when compared to the § 71.15(a) limit of 2 grams. This is illustrated by comparison of the mass limits in Tables 71-1 and 71-2 of § 71.22. Although this provision is for fissile material general licenses, and not fissile exemptions, the mass limits in these tables were determined by the NRC so they would each result in a similar system k_{eff}. The mass limit of 60 grams for ^{235}U in Table 71-1 is for 100 weight percent enriched uranium. The 235U mass limit for 5.0 weight percent enriched uranium from Table 71-2 is 108 grams. The ratio of the 235U mass limit for 5.0 weight percent enriched uranium (108 grams) to the ^{235}U mass limit for 100 weight percent enriched uranium (60 grams) is 1.8. This demonstrates that the 2.0 gram fissile material limit of § 71.15(a), which is based on pure ^{235}U, is equivalent in terms of reactivity to 3.6 grams of uranium enriched to 5.0 weight percent. Therefore, the § 71.15(a) limit of 2 grams fissile material bounds the 3.5 grams of 5.0 weight percent enriched ^{235}U per package in paragraph 417(c).

Paragraph 417(d) is similar to the existing exemption in § 71.15(a), but with a consignment limit of 15 grams. Although theoretically possible, it is not credible to accumulate sufficient numbers of packages, with up to 2.0 grams fissile material per package, to cause criticality concerns. This amount of material would have to be in at least a Type A package (Type B for more than 0.435 grams ^{239}Pu, or 0.016 grams ^{241}Pu), which must be demonstrated by licensees to withstand the normal conditions of transport tests defined by § 71.71. Under the hypothetical accident conditions tests in § 71.73, Type A packages may not survive intact. However, more than 250 of these packages would need to fail (based on the minimum critical mass for 233U from ANSI/ANS 8.1-2014, Ref. 17), have the fissile material from these packages consolidate and reconfigure into a favorable geometry, and be optimally moderated before a criticality is possible. The NRC staff does not consider this scenario credible, and therefore the consignment limit of paragraph 417(d) is not necessary.

The NRC staff considers the provision in paragraph 417(e) of SSR-6 to be conservative (45 grams represents less than one tenth of the minimum critical mass of ^{235}U), and could be incorporated into 10 CFR Part 71. However, the IAEA requirement to ship this material

"exclusive use" may not be appropriate in the NRC fissile exemptions, since they are designed to be safe without accumulation control. Therefore, if this provision is incorporated, it may not be included as a fissile exemption in § 71.15, but may be included as a separate provision. Also, the NRC staff has determined that a higher mass value is justified, due to the conservatism inherent in the exclusive use restriction. The NRC staff is considering a limit of 140 grams of ^{235}U given that this represents less than one fifth of a minimum critical mass under optimum conditions. This mass still represents a conservative limit for fissile material, provides safety equivalent with packages approved under 10 CFR Part 71, and could provide more flexibility for shipping individual contaminated items or small quantities of fissile material.

Note that for fissile nuclides other than ^{235}U (i.e., ^{233}U, ^{239}Pu, or ^{241}Pu), the amount of material that can be shipped under any of the provisions described above, or any other fissile material exemption or general license, is limited by the A2 value for that nuclide in Table A-1 of 10 CFR Part 71. The minimum A2 value for ^{233}U (6.0x10-3 TBq/ 1.6x10-1 Ci) corresponds to an equivalent mass of 16.5 grams, while the A2 values for ^{239}Pu and ^{241}Pu both correspond to a mass less than 0.5 grams. Fissile material in quantities greater than the A2 value must be transported in a Type B package, which has been demonstrated by the applicant to withstand both normal conditions of transport and hypothetical accident conditions without loss or dispersal of radioactive material, and has been approved by the NRC. Since the calculations that support the fissile material mass or concentration limits in the NRC fissile material exemptions and general licenses in 10 CFR Part 71 assume complete dispersal and reconfiguration into more reactive configurations, such limits will be conservative for material which will remain in Type B packages under all transportation conditions.

Factors for Consideration

- *Would adopting the fissile exceptions from SSR-6 paragraphs 417(c) and 417(e) as exemptions under 10 CFR Part 71, without the accompanying consignment limits and potentially with a higher mass limit than provided in 417(e), provide options that would be useful to fissile material licensees?*

  Exelon's Response - Nuclear power material and waste shipments typically meet current 10 CFR 71.15(a), (b), or (c) exceptions. Adding SSR-6 paragraphs 417(c) or (e) with or without consignment limits or exclusive use provisions would not adversely impact material or waste shipments. The NRC's discussion notes that the current regulation is written for package limits such that consignment limits are not necessary. Nuclear power material and waste fissile material levels are low fractions of the limits such that the package limits or consignment limits would not be challenged.

  Potential impact for nuclear power licensees for small gram amounts would be limited to instrument items containing fissile radionuclides. One of the NRC examples noted that the 2 gram limit of fissile material in the minimum hazardous material package size of 10 cm^3 could not present a criticality issue regardless of the number of packages to require consignment limits. Complexity of compliance should not be increased without a corresponding improvement in safety margin.

- *Would declining to adopt these provisions negatively impact international shipping of small quantities of fissile material?*

  Exelon's Response - Potential impact for nuclear power licensees for small gram amounts would be limited to instrument items containing fissile radionuclides only. Licensees would

follow the more restrictive international regulations as necessary for such an infrequent shipment.

Proposed Actions

- *Incorporate paragraph 417(c), without the associated consignment limit, as an additional fissile exemption under § 71.15.*
- *Incorporate paragraph 417(e) as a provision separate from § 71.15, with a corresponding increased fissile material mass limit of 140 grams.*
- *Not to incorporate the consignment limit associated with paragraph 417(d).*

Issue No. 1b: Competent Authority-Approved Fissile Exception, SSR-6 Paragraph 417(f)

The IAEA added a fissile exception provision in SSR-6 paragraph 417(f), for "a fissile material that meets the requirements of paragraphs 570(b), 606, and 802." Paragraph 570(b) indicates that there should only be one such fissile material per consignment unless otherwise approved. Paragraph 606 requires demonstration of subcriticality for fissile materials without the need for accumulation control under normal conditions of transport and hypothetical accident conditions. Paragraph 802 requires the material to have multilateral approval with a certificate stating that it meets the requirements for fissile material excepted by the competent authority.

This exception was added to SSR-6 in part to recognize that some competent authorities would like to approve exceptions for fissile material that are different from those in paragraph 417, similar to what the U.S. did in 2004. However, there is not currently a mechanism for issuing a "certificate of approval" for multilateral approval of the U.S.-specific fissile exemptions in § 71.15, as these exemptions are codified in the regulations, and licensees may self-certify such shipments, if contained in a Type A or excepted package.

It may be of use to domestic licensees to have a process in the U.S. regulations for approving exemptions for fissile material in addition to what is already codified in § 71.15. However, the NRC would need stakeholder feedback on the potential usefulness of such a process, and how best to implement it in the regulations.

Factors for Consideration

- *Would it be useful for licensees to have a mechanism in the NRC's regulations for facilitating multilateral approval of existing fissile exemptions in § 71.15, for international shipping?*

  Exelon's Response – Nuclear power materials would typically meet the exceptions in 10 CFR 71.15(a), (b), or (c) which are similar to 417(d) and (e). Licensees would attempt to avoid the exception in 417(f) since they would not have the ability to determine if the material would need accumulation control and would look to avoid multilateral approval. Paragraphs 417(d) and (e) have either consignment limits or exclusive use requirements which would have to be met for an international shipment, but avoid the multilateral approval requirements of 417(f). Other licensees might be more likely to need the exception in 417(f).

  SSR-6 paragraph 222(c) Fissile definition states: "*Material with fissile nuclides <0.25g are excluded from the definition of fissile material.*" The deminimus value in SSR-6 of 0.25g would exclude most nuclear power materials from the more restrictive fissile exception processes in SSR-6. Regulation 10 CFR 71 has no lower limit such that the presence of

any fissile material would trigger the review for the fissile exceptions. It is recommended that the NRC review how the 0.25g threshold in the SSR-6 Fissile definition affects other fissile provisions in both regulations.

