

July 8, 2014

Mr. Glenn M. Tracy
Director
Office of New Reactors
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Ms. Catherine Haney
Director
Office of Nuclear Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Industry input on NRC efforts to clarify 10 CFR Part 21; Docket ID: NRC-2012-0012

Project Number: 689

Dear Mr. Tracy and Ms. Haney:

Reporting of defects and failures to comply, and dedication of commercial-grade items are important activities of NRC-regulated entities, and we recognize the importance of clarifying the NRC requirements in these areas. In this regard, the Nuclear Energy Institute (NEI)¹, on behalf of the nuclear industry, has been working with the U.S. Nuclear Regulatory Commission (NRC) staff on efforts to clarify 10 CFR Part 21, as identified in SECY 11-0135.²

We recently participated in the NRC Vendor Workshop held June 12, 2014, and one of the NRC staff presentations outlined plans for 10 CFR Part 21 rulemaking. While rulemaking is always an option, our interactions to date with the NRC staff have focused on developing guidance that we believe is a viable alternative to rulemaking. We are concerned that focusing solely on rulemaking is premature given that

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.

² In SECY 11-0135, the NRC staff informed the Commission of their plans to clarify the requirements in 10 CFR Part 21, with the expressed intent of "improving Part 21 clarity, maintaining the original intent of the rule, and minimizing changes to currently compliant programs," and identified implementation issues in a draft Regulatory Basis issued in December 2012 (ML12248A200). I provided our initial input in a letter to Ms. Laura Dudes dated August 22, 2011 (ML112650013), where we stated that "the desired clarity can be provided most efficiently and effectively through new and revised regulatory guidance, and ... few if any rule changes appear necessary."

other alternatives exist and significant stakeholder concerns with the rulemaking (as discussed below) have not been addressed. This approach does not appear to be consistent with the NRC's Principles of Good Regulation or initiatives to address the cumulative impacts of regulation, and we request that the NRC delay its rulemaking activities to allow resolution of clarity issues through the development of guidance.

Through our discussions with the NRC staff on the issues identified in the draft Regulatory Basis, and our efforts to develop guidance, we remain confident that issues requiring enhanced clarity can be completely addressed through guidance, without any need to change the rule language in 10 CFR Part 21.³ Industry guidance documents, which clarify several of the issues, have already been submitted and are currently being reviewed for potential endorsement by the NRC, including EPRI guidance on software dedication (ML14085A054 and ML14085A084) and NEI guidance on the use of international accreditation for calibration and testing services (ML14155A354 and ML14155A355). The industry is finalizing additional guidance documents, that we plan to submit for NRC review and endorsement in the next few months, to clarify other issues, including NEI guidance on reporting and evaluation, and EPRI guidance on commercial-grade dedication. Given that clarifications can be achieved through guidance, the NRC's basis for revising rule language to reduce the number of words, as stated in the NRC Vendor Workshop, is an unnecessary use of resources.

We have noted that a few of the NRC-proposed "clarifications" constitute substantive changes to existing requirements, and are inconsistent with the long regulatory history of 10 CFR Parts 21, 50 and 70. These include changes in the areas of establishing the "point of discovery," duplicate reporting with 10 CFR 50.72 and 50.73, and the definition of "basic component" for fuel cycle facilities. The NRC-proposed changes to requirements in these areas are unnecessary because the existing requirements provide reasonable assurance of adequate protection of the public health and safety. Even if there were benefits associated with making the proposed changes to requirements in these areas, it does not appear that the NRC has considered the associated costs, consistent with the considerations in 10 CFR 50.109, nor that these costs could be justified. Specifically, the NRC-proposed changes would necessitate revisions to currently compliant programs, and would result in an unnecessary diversion of resources and increased costs to comply with the revised rules, contrary to the NRC's intent described in SECY 11-0135.

