

**Staff Responses to Public Comments on Draft Regulatory Guide DG-3037
“GUIDANCE FOR FUEL CYCLE FACILITY CHANGE PROCESSES”
(New Regulatory Guide)**

(Public comments have been edited for clarity)

Originators			
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Comment Number	Submitted By	Comment	Response
3037-1	USEC	The last sentence appears to be in conflict with 10 CFR 70.72(c) which only discusses the ISA Summary and not the ISA, therefore the last sentence in DG-3037 Section C, item 2.4b should be deleted.	A change has been made to the proposed language. Reference to the ISA has been removed. The purpose of including this sentence is for licensees to document the attributes associated with the sole IROFS so that they can be consistently evaluated. This is not a regulatory requirement but only an efficient, consistent way to evaluate the attributes of the IROFS and provide documentation necessary for inspection purposes
3037-2	USEC	NUREG-1520, Standard Review Plan for the review of a license Application for a Fuel Cycle Facility does not refer to any part of the documents submitted to the NRC to obtain a license as a “safety analysis report,” nor is the term ‘safety analysis report’ utilized anywhere in 10	The reference has been changed to the license application documents that are incorporated into the license upon approval. Some licensees refer to their license application as their Safety Analysis Report (SAR). There is no consistent term or reference for the license application once a license is approved and the license application is

		CFR part 70. While some licensees may have a document called a safety analysis report, introduction of this term in a Regulatory Guide, which provides generic guidance, is not appropriate. Moreover, it appears that this section provides a new interpretation of the regulations in 10 CFR 70.72. Accordingly, Item 5.b in Section C of DG-3037 should be deleted.	incorporated in the license. The term license in fuel cycle facilities has generally referred to the actual license where the possession limits and license conditions are provided.
3037-3	USEC	It would be helpful if the final 10 CFR 70.72 Regulatory Guide could include additional examples of items that generally are not associated with safety controls (and thus can be eliminated from consideration as a change that needs to be evaluated), and use e.g. in lieu of i.e. in the list.	No change has been made to the proposed content of the guide. Attempts were made by the NRC staff and members of the working group to provide examples that would help clarify the regulatory requirements. Due to the wide diversity of both the processes at fuel cycle facilities and the implementation of the safety program requirements associated with the ISA the NRC staff decided not to include specific examples.
3037-4	NEI/LES 8/18/09	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 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 CFR70.72(c)(3), should be read as meaning any change in 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	No change has been made to the proposed language. The purpose of the working group was to provide insights into how the change process was being implemented at different fuel cycle facilities and to understand their implementation of the requirements for NRC pre-approval. The goal of the working group was not to provide a consensus opinion but to develop guidance for the staff through understanding how implementation of the requirements for NRC pre-approval was currently being performed by licensees. In the initial rulemaking for Part 70, the staff position on altering a sole IROFS, ("You could make the change as long as you do not alter an item relied on for safety if it is the sole item mitigating an accident. That's what we talked about before with if you only have one item that's mitigating an accident, if you alter it, that's a positive or negative change, then that's something that NRC would want pre-approval for. The reason some people ask about the fact that it's a positive change, if you actually are using only one item

		decrease the effectiveness of these attributes of the sole IROFS are not considered alterations.	relied on for safety to mitigate an accident which could exceed the performance criteria, that is a very serious consequence, that's an important item relied on for safety and we want to know any changes, because it would only take one mistake for you to exceed the performance criteria.”),was distinctly provided in a public meeting (see PUBLIC MEETING ON PROPOSED RULECHANGE TO 10 CFR PART 70, Tuesday, March 23, 1999). The NRC staff explored the possibility of other considerations regarding alteration of sole IROFS during the working group meetings by soliciting opinions on the subject from licensees. NRC staff has evaluated these considerations and supports the position from the Part 70 rulemaking established by the staff at that time and reflected in the reg guide.
3037-5	NEI/LES 8/18/09	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.	Agreed, the sentence has been removed.
3037-6	NEI/LES 8/18/09	In the 2 nd sentence – Consider deleting the phrase “including criticalities and near criticalities”. The need for a strong configuration program is clearly made with out these words. In the beginning of the 3 rd 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.	Agreed, the phrase has been removed.
3037-7	NEI/LES 8/18/09	Page 3, Section B, “Discussion”, 1 st 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	A change to the language will be made. The change in language is now,” Furthermore, the documentation that the licensee submits annually to the NRC and maintains at the facility site has not always contained sufficient information for the NRC staff to independently determine how the licensee evaluated proposed changes against the criteria for

