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NUCLEAR ENERGY INSTITUTE

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Mr. John D. Kinneman
Director, Fuel Cycle Safety and Safeguards
Office of Nuclear Materials Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Industry Comments on Draft Part 21 Technical Basis as Discussed During April 11, 2013, Public Meeting

Project Number: 689

Dear Mr. Kinneman:

On behalf of the fuel cycle industry, the Nuclear Energy Institute (NEI)[1] appreciates the NRC staff presentation on and opportunity to discuss the Draft Technical Basis for the proposed 10 CFR part 21 rulemaking with U.S. Nuclear Regulatory Commission (NRC) officials during the April 11, 2013, public meeting in Atlanta. This letter summarizes the industry's comments and concerns expressed during that meeting and responds to the three questions on NRC meeting slide 20. We hope you will find this input useful as the NRC staff proceeds to finalize the technical basis and make a decision on whether to proceed with this rulemaking.

The Fuel Facilities Are in Compliance with Part 21

Most importantly, 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. Accordingly, we are skeptical that there is a compelling regulatory basis for the proposed rulemaking as

[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.

it relates to fuel cycle facilities. To ensure that our position is as informed as possible, the industry would be interested in reviewing any information to the contrary if the NRC has such information.

The Safety Basis for the Proposed Part 21 Rulemaking Remains Unclear

The industry has been discussing Part 21 proposed changes with the NRC since June 2011. Consistent with industry comments, it remains unclear as to what the safety or regulatory basis is for an NRC rulemaking to modify Part 21, which would apparently impose a more conservative and redundant reporting framework, including a significant expansion of commercial-grade dedication program applications at all regulated fuel facilities. Specifically, the NRC's new desired outcome of categorizing Items Relied for Safety (IROFS) as basic components (and thus applying Part 21 reporting requirements to IROFS) appears not only misguided but also 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 Part 21 explicitly. 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.
- 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 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. As a result, the industry most recently characterized this

rulemaking,[2,3] in the context of the cumulative impact of regulations initiative, as one that should be withdrawn to allow finite industry and NRC resources to focus on other industry or NRC-led initiatives that have the potential to result in safety improvements.

The Current Exemptions are Not Precedential

The staff states on page 14 of the Draft Regulatory Basis that it is important to add a new definition of basic component specific to Part 70 licensees because of the number of exemptions granted for new facilities and the "wide array of interpretations among licensees as to which items are basic components." We respectfully disagree with this statement. The fact is that the NRC's current preferred approach to this matter (the definition of a basic component for Part 70 licensees) has manifested itself through the relatively recent licensing process for one NRC enrichment facility, one facility currently under construction, and others to be constructed. In contrast, there is not a "wide array" of interpretations of Part 21 reporting requirements among the Part 40, 70 and 76 facilities which have been in operation since the 1950s, long before Part 21 was promulgated.

Further, and more fundamentally, the safety basis for applying the approach represented by the proposed definition of basic component to the entire fuel cycle fleet remains unclear. In that regard, NRC slides 9-10 from the April 13 public meeting may be somewhat misleading. Specifically, at least one exemption was voluntarily requested by the licensee and granted by the NRC based solely on the need for that facility which--per 70.23(b)--is required to maintain a 10 CFR Part 50 Appendix B Quality Assurance program. In this instance, adherence to the NQA-1 program to meet Appendix B requirements was *not* based on a safety concern, issue or finding by either the licensee or the NRC. Such facility-specific licensing actions are not, in and of themselves, an adequate regulatory basis for applying this approach across the industry.

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"—because the performance criteria are used as the consequence and/or occurrence component of risk in the risk reduction approach of the ISA process. 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.

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[2] NEI letter dated April 16, 2013 from Anthony Pietrangelo, NEI to Michael Johnson and Michael Weber, NRC.
[3] NEI letter dated April 3, 2013 from Janet Schlueter, NEI to John Kinneman, NRC

Further, according to NRC slide 9, 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 incentivize 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 administrative controls become more attractive to licensees is the exact opposite of what 70.64(b) encourages and some fuel facilities are doing today in the name of safety improvements. In this case, facilities are reducing reliance on administrative controls and increasing reliance on more reliable engineered controls.

