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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

Introduction

The scope of the following comments are focused on NRC proposed changes to 10 CFR Part 21 that are applicable to fuel cycle facilities licensed under 10 CFR Parts 70 and 76, and their direct suppliers. The general comments on NRC proposed changes included in Attachment 1 are also applicable to fuel cycle facilities.

NRC regulated fuel cycle facilities currently comply with NRC Part 21 reporting requirements for identifying, reporting and sharing generic failures or defects of structures, systems and components (SSCs) that could result in a substantial safety hazard (SSH) as defined in Part 21. Each fuel cycle facility has policies and procedures in place to ensure an effective Part 21 identification and reporting program that is subject to NRC inspection. Further, we are not aware of any insights, information, significant inspection findings, data or trends at fuel facilities that would indicate otherwise, and we do not see such data in the draft regulatory basis.

In the Background section of the Regulatory Basis, the NRC's characterization of Congress' intent contains an error. The last sentence on Page 4 reads "What was fairly clear was that Congress wanted the Commission to address basic components that have been identified to contain a defect, which could result in the plant failing to meet its licensing basis." (emphasis added) According to the Energy Reorganization Act (ERA), the law states that the scope is for the NRC to be notified of a failure to comply or defect that could create a substantial safety hazard. It is noted that not all failures to comply with the licensing basis could create a substantial safety hazard.

We are concerned that the NRC's new interpretation unnecessarily expands the scope of Part 21 beyond that which is authorized by the ERA. We are also concerned that the NRC's misinterpretation of the ERA scope supports the basis for many of the substantive changes to Part 21 requirements as they relate to fuel cycle facilities. The NRC should revise this and similar other statements in the Regulatory Basis to be consistent with the scope authorized by the ERA.

1) Lack of Regulatory Guidance

We support the NRC's plans to address the few minor Part 21 issues through development of guidance. Industry is interested in working with the NRC to develop guidance specific to fuel cycle facilities (either through inclusion in NEI 14-09, or in a separate guidance document).

We disagree with the NRC statement that "Part 21 does not reflect recent advances in the regulatory framework that address risk management and application of management measures, to ensure, in part, that items relied on for safety (IROFS) are available and reliable to perform their intended safety function." The requirements in Part 21 are performance based and are sufficiently flexible to address the current regulatory framework for fuel cycle facilities. In contrast, the NRC proposed changes to Part 21 relating to fuel cycle facilities would result in a prescriptive set of requirements for which the majority of the fuel cycle facilities may need to seek exemptions or would be subject to the backfitting of new requirements.

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The statement in Section 1(b), second paragraph, first sentence on page 10, and the associated footnote 4 for "certain nonreactor licensees" are misleading in that they imply that all facilities licensed under Parts 30, 40, 50 (other than power plants), 60, 61, 63, 70, 71 or 72 all have NRC approved QA plans. This is not correct for the majority of fuel cycle facilities. Only a few fuel cycle licensees currently have Appendix B or NQA requirements applicable to IROFS. Generally, if these nonreactor licensees cited in footnote 4 have an NRC approved QA plan, it is because they are a reactor component supplier or for shipping package activities.

The NRC states that there have been many repetitive problems with licensees and vendors implementing Part 21 that were identified during inspections and stakeholder interactions are significant enough to warrant action. The statement is misleading and incorrect for the majority of fuel cycle licensees. There have been no examples of "implementation problems" or "inspection findings" for fuel cycle facilities, except in a few minor cases where the facilities were implementing Part 21 requirements under Appendix B or NQA requirements applicable to IROFS. Unfortunately, the NRC does not provide any examples for stakeholders to confirm the NRC assertion.

3) Lack of Clarity in the Definition of Basic Component for Nonreactor Facilities and Activities

NRC's proposed change to the definition of basic components for facilities and activities licensed under 10 CFR Part 70 and subject to Subpart H is a new regulatory position that would greatly expand the scope and intent of Part 21 requirements beyond the scope of the ERA. The NRC proposed definition would include all IROFS for which a defect or failure to comply could cause the performance requirements of Section 70.61 to be exceeded. This is a substantial expansion as compared to the current scope of "...basic component means [an SSC]...in which a defect or failure to comply...could create a substantial safety hazard." The NRC proposed change is unnecessary and inappropriate for the following reasons:

- Part 21 currently requires all licensees to evaluate their SSCs whose failure could cause a SSH as defined in Part 21.
- Based on a review of the 2000 NRC rulemaking involving 10 CFR Part 70, including Commission statements of consideration, and the recollections of individuals involved in that rulemaking, we believe that the ISA rule and definition of performance criteria and IROFS were never considered to automatically apply Part 21 to any or all IROFS. Further, there was no discussion during development of the ISA rule of any intent to apply, or a nexus with, a one-to-one definition of IROF with the Part 21 definition of basic component. Therefore, current efforts by the NRC to equate the definition of a SSH to the performance criteria in 70.61 are simply not justified or necessary and potentially constitute a backfit.

