From:	SCHLUETER, Janet
To:	Vietti-Cook, Annette
Cc:	Layton, Michael; Hamdan, Latif
Subject:	[External_Sender] Industry Comments on Draft Regulatory Basis for 10 CFR Part 71, "Harmonization of Transportation Safety Requirements with International Atomic Energy Agency Standards;" Docket ID NRC-2016-0179
Date:	Tuesday, May 28, 2019 5:08:01 PM
Attachments:	05-28-19_NRC_Industry Comments on Draft Part 71 Regulatory Basis.pdf

THE ATTACHMENT CONTAINS THE COMPLETE CONTENTS OF THE LETTER

May 28, 2019

Ms. Annette Vietti-Cook
Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001
ATTN: Rulemakings and Adjudications Staff

Submitted via Regulations.gov

Subject: Industry Comments on Draft Regulatory Basis for 10 CFR Part 71, "Harmonization of Transportation Safety Requirements with International Atomic Energy Agency Standards;" Docket ID NRC-2016-0179

Project Number: 689

Dear Ms. Vietti-Cook:

The Nuclear Energy Institute (NEI), on behalf of its members, submits the following comments on the subject Draft Regulatory Basis for Part 71 published in the Federal Register on April 12, 2019 for public comment by May 28, 2019. We appreciate the thorough U.S. Nuclear Regulatory Commission (NRC) staff presentation and discussion on the 15 regulatory issues contained in the Draft Regulatory Basis during the April 30, 2019 NRC public meeting. In that regard, we have not identified any additional action alternatives or regulatory issues to be analyzed by NRC.

In summary, we trust that NRC will find these comments useful and informative, assuming it finalizes the draft revised regulatory basis and proceeds to the proposed rule phase. We look forward to future engagement on this important generic regulatory area and trust that NRC will work to take a more holistic approach to the various transportation-related ongoing regulator initiatives. Please contact me with any questions or comments about the content of this letter.

Sincerely,

Janet R. Schlueter
Senior Director,
Fuel & Radiation Safety

Nuclear Energy Institute
1201 F St NW, Suite 1100
Washington, DC 20004
www.nei.org

P: 202.739.8098
M: 202.468.6673
E: jrs@nei.org

JANET R. SCHLUETER
Senior Director,
Fuel and Radiation Safety

1201 F Street, NW, Suite 1100
Washington, DC 20004
P: 202.739.8098
jrs@nei.org
nei.org

NUCLEAR ENERGY INSTITUTE

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The industry takes seriously its commitment to the safe and secure transport of licensed radioactive material, from the smallest vial of medical radioisotope to used nuclear fuel, as is evidenced by the industry's strong safety record over many decades. We also appreciate efforts by NRC and the U.S. Department of Transportation staff to harmonize their respective transportation related requirements with those of the International Atomic Energy Agency in Specific Safety Requirements Version-6, 2012 and 2018 editions. As you are aware, every NRC licensee category is impacted by transportation requirements in one way or

[1] The Nuclear Energy Institute (NEI) is responsible for establishing unified policy on behalf of its members relating to matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect and engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations involved in the nuclear energy industry.

another. That being said, it should also be recognized that there are other regulatory programs of mutual interest to NRC, its licensees and the international community that NRC has made conscious decisions not to adopt. These include but are not limited to certain worker exposure limits and clearance of slightly radioactively contaminated materials or items. As such, NRC could independently conclude that, from a transportation safety or security perspective, it is not necessary to adopt in whole or in part SSR-6, versions 2012 and 2018. There is no evidence or data to suggest that the current Part 71 requirements are not adequate.

Holistic Approach to Transportation-Related Regulatory Initiatives:
It should be noted that there are several ongoing NRC transportation related initiatives that should be carefully considered, interdependencies identified and, if at all possible, resolved in tandem with any Part 71 rulemaking. For example: 1) current Draft Guidance-7010 which is out for comment until June 7 and could be used to impose onerous and not risk-informed leak test package requirements in the absence of a rule change (i.e., ANSI 14.5 version 2014); 2) NRC's ongoing effort to revise the Reactor Oversight Process' Significance Determination Process for radiation protection related findings in transportation and other licensed programs; 3) NEI's Part 71 related January 19, 2017 letter comment regarding necessary changes to NUREG-1608 to allow for "dose averaging" consistent with NRC's approach on radioactive waste concentration averaging (i.e., 2015 Branch Technical Position); and 4) the need for an NRC decision on the appropriate package Certificate of Compliance term, e.g., 10 years and its potential impact on Issue 10, Transitional Arrangements in the Part 71 draft Regulatory Basis. The scope and inter-dependencies of these initiatives should be clearly defined and coordinated to ensure internal regulatory consistency both from a risk management and efficiency perspective. Presently, these regulatory initiatives are on very different timelines and managed by different program areas within NRC. Both industry and NRC would benefit from a more holistic approach to the transportation regulatory arena particularly in view of the increasing number of commercial nuclear power plants to be decommissioned and the transport of decommissioning wastes and, ultimately, used fuel. We stand ready to assist in this regard.