		maintained at the facility site has not always contained sufficient detail for NRC to independently determine whether the licensee evaluated and documented the requirements for <u>making changes allowed under 10 CFR70.72 NRC approval</u> in a manner consistent with the regulations.”	NRC prior approval in 10 CFR 70.72(c)..”
3037-8	NEI/LES 8/18/09	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.”	No change has been made to the proposed language. The staff believes that all changes to the facility as specified by the regulation need to be evaluated (screening is a form of evaluation) not just those that could affect the safety program. The regulation requires that, “The licensee shall establish a configuration management system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel.
3037-9	NEI/LES 8/18/09	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).	See comment above.
3037-10	NEI/LES 8/18/09	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.	The following change has been made to the proposed language. “Section 3 of this regulatory guide provides guidance on meeting the documentation requirements specified in 10 CFR 70.72(f).”
3037-11	NEI/LES 8/18/09	Page 4, Item 2.1.b – The last sentence provides an example that is awkward. We suggest rewording the sentence as	A change to the language has been made. The proposed wording “unless described for another facility,” is not clear and could be interpreted 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."	another facility not operated by the licensee. The staff believes that supplementing the current wording with "unless it is used elsewhere in the facility and is already described in the ISA summary," provides more definitive guidance. This phrase will be added to the guidance.
3037-12	NEI/LES 8/18/09	<p>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.”</p> <p>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.</p>	<p>See 3037-4.</p> <p>A change to the language will be made. The staff believes the following modification to the last sentence is appropriate guidance with the following modification, “Licensees should document the attributes considered and relied upon in their evaluations, but do not need to fully describe them in the ISA summary.”</p>
3037-13	NEI/LES 8/18/09	Page 5, Item 2.4.c – Reword the end of the last sentence as follows: “that could	See 3037-1.

		affect the likelihood of failure of the IROFS.”	
3037-14	NEI/LES 8/18/09	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.	No change has been made to the proposed language. This section refers to the guidance for meeting the requirements of 10 CFR 70.72(f)
3037-15	NEI/LES 8/18/09	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.	A change to the language will be made. The staff agrees and will make the following modification. “For changes that will remove an IROFS(s), the licensee should demonstrate either that the IROFS(s) being removed is not needed to meet the performance requirements or that it will be replaced with an IROFS(s) that provides at least an equivalent safety function.”
3037-16	NEI/LES 8/18/09	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.	A change to the language will be made. The staff agrees and will make the following modification. “any additional information available for inspection at the site that may expedite the staff’s annual review of the changes such as the reason for the changes, and reference to the specific safety program records, date of the change, and unique change identifier.”
3037-17	NEI/LES 8/18/09	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	A change to the language will be made. The staff agrees and will add the proposed wording.

		additional information or may inspect records at the site for selected changes as part of its review.”	
3037-18	NEI/LES 8/18/09	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.	A change to the content will be made. The staff agrees and will make the following modification. (6) Other material control procedures - 10 CFR 70.32(c)(iii)
3037-19	NEI/LES 8/18/09	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.	See 3037-2.
3037-20	NEI/LES 8/18/09	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.	A change to the content will be made. The staff agrees and will add the term sole to the definition of alter. The following definitions in the glossary were modified to include regulatory citations: safety program and process safety information.
3037-21	LES -10/16/09	Louisiana Energy Services, LLC (“LES”) understands that the Nuclear Regulatory Commission (“NRC”) staff is developing	Although this comment was submitted following closure of the public comment period for DG-3037, and was not tied specifically to that document, it is

		<p>new guidance that may limit the ability of Part 70 licensees to initiate design changes in the field during construction of an NRC-licensed facility without first obtaining NRC approval. As explained below, LES believes that current NRC regulations and guidance appropriately permit licensees to initiate changes during the construction process in accordance with the licensee's design control and configuration management programs, but require final implementation to be based on any necessary NRC approval of the change. For this reason, LES believes that the potential new Staff guidance is contrary to existing NRC regulations and practice, and urges the NRC not to impose new guidance that would hinder the ability of Part 70 - as well as Part 52 -- licensees to carry out construction of new facilities in a timely and efficient manner.</p>	<p>clearly relevant to the change control processes identified within. However, the staff disagrees that a change in interpretation was promulgated by issue of this regulatory guide. The guidance within the guide simply clarifies the interpretation of 10CFR 70.72 based on the experience to date with licensee implementation of change processes. Staff does not believe that that this regulatory guide has any impact on the Issues related to changes performed at-risk during construction. Although, at-risk change issues may be addressed in a future revision of the regulatory guide.</p>
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