

Response to Public Comments on Draft Regulatory Guide (DG) -3037
“Guidance for Fuel Cycle Facility Change Processes”
(Proposed New Regulatory Guide (RG) 3.74)

Comments received from:

Nuclear Energy Institute (NEI) 1776 I St. N.W., Suite 400 Washington, DC 20006 (ML11262A121)	Urenco (UUSA) Louisiana Energy Services (LES) PO Box 1789 Eunice, NM 88231 (ML11279A103)	Nuclear Fuel Services Inc.(NFS) 1205 Banner Hill Road Erwin, TN 37650 (ML11279A101)
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Public Comments & Resolutions

Source of Comment	Comment	Resolution
1 NEI	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.	The Staff agrees and has added text that discusses the applicability of the guidance for certain Part 40 applicants.
2 NEI	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.” <i>Shalala v. Guernsey Memorial Hosp.</i> , 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.	A footnote has been added to Section A of the Regulatory Guide where the Congressional Review Act is referenced, clarifying that designating regulatory guides as “rules” under the Congressional Review Act does not change the fact that compliance with regulatory guides is not required.

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<p>3 NEI</p>	<p>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.</p>	<p>No change to the current text.</p> <p>The term “timely” here comes from the subpart H rulemaking for Part 70 referenced in Section A of the Regulatory Guide. The sentence quoted in the comment simply indicates that the NRC staff is to be kept aware of all changes to the safety program. For changes that affect the ISA summary, licensees are required to annually submit revised ISA summary pages, pursuant to 10 CFR 70.72(d)(3). This update frequency allows NRC staff to review these changes in enough time to ensure that the licensee’s evaluations of potential impacts to health and safety are accurate. It also allows NRC staff to maintain relatively current facility and safety information on the docket at all times. The staff recognizes that some facility changes, as may be reflected in the revised ISA summary pages, may be more than one year old by the time the revised ISA summary is submitted.</p>
<p>4 NEI/NFS</p>	<p>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.</p> <p>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</p>	<p>The Staff agrees and has removed the second sentence and placed it in Section C, Item 2.4.b.</p> <p>Section 2.1.a has been changed to reflect that the examples may not always require prior approval. The staff expects that changes that would require prior approval are new types of accident sequences that are associated with hazards that did not</p>

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	<p>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.”</p> <p>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</p>	<p>previously exist. Changes to supporting systems or chemicals that don’t directly result in a new hazard to the facility would not be considered new types of accident sequences by the staff.</p> <p>The requirement to submit an amendment request assumes that the change to the facility would generally be significant and likely related to nuclear safety. The staff recognizes that that there may be changes to the worker safety program that would not require a license amendment. The blue tooth technology example is illustrative of why a questioning attitude for evaluation of changes is preferred. This type of technology may be used in such a manner that is benign, or, in an manner that could create a control system vulnerability. The licensee’s evaluation of the change, which must be maintained pursuant to 10 CFR 70.72(f), should provide sufficient information as to why there is no new type of accident created, and is to be made available for NRC review when requested.</p> <p>There is no change in regulatory position by the staff regarding 10 CFR 70.72(d)(2).. The change process as summarized in this comment is acceptable. The level of detail expected by the staff regarding all changes to the safety program made in the previous year for which the licensee did not receive prior NRC approval is a brief summary,</p>
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	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.	consistent with the terms of 10 CFR 70.72(d)(2).. The brief summary need not separately summarize every change made to safety program information in the previous year. Details regarding changes made to process safety information would be kept by the licensees on site and would be available to the staff for inspection or by request. The licensee’s evaluation should provide information sufficient to explain why there is no new hazard created.
5 NEI/NFS	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.	The staff disagrees. Item 1 discusses the general scope of 10 CFR 70.72, and its scope is not limited to changes that “could affect the safety program.”
6 NEI/NFS	Page 3, Section C, Item 1.b.3. The phrase “that could affect the safety program” should be added to the end of the sentence for clarity and consistency.	See staff response in Comment 5 above.
7 NEI/NFS	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.	There is no change in regulatory position by the staff. The evaluations performed by licensees to evaluate the need for prior NRC approval are to be kept on site as provided in 70.72(e). These evaluations need not be submitted to the NRC as part of the annual summaries required by 10 CFR 70.72(d)(2). These evaluations would be kept by licensees on site and be available for inspection or request by NRC staff. Text has been added to clarify this in C.2.a. The last sentence in Section C.2.a has been removed as the staff finds that it did not provide guidance relevant to this section.