Future Rulemaking to Address Deployment of High Assay Low-Enriched Uranium Fuel:
Many advanced reactor designs and some fuel designs for existing light water reactors will utilize uranium enrichments up to 19.75%. It should be recognized that a separate NRC rulemaking will likely be needed in the relative near term to support the transport of high assay low-enriched uranium fuel. Industry appreciates the current level of NRC engagement on this matter and will continue to keep NRC apprised of industry's regulatory needs and associated timeline.

Regulatory Issues Addressed in Current Part 71 Draft Regulatory Basis:
Should this rulemaking proceed, we generally support NRC's conclusion that most of the 15 identified regulatory issues should be addressed through rulemaking versus other means. The rulemaking option is more efficient and allows both NRC and industry to avoid the unnecessary costs associated with the preparation, submittal, and NRC review and decision making on licensee-specific amendment or exemption requests (e.g., Issue 7-new large solid contaminated object category which will eliminate the need for special permit package

authorizations). For some issues, the rulemaking option results in less restrictive requirements (e.g., Issue 2-reduced external pressure design) or less burdensome ones (e.g., Issue 6-deletion of current leaching test requirement). It should also be noted that, in Issue 12-reporting on Quality Assurance (QA) program changes, industry would prefer revised guidance versus a rulemaking since current programs are adequate, and consistency between NRC regulatory programs is not necessarily needed or desirable. See the discussion on Issue 12 below.

We offer the following comments on Issues 4, 9, 10 and 12 for staff consideration:

- **Issue 4: Solar Insolation** – The two elements of this issue are: a) a change in units in 10 CFR 71.7(c)(1) thus increasing the solar heat load by approximately 3%; and b) fire test initial conditions. As NEI's January 2017 letter to NRC stated, the change in solar heat load has implications to include the need for new thermal analysis and testing for existing US-licensed packages both during normal conditions of transport and new requirements for hypothetical accident conditions. Such analyses and testing is costly in the absence of an identified safety issue. One alternative would be for NRC to "grandfather" or exempt currently approved transportation packages since they remain safe for use. At a minimum, packages used exclusively for transportation within the continental U.S. could be exempted.

- **Issue 9: Aging Management** – NEI's 2017 letter stated that industry does not support the imposition of new aging management requirements because they would not add value or additional protection of the worker, public or environment. There is negligible degradation of Category A or B labeled package components (which are required to maintain their safety function) when the package is not in use due to package material composition. Thus, aging management requirements would only serve as an administrative burden to both NRC and the Certificate of Compliance (CoC) holder. That being said, should NRC proceed to promulgate a new aging management requirement, it should be limited to radioactive transport package cask CoCs and not applied to the spent nuclear fuel/Greater-Than-Class-C dual purpose storage and transport canister which is monitored by the canister CoC's aging management program.

- **Issue 10: Transitional Arrangements** – As the Draft Regulatory Basis states on page B-53, NRC adopted grandfathering provisions in 10 CFR 71.19 for previously approved packages as part of a 2004 rulemaking. Specifically, "packages approved… and designated as "-85" in the package identification number may not be fabricated after December 31, 2006 but *may still be used [emphasis added]*." It seems only logical that NRC would take an analogous approach in this rulemaking. Specifically, packages designated as "-96" in the package identification number may not be fabricated after December 31, 2028 but *may still be used.* Instead, NRC proposes to phase out use of the "-96" designated packages and require multilateral approval for packages used for international shipment. It is unclear why NRC is not allowing for the continued use (at minimum, domestically) of a currently safe transport package simply based on the perceived need for harmonization. Also, the NRC's

proposed approach has cost impacts on industry to design, fabricate and seek NRC approval of such new packages to replace the ones being used safely by industry today.

