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Ms. Cindy K. Bladey
Chief, Rules, Announcements and Directives Branch
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Industry Comments on Draft Regulatory Guide-3037, "Guidance for Fuel Cycle Facility Change Processes" issued July 2011 (Docket ID NRC-2009-0262)

Project Number: 689

Dear Ms. Bladey:

On behalf of the fuel cycle industry, the Nuclear Energy Institute (NEI)[1] submits the following general comments and attached specific comments for the staff's consideration as it finalizes Draft Regulatory Guide DG-3037 on the facility change process for fuel facilities which was issued in July 2011 for public comment. We appreciate that the U.S. Nuclear Regulatory Commission (NRC) granted industry's request for an extension of the comment period from August 12 to September 16, 2011, as industry has been focusing simultaneously on several high priority regulatory matters, e.g., Proposed Part 40 rulemaking and the fuel cycle oversight process while assuring the safe operation of its facilities. In that regard, this guide does not appear to be applicable to Part 40 facilities yet the facility change requirements proposed in 10 CFR 40.86 are analogous to those in 10 CFR 70.72. NRC should consider clarifying this issue in the final guidance document.

By way of background, NRC and industry recognized the need for additional guidance on this important topic as early as 2007, subsequently formed an NRC-industry co-chaired working group to develop it, and NRC issued the first version of DG-3037 in 2009 for public comment. Industry

[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.

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supported the related 2009 and 2010 NRC public meetings, and submitted comments on DG-3037 to NRC in an NEI letter dated August 14, 2009. To that end, we respectfully request that NRC inform industry of its disposition of industry comments prior to issuance of the final guide given the history of this regulatory issue and its generic nature to the nuclear industry as a whole, as discussed later in this letter. Our general comments on DG-3037 are summarized below.

First, based on our review of the current DG-3037, industry believes that it provides minimal clarity on the 10 CFR 70.72 facility change process and, where appropriate, we offer specific edits in the enclosure to provide additional clarity. As you area aware, this regulatory issue remains critical and of the utmost importance to the fuel cycle industry since one new fuel facility began operations in 2010 and four facility applications are under active NRC review with construction to begin as early as 2012. In that regard, in a letter dated January 24, 2011 from NRC to Louisiana Energy Services, NRC acknowledged that there may be some circumstances where changes may be implemented prior to formal NRC approval and stated its intent to engage industry to determine the appropriate circumstances where changes can be made pending final NRC approval of a submitted license amendment request. Industry welcomes such a public dialogue with NRC to ensure a mutual understanding of these important matters. As noted in a letter dated September 8, 2011 from NEI to NRC on proposed changes to the NRC Enforcement Policy, NEI believes that a similar process to NRC's Changes during Construction (CdC) Preliminary Acceptance Review (PAR) process, which is currently under development for new reactors, should be considered for use in facilitating changes during construction needed at NRC-licensed fuel cycle facilities. We look forward to working with NRC in developing a similar process.

Secondly, it is also important to recognize the need for consistency in facility change management processes, requirements and expectations across the entire commercial nuclear industry. Licensees and applicants under 10 CFR Parts 40, 50, 52, 70, and 72, routinely develop, implement and rely on effective configuration management programs and processes to ensure compliance with their respective regulatory requirements. For example, in 2010, industry submitted NEI-96-07, Appendix C for NRC review and endorsement and responded to NRC comments by issuing a subsequent version in 2011. NRC is also preparing to issue a Draft Interim Staff Guidance on this matter which is informed by NEI-96-07, Appendix C. In that regard, our comments on this version of DG-3037 are informed by these related efforts but could be influenced further by final NRC guidance issued for various licensee categories. We trust that NRC will, prior to issuing DG-3037 in final, ensure that this generic regulatory matter is coordinated internally to ensure consistency across NRC while allowing an appropriate degree of flexibility for changes during construction and operations across the entire nuclear industry. This should be a risk-informed graded approach that is also applied to NRC's current efforts to modify the enforcement policy by addressing inspection findings involving the change process and compliance with regulatory commitments and requirements.