- *Is there value to licensees in having a process in the regulations for approving exemptions for fissile material beyond what is in § 71.15 for domestic shipment?*

  Exelon's Response – Nuclear power licensees generally have no issues with the current exceptions in §71.15. Other licensees may be more greatly affected.

- *Would declining to adopt these provisions negatively impact international shipping of fissile exempt material?*

  Exelon's Response – Nuclear power licensees would most likely use 417(d) or (e) exception and avoid the use of 417(f). Other licensees may be more greatly affected.

Proposed actions

Not to adopt SSR-6 paragraph 417(f), absent stakeholder feedback that multilateral approval of existing NRC exemptions for fissile material is necessary.

Not to incorporate a process in the NRC's regulations for approving exemptions for fissile material beyond what is in § 71.15 for domestic shipment, unless there is significant stakeholder feedback that this would be useful.

Issue No. 1c: CSI-Controlled Fissile Material Packages, SSR-6 Paragraph 674

In 2012, the IAEA added provisions in paragraph 674 for CSI-controlled packages of fissile material, analogous to the fissile material general license requirements in §§ 71.22 ("General license: Fissile material") and 71.23 ("General license: Plutonium-beryllium special form material"). Paragraph 674(a) contains fissile material mass limits (per Table 13 in paragraph 674) and a CSI determination for packages with a minimum external dimension of 10 centimeters, which are not required to withstand normal conditions of transport in paragraphs 719 - 724. Paragraph 674(b) contains similar fissile material mass limits, and a formula for determination of a lower CSI, for packages which withstand normal conditions of transport while maintaining a larger minimum external dimension of 30 centimeters. Paragraph 674(c) contains the same CSI calculation as paragraph 674(b), for packages that withstand normal conditions of transport while maintaining a minimum external dimension of 10 centimeters, with a limit of 15 grams fissile material per package.

Both §§ 71.22 and 71.23 have CSI determinations based on fissile material mass. Only licensees of the NRC with an approved quality assurance program can transport using a general license, and the quantity of material must be limited such that it can be transported in a Type A package. The mass values in Tables 71-1 and 71-2 of § 71.22, and for plutonium in § 71.23, are supported by assessments performed in NUREG/CR-5342. These assessments were intended to determine mass limits that provide safety equivalent to that provided by packages certified per the criteria of §§ 71.55 and 71.59 (Section 5.3.2 of NUREG/CR-5342). Although it is difficult to make a direct comparison of 10 CFR Part 71 and IAEA SSR-6 mass values for these provisions, given the differences between the provisions and the fewer enrichment steps in the SSR-6 values, the mass limits in the 10 CFR Part 71 fissile material general licenses are generally higher. Additionally, Table 71-1 of § 71.22 provides mass limits

for fissile materials mixed with substances having an average hydrogen density less than or equal to water, and also provides lower mass limits if the fissile material is mixed with substances having an average hydrogen density greater than water (e.g., polyethylene, hydrocarbon oils). This distinction is not made in IAEA SSR-6, and the mass limits in SSR-6 paragraph 674 are based on criticality safety with fissile materials mixed with high hydrogen density moderators.

Other than mass limits, the major differences between the NRC's regulations and the IAEA's SSR-6 paragraph 674 is that §§ 71.22 and 71.23 require the use of a Type A package and establish CSI values based on that requirement. Conversely, SSR-6 paragraph 674 allows the use of packages that are not subjected to the tests for normal conditions of transport (paragraph 674(a)). Additionally paragraph 674 has two provisions for packages that are subjected to the tests for normal conditions of transport – paragraph 674(c) for packages limited to 15 g per package and 674(b) for packages that maintain a 30 cm outer dimension. The NRC general license require that material is transported in at least a Type A package, and that there is only a single CSI calculation based on the package maintaining a minimum external dimension under normal conditions of transport and the material being released under hypothetical accident conditions.

The NRC staff does not propose to adopt the changes in IAEA SSR-6 paragraph 674, because the NRC staff has determined that the mass limits and other requirements in §§ 71.22 and 71.23 are appropriate for providing criticality safety equivalent to packages approved under 10 CFR Part 71.

Factors for Consideration

- *Are the existing mass limits for the fissile material general licenses in §§ 71.22 and 71.23 appropriate for providing criticality safety of these types of shipments?*

  Exelon's Response - The regulations in §71.22 and §71.23 do not represent an unusual burden to nuclear power licensees. Nuclear power material and waste types meet §71.15 exceptions and are not applicable to §71.22 and §71.23. The NRC notes that the current mass limits from the CSI calculation provide adequate safety margin. SSR-6 has different criteria based on the size and other criteria. Complexity in compliance should not be increased without a corresponding increase in safety margin.

- *Would declining to adopt these provisions negatively impact international shipping of small quantities of fissile material?*

  Exelon's Response - An international, small quantity fissile shipment would be rare. If international regulations were more stringent than domestic regulations, then they would be followed. There is no need to unnecessarily complicate regulations applied to all domestic shipments for rare international shipments.

Proposed action

- *Not to adopt the changes in IAEA SSR-6 paragraph 674.*

Issue No. 1d: Plutonium Shipments in Type A Packages, SSR-6 Paragraph 675

Paragraph 675 of SSR-6 is a provision for shipping plutonium in a non-fissile package, with accumulation control provided by the calculation of a CSI. Plutonium is limited to 1000 grams per package, and no more than 20 percent of which may be the fissile isotopes of plutonium (^{239}Pu and ^{241}Pu). This same criterion for plutonium was previously a provision in paragraph 417, with no accumulation control. Section 71.15(f) currently includes the provision without accumulation control.

This exemption pertains to the shipment of low-assay plutonium, such as heat sources, with a high percentage of nonfissile ^{238}Pu and a low percentage of fissile nuclides of plutonium (^{239}Pu or ^{241}Pu). The presence of the nonfissile plutonium isotopes provides significant parasitic neutron absorption and eliminates the potential for criticality for this mass of plutonium.

Additionally, due to the low A_2 values associated with nonfissile plutonium (which corresponds to less than one hundredth of a gram for ^{238}Pu), almost all shipments under this exemption will be required to be transported in a Type B package. Type B packages limit the release of material under both normal conditions of transport and hypothetical accident conditions, and provide fissile material separation and additional neutron absorption to further limit criticality.

Although the NRC staff has determined that the fissile exemption in § 71.15(f) is safe without accumulation control, there may be value in limiting accumulation through the use of a CSI, in order to be consistent with the IAEA regulations. However, based on the low numbers of Type B packages certified to transport this type of material, the NRC staff believes that these packages are not often shipped internationally, and that when they are, they are in single or small numbers of packages.

The NRC staff does not propose to adopt the changes in IAEA SSR-6 paragraph 675 since the existing fissile exemption in § 71.15(f) will ensure the package is subcritical without accumulation control provided by a CSI calculation. However, if there is stakeholder feedback that consistency is needed between SSR-6 paragraph 675 and § 71.15(f) to facilitate international shipping of NRC approved packages, then the NRC staff will consider making the change. Note that, similar to IAEA SSR-6, such a provision may be moved from the fissile exemptions in § 71.15 to another part of the regulation.

Factors for Consideration

- *Do licensees still use this exemption, and would the change to require a CSI be burdensome (i.e., prevent currently authorized shipments)?*

  Exelon's Response – The exemption in §71.15(f) is not used in nuclear power material and waste shipments. Even instruments with fissile material would more likely be composed of uranium and not plutonium. This exception would have most often been applied to the shipment of Plutonium-238 batteries and not relevant to nuclear power. The CSI calculation would not be a burden for such an infrequent shipment.

- *Is this material often shipped internationally, such that there would be an incentive to adopt the IAEA CSI limitation in NRC regulations for consistency?*

  Exelon's Response – This material type is not shipped by nuclear power licensees; perhaps other licensees are more greatly affected.