- **Issue 12: Quality Assurance Program Biennial Report – Alternative Approach Suggested** NRC is proposing to modify 10 CFR 71.106 to add a new requirement for a biennial report to NRC even if no changes were made to a quality assurance program (QAP) in the prior 24 months. NRC stated this change is to more clearly align section 71.106 with 10 CFR 50.71(e)(2). Perhaps the approach in Part 50 is wrong. Specifically, there is no safety reason to align requirements for a Part 71 QAP to an operating reactor's QAP. An additional Part 71 reporting requirement would be duplicative of the reactor inspection process whereby such changes are already routinely reviewed by inspectors. Since many Part 71 QAPs do not routinely change and no safety significant issues have been identified from these reviews, requiring periodic "no-change" reports is an unnecessary, administrative burden on QAP holders without a clear regulatory need, articulated benefit or safety concern. Further, existing fuel cycle licensees have several licensing basis documents that do not require any periodic report to NRC for "no program changes" in the preceding 24 months (e.g., radiation and environmental protection programs, material control and accounting, physical security). Additionally, Part 72 does not include a periodic reporting requirement and some reactors are licensed under 10 CFR Parts 50 and 72 for spent fuel management. In summary, there's no regulatory safety basis for the Part 71 QAP to be treated any differently by the licensee or regulator than they are today. Further, NRC inspection processes including Resident Inspectors can quickly and easily determine if changes were made to a QAP since the last inspection.

  As an alternative, NRC could simply delete one sentence from Regulatory Guide 7.10, Revision 3 as follows: "All changes made to an approved QA program description must be reported to the NRC every 24 months. ~~If the QA program approval holder has not made any changes to their approved QA program description during the preceding 24-month period, then the QA program approval holder would indicate to the NRC that no changes have been made.~~ Additionally, each QA program approval holder must maintain records of all QA program changes, in accordance with new §71.106(c)."

Additional Industry Comment for Staff Consideration:
The following comment in NEI's January 19, 2017 letter does not appear to have been, but should be, addressed in the Draft Regulatory Basis. We request that NRC consider it in this rulemaking.

- 2017 Letter Attachment, General Comment 1 – "NRC should evaluate the Highway Route Control Quantity (HRCQ) notification requirements in Part 71 and harmonize it with the notification requirements for category 1 quantities of radioactive material in Part 37. While the requirements are closely aligned, licensees may have HRCQ and Category 1 material as part of the same shipment. In these situations, licensees are required to perform two notifications of the same information to the same individuals. This process could be improved through revised rule language."

NRC Cost Estimates:
We have reviewed the completeness and accuracy—relative to this phase of the rulemaking process—of the draft NRC cost estimates for each Issue and offer the following preliminary comments.

- Issue 4-Solar Insolation: It should be noted that, contrary to NRC's conclusion, industry will incur costs for additional package testing, analysis and submittal of information to NRC.
- Issue 10-Transitional Arrangements: It must be recognized that the NRC estimated costs for amending a CoC is dwarfed by orders of magnitude by the costs of designing, fabricating and receiving NRC approval for a new transportation cask to replace the "-85" and "-96" versions in use. Such costs would likely be passed down to the end user in the absence of a clearly defined safety issue.
- Issue 12-QA program biennial reporting: New biennial reporting results in a new and unnecessary administrative burden for licensees, and comes at a cost for both licensees who must prepare, review and submit biennial reports to NRC and to NRC who, presumably, must track and review such reports.

Assuming the rulemaking proceeds to the proposed rule phase, industry will re-review such estimates and provide input as warranted. We also look forward to NRC issuing for public comment revised guidance documents to support this rulemaking, e.g., NUREG-1608, NUREG-1609 and Regulatory Guide 7.9.

In summary, we trust that NRC will find these comments useful and informative, assuming it finalizes the draft revised regulatory basis and proceeds to the proposed rule phase. We look forward to future engagement on this important generic regulatory area and trust that NRC will work to take a more holistic approach to the various transportation-related ongoing regulator initiatives. Please contact me with any questions or comments about the content of this letter.

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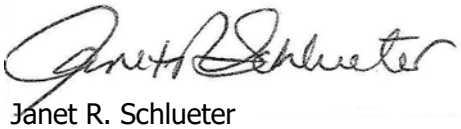

Janet R. Schlueter

c: Mr. Michael Layton, NMSS/DSFM, NRC
Mr. Latif Hamdan, NMSS/DSFM, NRC