Finally, industry suggests that NRC issue DG-3037 in final without the use of broad and generic statements alluding to incidents, inconsistencies, and insufficient detail as included within Sections A and B of the DG, in the absence of a significant safety issue or concern. The NRC staff should specifically examine the subjective text in Section A (2nd Paragraph) and Section B (2nd and 3rd Paragraphs) and consider removing or modifying it.

Thank you for the opportunity to submit these general comments and attached specific comments for the staff's consideration, and we look forward to hearing from NRC on how it dispositions industry's comments and then reviewing the final guidance document. If you have any questions on this matter, you may contact me or Andrew Mauer of my staff (202-~~738~~-8018; anm@nei.org).

Sincerely,

Janet R. Schlueter

Enclosure

c: Mr. John D. Kinneman, NMSS/FCSS, NRC
Mr. Anthony T. Gody, Jr., Region II/DFFI, NRC
Mr. Kevin J. Morrissey, NMSS/FCSS/SPTSD, NRC

ENCLOSURE

INDUSTRY SPECIFIC COMMENTS ON AND EDITS TO DG-3037 ON THE FACILITY CHANGE PROCESS ALLOWED BY 10 CFR 70.72

Page 2, Section A. "Introduction", Paragraph 1
This guide does not appear to be applicable to Part 40 facilities yet the facility change requirements proposed in 10 CFR 40.86 are analogous to those in 10 CFR 70.72. NRC should consider clarifying this issue in the final guidance document.

Page 2, Section A. "Introduction", Paragraph 2
"This regulatory guide is a rule as designated by the Congressional Review Act (5 U.S.C. 801-808). However, the NRC has determined that this regulatory guide is not a major rule as designated by the Congressional Review Act and has verified this determination with OMB."

NEI understands that with certain limited exceptions, the definition of "rule" under the Congressional Review Act (5 U.S.C. 804) parallels the definition of "rule" provided in the Administrative Procedure Act (5 U.S.C. 551). In turn, the Administrative Procedure Act broadly defines "rule" to include regulatory tools, such as "interpretive rules," which are "issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers," but "do not have the force and effect of law." *Shalala v. Guernsey Memorial Hosp.*, 514 US 87, 99 (1995). Thus, NEI does not interpret the above-quoted statement regarding the Congressional Review Act to have any impact on, or contradict, the NRC's statement that "[r]egulatory guides are not substitutes for regulations and compliance with them is not required." DG-3037, at pg. 2. While NEI does not believe that the NRC intended to change the legal effect of this Regulatory Guide by including the statement regarding the Congressional Review Act, we recommend that the NRC provide a more explicit explanation to this effect to avoid confusion.

Page 2, Section B. "Discussion" Paragraph 4
"The ISA summary is a major element of the facility's safety program, and the NRC staff reviews it to maintain timely knowledge of changes to the facility and its safety program."

The ISA summary does not necessarily provide "timely" knowledge to NRC as the term is typically used by NRC in its regulations and guidance, e.g., days, months. Rather, the ISA Summary is an extract of more complete safety documentation used at the site. Essentially, the purpose of the ISA Summary is to meet a Part 70 regulatory requirement. Also, the NRC staff reviews the annual summary of changes once a year at some point after its submittal depending on available resources; therefore, it should be recognized that some facility modifications could be more than one year old by this time.

Page 3, Section B. "Discussion" First Paragraph Following Bulleted Items
First, the second sentence should be moved to Section C, Item 2.4 since it is relevant to sole IROFS. Also, for changes that require NRC approval, the licensee must submit a license amendment request

pursuant to 10 CFR 70.72(d)(1). Additional clarity is needed regarding what information in the license application a licensee would amend. For example, if a licensee finds a control system that uses blue-tooth technology and if the licensee does not have prior experience with this technology, the guide implies that NRC would expect the licensee to submit a license amendment. Another example would be where a chemical process change is made (HCL instead of HNO3) and DG Item 2.1.a. implies that NRC would consider such a change to be a "New Type of Accident Sequence."