Proposed action

- *Not to adopt the changes in IAEA SSR-6 paragraph 675.*

Issue No. 2: Consideration for Adopting a Change to the Reduced External Pressure Design Requirement for Transportation Packages

The NRC staff is considering changing the value in § 71.71(c)(3) for the reduced external pressure to the value in the DOT's regulation in 49 CFR 173.412(f). This change to the NRC's regulations is necessary to 1) align the NRC's regulations with the requirements of IAEA transport regulations for this specific requirement; 2) be consistent with the current DOT regulations for design requirements for Type A packages (as found in 49 CFR 173.412(f)); and 3) provide a more realistic assessment of the reduction of the external pressure that is typically experienced during ground transport of radioactive material.

The IAEA provides advisory/guidance material related to the transportation of radioactive material in their "Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material" (SSG-26, Ref. 18). Within paragraph 659.10 of SSG-26, the discussion related to the reduced external pressure cites an ambient pressure value of 60 kilopascals (kPa). Specifically, this paragraph references paragraph 645 in SSR-6. As related to a Type A package, paragraph 645 of SSR-6 states, "The containment system shall retain its radioactive contents under a reduction of ambient pressure to 60 kPa."

In a final rule published by the DOT on July 11, 2014 (79 FR 40590, Ref. 19), with an effective compliance date of July 13, 2015, the DOT harmonized its regulations in 49 CFR to the IAEA's "Regulations for the Safe Transport of Radioactive Material," (TS-R-1, Ref. 20). In the section by-section review, the DOT provides a discussion related to the decision for changing the value for the external pressure that a Type A package must be designed to in order to ensure that the package is capable of retaining its contents under the reduction of ambient pressure. The value of 25 kPa (3.6 pounds per square inch absolute (psia)) was changed to 60 kPa (8.7 psia) in 49 CFR 173.412(f). This design requirement is an assessment of the containment system of a Type A package and is in addition to several other design requirements (see 49 CFR 173.412(a) - (k)).

The DOT requirement in 49 CFR 173.412(f) is harmonized with IAEA's TS-R-1, which also aligns with the requirements in SSR-6. The NRC also issued a final rule (80 FR 33988, 6/12/15, Ref. 13) to harmonize with TS-R-1 however, the NRC did not make a change to the reduced external pressure requirement found in § 71.71(c)(3) at that time. Thus, the NRC regulations are not harmonized with either the IAEA regulations or the DOT regulations for the reduced external pressure requirement. Since the NRC is considering changes based on the SSR-6, a change to § 71.71(c)(3) would harmonize the NRC's regulations with both the international transport regulations and the current domestic regulations for this specific design requirement.

In § 71.71, the NRC specifies the requirements for normal conditions of transport that the package design must meet. As related to reduced external pressure, the current § 71.71(c)(3) requires that the package be designed to withstand 25 kPa (3.6 psia). The NRC staff is considering changing this value to 60 kPa (8.7 psia).

When considering the transportation package design, real-world conditions that the package might experience during transportation should be considered. This is true for the reduced

external pressure design requirement. The Mt. Evans Scenic Byway in Colorado has the highest elevation of any paved road in the United States at 14,130 feet (4306.8 meters). At this elevation, assuming a temperature of -40 C (-40 F) in still air as cited in § 71.71(c)(2) for normal conditions of transport, the external pressure (absolute) a package would be subjected to is estimated to be 55.8 kPa (8.1 psia). This corresponds to an external pressure drop of 45.5 kPa (6.6 psi) relative to atmospheric pressure at sea level (101.325 kPa or 14.7 psia) and at 12 C (10.4 F) in still air. Therefore, the NRC staff is considering adopting a 60 kPa (8.7 psia) reduced external pressure to be more representative of the real-world conditions found for most roads in the U.S. (55.8 kPa vs 60.0 kPa).

In evaluating all the information, the NRC staff generally agrees with the DOT's assessment that "...since packages currently have to withstand a reduction in ambient pressure from 100 kPa to 25 kPa, they should already be able to meet the new requirement," (Ref. 19). Since applicants or licensees should already be able to meet the requirement that the adoption of a 60 kPa external pressure (8.7 psia) requirement, this proposed change is not expected to increase regulatory burden. Structural components in a representative NRC-approved transportation package are not expected to change drastically as a result of the change in reduced external pressure since their design is typically determined by the conditions and tests required under hypothetical accident conditions (§ 71.73).

Factors for consideration

- *What will be the impact to package designs if the reduced external pressure requirement is changed from "25 kPa (3.5 lbf/in2) absolute" to 60 kPa (8.7 psia)?*

  Exelon's Response – The NRC response notes that DOT requirements for Type A packages already require the 60 kPa design requirement which matches SSR-6. Type B containers are more durable than Type A containers and should reasonably be able to meet the pressure reduction requirement as well.

- *How will the proposed change impact the Safety Analysis Reports that are prepared and submitted to the NRC in support of the safety of Type AF and Type B packages?*

  Exelon's Response – The NRC would need to determine a date for licensees to submit new testing documentation and permit the use of existing packages until the NRC's review and approval is complete. Overall compliance between licensee submittals and NRC approval would likely be a two-year period or longer.

Proposed action

- *§ 71.71(c)(3) – Revise*
  (3) Reduced external pressure. An external pressure of 60 kPa (8.7 psia).

Issue No. 3: Type C Package

The current IAEA regulations require a Type C package to withstand severe accident conditions in air transport without loss of containment or significant increase in external radiation levels. The NRC's and DOT's regulations do not contain Type C package requirements. The NRC regulations do have specific requirements for evaluating the safety of air transport of fissile material and plutonium (§71.55(f); §§ 71.64 and 71.74).

The IAEA Type C requirements (paragraphs 669-672 in SSR-6) apply to packages subject to air transport that contain a total activity above the following thresholds: for special form material- 3,000A_1 or 100,000A_2, whichever is least; and for all other radioactive material 3,000A_2. Below these thresholds, Type B packages would be permitted to be used in air transport. The IAEA Type C package test sequence is more stringent than those for Type B packages. The tests for Type C packages include:

- *A 9-m drop test;*
- *A dynamic crush test from a 500 kg mass dropped 9 m onto the package;*
- *A puncture–tearing test;*
- *A 60-minute fire test instead of the 30 minute fire test for Type B packages; and*
- *90 m/s impact test.*

According to the IAEA (SSG-26, Ref. 18), Type C package designs are expected to survive more severe aircraft accidents than Type B package designs. Specific Type C package acceptance criteria are established for evaluating the performance of the material during and after the tests (less than 100A_2 in gaseous or particulate form of less than 100 micrometer aerodynamic equivalent diameter and less than 100A_2 in solution). These performance and acceptance requirements are intended to ensure that these materials can continue to be transported safely aboard aircraft.

On April 30, 2002, the NRC issued a proposed rule in the Federal Register (67 FR 21390, Ref. 20) which evaluated the possibility of adding regulations for Type C Packages. In the 2002 proposed rule, the NRC proposed to not adopt the IAEA standards for Type C packages and low dispersible material (LDM). As a rationale for not adopting the IAEA's regulations, in the proposed rule, the NRC stated:

> *"(1) IAEA development of aircraft accident severity information through a coordinated research project for further evaluation of the Type C and LDM requirements;*
>
> *(2) the fact that there are very few anticipated shipments affected by these requirements;*
>
> *(3) DOT rules that permit the use of IAEA standards in nonplutonium import/export shipments of foreign certified Type C containers, so that international commerce is not impacted;*
>
> *(4) NRC's domestic regulations currently in place (§§ 71.64 and 71.74), based on specific statutory mandates, governing air transport of plutonium (plutonium air transport was a considerable factor in IAEA adoption of Type C provisions); and*
>
> *(5) comments made by the public on the issues which generally disagreed with or questioned the rigor of the Type C tests, and supported NRC maintaining its current regulatory requirements for the safety of plutonium air shipments."*

In the proposed rule, the NRC also requested public comment on the need for Type C packages, specifically the number of package designs and the timing of future requests for Type C package design approvals for domestic air transport.

In the final rule issued on January 26, 2004, (69 FR 3698, Ref. 11) the NRC did not adopt these regulations for Type C packages and LDM. The NRC stated that it was not adopting these standards for two reasons:

1) the U.S. regulations in § 71.64 and § 71.74 governing plutonium air transportation to, within, or over the United States contains more rigorous packaging standards than those in the IAEA TS–R–1;

2) the NRC's perception was that there is a lack of current or anticipated need for such packages, and the NRC acknowledges that the DOT import/export provisions permit use of IAEA transport regulations.

