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June 8, 2012

Mr. Michael F. Weber
Deputy Executive Director for
Materials, Research, State and Tribal Programs
Office of Executive Director
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Regulatory Process Concerns Regarding Current NRC Position on Design Features (see NRC letter dated May 7, 2012 to NEI)

Project Number: 689

Dear Mr. Weber:

On behalf of the fuel cycle industry, the Nuclear Energy Institute (NEI)¹ writes to express its significant concern regarding the regulatory process employed by the U.S. Nuclear Regulatory Commission (NRC) staff in arriving at, communicating, and implementing its current position on industry's long-standing use of the design features concept at some fuel cycle facilities implementing Integrated Safety Analysis (ISA) programs pursuant to 10 CFR Part 70 Subpart H. Specifically, the regulatory position documented in NRC's May 7, 2012 letter² does not reflect the fact that NRC has approved ISA methodologies which rely on the use of facility-specific features (e.g., initial conditions of process equipment, structures, and structural components) that are not identified and listed as Items Relied on for Safety (IROFS). Rather, such features are identified in the ISA in terms of descriptions of each process as required by 10 CFR 70.65(b)(3). These process descriptions, and associated drawings that depict the process, identify features that reflect normal operating conditions that exist prior to determining process deviations (i.e., upset conditions or credible abnormal events). Such features could also include an attribute of the design or a bounding initial condition that renders an accident sequence as "not credible". This methodology has been

¹ NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

² Letter from John D. Kinneman (NRC) to Janet R. Schlueter (NEI), "U.S. Nuclear Regulatory Commission Response on Use of Design Features to Meet Requirements in Title 10....."

incorporated as the direct result of applying effective and relevant chemical industry process hazards analyses guidelines endorsed by NRC in NUREG-1513 and NUREG-1520, and we believe it is consistent with the requirements of Part 70 Subpart H. Nonetheless, the staff seems intent on imposing this changed position without giving meaningful consideration to the burden associated with this change. This is especially troubling given that the staff has not identified a safety issue that compels re-categorization of process equipment that was considered as the initial conditions and bounding assumptions of the analysis (i.e., design features) as IROFS. Industry believes that such re-categorization will divert scarce resources that would otherwise attend to higher priority and safety valued activities to a very resource intensive licensing initiative that would yield minimal, if any, safety benefit. Additionally, while the May 7th NRC letter acknowledges the need for guidance, the staff has not issued any guidance to assist licensees with implementing this changed position or offered a timeline for doing so. Based on our lengthy experience with this issue, we propose a path forward, which is described later in this letter for your consideration.³

Background

Both industry and NRC have worked diligently to address the proper use of the design features concept; however, it is clear that after nearly three years of engagement, we disagree with the staff position articulated in the May 2012 letter. Specifically, much of the impetus for revising Part 70 in the late 1990s was to require a more integrated and risk-informed hazards analyses of site operations. The purpose was to ensure that facility resources were allocated to and focused on the higher risk activities, creating a critical differentiation of IROFS for operations personnel. While it is recognized that the starting point for each facility-specific ISA was not well defined at the time, these analyses were based on credible and applicable chemical industry standards, which NRC endorsed as appropriate for accomplishing the hazards analysis required by regulation and supported by guidance.

In addition, each licensee submitted their ISA methodology for NRC approval prior to developing the ISA and submitting the ISA Summary to NRC for approval. The ISA Summary--currently submitted annually to NRC--included the process equipment descriptions and, for many, the use of and reliance on the concept of design features with a complete list briefly describing each IROFS in sufficient detail to understand its functions in relation to the performance requirements of § 70.61. Licensees applied controls and control systems (i.e., IROFS) to meet the performance requirements and, in some cases, process equipment did not reach the threshold of IROFS designation and were identified as initial conditions or bounding assumptions (e.g., design features as described in NUREG-1520, pages 3-B-4, 5 or a similar term of art). The staff's current position blurs and undermines the fundamental and previously accepted distinction between initial conditions or bounding assumptions (process design features) and IROFS while failing to identify a safety concern.

³ Please note that Industry does not intend this letter to be a petition for rulemaking.

It is also important to note that this issue is relevant to fuel facilities licensed and expected to be licensed in the near term under 10 CFR Part 40.⁴ In that regard, we reviewed SECY-12-0071 and noted the dismissive tone of many of the staff's responses to stakeholder comments submitted on the proposed rule. Specifically, industry comments on the proposed Part 40 were submitted in earnest to address current Part 70 implementation issues, including the use of design features, which will now be propagated into Part 40. After participating in the February 2008 NRC public meeting on Part 40 (first of two meetings), industry suggested: 1) in its Part 70 petition for rulemaking; 2) during the August 2011 Part 40 public meeting (held at industry's request); and 3) in comment letters on proposed Part 40 that conforming changes to each Part would be necessary to address ongoing implementation issues, and were an efficient and desirable outcome. However, such modifications have not been included in the draft final Part 40 rule currently before the Commission for approval.

