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Mr. Michael T. Lesar
Chief, Rulemaking and Directives Branch
Office of Administration
U.S. Nuclear Regulatory Commission
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Washington, DC 20555-0001

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RULES AND DIRECTIVES
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OFFICE OF ADMINISTRATION

Subject: Notice of Availability of Draft Regulatory Guide, DG-3037 on Guidance for Fuel Cycle Facility Change Process as allowed by 10 CFR Part 70.72

Project Code: 689

Dear Mr. Lesar:

On behalf of the fuel cycle industry, the Nuclear Energy Institute¹ submits the following comments for the staff's consideration in finalizing the subject guidance document on the fuel cycle facility change process as allowed by 10 CFR Part 70.72. As stated in the draft guidance, industry previously raised concerns regarding the current facility change process requirements promulgated in 2000 in a white paper submitted to the U.S. Nuclear Regulatory Commission (NRC) in 2007. The paper identified inconsistencies in reporting requirements, areas needing clarification, and other implementation matters. We appreciate the NRC's effort in developing DG-3037 to address these matters, and believe that many of industry's concerns have been addressed with a few exceptions as noted below.

We offer the following two general comments and specific comments and edits, all discussed in the enclosure, for your consideration as you finalize the guidance document. We trust that you will find the industry comments useful and consistent with those provided previously.

First, regarding the discussion on page 5, item 2.4 b on alteration of a sole Item Relied on For Safety (IROFS), we are concerned that the wording of this item does not reflect the Working Group's consensus position but rather subsequent NRC comments during the June 2008 NRC Fuel Cycle

¹ NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry. 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, nuclear material licensees, and other organizations and individuals involved in the nuclear energy industry.

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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.

Secondly, we offer two comments on page 3 of the draft guidance to limit its scope. Specifically, "all changes" to a licensee's safety program should be qualified to be limited to only those that "could affect the safety program" so as not to capture changes that are administrative in nature, e.g., paint color.

Thank you for the opportunity to comment on the draft guidance, and we look forward to reviewing the final version. Any questions or comments on this matter should be directed to me or Janet Schlueter (jrs@nei.org; 202-739-8098).

Sincerely,



Felix M. Killar, Jr.

Enclosure

c: Ms. Margaret Kotzalas, NMSS/FCSS

Specific Comments on DG-3037 on Part 70.72 Facility Change Process

1. **Page 2, Section B, "Discussion"** – The first sentence should be deleted. The need for a strong configuration management program is clearly made with the remaining sentences in the paragraph.
2. **In the 2nd sentence** – Consider deleting the phrase, "including criticalities and near criticalities". The need for a strong configuration management program is clearly made without these words. In the beginning of the 3rd sentence, change the word "many" to "some". "Many" implies that there are a significant number of changes in this category, and there does not seem to be data to support that implication.
3. **Page 3, Section B, "Discussion", 1st full paragraph on the page** (starts with "Because licensees use..."), **last sentence of paragraph** – We suggest the following word change to improve readability: "Furthermore, the documentation submitted annually to the NRC and maintained at the facility site has not always contained sufficient detail for the NRC to independently determine whether the licensee evaluated and documented the requirements for making changes allowed under 10 CFR 70.72 ~~NRC approval~~ in a manner consistent with the regulations."
4. **Page 3, Section C, "Regulatory Position", (1) Scope of 10 CFR 70.72**
Item "a", 1st sentence – We suggest rewording the sentence as follows to clarify that the focus is on evaluating changes that could affect the safety program, rather than changes that clearly do not (e.g., paint color, shrubbery, administrative procedures): "The configuration management program, as established in accordance with 10 CFR 70.72(a), should be used by licensees to evaluate changes that could affect the safety program."
5. **Item "b", (3)** – We suggest adding a comma after "process change" at the end of the sentence, and then adding the phrase "and that could affect the safety of operations." This would clarify that the focus is on evaluating changes that could affect the safety program, rather than changes that clearly do not (e.g., administrative procedures).
6. **Page 4, Section C, "Regulatory Position", (2) 10 CFR 70.72(c) Prior Approval** – We suggest deleting the word "requirements" from the end of the last sentence in the paragraph at the top of the page. The sentence is clear without this word, and the Regulatory Guide is guidance and compliance with the Guide is not required.
7. **Page 4, Item 2.1.b** – The last sentence provides an example that is awkward. We suggest rewording the sentence as follows: "For example, adding a sprinkler system to an area where moderator is not currently available would be considered a new type of accident unless described for another facility elsewhere in the ISA summary."

8. **Page 5, Item 2.4.b** – Regarding alteration of a sole IROFS. The wording of this item does not reflect the Working Group’s consensus position, but rather subsequent NRC comments made during the June 2008 NRC Fuel Cycle Information Exchange. We strongly suggest that the wording be modified to reflect the Working Group 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.”

Finally, consider deleting the last sentence as it appears to be in conflict with 10 CFR 70.72(c) which only discusses the ISA summary, and not the ISA. Leaving it in might; however, provide a clarification that NRC does not expect to see this level of detail in the ISA summary.

9. **Page 5, Item 2.4.c** – Reword the end of the last sentence as follows: “that could affect the likelihood of failure of the IROFS.”
10. **Page 5, Section 3, “Documentation Requirements”** – Delete the word “Requirements” from the section title. The title is clear without this word, and the Regulatory Guide is guidance and compliance with the Guide is not required.
11. **Page 6, Item 3.a.2** – The wording of this item implies a one-to-one relationship, i.e., one IROFS is removed, one IROFS is added. It should be recognized that this may or may not be the case depending on the control set(s) needed for an accident sequence.
12. **Page 6, Item 3.b.2 and 3** – Items 2 and 3 were discussed by the Working Group as items that “would facilitate NRC review of the annual summary of changes, but is not required.” Although the word “should” is used to introduce Items 1, 2, and 3, it implies that that this level of detail should be provided to NRC in the annual summary, rather than be available for inspection at the site.
13. **Page 6, Item 4.a** – Most, if not all, licensees submit a list of physical changes to the facility rather than descriptions of changes to process safety information (e.g., calibration procedures, PHAs, NCS evaluations/analyses, FHAs, drawings, process specifications). The item as stated would present additional burden for the licensee for no added value. The examples of process safety information above are reviewed during periodic inspections at the site. Suggest adding the following words to the end of the last sentence: “The NRC may request additional information or may inspect records at the site for selected changes as part of its review.”

14. **Page 6, Section 5, "Other Changes"** – Changes are also allowed under 10 CFR 70.32(c)(iii); therefore, suggest adding this reference to the list.
15. **Page 7, Item 5.b** – While we recognize that the terms "safety analysis report" (SAR) and "license application" may both be used within the fuel cycle industry, both the terms are not routinely used or used interchangeably within this draft guide. Also, "SAR" is not used at all in NUREG-1520 or 10 CFR Part 70 while the term "license application" is used. We suggest that the guide be modified to routinely include both terms to avoid any misunderstanding by NRC or licensees.
16. **Page 10, Glossary** – The terms "ISA", "ISA summary", "IROFS", and "Management Measures" are already defined in 10 CFR 70.4. The regulatory definition should either be referenced by citation in each of these, or repeated word for word. The word, "alter" refers only to "sole IROFS", but the word "sole" is missing from the definition. Also, the definition must be modified if the text section (2.4.b) changes. The terms "Process safety information", "safety program", and "sole IROFS" also have regulatory citations from Subpart H that should be included in the glossary.