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Ms. Marissa G. Bailey
Director, Fuel Cycle Safety and Safeguards
Office of Nuclear Materials Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Industry Strategy to Address Recent 10 CFR Part 70.72 Change Management Issues

Project Number: 689

Dear Ms. Bailey:

On behalf of the fuel cycle industry, the Nuclear Energy Institute (NEI)¹ submits the following proposal to address a recent industry-identified potential generic issue with implementation of 10 CFR Part 70.72, "Facility Changes and Change Process." We hope you will find this input useful as we work together to define the problem statement, draft additional NRC-endorsed guidance, and ensure clear expectations with regard to the existing requirement and the change management processes in use today at operating fuel facilities licensed pursuant to 10 CFR Part 70.

Background and Problem Statement

Since 2000, the fuel cycle facilities licensed by the U.S. Nuclear Regulatory Commission (NRC) pursuant to Part 70 have been in compliance with the requirements in section 70.72, as demonstrated by numerous NRC inspections. Licensees implemented programs consistent with the rule, relevant guidance in NUREG-1520 and Regulatory Guide (RG) 3.74 issued in 2011, and these programs are routinely inspected by NRC.

Recently, the NRC identified two Severity Level IV non-cited violations (NCVs) at a Part 70 fuel facility. Because of the potential generic nature of the NCVs, there is an urgent need for additional regulatory guidance that includes additional examples of when NRC pre-approval of certain facility changes is and is not

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

required. Such guidance could be in the form of modifications to RG 3.74 or a new guidance document, either of which could be generated by the NRC staff or the industry. We believe the most expeditious approach would be for the industry to take the lead on developing a draft problem statement and draft guidance for NRC endorsement as discussed below.

Further, since raising this issue to the NRC's attention in April, the NRC has identified an Unresolved Item (URI) at two additional Part 70 fuel facilities. The NCVs and URIs have caused the industry to be unsure of the potential regulatory problem, deficiency or compliance issue that needs to be addressed. A problem statement that clearly articulates the regulatory concern needs to be documented to inform the guidance development efforts. The industry would like to work with the NRC in the near term to define the problem statement and move forward with development of draft guidance for NRC endorsement.

Cumulative Effects of Regulation – “High Priority” Ranking for 70.72 Issue

The Part 70 fuel facilities consider the timely and full resolution of this new generic issue to be a “high priority” within the context of the Cumulative Effects of Regulation (CER) initiative. It is important to note that this ranking is *not* based on an identified safety or risk issue or concern. Rather, the “high priority” ranking is due to:

- 1) the need for increased regulatory stability
- 2) the large number of section 70.72 determinations currently made per year per facility on whether NRC pre-approval is needed on certain facility changes. (As stated by an industry representative during the June 2013 Fuel Cycle Information Exchange, a Part 70 facility might make literally thousands of 70.72 determinations per year)
- 3) the potential that this is a compliance issue warranting industry action.

It is clear that there is not a common interpretation by the NRC and the industry of the RG 3.74 guidance on section 70.72. The potential impact of any new or revised NRC expectations with this 13-year old rule is obviously of great import to the industry. Of particular concern is any expectation that would result in an increase in the type, scope and number of required NRC pre-approvals in the absence of a clear safety concern, or that would result in an increase in the administrative burden regarding adequate documentation in the absence of any safety benefit.

Further, a reallocation of finite industry resources at Part 70 facilities—through at least the end of this calendar year—will be needed to address this new “high priority” generic regulatory issue. Thus, considering the breadth, scope and number of current regulatory initiatives afoot, the industry will find it very difficult to devote resources to certain current or future regulatory initiatives² in the absence of a safety concern being identified.

² J. Schlueter, NEI, to J. Kinneman, NRC, letter on Cumulative Impact of Regulation and Prioritization of Initiatives, April 3, 2013, ADAMS Accession number ML13095A366.

Next Steps and Proposed Schedule

We believe the first step is for the industry to draft a problem statement that clearly articulates the regulatory concern followed by guidance development. As such, the industry has formed a working group that proposes to take the following steps this year:

July: The industry develops a draft problem statement.

August: The industry provides the draft statement to the NRC for review and comment, and discussion with the industry during a publicly noticed teleconference in August where industry would also solicit NRC input on content and scope of the draft guidance.

August – early September: The industry modifies the problem statement based on NRC input to ensure it is mutually agreed upon and proceeds to draft supplemental guidance based, in part, on recent inspection results. Draft guidance would likely be discussed in one or more additional public meetings this fall.

September: The industry supports an NRC public meeting to discuss draft guidance.

Meeting Purpose: Discuss the scope, content, and clarity of the draft guide, ensure mutual understanding of its intent and meaning, and solicit further NRC input on suggested examples.

Timing: The meeting date should coincide with the fall CER public meeting, as discussed during the June 10 CER public meeting.

October: The industry modifies the draft guidance based on NRC feedback and determines whether additional NRC interaction is needed prior to submitting the guidance to the NRC for endorsement.

November: The industry submits the proposed final guidance to NRC for endorsement, assuming that little to no additional interaction needed after the September meeting.

NRC-Industry Interactions

During the regulatory interactions needed on the problem statement and guidance development outlined above, the NRC should share its concerns with the current implementation of 70.72 and provide its suggestions and examples for inclusion in the supplemental guidance. Such interactions and the incorporation of NRC input into the draft guidance would enhance regulatory efficiency associated with the NRC review and approval of the document.

Further, public discussions will help determine the form of the guidance, e.g., suggested modifications to RG 3.74 or a new NEI 13-XX document that would be endorsed by the NRC and referenced in RG 3.74 as an acceptable method available to licensees to demonstrate compliance with 70.72. Either way, the desired

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outcome is NRC-endorsed supplemental guidance for use by the industry that provides finality to the issue in the absence of a new safety concern.

Finally, any supplemental guidance including additional examples should not be considered by the NRC or the industry to be all inclusive so as to preclude licensees from making judgments outside those provided or discussed in the guidance. In other words, the guidance represents one acceptable method for licensees to demonstrate compliance with the requirement; it is not the only method, since licensees may propose alternatives for NRC acceptance.

In Closing

The fuel cycle facilities understand and respect their obligation to adhere to the change management requirements in 10 CFR 70.72 and, in doing so, fully support efforts to provide supplemental guidance on this important topic. Because of the significance of this issue, we request a prompt response on the industry proposal contained in this letter including whether the NRC can support the proposed schedule.

We look forward to further discussions at your earliest convenience. If you have any questions, please feel free to contact me or Andrew Mauer (202-739-8018; anm@nei.org).

Sincerely,



Janet R. Schlueter

c: Ms. Catherine Haney, NMSS, NRC
Mr. Anthony T. Gody, Jr., R-II/DFFI, NRC
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Mr. Robert K. Johnson Jr., NMSS/DFCSS/FMB, NRC