Chronology

We also believe that the history of this regulatory issue should not be summarily dismissed as it demonstrates an implied and, in some cases, explicit acceptance by NRC of the use of design features by some facilities to demonstrate a risk graded approach to safety analyses. The history is briefly summarized as follows:

- **September 2000** - Current Part 70 rule is promulgated without associated NRC guidance.
- **2000 - 2008** - ISA Methodologies are developed by licensees and approved by NRC. Licensees continue to develop new ISA plans, perform ISA related work, submit annual summaries for review, and maintain ISAs. Formal review of the ISA including RAI's (some of which touch on the design feature topic) with vertical and horizontal "slice" visits by NRC staff to test the details of the methods applied to the site specific ISA's also were performed prior to NRC approval of the ISA. Some methodologies included the use of the concept of design features and bounding assumptions. We are not aware of any expressed NRC objection to this approach.
- **May 2001** - NUREG-1513 was issued which recognizes the American Institute of Chemical Engineers (AIChE) 1992 guidance as "the AIChE text is clear, comprehensive, and is well-suited to practitioners of hazards analysis." This methodology clearly distinguishes between process equipment (i.e., design features) and safety controls (i.e., IROFS) and was the basis for most licensee ISA methodologies.
- **March 2002** - NUREG-1520, Rev. 0, issued after licensees had submitted their ISA plans for approval and were well into the work of preparing for and conducting ISAs in accordance

⁴ NEI letter dated September 9, 2011 to Annette Vietti-Cook, Secretary to the Commission.

with their approved plans. It contained no information contrary to that in NUREG-1513 nor the principles described in the AIChE handbook.

- **Late 2008** - In the absence of any generic communication or discussion with industry, NRC begins questioning ISA records and documentation and taking enforcement action against individual licensees.
- **Summer 2009** - In good faith, industry identifies a generic issue with regard to the distinction between the concept of design features and IROFS, based on facility-specific NRC actions. Industry promptly raises the issue to NRC with the goal of identifying a mutually-acceptable solution (e.g., guidance or rulemaking).
- **2009 - 2011** - Industry engages with NRC staff during several public meetings on the topic of design features in order to develop a generic solution.
- **May 2010** - NRC issues Rev. 1 of NUREG-1520. Pages 3-B-3 and 4 provide the following guidance "...facility or process features (or physical and chemical phenomena) that can affect the initiating event likelihood may be identified as initial conditions or bounding assumptions. The important factor is that these initial conditions and bounding assumptions must be identified and, if susceptible to change over the lifetime of the facility (such as through process deviations or facility changes), must be appropriately maintained."
- **2010 - 2011** - NEI, on behalf of industry, submits three letters to NRC (e.g., one of which was a "white paper" discussing industry's use of design features and one included a markup of NUREG-1520) to facilitate timely resolution of this generic issue.
- **May 2012** - NRC letter to NEI with final position on design features, which is inconsistent with the agency's prior position in the absence of a safety issue. No implementation guidance issued in draft or final and no timeline provided for its development and issuance; nor any clarity on enforcement treatment of the position's application to the licensee.

Suggested NRC Next Steps

Given this protracted history, we recommend that NRC senior management take the following steps: If a change in position regarding the distinction between design features and IROFS is deemed necessary after appropriate consideration of the concerns described in this letter and cumulative effects of such a position, direct the staff to utilize one of the agency's existing, transparent regulatory processes to effect such a change (e.g., issue a proposed rule or new or revised guidance articulating the changed position and its regulatory basis).⁵ Further, if the staff believes that the distinction between design features and IROFS presents a compliance issue for some (a position with which the industry disagrees), enforcement discretion or similar regulatory posture should be

⁵ We are aware of draft NRC design features guidance made available to support an April 2010 meeting. This guidance was not issued in draft for comment but its issuance could be an appropriate next step.

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exercised to allow corrective action to be taken on an appropriate schedule – given the absence of an identified safety issue and the history of this issue.

Cumulative Effects of Regulatory Action

Resolution of this matter is of utmost importance to industry. More specifically, in the absence of NRC guidance on its revised position, the May letter to NEI has resulted in some confusion by licensees on the appropriate next step. As such, one facility filed a 24-hour non-compliance report with the agency. Prior to that, one facility filed a 24-hour non-compliance report with the agency based on the NRC's June 28, 2010, summary of a public meeting on the use of design features. Further, facility-specific activities undertaken to "conform" to NRC's position have been and will continue to be technically complex and time consuming, and will divert limited facility resources from day-to-day operations in the absence of a clearly articulated safety issue. This outcome is clearly undesirable and unacceptable. In light of recent discussions with NRC staff on such issues as: 1) possibly new NRC positions on existing Part 21 reporting and dedication requirements for IROFS; 2) the Unresolved Regulatory Issues identified as a result of the Post-Fukushima Temporary Instruction; and 3) related regulatory initiatives and rulemakings (e.g., Parts 40 and 74, cyber security, chemical security, etc.), we are very concerned about the cumulative effects of this non-safety based NRC regulatory action when combined with potential actions needed by licensees to address other priority matters.

Given the importance of this matter, we would welcome additional dialogue and a prompt response to this letter. Should you have any further question, please do not hesitate to contact me at 202.739.8098; jrs@nei.org.

Sincerely,



Janet R. Schlueter

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