Finally, the licensee must briefly summarize all changes to the safety program made in the previous year for which it did not receive prior NRC approval and submit them in an annual report to the NRC under 10 CFR 70.72(d)(2). For example, if a licensee decides to lower the threshold for requiring hearing protection, or for ALARA purposes, increases the PPE required for a job, these actions constitute "changes to the safety program." However, licensees do not currently submit these types of changes to the NRC in the annual summary of changes. Rather, in accordance with 10 CFR 70.72, licensees submit an updated ISA Summary and a listing of facility modifications made during the year and do not send in a summary of all changes to the safety program made during the previous year. NRC has not provided a corresponding technical basis to justify this apparent change in regulatory position.

Page 3, Section C, Item 1.a.
The phrase "that could affect the safety program" should be added to the end of sentence one for clarity and consistency with sentence three of this Item.

Page 3, Section C, Item b.3.
The phrase "that could affect the safety program" should be added to the end of the sentence for clarity and consistency.

Page 4, Section C, Item 2.a.
"The written evaluation . . . should clearly document the licensee's reasoning." NRC should clarify whether this evaluation refers to the one on site or the information in the annual update to the ISA Summary. The regulation only requires that a list of such changes be provided along with an updated ISA Summary. It does not necessarily require this list or the annual summary of changes to include a licensee justification for their exclusion from pre-approval by NRC. NRC has not provided a corresponding technical basis to justify this apparent change in regulatory position.

Also, the phrase, " . . . simple reliance on the level of detail and description provided in the ISA Summary is not sufficient" warrants clarification as industry is unsure of NRC's expectation with regard to the ISA Summary.

Page 4, Section C, Item 2.1.a.
The section title includes the words "types of accident" but these words are missing from the first sentence in the paragraph. In their absence, the sentence takes on a new and perhaps unintended meaning. Also, the examples could potentially be problematic for licensees depending on how an

inspector interprets the applicability of the examples during an inspection. We suggest an alternative example such as, "a licensee that adds processing of UF6 to its facility and currently does not store or process UF6." Such an example would be clear that new types of accident sequences would require a pre-approval by NRC.

Also, industry does not believe that " . . . adding a sprinkler system to an area where the moderator is not currently available," is necessarily a new type of accident sequence. Moderator intrusion is a possibility anywhere, and licensees already have many similar moderator intrusion situations and accident sequences. For example, fire-fighting scenarios need to be addressed whether or not sprinklers have been used for this function in the past or not. This Item appears to conflict with the Item immediately following, which reads " . . . unless the chemical is used elsewhere in the facility and is already described in the ISA Summary."

Page 5, Section C, Item 2.4

Industry is concerned that, like the 2009 version of this guide, the wording of this Item does not reflect the 2007 working group's consensus position but rather subsequent NRC comments during the June 2008 NRC Fuel Cycle Information Exchange. As such, we suggest that the wording on the alteration of a sole IROFS be modified to reflect the consensus position, particularly in the absence of a demonstrated safety basis that would necessitate NRC review of licensee-initiated program changes that "positively" affect sole IROFS and therefore increase the safety margin. Also, the term "alter," as it is used in 10 CFR 70.72(c)(3), should be read as meaning any change to the IROFS that will decrease the effectiveness of any of the attributes related to the safety function of the sole IROFS. Changes that do not decrease the effectiveness of these attributes of the sole IROFS are not considered alterations.

Page 5, Section C, Item 3.a.1.

" . . . the licensee should demonstrate that the ISA Summary already lists accident sequences of the same type." NRC should clarify the term "demonstrate." For example, if there are pre-existing accident sequences of the same type, the conclusion should be self-evident. The same concept and comment applies to Sections (2) and (4) immediately below.

