

DOUGLAS J. WALTERS
Vice President, Regulatory Affairs

1201 F Street, NW, Suite 1100
Washington, DC 20004
P: 202.739.8093
djw@nei.org
nei.org



May 5, 2015

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

Subject: Industry Comments on NRC's Revision 1 of the *Draft Regulatory Basis to Clarify 10 CFR Part 21, "Reporting of Defects and Noncompliance,"* dated March 2015; Docket ID: NRC-2012-0012

Project Number: 689

Dear Mr. Tracy:

The Nuclear Energy Institute (NEI)¹, on behalf of the nuclear industry, appreciates the opportunity to comment on the U.S. Nuclear Regulatory Commission's (NRC's) Revision 1 of the *Draft Regulatory Basis to Clarify 10 CFR Part 21, "Reporting of Defects and Noncompliance,"* (March 2015) (ML14135A207)(draft Reg. Guide).

Our detailed comments are included in Attachment 1 for reactor facilities and in Attachment 2 for fuel cycle facilities. Our overarching concern however is that NRC should pursue the most effective and efficient path to improve clarity for the existing 10 CFR Part 21 (Part 21). We believe this can be best accomplished by completing the review and endorsement of the existing industry guidance on Part 21 and evaluating the need for rulemaking after guidance is endorsed and has had some run time.

Implementation of Part 21 requirements over the last 38 years has been and continues to be largely successful. There are no deficiencies in the Part 21 requirements; however, a lack of clear guidance has resulted in a few minor clarity issues. Last year, the industry submitted two guidance documents that address all NRC-identified issues associated with clarifying the existing Part 21 requirements: NEI 14-09, Revision 0, (ML14245A415) was submitted in August 2014 and Revision 1 to EPRI NP-5652 and TR-102260

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.

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(ML14265A198) was submitted in September 2014. The NRC participated in the development of these guidance documents. The need for regulatory clarity is noted in the NRC letter to NEI dated October 28, 2014 (ML14232A816), which responded to industry input contained in our July 8, 2014 letter (ML14189A169). The NRC response states that "The staff is aware of the compliance challenges associated with Part 21 implementation." Given this acknowledgement it is unclear why, to-date, there has not been any acknowledgement of the two industry guidance documents or meetings scheduled to discuss these documents in more detail.

Delays in reviewing and endorsing the industry guidance documents means the clarity contained in them cannot be realized by the industry. The delay also raises concerns that the NRC does not find the guidance acceptable and may be considering new or changed regulatory positions. This is unsettling and creates regulatory uncertainty. Furthermore, it allows the compliance challenges to continue.

Additionally, the proposed rule is now scheduled for issuance in January 2017 (ML14345A672). This is about a four year delay from the original scheduled date presented in SECY 11-0135 and further contributes to regulatory uncertainty.

Although the intent of both efforts is to clarify regulatory requirements, there is no reason that these activities need to be coupled. Because the industry guidance clarifies existing requirements, it can be endorsed without a rule change. Similarly, a proposed rule change that only clarifies existing requirements would not invalidate the endorsed industry guidance. Decoupling also does not duplicate work, but rather allows clarity to be achieved in the near term by focusing on review and endorsement of guidance. This approach aligns with the NRC's Office of Inspector General's recommendation that the staff expedite review of the industry guidance (ML15089A311).

Regarding the draft Reg. Basis, we believe it is proposing new and changed regulatory positions which will greatly expand the scope and intent of the existing Part 21 requirements. For example, the proposed rule changes that would substantively change the Part 21 requirements are: 1) the definition of discovery, 2) the duplication of evaluations with 10 CFR 50.72 and 50.73, and 3) the definition of basic component for fuel cycle facilities. These new regulatory positions are based on what we view as significant inconsistencies and inaccuracies in the draft Reg. Basis rationale for Part 21 rulemaking, and are inconsistent with established regulatory language and positions found in the Part 21 regulations, statements of consideration issued to support previous final and amended rules, and policy papers (e.g., SECY-09-150). These substantive changes to the requirements proposed in the draft Reg. Basis do not address any safety issues, but will result in considerable costs to revise currently compliant industry programs and procedures.

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We are concerned about the draft Reg. Basis portrayal of substantive changes to the regulations as "clarifications," as the characterization is incorrect and could undermine the normal procedural steps to ensure an appropriate backfit evaluation is performed, consistent with 10 CFR 50.109, to determine if the proposed changes are justified. In our assessment, the NRC proposed rule changes are not justified on a cost-benefit basis. We urge the NRC to change the planned path forward so that the agency does not continue missing opportunities to improve clarity. We reiterate our request that the NRC complete review and endorsement of the industry guidance and postpone consideration of rulemaking until after guidance is endorsed. To this end, we request that the NRC commit to a timely schedule to review and endorse both industry guidance documents by October 30, 2015.

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

Sincerely,



Douglas J. Walters

c: Mr. Mark A. Satorius, EDO, NRC
Mr. Michael R. Johnson, EDO, NRC
Mr. Michael C. Cheok, NRO/DCIP, NRC
Ms. Catherine Haney, NMSS, NRC
Ms. Margaret M. Doane, OGC, NRC
Mr. Stephen D. Dingbaum, OIG/AIGA, NRC