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- Part 70, Subpart H (the ISA rule):
 - requires licensees to monitor IROFS performance and failures, investigate such failures subject to NRC review and report them to the NRC when required
 - requires management measures to assure the availability and reliability of IROFS
 - provides for a graded QA program to ensure IROFS perform their intended function but does not impose NQA-1 or Part 50, Appendix B, QA program requirements.
- Part 70.64(b) states a preference for engineered controls over administrative controls due to their higher reliability. However, the staff's approach provides an incentive for the opposite outcome (see discussion below), making fewer controls subject to Part 21 reporting. The processing and manufacturing operations, as well as the safety systems, at Part 70 facilities are highly diversified and one facility's reports would be of little or no use to other facilities. Currently, the industry routinely discusses events and information of this type through the NEI's Fuel Operations Committee to share operational experience and lessons learned.

We disagree with the NRC's assertion that there is lack of clarity in the definition of basic component in the regulations, that this lack of clarity has resulted in inconsistent interpretation by industry, that these inconsistencies have limited evaluation and reporting under Part 21, and without changes to the requirements in Part 21 these factors will negate the underlying provision of Section 206 of the ERA. Addressing clarification issues through guidance can be effective in assuring that implementation of Part 21 is consistent with the requirements and licensing bases of fuel cycle facilities. Furthermore, the NRC has not provided any examples, in the form of violations documented in NRC inspection reports, where the NRC has not been notified of a Part 21 issue at a fuel cycle facility, or where the fuel cycle facility industry has not complied with the underlying provisions of the ERA. The NRC should provide these examples so that stakeholders can understand the NRC's underlying concern and determine the root cause of any noncompliance issues.

We believe that NRC licensees, including the fuel cycle facilities, understand and respect their obligation to protect public health and safety against hazards. In this case, however, the NRC has not yet provided a compelling reason to fix something that is not broken.

The Current Exemptions are Not Precedential

The staff states in the Draft Regulatory Basis (Section 3(a), last paragraph on page 15) that "Exempted definitions have been requested by and granted to multiple applicants and licensees that are constructing and operating new fuel cycle facilities. The exempted definitions have been very similar to the definition cited above and have all sought to define a basic component in terms that are defined within the regulatory structure of 10 CFR 70 (i.e. IROFS and performance requirements)". This statement is misleading. According to the footnote to this section, the multiple applicants NRC has referred to are two enrichment facilities and one MOX facility, who have adopted Appendix B or NQA requirements applicable to IROFS. The exemptions are only necessary to

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address the specific conditions when a facility licensed under Part 70 is also subject to QA requirements in 10 CFR Part 50, Appendix B. These exempted definitions are not applicable to Part 70 licensed facilities that are not subject to the 10 CFR Part 50, Appendix B, QA requirements. The majority of the facilities licensed under Part 70 have not requested similar exemptions. Imposing these exempted definitions would also impose other NRC requirements on Part 70 facilities and must be evaluated as backfits.

The Lowered Risk Threshold for Reporting is Not Justified

The staff proposes to modify the Part 21 definition of basic component—only for fuel facilities—by linking the 10 CFR 70.61 performance criteria to the current Part 21 definition of SSH in the absence of insights, information or data to support such a revision. It is important to note that exceeding the existing performance criteria would not necessarily result in a SSH as currently defined in Part 21—“loss of safety function to the extent that there is a major reduction in safety”. The performance criteria is the risk assignment factor used to demonstrate a credible accident sequence is highly unlikely. Licensees must demonstrate in the ISA process a credible event is highly unlikely considering both the event frequency of occurrence and providing controls (items relied on for safety (IROFS) to prevent or mitigate it. A failed control when multiple controls exist only changes the risk factor from highly unlikely to either unlikely or not unlikely and does not mean an unsafe condition exists. Meeting performance criteria is merely a condition for continued operation. In the nuclear power plant arena, the reporting of Part 21 comes into consideration when Appendix B-based quality barriers do not properly identify the nonconformance. This new and unjustified lowered risk level of reporting for fuel facilities is therefore not commensurate with that applied to commercial operating nuclear power plants.