The NRC has not altered its view on the reasons listed above for not adopting the standards for Type C packages and LDM.

Factors for consideration

- *Is there a need to transport NRC-approved packages that contain a Type C quantity, as defined in SSR-6 paragraph 558a, by air internationally?*

  Exelon's Response – There is no need for Type C packages for nuclear power licensees. Licensees are required to use a Type C package by air if >3000 A_2 radionuclide quantity. Nuclear power licensees do not have materials which would concentrate such a high activity in a small package for air transport. Other licensees may be more greatly affected.

Proposed actions

- *Continue to evaluate whether there is a need to adopt the IAEA regulations for Type C packages.*

Issue No. 4: Solar Insolation

The IAEA, in Safety Series No. 6, "Regulations for the Safe Transport of Radioactive Material, 1985 Edition (as amended in 1990)," (Ref. 10), revised the units used for solar insolation for normal conditions of transport from "g-cal/cm2 for 12 hours per day" to "W/m2 for 12 hours per day." When the IAEA changed the units, it kept the same values, thus increasing the solar heat load by approximately 3 percent. The NRC units for solar insolation in § 71.71(c)(1) were last revised in 1983, therefore the units in the NRC regulations have not been revised to match the IAEA's change in units. Consequently, the 10 CFR Part 71 units are still g-cal/cm2. In addition, the IAEA regulations (paragraph 728) state that the solar insolation, in addition to the maximum ambient temperature, shall be an initial condition to the fire test for hypothetical accident conditions. The NRC's regulations do not specify that solar insolation be an initial condition to the fire test in §71.73(c)(4).

The NRC staff is considering revising the solar insolation data table to harmonize with the IAEA's regulations. The table in § 71.71 would potentially be revised to read:

INSOLATION DATA

Form and location of surface	Total insolation for a 12-hour period (W/m^2)
Base	None
Other surfaces	800
Flat surfaces not transported horizontally	200
Curved surfaces	400

In addition to the potentially revised table above, the NRC staff is considering adding solar insolation as an initial condition to the fire test in §71.73(c)(4). Both of these changes will increase the solar load in the heat test for normal conditions of transport and as a precursor to the fire test for hypothetical accident conditions. Since the U.S. regulations are not consistent with the IAEA requirements (paragraph 657 in SSR-6), packages that are approved by the NRC for transport within the U.S. must have a separate thermal evaluation to be evaluated by a foreign competent authority for revalidation of the DOT certificate of competent authority.

Factors for consideration

- *Should the NRC change the units used for solar insolation from g-cal/cm2 to W/m2 for the heat test for normal conditions of transport to be consistent with the IAEA's safety standards?*

  Exelon's Response – The NRC noted that keeping the same values, but changing the units, resulted in an increase on the solar heat load by approximately 3% in SSR-6. This is not an issue for domestic Type B shipments. Nuclear power licensees would most likely use a Type A package for international shipments and not be affected.

- *Should the NRC add solar insolation as an initial condition to the fire test for hypothetical accident conditions to be consistent with the IAEA's safety standards?*

  Exelon's Response – Complying with these values are necessary for unilateral approval of a Type B container. This would avoid delays seeking multilateral approval for affected shipments. Other licensees may have a greater need for Type B packages for international shipments.

- *What, if any, are the implications for certificate holders of NRC-approved packages?*

  Exelon's Response – The NRC would need to determine a date for licensees to submit new testing documentation and permit the use of existing packages until the NRC review and approval is complete. Overall compliance between licensee submittals and NRC approval would likely be a two-year period or longer.

Proposed actions

- *Revise the units in the table in § 71.71 to W/m2.*
- *Add solar insolation as an initial condition to § 71.73(c)(4).*

Issue No. 5: Replace Radiation Level with Dose Equivalent Rate

The NRC staff is considering a change to provide consistency within 10 CFR Part 71 and harmonize with the IAEA's proposed revisions in DS495. Specifically, the NRC staff is considering a change to the § 71.4 definitions to provide clear and consistent definitions with the international community that can be used to accurately communicate requirements to licensees.

The IAEA is proposing to remove the definition and term "radiation level" and replace it with the definition of "dose equivalent rate" in the DS495. The IAEA also proposes to use dose equivalent rate throughout DS495. The IAEA's proposed change is to provide consistency for the use of "dose equivalent rate" throughout various IAEA documents and the proposed SSR-6.

Additionally, "dose equivalent rate" has universal scientific meaning with the standard radiation practice (Ref. 21).

Currently, the NRC does not have a definition for "radiation level" or "dose equivalent rate" in § 71.4 definitions; however, § 20.1003, "Definitions" contains a definition for "dose equivalent." The definition in 10 CFR Part 20 for "dose equivalent" is similar to the proposed definition of "dose equivalent rate" in DS495:

> *Section 20.1003: "Dose equivalent means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and Sievert (Sv)."*
>
> *DS495, Paragraph. 220 bis. Dose equivalent rate shall mean the ambient dose equivalent or the directional dose equivalent, as appropriate, per unit time, measured at the point of interest and expressed in millisieverts per hour or microsieverts per hour."*

The NRC staff is considering revising § 71.4 to include a definition for "dose equivalent rate" that would harmonize 10 CFR Part 71 with the IAEA's proposed regulations, and maintain consistency with the 10 CFR Part 20 definition. In addition, the NRC would need to change the term "radiation level" throughout 10 CFR Part 71 to "dose equivalent rate." The NRC staff is considering this because "dose equivalent rate" is the name of the measurement being taken to compare against the limits for radiation level in § 71.47, "External radiation standards for all packages" as defined by the International Commission on Radiological Protection (Ref. 22).

Factors for Consideration

- *Does the term and definition of dose equivalent rate conflict with existing radiation protection programs, or introduce other issues or concerns to NRC licensees and certificate holders?*

  Exelon Response - Action should be taken in this area for alignment between the NRC and DOT. The DOT has already taken action and revised the radiation level definition in § 173.403. The DOT definition should be altered. SSR-6 discusses the "dose equivalent rate" without further clarification while the DOT definition discusses the dose equivalent rate as the "sum of the dose equivalent rates from all types of ionizing radiation present including alpha, beta, gamma, and neutron radiation."

  Regulatory Guide 7.9, *"Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material,"* Section 5.1 is very clear that the radiation types of interest for analyses of normal conditions of transport and hypothetical accident conditions are deep dose gamma and neutron radiation levels. Additionally NUREG-1609, *"Standard Review Plan for Transportation Packages for Radioactive Material,"* also clarifies the radiation types of interest are gamma and neutron. Gamma and neutron radiation types are used for compliance with radiation level limits for normal conditions of transport (200 mrem/hr package dose rate limit and 10 mrem/hr for the Transport Index (1m)) and hypothetical accident conditions (1000 mrem/hr at 1m). Neither alpha nor beta radiation types are included in the radiation levels. Alpha and beta radiation types are always mentioned with contamination limits in Bq/cm^2 and not radiation levels in units of mSv/hr.

  Alpha emitting radionuclides cannot penetrate the skin to provide an external dose equivalent. Alpha emitting radionuclides are only an internal dose hazard and there is no means to express it as an external dose type measureable by a handheld instrument. It is

understood that there may be gamma radiation emissions associated with an alpha emitting radionuclide and the gamma radiation would currently be measured with an instrument used for detecting deep-dose gamma radiation.

Alpha and beta contamination limits already exist in 49 CFR 173.443. Beta emitting radionuclides have a separate regulatory shallow dose limit from the gamma and neutron deep dose radiation types and they would not be additive for the same limit. Additionally, neither alpha nor beta radiation types would be capable of penetrating a package surface to produce an external radiation level. Neither alpha nor beta would be measurable at the 1m and 2m regulatory distances. Alpha and beta radiation types would only be measurable as external surface contamination on a package. Only deep dose gamma and neutron radiation types would be capable of penetrating a package to produce a measurable radiation level.