Industry Responses to NRC Questions on Meeting Slide 20

The following discussion responds to the three questions asked of the industry by the NRC on meeting slide 20 used during the April 11 public meeting.

1. **Industry ideas for clarifying definition of basic component and justification**

As discussed during the April 11, 2013, public meeting, the industry believes that the focus of any Part 21 rulemaking should first consider the definition of SSH, rather than basic component. Instead, the draft regulatory basis proposes a new definition of basic component specific to fuel cycle facilities, which is directly linked to SSH, but the regulatory basis is silent on the adequacy of the current SSH definition. As a result, the industry offers the following proposed definition of SSH--specific to fuel facilities--for NRC's consideration should the NRC decide to proceed with rulemaking.

The following proposed definition addresses the unique risks posed by fuel cycle facilities, such as soluble uranium and chemical exposures, and could be used by the industry to determine whether they have basic components subject to a revised Part 21.

Substantial Safety Hazard — A condition in which no safety or security control exists so that the degree of protection provided to the public health and safety could result in:

(1) An acute worker dose of 1 Sv (100 rem) or greater total effective dose equivalent
(2) An acute dose of 0.25 Sv (25 rem) or greater total effective dose equivalent to any individual located outside the controlled area
(3) An intake of 30 milligram or greater of uranium in soluble form by any individual located outside the controlled area
(4) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that:

(i) Could endanger the life of a worker, or
(ii) Could lead to irreversible or other serious, long-lasting health effects to any individual located outside the controlled area.

2. What are the concerns with implementation of Part 21?

- **Vendors –** There are virtually no qualified vendors for the type of safety-related components that are in use in the safety-related systems at fuel facilities. This shortage translates to a very significant component qualification or dedication effort for literally thousands of items (assuming all IROFS are basic components which is an assumption the industry disputes) that are in service today or could be in service tomorrow.
- **Commercial Grade Dedication (CGD) –** Most of our safety controls that form IROFS are off-the-shelf items and are therefore configured from a number of components, all of which would need commercial grade dedication—this would be a significant manpower effort for questionable benefit. In fact, dedication in this context could be a significant resource diversion from ensuring continued safe operations.
- Further, this CGD concept for fuel facilities that are not subject to Part 50 Appendix B requirements would be a completely lopsided burden that would be imposed on the licensee only. For reactors and others under Appendix B, there is a shared responsibility related to Part 21 reporting (both the qualified vendors and licensees have responsibility).
- Irrespective of Part 21, licensees must meet the performance requirements of Part 70 which include graded QA, performance monitoring, and corrective action for IROFS and reporting of certain conditions to the NRC. Therefore, the quantifiable benefit from diverting finite available resources is questionable at best.
- **Technical Experts –** Some licensees have already estimated the need for at least approximately six full-time personnel in quality assurance, engineering, and purchasing to oversee the program that would result from the staff proposal, and there is an undetermined impact to facility work practices and increased cost of procured items. These impacts do not appear justified from a safety perspective and might warrant a backfit analysis since the application of Part 21 to IROFS was not

even mentioned, and to the best of our knowledge not even considered, in the revised ISA rule in Part 70 that went into effect in 2000.

3. **What do licensees do currently to ensure compliance with Part 21?**

As stated previously, the fuel cycle facilities are subject to and are in compliance with current Part 21 requirements for identifying, reporting and sharing generic failures or defects of SSCs that could result in a SSH as defined in Part 21. Each 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. To ensure that our position is as informed as possible, the industry would be interested in reviewing any information to the contrary if the NRC has such information.

In closing, we look forward to further discussions on this topic and those which were the subject of the May 30 NRC public meeting, e.g., definitions of point of discovery, deviation and defect. 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. Leonard D. Wert, Jr., R-II/RA, NRC
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