Further, the proposed definition is based on precedent, existing guidance and a Memorandum of Understanding with the Occupational Safety and Health Administration. Based on the information the industry has reviewed to date, these sources do not, in and of themselves, appear to form an adequate safety basis for such a fundamental definition change. Also, such an overly conservative approach has not been justified, especially in view of the fact that the performance-based approach in Part 70 has provided an adequate safety basis for NRC regulation of the fuel facilities for a long time.

The New Disincentive for Use of Engineered Controls

The industry is concerned that one apparent unintended consequence of applying the staff's proposed new definition of basic component is that it results in a disincentive for the use of more reliable engineered controls—as preferred by 10 CFR 70.64(b)—and incentivizes the licensee to use administrative controls as IROFS. In the staff's proposal, administrative controls are segregated from engineered controls. While this may make sense with regard to Part 21, this is further indication that to equate IROFS to basic component was not contemplated by the ISA rule. Under the proposed changes, only engineered controls require the application of Part 21. Because the burden of applying Part 21 to engineered controls is so great, licensees might be inclined to apply more administrative controls and fewer engineered controls in their safety systems. Such an outcome where

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administrative controls become more attractive to licensees is the exact opposite of what §70.64(b) encourages and what some fuel facilities are doing today in the name of safety improvements. Under the existing requirements, facilities are reducing reliance on administrative controls and increasing reliance on more reliable engineered controls.

Additional Concerns

Section 3(c), third full paragraph, third sentence, page 20, "Thus, the fact that the performance requirements in 10 CFR 70.61 provide for protection of the worker is not contrary to equating these requirements with the Part 21 definition of "substantial safety hazard." This statement is very misleading as written. §70.61(b) 1 thru 4 define high consequence events that must be prevented or mitigated (e.g. 100 and 25 Rem, etc). If the frequency of occurrence of a credible event is determined to be less than or equal to 10^{-4} per event per year, engineered or administrative controls (IROFS) are identified and maintained to either prevent the event from occurring or mitigate its consequence. The loss or degradation of a selected IROFS in a particular accident sequence may cause a failure to meet performance requirements, but without an initiating event, will not cause any of the consequences in §70.61(b). Failure to meet performance requirements is a limiting condition of operation and may be reportable to NRC, but does not cause a substantial safety hazard.

Chapter 3, Section (C) beginning with the last sentence on page 60, "For materials and nonreactor facilities and activities, the current regulations and guidance would remain inadequate in describing NRC's requirements for dedication and could result in additional future licensing and exemption requests. The many repetitive problems with commercial grade dedication provide sufficient evidence that some type of regulatory action is needed to minimize these recurrent compliance problems." The statement is misleading because rather than this being a fuel cycle industry issue, the dedication issues being referred to have all occurred at the few facilities who have adopted Appendix B or NQA requirements applicable to IROFS and currently have a dedication requirement. This issue is best addressed through guidance and does not require rulemaking to clarify.

15) Lack of Clarity in Evaluating and Reporting Requirements for Part 70 Licensees

We agree with the NRC that rulemaking would result in an overly-prescriptive rule and could also result in unintended consequences by forcing applicants and licenses to revise procedures when such changes are not necessary to comply with the current requirements and should be at the discretion of the applicant or licensee. The flexibility afforded by addressing this topic through guidance is appropriate and consistent with a more risk-informed performance-based approach to the regulatory framework.

Industry is concerned about the NRC's proposed resolution of this topic as it appears to be inconsistent with the current licensing bases of many fuel cycle facilities. We are interested in working with the NRC to develop guidance specific to fuel cycle facilities (either through inclusion in NEI 14-09, or a separate guidance document), and we believe a solution can be developed that provides clarity in a manner consistent with the existing requirements and licensing bases.

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D) Definition of Dedicated Entity

The staff states in the Draft Regulatory Basis (Section D(b), last paragraph on page 61) that "Since 2008, the NRC has approved a number of exemption requests that have been submitted to the agency by fuel cycle facility applicants and licensees because of their inability to effectively design and construct new enrichment and fuel fabrication facilities under the current provisions of Part 21." This statement is misleading. The only known applicants that have sought exemptions to Part 21 are two enrichment facilities and one MOX facility, which have adopted Appendix B or NQA requirements applicable to IROFS. These exemptions have not been requested by any other fuel cycle facilities and should not be incorporated into the regulations as a backfit on facilities that do not wish to take exemption to these requirements. We do agree that the definition of dedicating entity could be clarified in guidance.