Page 5, Section C, Item 3.a.3.

Consistent with our comment on Section C, Item 2.4, we suggest that the wording on the alteration of a sole IROFS be modified to reflect the consensus position, particularly in the absence of a demonstrated safety basis that would necessitate NRC review of licensee-initiated program changes that "positively" affect sole IROFS and therefore increase the safety margin.

Page 6, Section C, Item 4.a.

"...the NRC requires licensees to submit an annual report briefly summarizing all such changes made to the safety program in the previous year, in accordance with 10 CFR 70.72(d)(2). This provision's reference to 10 CFR 70.62(a)(2) is to the facility safety program records, which consist of the process safety information, the ISA, and the management measures."

Licensees are not required to send a summary of "all changes made to the safety program" made during the previous year nor has the annual summary typically included "process safety information." First, many portions of facility safety programs fall outside the requirements of 10CFR70. Second, the DG-3037 interpretation of this provision's reference to 10 CFR 70.62 (a)(2) appears to be new. Since January of 2005, licensees have submitted an updated ISA Summary to the NRC each year and a listing of facility modifications made during the year. This summary of facility modifications and changes to the ISA Summary capture the essence of the individual changes to the required documents. Industry and heretofore, the NRC has not expected licensees to submit summaries of each individual change to facility drawings, process flow sheets, standard operating procedures, safety analyses (radiological, chemical, criticality etc.), management measures (PM, instrument calibrations, training module etc.) that constitute the entire list of documents that are required to be maintained by 10CFR70.62 (2) paragraphs b-d. NRC has not provided a corresponding technical basis to justify this apparent change in regulatory position.

Page 6, Section C, Item 4.b.

It is not clear whether this paragraph applies to the annual summary of facility changes or the annual update of the ISA Summary. Industry suggests that the wording of the first sentence in the 2009 version of DG-3037 be retained ("the annual summary of facility changes should include the following information") since it is more clear with regard to what we believe is NRC's intent with this Item. Additionally, Items 2 and 3 were discussed by the Working Group as s that "would facilitate NRC review of the annual summary of changes, but is not required." Although the word "should" is used in the 2009 version to introduce Items 1, 2, and 3, it implies that this level of detail should be provided to NRC in the annual summary, rather than be available for inspection at the site.

Also, there appears to be a clerical error in Item b.3. Specifically, the first line of Item b.3. prior to the word, "any" appears to be a repeat of the text in the preceding Item b.2.

Page 6, Section C, Item 4.c.

Similar to our comment on Section 4.b, the Section appears to be an additional and excessive requirement. This information should be self-evident, and if not, is available for on-site inspection. Also, we suggest that the last sentence before the numbered list be modified consistent with the 2009 version to state: "It would be beneficial, though not required, to indicate....."

Page 7, Section C, Item 5.c.-e.

These sections appear as though they should be a sub tier under 5.b. Items c. and e. seem overly prescriptive. Specifically, not all impacts on licensee methodologies should require NRC pre-approval as suggested in Item c.1. Item c. should be revised to read:

Considerations for the need for prior approval should include the following:

1. Does the change decrease the level of effectiveness of the design basis as described in the LA?
2. Does the change result in a departure from the methods of evaluation described in the LA used in establishing the design basis?
3. Does the change result in degradation in safety?
4. Does the change affect compliance with applicable regulatory requirements?; or
5. Does the change conflict with an existing license condition?

With the proposed change to Item c., Item e. is no longer necessary and should be deleted.

Page 10, Glossary

The terms, "ISA," "ISA Summary," "IROFS," and "management measures" are all defined in 10 CFR Part 70 and are proposed for 10 CFR Part 40. We encourage NRC to reference these regulatory definitions to ensure that they remain consistent with any rule changes that might come into effect through the current Part 40 rulemaking including possible conforming changes to Part 70. For example, in the NEI industry comment letter on Part 40 dated September 9, industry suggested edits to certain definitions to include the term, "design features."