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LTR-NRC-15-51

June 18, 2015

Subject: Westinghouse comments on Revision 1 of the Draft Regulatory Basis to Clarify 10 CFR Part 21, "Reporting of Defects and Noncompliance," dated March 2015 (ML14135A207)

Dear Mr. Cheok,

Westinghouse Electric Company LLC (Westinghouse) appreciates the opportunity to provide comments 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," dated March 2015 (ML14135A207).

Westinghouse endorses the comments submitted by the Nuclear Energy Institute (NEI) "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" (ML15131A366). Rather than reiterate the comments previously submitted by NEI in their May 5th letter, Westinghouse would like to add our own perspective on the issue of the development of staff endorsed guidance for Part 21 and the impact of the proposed rule on fuel cycle facilities (FCFs).

As seen in the following summary, the evolution of the NRC staff's views on clarifying Part 21 requirements through guidance has been inconsistent and the change from guidance development to rulemaking lacks justification. NRC has been working on a guidance document for Part 21 since at least 2011. In response to the NRC's Office of Inspector General's (OIG's) Audit Report OIG-11-A-08, "Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance", dated March 23, 2011 (ML110820426) recommendation two, the staff committed to "[e]xpeditious publication of interim guidance that specifies requirements for Part 21 reporting in accordance with the *Energy Reorganization Act of 1974, As Amended, Section 206, and Noncompliance*." The target completion date for the publication of the interim guidance was March 2012. Later in 2011, in SECY-11-0135, "Staff Plans to Develop the Regulatory Basis for Clarifying the Requirements in Title 10 of the Code of Federal Regulations Part 21, "Reporting of Defects and Noncompliance", dated September 29, 2011 (ML112430138), the staff told the Commission that they were developing guidance to address ambiguous definitions and clarify expectations with regard to Part 21, the staff also noted that no regulatory guidance had ever been issued for Part 21.

However, in the analysis and status of recommendations memo for OIG-11-A-08, dated December 20, 2012 (ML13007A030) it became clear that the staff had changed its position and decided to focus staff

resources on the development of the Part 21 regulatory basis. In the memo the OIG analysis states, in part, “OIG noted that publication of a regulatory basis document does not provide guidance but communicates the proposed basis for future rulemaking”. In addition, the OIG analysis says that the “agency reiterated that a form of interim guidance was earlier promulgated via the 2011 and 2012 NRC Regulatory Information Conferences, and that the slide presentations from those presentations are publically available via the agency web site and serve as guidance.” Westinghouse believes that presentations made at public meetings are not an effective means of providing enduring guidance and are certainly not a good substitute for a regulatory guide.

To that end, NEI submitted NEI 14-09, Revision 0, “Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance”, dated August 28, 2014 (ML14245A417) for review and endorsement. The issuance of a regulatory guide endorsing NEI 14-09 is the most efficient and effective way for the NRC to achieve its regulatory objectives. However, the staff stated in a public meeting on April 28, 2015 (ML15105A288) that, in essence, its hands were tied with respect to issuing guidance on the existing rule because the rulemaking process to revise 10 CFR Part 21 had started. The basis for the staff’s statement was the cumulative effects of regulation (CER) paper, SECY-11-0032, “Consideration of the Cumulative Effects of Regulation in the Rulemaking Process,” dated March 2, 2011 (ML110190027) and the associated Staff Requirements Memorandum. In that paper, the staff commits to provide draft guidance at the proposed rule stage and final guidance at the time of final rule publication as enhancements to the rulemaking process. This alignment of guidance within the rulemaking process does not prohibit issuing guidance on an existing rule, and Westinghouse believes the staff position in this case is an incorrect interpretation of Commission direction. It would be ironic if a Commission initiative designed to reduce regulatory burden is instead used to justify more regulation.

As to the impact on FCFs, the staff’s updated draft regulatory basis includes a process by which additional components at FCFs would be deemed to be basic components for the purpose of reporting under Part 21. The Columbia Fuel Fabrication Facility (CFFF) has an existing and compliant Part 21 program, which uses the existing consequence criteria for substantial safety hazard found in NUREG-0302. Westinghouse believes that the staff’s proposed new requirements for basic components at FCFs would result in an unwarranted lowering of the consequence threshold and additional requirements for basic components at an FCF. Consequently, the staff’s updated draft regulatory basis would result in additional basic components, procurement controls, commercial grade dedication and other requirements which would require additional resources with no added safety benefit. The staff acknowledged in the April 28 public meeting (ML15105A288) that they were unaware of any misreports or safety issues at fuel cycle facilities as a result of inadequate Part 21 implementation or differences in interpretation of the rule as it is currently written. If the NRC staff truly believes there is lack of Part 21 reporting on behalf of activities at fuel cycle facilities, the staff should collect data and evidence to verify their hypothesis. This rulemaking seems to be a solution in search of a problem.

When viewed through the lens of the May 19, 2015 Commission Briefing on the Cumulative Effects of Regulation and Risk Prioritization Initiatives and the Staff Requirements Memorandum, “Staff Requirements – SECY-15-0015- Project AIM 2020 Report and Recommendations,” dated June 8, 2015 (ML15159A234), it is clear that the staff’s rulemaking effort on Part 21 merits a fresh look. During the May 19th Commission Briefing, there was agreement among industry, staff and the Union of Concerned Scientists’ representative on the appropriateness of prioritizing issues and actions based on safety significance. If a prioritization were to be performed, Westinghouse believes the Part 21 rulemaking would be ranked very low in that context. The NRC has not provided any basis for rulemaking other than providing clarity, an objective that is better accomplished through guidance.

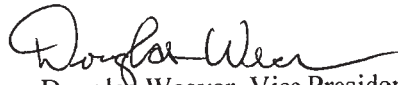
The staff has expended considerable resources on this effort and will need to invest considerably more to bring a rulemaking to completion, and yet this staff initiated rulemaking has not been explicitly approved

by the Commission and there is no guarantee that it ever will be. In keeping with the NRC's own Principles of Good Regulation, and being sensitive to the resource constraints that exist at NRC and within industry, Westinghouse respectfully suggests that this rulemaking be terminated. The staff should promptly review and endorse the NEI guidance and then re-evaluate the need for rulemaking once the guidance has been in effect for an appropriate period.

If the staff still believes that rulemaking is needed after industry guidance has been endorsed, then Westinghouse would encourage the NRC to perform a backfit analysis on the rulemaking to determine if the proposed changes are justified.

If you have any questions, please feel free to contact me or Rob Theuret (412.374.5304; theurer@westinghouse.com).

Sincerely,


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