It is recommended that both 10 CFR 71 and 49 CFR be aligned to clarify radiation levels as "deep-dose equivalent (gamma and neutron as applicable)" and not dose equivalent (alpha, beta, gamma, and neutron). This would align with the analyses for normal conditions of transport and hypothetical accident conditions. Even with a clarification of deep dose equivalent, most packages would not have a neutron component, such that licensees should not be expected to measure a neutron radiation level for every package. All packages are currently monitored with a gamma sensitive deep dose instrument, and neutron measurements should be made for only discrete neutron sources. Beta and alpha surface contamination measurements would be made with the appropriate contamination monitoring instruments as they are done by licensees today. This has been historical industry performance, but the recent DOT definition created confusion for licensees.

It is very important that the NRC use this opportunity to clarify the radiation level definition which would result in alignment with the DOT.

- *Are there other definitions of terms that are recommended for incorporation in 10 CFR Part 71?*

  Exelon's Response – It is recommended that the application of the 0.25g threshold in the Fissile definition be reviewed. 10 CFR 71 does not have an equivalent threshold which causes differences in the application of the fissile exception regulations.

Proposed actions

- *Evaluate whether a definition for dose equivalent rate is needed in 10 CFR Part 71.*
- *If needed, the NRC staff would add a definition for dose equivalent rate to § 71.4 and use that term consistently within 10 CFR Part 71.*

Issue No. 6: Deletion of the Low Specific Activity-III Leaching Test

For low specific activity (LSA) material, § 71.4 includes definitions for LSA-I, LSA-II, and LSA-III. LSA-III material includes solids, excluding powders, with an estimated average specific activity limit of 2 x 10-3A2/g, and meets § 71.77, "Qualification of LSA-III Material" requirements. Section 71.77 includes a leaching test with immersion of the specimen material for 7 days. The IAEA is proposing to eliminate the LSA-III leaching test in DS495 paragraphs 409, 601 and 701. Consequently, the NRC staff is considering corresponding revisions to §§ 71.4 and 71.77 to remove any reference to the leaching test.

The IAEA provides guidance material related to the transportation of radioactive material in SSG-26 (Ref. 18). Specifically, Subsection 601.2 in Section VI, "Requirements for Radioactive Material and for Packagings and Packages," includes a discussion on the LSA-III leaching test release limit of 0.1A_2/week. Additionally, Appendix I, "The Q System for the Calculation and Application of A1 and A2 Values," provides guidance related to the exposure pathways to a bystander near a transportation package. Collectively, this guidance information demonstrates the low inhalation risk associated with LSA-III material (SSG-26 paragraphs I.9 and I.37 through I.40).

Consistent with the specific assumptions of the IAEA's Q System (SSG-26 paragraph I.9), the IAEA regulations provide that the total body intake during transportation of radioactive material must be limited to 10-6A_2 to maintain consistency associated with the use of a Type A package during transport. For LSA-III material, which is not required to be transported in a Type A package, the dispersible radioactive contents may not exceed 0.1A_2. The purpose of the leaching test is to confirm the 0.1A_2 limit after 7 days of immersion of the sample material.

When establishing the low average specific activity limits for LSA material in the transport regulations, the IAEA based its assumptions on the fact that it is highly unlikely that, under circumstances arising during transportation, a sufficient mass of such material could be taken into the body resulting in a significant radiation hazard. Additionally, the IAEA's exposure models assume that it is unlikely that a person would remain in a transportation-related atmosphere long enough to inhale more than 10 mg of material (SSG-26, paragraphs I.68 and 226.1).

At the IAEA, it is the TRANSSC that is responsible for considering changes to both SSR-6 and SSG-26. Such changes are proposed by Member States (i.e., countries) through their participation in TRANSSC meetings and related organized working groups and research projects.

In April 2015, an international working group meeting was conducted in Cologne, Germany to discuss issues related to LSA-II and LSA-III material, with special attention on the need for the LSA-III leaching test. The results of this working group were reported at the IAEA's June 2015, "TRANSSC 30" meeting as Information Paper #10 and agenda item 4.1 (Ref. 23). The need for the leaching test was questioned because it was determined by the working group to have no relevance for the inhalation risk of exposure to material during transport. The inhalation risk is used to determine the average specific activity limits for both LSA-II and LSA-III material, which are 10-4A2/g and 2 x 10-3A2/g, respectively. Related investigations dating back to 2003, (and which are referenced in Information Paper #10, Ref. 23) revealed that the amount of released radioactive material leading to an inhalation dose under mechanical accident conditions of transport greatly depend on the physical form of the LSA material. The primary difference between LSA-II and LSA-III materials is that LSA-III is limited to solid material, excluding powders. Due to the solid nature of the LSA-III material, the amount of airborne radioactivity released during a mechanical accident condition of transport leading to an inhalation dose is at least a factor of 100 lower for LSA-III solids than for LSA-II solids in powder form. This much lower airborne release for LSA-III material due to its non-readily dispersible form compensates more than its allowable 20 fold increase in average specific activity compared to LSA-II material in powder form. Due to the non-dispersible form of the LSA-III material, the working group determined and recommended to TRANSSC 30 that there was no need to take credit from a leaching test to justify this allowable 20-fold increase in average specific activity between LSA-III and LSA-II material.

The working group's review of the LSA-II and LSA-III concepts as well as related analysis of theoretical investigations concludes that the limitations of the average specific activities to 10-4A_2/g for LSA-II, and 2 x 10-3A_2/g for LSA-III material and the exclusion of powder from the LSA-III definition collectively ensure that the effective dose criterion of the IAEA's transport regulations is met. The derivation of the LSA-II and LSA-III quantity limits is based on maintaining the dose criterion of 50 mSv to persons in the vicinity of a severe transport accident.

The working group concluded that the currently-required leaching test for LSA-III material does not contribute to the 50 mSv effective dose transport safety limit. Therefore, the working group recommended to TRANSSC 30 that the leaching test is not necessary or justified and its removal from the transport requirements is appropriate.

The NRC staff concludes that requiring the LSA-III leaching test is not necessary, as the test does not increase the safety of the material during transport, and the test does not decrease the inhalation pathway exposure when compared to LSA-II material in powder form. The NRC staff considered the information provided both by the LSA-II and LSA-III working group and that was discussed at the TRANSSC 30 meeting. The NRC staff also considers that removal of the leaching test would also reduce regulatory burden for shippers, but reasonable assurance of safety for transport of LSA-III material would be retained.

Factors for consideration

- *What would be the impact of removing the leaching test from the regulations as a qualification for LSA-III material?*

  Exelon's Response - The relevant material for nuclear power licensees would be materials solidified in concrete or other binders. These waste forms are infrequent. Process Control Programs (PCPs) would be used to ensure the mixtures and processes used would produce a waste form that would produce similar results as a test specimen used to certify the process. The presence or absence of the leaching requirement for process certification would not have a significant impact.

- *Should 10 CFR Part 71 be revised to remove the leaching test for LSA-III material?*

  Exelon's Response - The NRC should review assumptions used by burial sites to ensure these leaching requirements are not part of assumptions for compliance at burial sites. Elimination of controls of a variable used for burial site compliance would be an undesired consequence. Otherwise, the elimination of the test would be of no adverse impact.

Proposed actions

- *In § 71.4: remove the reference to § 71.77 in the LSA-III definition;*
- *In § 71.4: remove reference to the leaching test in paragraph (3)(ii) within the definition of LSA-III;*
- *Remove § 71.77; and In § 71.100: remove the reference to § 71.77.*

Issue No. 7: Introduction of the Provisions for Large Solid Contaminated Objects (Surface Contaminated Object (SCO-III))

The demand for decommissioning activities will increase due to the number of commercial nuclear power plants that are shutting down operations. Decommissioning activities can include transporting large radioactive objects, for example, steam generators, coolant pumps, and pressurizers. Currently, the regulations in § 71.4 contain definitions for LSA material and Surface Contaminated Object (SCO), including SCO-I and SCO-II. In general, most large radioactive objects could be characterized for transportation as one of the two SCO categories, either SCO-I or SCO-II.