We understand that the NRC is planning to issue a revision to the draft Regulatory Basis for clarifying the 10 CFR Part 21 requirements and may include a proposed draft rule. We are concerned that the NRC focus on revising the rule language indicates that the NRC has already determined that rulemaking will be pursued, even if issues remain unresolved and other alternatives are available, and may be inconsistent with the NRC's rulemaking process. Since the publication of the draft Regulatory Basis in 2012, we have continued to

³ Addressing the duplication of 10 CFR 50.55(e) and 10 CFR Part 21 could be addressed by eliminating 10 CFR 50.55(e); however, this would be accomplished through a rulemaking for 10 CFR 50.55(e).

raise our concerns about NRC's plans in these areas⁴; however, the NRC still has not resolved these concerns or provided adequate justification to support rulemaking in these areas. In addition, there is little expectation that the next revision to the regulatory basis will address stakeholder concerns because there have been few opportunities to discuss them in any detail at public meetings since early 2013. Specifically, the following important issues, which were notably absent from the NRC's update of the Part 21 rulemaking efforts at the NRC Vendor Conference on June 12, 2014, are awaiting NRC action to enable stakeholder involvement.

- We have not received NRC feedback on a white paper we submitted in February 2014 (ML14059A217 and ML14059A218) that contains guidance language that clarify issues related to evaluation and reporting, including the unresolved issue of establishing the "point of discovery." We value any early NRC feedback, as we plan to incorporate the language from the white paper into industry guidance that we plan to submit for NRC review and endorsement as early as July 2014.
- We are still awaiting NRC-identified examples that clarify the issue of using evaluations and reports pursuant to 10 CFR Part 50.72 and 50.73 to satisfy the requirements of 10 CFR Part 21. The NRC indicated at a public meeting on May 30, 2013, that they would develop examples to clarify how the NRC believes the rule language is inconsistent with the original intent of the regulation (ML13172A093). Absent such examples, the basis for the NRC's concern about the current rule language is unclear.
- We have not received NRC feedback on concerns raised by the fuel cycle facilities as early as May 2013. Specifically, these include but are not limited to: 1) the potential for a lower risk reporting threshold at fuel facilities; 2) the fact that current exemptions are not precedential; 3) the fact that NRC is potentially creating a disincentive for the use of engineered controls (versus administrative controls); and 4) the fact that the safety basis for the proposed changes remains unclear.
- We are still waiting for the NRC to issue a white paper detailing insights from their site visits of fuel cycle facilities to inform the NRC proposal to revise the definition of "basic component" for fuel cycle facilities, which we understood, during NRC meetings held in October 2013 and January 2014, the NRC planned to issue in early 2014. This white paper would provide beneficial insights for industry to understand the basis for NRC's apparent planned revisions to 10 CFR Part 21, particularly a revised definition of "basic component."

Based on the above discussion, we recommend that the NRC delay the schedule for proposing rulemaking, and postpone publication of the revised draft Regulatory Basis, until all of the power-reactor-related guidance is completed and endorsed by the NRC, and the NRC addresses significant fuel cycle industry concerns prior to issuing any NRC draft guidance for comment. This approach also ensures the NRC focuses on resolving significant stakeholder concerns through the guidance development process and avoids unnecessary or unintended substantive changes to the requirements, which is a potential outcome of an

⁴ J. Schlueter, NEI letter to J. Kinneman, NRC dated April 3, 2013 on the cumulative effects of regulation; J. Schlueter, NEI letter to J. Kinneman, NRC dated May 31, 2013 on the draft regulatory bases.

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approach focused on rule changes. After the guidance is in place to address the clarity issues for 10 CFR Part 21, if there still remain issues that could not be clarified through guidance and can only be clarified through rulemaking, then a more focused rulemaking could be pursued. At this time, NEI takes no position on the need for such a rulemaking. We believe this is the most effective and efficient approach to achieving the desired clarity. Further, a focus on resolving issues related to clarity through guidance would be consistent with both the NRC's Principles of Good Regulation and initiatives to address the cumulative impacts of regulation (ML13113A163 and ML1311A172).

If you have any questions, please feel free to contact me, Marc Nichol (202.739.8131; mrn@nei.org) or Janet Schlueter (202.739.8098; jrs@nei.org).

Sincerely,

A handwritten signature in black ink that reads "Douglas J. Walters". The signature is written in a cursive, flowing style.

Douglas J. Walters

c: Mr. Michael C. Cheok, NRO/DCIP, NRC
Ms. Marissa G. Bailey, NMSS/FCSS, NRC
Ms. Margaret M. Doane, OGC, NRC
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