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<p>8 NEI/NFS</p>	<p>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.”</p>	<p>The staff agrees, and the first sentence has been modified accordingly.</p> <p>The text has also been modified to reflect the fact that the examples “may” be types of new accident sequences. The staff expects that a new type of accident sequence would be the result of a new hazard introduced in the facility. The staff position is that changes to supporting systems or materials that don’t directly result in a new hazard to the facility do not constitute a new type of accident sequence. However, the licensee’s evaluation should be sufficient to provide an understanding of why there is no new hazard created.</p>
<p>9 NEI/NFS [comment “23 LES” should also be stated here]</p>	<p>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.</p>	<p>The staff understands that a consensus position on altering a sole IROFS was proposed by the 2007 working group. However, the 2000 rulemaking establishing subpart H of Part 70 was based, in part, on the assumption that sole IROFS were the only control credited by licensees with mitigation or prevention of an accident with consequences exceeding the 70.61 performance requirements. To that end, a sole IROFS is at the high end of risk significance, and any change to a sole IROFS would warrant NRC prior approval.</p> <p>Regarding the comment that changes to sole IROFS which increase the safety margin or are otherwise positive should not require prior approval, the staff continues to</p>

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		construe 10 CFR 70.72(c)(3) broadly, Changes to sole IROFS are to be reported, regardless of their net effect on margin.
10 NFS	Page 5, Section C, Item 3, "Documentation Requirements" Suggest deleting 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	The staff agrees and has changed the text in the title to remove “requirements.”
11 NFS	Page 5, Section C, Item 3.a.(2) The wording of this Item implies a one-to-one relationship - one IROFS is removed, one IROFS is added. This may or may not be the case depending on the control set(s) needed for an accident sequence.	The staff agrees and has changed the text to reflect that one or multiple IROFS may be involved in the replacement.
12 NEI	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.	As used here, the word “demonstrate” means that the licensee should include documentation in the evaluation as to whether prior NRC approval is needed. Such documentation should be clear, complete and provide reference to supporting information. No change to the RG text has been made.
13 NEI/NFS	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.	See Comment 9 resolution.
14 NEI/NFS	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.” 4 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	No change in regulatory position was intended. The wording of section 4.a has been revised to remove the implication that each individual change made in the previous year is to be separately summarized. See also Comment 4 resolution.

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	<p>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.</p>	
15 NEI/NFS	<p>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.</p>	<p>Items 4.a and 4.b have been modified to clarify that the annual summaries being referenced there are those required by 10 CFR 70.72(d)(2). The text has also been modified to reflect that items formerly (2) and (3) are optional. The staff agrees and has removed the repetitive language from the bullet.</p>
16 NEI/NFS	<p>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.....”</p>	<p>The purpose of Section C.4.c is to provide guidance regarding changes to the ISA Summary to be included as part of the annual summary of facility changes. The staff agrees that additional information that may support the staff review is optional. The text has been modified to reflect that additional information is optional.</p>
17 NEI/NFS	<p>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.</p>	<p>The staff agrees and has changed the introductory text of item 5.c to state:</p>

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	<p>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: 5 Considerations for the need for prior approval should include the following:</p> <ol style="list-style-type: none"> 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? <p>With the proposed change to Item c., Item e. is no longer necessary and should be deleted.</p>	<p>“Considerations for the need for prior approval include the following:”</p> <p>The staff believes that the examples listed provide general guidance as to when prior approval would and would not be needed, and it has been included in sections 5.d-e. .</p>
18 NEI/NFS	<p>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.”</p>	<p>The staff agrees that as a general matter, defined terms in the proposed part 40 ISA regulations should be substantially the same as the defined terms in the existing part 70 ISA regulations.</p>
19 LES	<p>Section C.2.3.a(3). Clarification should be added that defines under what conditions this type of shift in preferred hierarchy would be approved by the NRC.</p>	<p>No change to the text has been made. The staff is providing guidance that suggests that the evaluation for determining equivalent replacement consider such factors as the type of control. Because there are many variables that can be used in making the determination of equivalence, no prescriptive change of type can be considered acceptable or not without weighing all dependent considerations of the evaluation.</p>
20 LES	<p>The guide makes no mention of 10 CFR 70.72(c)(4). This subsection is not self evident since the NRC sometimes interprets "section" to mean "part"</p>	<p>No change to the text has been made. The words “this section” in 70.72(c) (4) refer to</p>