The NRC issued Generic Letter 96-07 "Interim Guidance on Transportation of Steam Generators" in 1996 to address issues raised by licensees with respect to the transportation requirements for steam generators (Ref. 24). Generic Letter 96-07 provides suggestions agreed upon by the DOT and the NRC for assessing the characteristics for transporting steam generators. Generic Letter 96-07 also states, "[t]he shipment of steam generators and other large components may be specifically addressed in future guidance and international and domestic transportation regulations."

In 2004, the NRC determined (69 FR 3698, 1/26/04, Ref. 11) that special package authorizations were necessary because there were no regulatory provisions in 10 CFR Part 71 concerning large nonstandard packages. For example, a special package authorization was issued for the West Valley Melter Package from the West Valley Demonstration Project. In some instances, large radioactive objects may still need special package authorizations. Therefore, the NRC staff is not considering making any changes to § 71.41(d) at this time. In SSG-26 (Ref. 18), the IAEA includes Appendix VII, "Guidance for transport of large components under special arrangement." As described in Appendix VII, the IAEA provides background information for large component transport, guidance information related to safety concepts, and recommended criteria for the approval of a special arrangement for transporting a large component. The information in SSG-26 is guidance material; this information is not included in the IAEA transportation regulations.

During the TRANSSC 30 meeting in June 2015, Member States proposed revising SSR-6 to add a third category of SCO to the transportation regulations to gain a more consistent approach for the transportation requirements for large radioactive objects. If adopted, the third category of SCO would be called SCO-III.

In DS495, the IAEA proposed a provision and added/revised related regulatory text. Specifically, the IAEA proposed provisions for large solid contaminated objects under a new Surface Contaminated Object category called SCO-III. To harmonize with DS495, the NRC staff is considering revising § 71.4 to include the provisions for SCO-III. Specifically, NRC staff is considering adding the following provisions from DS495 paragraph 413(c) to § 71.4 as follows:

> *Surface Contaminated Object (SCO) means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of three groups with surface activity not exceeding the following limits:*
> *(1) SCO I: (as is)*
> *(2) SCO-II: (as is)*
> *(3) SCO-III: A large object for which:*
> *(i) All openings are sealed to prevent the release of radioactive material during routine conditions of transport;*

(ii) The inside of the object is as dry as practicable;
(iii) The non-fixed contamination on the external surface does not exceed the contamination limits specified in the DOT's regulations in 49 CFR 173.443;
(iv) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm2 does not exceed 8 x 105 Bq/cm2 (20 microcuries/cm^2) for beta and gamma emitters and low toxicity alpha emitters, or 8 x 104 Bq/cm2 (2 microcuries/cm^2) for all other alpha emitters, unless it can be demonstrated that, in accident conditions of transport, the activity intake by a person in the vicinity of the accident does not exceed 10-6 A_2 or a corresponding inhalation dose of 50 mSv (5000 mrem).

The NRC staff is considering potential conforming changes that would harmonize domestic and international regulations in the event the IAEA adopts the provisions of SCO-III.

Factors for consideration

- *How beneficial would adding the new provisions for SCO-III to the domestic transportation regulations be?*

  Exelon's Response - Creating a regulation for the shipment of SCO-III large components, rather than applying for a special permit, would simplify compliance for both the regulator and licensee. This would not be a frequent shipment type, but it would create a regulatory framework to avoid special permits. There are already provisions in 49 CFR related to shipping unpackaged SCO-I items and the NRC should review those provisions (e.g., contamination levels, placarding, etc.) to ensure no conflicts or gaps are created.

- *Should the NRC adopt the proposed provision for SCO-III into § 71.4?*

  Exelon's Response – Creating a regulation for the shipment of SCO-III large components, rather than applying for a special permit, would simplify compliance for both the regulator and licensee.

- *Is there a need for the NRC to provide guidance on the provisions for SCO-III?*

  Exelon's Response – The provisions for using SCO-III should be put into the regulations to ensure consistent compliance.

- *Is there a need to update NUREG-1608/RAMREG-003, "Categorizing and Transporting Low Specific Activity Materials and Surface Contaminated Objects" (1998) (Ref. 25)?*

  Exelon Response - An update of NUREG-1608 with the addition of examples for compliance with the new SCO-III category would also be helpful to both regulators and licensees. The document contains critical sections for compliance such as section 5.2.1 with the 2_{A1} fraction quantity that can be used as a threshold for compliance with the 1 rem at 3-meter dose rate limit. Section 3.3.1 is also critical as it describes a methodology for shipping SCO material in a very practical manner that is applied by most shippers and incorporated into shipping software. This document already contains key items for compliance and must be kept up to date or codified into regulation. The addition of provisions for the new SCO-III category would only enhance this critical compliance document for both regulators and licensees.

Proposed action

- *In coordination with the U.S. DOT, make appropriate changes to § 71.4 to align with changes made by the U.S. DOT and the IAEA.*

Issue No. 8: UF6 Packages

Packaging used to transport UF6 cylinders (primarily 30B cylinders) are subject to the requirements in § 71.55, "General Requirements for Fissile Material Packages." Section 71.55(g) outlines the requirements for UF6 packages to be exempt from the requirements of § 71.55(b). One of the requirements for the exemption is described in § 71.55(g)(1) that following the tests for hypothetical accident conditions, outlined in § 71.73, "there is no physical contact between the valve body and any other component of the packaging, other than at its original point of attachment, and the valve remains leak tight."

In the IAEA's DS495, there are proposed changes to add "plugs" to paragraph 680(b)(i) (emphasis added below):

> *Paragraph 680(b)(i): Packages where, following the tests prescribed in paragraph 685(b), there is no physical contact between the valve or the plug and any other component of the packaging other than at its original point of attachment and where, in addition, following the test prescribed in paragraph 718, the valve and the plug remain leaktight;*

This was proposed because the IAEA working group's assessment of package designs for the transport of UF6 in 30B cylinders has shown in some cases that there could be contact between overpack and plug surface when subjected to the 1 meter or 9 meter drop tests. In such cases it is not obvious that the plug would remain leaktight, which implies some uncertainty about water intrusion into the UF6 cylinder and whether it remains subcritical. The IAEA is proposing that the 30B cylinder's plug, should also be included in the requirements of 680(b)(i). The 30B cylinder's plug has the same safety function as the valve for excluding water and might be subjected to some mechanical interaction with other components of the packaging during the tests for hypothetical accident conditions. The UF6 cylinder is the only water barrier for preventing inleakage of water. (Ref. 21)

The NRC staff has evaluated the work done at the IAEA and has participated in the TRANSSC meetings where this was discussed. The NRC staff is evaluating whether to make the same change to its regulations in § 71.55(g)(1) to add the plug in addition to the valve.

Factors for Consideration

- *What is the impact of adding the "plug" to § 71.55(g)(1)?*

  Exelon's Response – This package type is not related to nuclear power licensees. Other licensees might be more greatly affected.

- *If the NRC were to add the requirement that the plug cannot contact any other part of the packaging, would there be an impact on current package designs based on previous testing of the package for hypothetical accident conditions?*

  Exelon's Response – This package type is not related to nuclear power licensees. Other licensees might be more greatly affected.

Proposed action

- *Revise § 71.55(g)(1) to read:*
  "Following the tests specified in § 71.73 ("Hypothetical accident conditions"), there is no physical contact between the valve body or the plug and any other component of the packaging, other than at its original point of attachment, and the valve and plug both remain leak tight;

Issue No. 9: Aging

In DS495, the IAEA proposes to include the requirement to consider aging mechanisms in the design and evaluation of the transport package (paragraph 613). In addition to aging mechanisms, the requirements in DS495 will also require that for shipment after storage, the applicant for a certificate shall state and justify the consideration of aging mechanisms in the safety analysis and within the proposed operating and maintenance instructions. Note that DS495 is silent on whether the application is for a new, amended or renewed certificate of compliance. The NRC staff is considering whether to harmonize its regulations with the IAEA's DS495 proposals on aging.

For packages that are intended to be used for transport after storage, the standards in DS495 would require that an application for approval shall include aging mechanisms in the safety analysis report, including in the proposed operating and maintenance instructions. While there may be an aging management program for the duration of storage, any changes to the package during storage shall be evaluated for transport. In addition, the IAEA proposals in DS495 paragraph 809 require that, packages that will be transported after storage, the safety analysis report shall include a gap analysis program. The gap analysis program should discuss package changes during storage due to aging, whether or not those changes affect the package performance during transport and consider changes of regulations and technical knowledge while the package is in storage.

The NRC staff has the understanding that aging management reviews of packaging would address mechanisms and effects that could adversely affect the ability of the packaging from performing its intended functions. Also, that all packages or packagings, whether in use or being stored in between uses, will age over time.

The NRC regulations in 10 CFR Part 71 do not explicitly call out aging mechanisms. However, prior to use, pursuant to § 71.87(b), licensees are required to determine that "[t]he package is in unimpaired physical condition except for superficial defects such as marks or dents." This determination should identify any degradation or aging of the package or packagings intended function. During the NRC review of the package design, the NRC ensures that operating procedures in the safety analysis report contain a statement requiring package inspection pursuant to § 71.87. These inspections should detect wear on a packaging prior to it becoming detrimental to the package operations and potentially impacting the public health and safety. In addition, the DOT requirements in 49 CFR 173.475(b) require that all shippers of radioactive material packages ensure the package is in unimpaired physical condition. These regulations are silent on parts of the package that cannot be readily observed, such as the internals of a spent fuel canister in storage.

Factors for consideration

- *Given the NRC and DOT inspection requirements in § 71.87(b) and 49 CFR 173.475(b), respectively, should the NRC revise its regulations to explicitly require applicants for a certificate of compliance to consider aging effects in their safety analysis report?*

  Exelon's Response - Existing package inspection standards look for any form of degradation regardless of the origin. Age related effects are already taken into account when looking at gaskets, package surfaces for corrosion, etc. SSR-6 provides no quantitative measures to inspect for aging. If a condition is degraded, it is corrected, regardless of the cause.

  If the term "aging" is added to 10 CFR 71 in the same vague manner as SSR-6, then it adds no value. Certificate holders would need clear guidance on how to include aging in analyses for consistency. This discussion is more relevant for licensees which are certificate holders. Any logic created would also likely apply to 49CFR, so care should be applied to not create ambiguous regulations which would complicate compliance for regulators and licensees.

  Ultimately, the issue will have to be addressed for an international shipment with a Type B package. Package certificate holders would need to create analysis related to aging for competent authority approval by the DOT for an international shipment. Changes might not be substantive, but the topic of aging would have to be addressed.

- *Should the NRC require packages that are to be used for transport after storage to provide a gap analysis that includes package changes during storage due to aging and whether or not those changes affect the package performance during transport?*

  Exelon's Response – Existing inspections in the U.S. look for any form of degradation, regardless of the mechanism and should be acceptable. Licensees are already looking for degraded gaskets or rusted components as part of normal inspections. The NRC should seek further clarification from the IAEA on how they expect aging to be applied.

Proposed action

- *Considering whether to add aging management considerations to 10 CFR Part 71.*

Issue No. 10: Transitional Arrangements

Historically, the IAEA, DOT, and NRC regulations have included transitional arrangements or "grandfathering" provisions whenever the regulations have undergone major revision. The purpose of grandfathering is to minimize the costs and impacts of implementing changes in the regulations. Package designs and packagings compliant with the existing regulations do not become "unsafe" when the regulations are amended (unless a significant safety issue is corrected in the revision).

Grandfathering typically includes provisions that allow for: 1) continued use of existing package designs and packagings already fabricated, although some additional requirements may be imposed; 2) completion of packagings in the process of being fabricated or that may be fabricated within a given time period after the regulatory change; and 3) limited modifications to package designs and packagings without the need to demonstrate full compliance with the

revised regulations, provided that the modifications do not ignificantly affect the safety of the package.

As proposed in paragraphs 819-821, 823 and 833 in DS495, the IAEA regulations would only recognize the "grandfathering" of package designs certified under the 1985 and 1996 editions of the IAEA's regulations (Refs. 10 and 12 respectively). Package designs approved under the 1973 edition of SS No. 6 would be required to be re-certified, removed from service, or shipped via exemption (i.e., special arrangement) (Ref. 3). The revised IAEA requirements would also prohibit, after 2028, the new manufacture of packages that do not meet the current IAEA regulations. If this approach to "grandfathering" is adopted in the DOT and NRC regulations, package designs approved to earlier versions of DOT and NRC regulations (i.e., those based on 1973 IAEA regulations) would be required to be re-certified, removed from service, or shipped via exemption. The IAEA also proposes to revise the package identification marks to delete "-96" for those that meet the post-2018 requirements.

Factors for Consideration

- *Should the "grandfathering" of previously approved packages be limited to those approved under the last two major revisions (1996 (Ref. 9) and 2004 (Ref. 11)) of the NRC regulations (i.e., continue to authorize packages for which the package identification has either a "-85" or a "-96")? If not, on what basis should the "grandfathering" of previously approved packages be allowed?*

  Exelon Response – Limitations to grandfathering clauses is important as it ensures all packages meet a minimum standard of performance. It is also understood that an acceptable package under old design criteria could be resubmitted with newer criteria if the package meets the updated standards. The NRC should assess costs and risks associated with the recommendations in SSR-6 to make a more informed decision. The NRC response noted that it already had experience with timelines for rule changes in 2004 and should use that experience when considering timeframes for this regulation change.

- *How long should "grandfathered" packages be allowed to be fabricated or used?*

  Exelon's Response – The NRC response noted that it already had experience with timelines for rule changes in 2004 and should use that experience when considering timeframes for this regulation change.

- *What type and magnitude of package design changes should be allowed for "grandfathered" packages before re-certification to the current set of regulations is required?*

  Exelon's Response – If a proposed modification improves package performance for scenarios for normal conditions of transport or hypothetical accident conditions, then those changes should be approved. Ultimately, the grandfathering period will expire and the package certificate holder will need to decide whether to submit for approval under new standards or let the certificate expire.

- *In the 2004 NRC rule change (Ref. 11), the NRC granted a 4-year period, after adoption of the final rule, for which packages that were being phased out could still be used. At the time, the NRC determined that 4 years would be a sufficient length of time to either develop replacement package designs or show that packages that are being phased out will meet the current package design requirements in 10 CFR Part 71. What is an appropriate time*

period for "grandfathered" packages to be phased out that will allow package designers to either bring these packages into compliance with the new regulations or obtain approval of replacement package designs?

Exelon's Response – The NRC should use the experience from the 2004 rule change when considering timeframes for this regulation change.

Proposed action

- *Considering whether to include transitional arrangements or "grandfathering" provisions.*

Issue No. 11: Adequate Space for Liquid Expansion Clarification

Subpart G to 10 CFR Part 71, "Operating Controls and Procedures," contains requirements for NRC licensees to ensure that, during loading of packages containing liquids, the licensee maintains adequate head space (ullage) for thermal expansion. Section 71.87(d) requires that prior to each shipment, licensees transporting licensed material shall ensure that "any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid." While adequate head space is required for a licensee using the packaging to transport licensed material, it does not apply to non-NRC licensees or NRC licensees who are not transporting licensed material.

During the NRC's review of applications for either a new certificate of compliance or an amendment to an existing certificate, staff should review whether the requirements in § 71.87 are reflected in the operating procedures of the safety analysis report, as appropriate. By placing these items in the portion of the safety analysis report referenced in the certificate of compliance (typically the operating procedures), all users of the package, whether NRC licensees or not, must perform them.

The DOT's regulations also require sufficient head space (also called ullage or outage in the DOT requirements) in 49 CFR 173.24(h), "General Requirements for Packagings and Packages." The requirement in 49 CFR 173.24(h)(1) states that "when filling packagings and receptacles for liquids, sufficient ullage (outage) must be left to ensure that neither leakage nor permanent distortion of the packaging or receptacle will occur as a result of an expansion of the liquid caused by temperatures likely to be encountered during transportation." The DOT also has a requirement in 49 CFR 173.412(k) for Type A packages requiring them to be designed to "provide for ullage to accommodate variations in temperature of the contents..." The NRC does not have an comparable requirement for Type B packages in 10 CFR 71.43, "General standards for all packages," to that in 49 CFR 173.412(k). (The DOT's regulations for Type B packages refer back to the NRC's regulations.) Even though the NRC's regulations lack a comparable requirement for the head space specifics in the design, any package design certified by the NRC, whether the shipper is an NRC licensee or not, must comply with the DOT regulations of 49 CFR 173.24(h) on head space/ullage.