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<p>21 LES</p>	<p>Section C.5. LES has concerns with portions of Section C.5, "Other Changes," of DG-3037. The NRC explains that this section "discusses changes that are outside the provisions of [the] 10 CFR 70.72" change control process. However, with the exception of Section C.5.a, the NRC does not explain the regulatory basis for the agency's positions set forth in Sections C.5 - in particular, C.5.b through e. In our view, this section would set forth new regulatory staff positions that go beyond existing regulations.</p> <p>Section C.5.b states in part that "the NRC would consider a license condition to allow changes to licensing documents, such as the license application or supporting documents referenced in the license, without prior NRC approval." The draft Regulatory Guide does not explain this provision or the regulatory basis. Current NRC regulations in Part 70 do not prescribe a specific mechanism to control changes to licensing documents including "supporting documents referenced in the license." Section 70.72 establishes the process for controlling facility changes for Part 70 licensees. Accordingly, because position C.5.b appears to go beyond existing regulatory requirements, LES suggests that it not be adopted as part of DG-3037 without further industry discussion.</p>	<p>section 70.72.</p> <p>The provisions of 10 CFR 70.72 apply to the items listed in 70.72 (a) and (c). Changes to licensing documents are outside the scope of 10 CFR 70.72. There are no requirements that specify when changes to licensing documents must have prior NRC approval. The staff does not agree that section C.5.b goes "beyond existing regulatory requirements." The broad terms of 10 CFR 70.34 place no restrictions on the subject matter of requests for license amendments, and a licensee may thus request that a license condition be added as described in section C.5.b of the Regulatory Guide.</p>
<p>22 LES</p>	<p>Section D. Implementation</p> <p>" First paragraph under "Applicant and Licensees' Use", last sentence. Both here and under "NRC Staff Use" the NRC is taking the position that the staff may require the use of this regulatory guide (RG) if seeking a license amendment or change and that this guidance may also be used if a rule is issued. This implies the NRC may impose this RG for licensee submitted requests. Since the RG is only guidance, further clarification should be provided that explains how this decision will be made</p>	<p>As stated in Section A of the Regulatory Guide, this guidance to part 70 fuel cycle facilities is not legally binding, and adherence to it is thus not required in connection with amending part 70 licenses.</p>
<p>23 LES</p>	<p>In addition, and relevant to UUSAs comments on the earlier (June 2009) version of DG-3037, the following statements should be considered:</p> <p>Comments 3037-4 and 12. UUSA notes that, changes that increase margin or are positive should not require NRC prior approval. The NRC's response to this comment states: "...we want to know any changes, because it would only take one mistake for you to exceed the performance criteria." If such a concern exists, the NRC could request such changes be communicated sooner - but not for approval.</p>	<p>See response to comment # 9 above.</p>

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24 LES	Comment 3037-21. UUSA requests that the term "implementation" be clarified, as this defines when prior approval is required. Further, UUSA suggests this term be defined as: "the point in time when the IROFS, design feature or other control must be in operation/operable to perform a required function to prevent or mitigate a hazard".	The staff is currently evaluating its position regarding the change process during the construction period for fuel cycle facilities and compliance with the Part 70.72 regulations. This evaluation is looking at the commenter's proposed definition of the term "implementation" and the impact on when licensees can begin making changes during construction. This effort may incorporate policies being developed to implement Part 52. For the interim, the staff has provided a position regarding changes during construction in ML102910119. This position may be incorporated into a future revision of this RG.
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