To clarify the design requirements on head space, the NRC staff is considering adding language to § 71.43, "General standards for all packages," which would require an applicant for a new or amended certificate to provide sufficient head space in the design of a package. Adding this general standard would align the NRC regulations with the DOT regulations in 49 CFR 173.412(k). Also, adding this provision into § 71.43 will ensure that it applies to all packages during the design phase and therefore will ensure that all shipments of liquid in an NRC-

approved package, whether transported by NRC licensees or not, have adequate head space for liquid expansion.

Factors for consideration

- *Is clarifying language about adequate head space/ullage in § 71.43 needed?*

  Exelon's Response - There are already provisions for "ullage" in 49 CFR and this would be an opportunity for the NRC to align with SSR-6 and 49 CFR.

Proposed action

- *Add the following language to § 71.43:*
  (i) A package must be designed, constructed, and prepared for shipment so that under the tests specified in § 71.71 ("Normal conditions of transport") § 71.73 ("Hypothetical accident conditions") so that neither leakage nor permanent distortion of the packaging or system containing the liquid will occur as a result of an expansion of the liquid.

Issue No. 12: Quality Assurance Program Clarification

On June 12, 2015, the NRC issued a final rulemaking to amend 10 CFR Part 71 regulations (80 FR 33988, Ref. 13). Among the amendments made was an update to the administrative procedures for the quality assurance program (QAP) requirements described in 10 CFR Part 71, Subpart H, "Quality Assurance." Specifically, § 71.106 was added to establish requirements that will apply to changes to QAPs and included associated reporting requirements to the NRC. The regulations state that QAP approval holders are required to submit to the NRC every 24 months, changes to their QAP that do not reduce commitments. Also, according to the language provided in the Statement of Considerations (SOC) associated with this rule, if no changes were made to the QAP in the preceding 24 months, a report is required to be submitted stating no changes were made. The SOC included a question, "How frequently do I submit periodic updates on my quality assurance program description to the NRC?" (80 FR at 33994(II)(J)). In response, the NRC stated: "[i]f a quality assurance program approval holder has not made any changes to its approved quality assurance program during the preceding 24 month period, the approval holder will be required to report this to the NRC." Similar language is also reflected in the guidance document accompanying the rule, Regulatory Guide (RG) 7.10, Revision 3, "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material," (Ref. 26). This language was intended to be put into the rule to be analogous with the 10 CFR Part 50 regulations, specifically § 50.71(e)(2). The NRC has received questions from industry on this subject since the language in § 71.106 is silent on this scenario. The NRC staff is considering clarifying § 71.106 to more clearly align with § 50.71(e)(2) and the NRC's stated intent in the SOCs and RG 7.10. Specifically, the NRC staff is considering revising § 71.106 to clarify that a biennial report must be submitted to the NRC, even if no changes are made to the QAP during the reporting period.

Factors for Consideration

- *Should the language be clarified to include the requirement to submit a biennial report even if no changes are made during the reporting period?*

Exelon Response - Licensees should submit a letter every two years whether changes were made or not. If no letter is sent, then the regulator would not know if any changes were not made or if the licensees forgot to send the letter. The NRC engaged in risk-based regulation when they permitted licensees to make changes of low safety significance without prior NRC approval provided they send a copy of those changes to the NRC every two years. Requesting a letter to be sent stating that no changes were made over the two-year period is a small cost for the significant improvement in the regulation.

- *Is there an alternative to explicitly stating the requirement?*

Exelon Response – There is no alternative to explicitly stating the requirement or inconsistent compliance will result.

Proposed action

- *In § 71.106(b): add language to clarify that a biennial report must be submitted to the NRC even if no changes are made to the QAP during the reporting period.*

Issue No. 13: Clarification of Type A Package Requirements in § 71.22 – General License: Fissile Material, and § 71.23 – General License: Plutonium-Beryllium Special Form Material

The general licenses in §§ 71.22 and 71.23 are currently limited to Type A quantities of material transported in a Type A package (see §§ 71.22(a) and (c)(1) and 71.23(a) and (c)(1)). This restriction to a Type A package is not consistent with the mass limits for some fissile nuclides. For example, the limit of 37 grams ^{239}Pu in Table 71-1 corresponds to a mass that is more than 85 times the A_2 quantity. The general license can't be used for ^{239}Pu in excess of 0.435 grams. Similarly, the mass limit of 240 grams ^{239}Pu, ^{241}Pu, or any combination of these radionuclides in § 71.23, is more than 21 times the A_1 value (for special form material) for ^{241}Pu of 11 grams. Due to these inconsistencies, the staff believes the limitation to a Type A quantity in a Type A package is in error.

Shipping material that meets the mass limits of the general licenses in §§ 71.22 and 71.23 in a Type B package would not invalidate the criticality safety conclusions associated with these mass limits. In fact, the material would then be less likely to present a criticality hazard, as Type B packages generally have more mass, which would increase neutron absorption, and limit releases under hypothetical accident conditions. Therefore the NRC staff is of the view that the mass limits determined to assure subcriticality in Type A packages under §§ 71.22 and 71.23, will also assure subcriticality in Type B packages. Removing the restriction to Type A material in a Type A package will correct the inconsistences between the mass limits and package restrictions discussed above.

Factors for consideration

- *Should the NRC correct the §§ 71.22 and 71.23 criteria to remove the restriction that the material be limited to a Type A quantity, and state that the material must be shipped in a Type A or Type B package?*

Exelon's Response - If the CSI calculations and associated mass limits are all that is needed to determine the safety margin, then the arbitrary statement regarding a Type A quantity is not relevant. The NRC proposal would be to keep the CSI limitations and licensees would follow

the other regulations related to the use of Type A and Type B packages. As an example, there are provisions to put more than a Type A quantity of LSA material in a Type A container provided the unshielded material is <1 rem/hr at 3 meters. The CSI limits in § 71.22 and § 71.23 would be used to provide safety margin for criticality and licensees would use the other normal regulations for Type A or Type B package use. The proposed action simplifies compliance.

Proposed actions

- *Revise §§ 71.22(a) and 71.23(a) to state that the material must be in a Type A or Type B package, consistent with the radiological and containment requirements of 10 CFR Part 71.*
- *Remove the restriction in §§ 71.22(c)(1) and 71.23(c)(1) that the material be limited to a Type A quantity.*

Issue No. 14: Clarification of 233U Restriction in § 71.22 – General License: Fissile Material

Table 71-2 of the general license in § 71.22 cannot be used if "Uranium-233 is present in the package," according to § 71.22(e)(5)(i). The initial intent of this provision was to limit ^{233}U to levels below the detection limit of existing methods. As has been pointed out by several stakeholders, it is now possible to detect ^{233}U at a much lower level than previous equipment was capable of detecting, to the point that it prevents the use of this general license for some material with very low levels of ^{233}U.

In order to limit ^{233}U to an amount that will not affect the criticality safety of quantities of 235U under this general license, the provision could be modified to indicate that 233U must be less than 1.0 percent of the mass of ^{235}U. This is consistent with the way that ^{233}U is limited in the fissile exemption in § 71.15(d), for uranium enriched in ^{235}U up to 1.0 percent by weight.

Factors for consideration

- Should the NRC limit ^{233}U to less than 1.0 percent of the mass of ^{235}U when using table 71-2 of § 71.22?

  Exelon Response - The NRC should add limits for Uranium-233 as appropriate now that newer technologies can detect Uranium -233. This affords the ability to transport the material and have clear regulation and safety margin.

Proposed actions

- *Revise § 71.22(e)(5)(i) to replace "Uranium-233 is present in the package;" with "The mass of uranium-233 exceeds 1 percent of the mass of uranium-235."*

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