



NUCLEAR ENERGY INSTITUTE

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OFFICE OF SECRETARY
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ADJUDICATIONS STAFF

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September 9, 2011

Ms. Annette L. Vietti-Cook
Secretary to the Commission
Attention: Rulemakings and Adjudications Staff
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Industry Comments on Domestic Licensing of Source Material – Amendments/Integrated Safety Analysis, Proposed Part 40; RIN 3150-A150; NRC Docket 2009-0079 (76FR28336, May 17, 2011)

Project Number: 689

Dear Ms. Vietti-Cook:

On behalf of the fuel cycle industry, the Nuclear Energy Institute (NEI)¹ submits the following industry comments on the proposed Part 40 rule applicable to certain fuel cycle facilities. We appreciated the favorable agency response to our June 21, 2011, letter request for a public meeting on the proposed rule that was held on August 17, 2011, and an extension of the comment period for the rule and Draft NUREG-1962 until September 9, 2011. The meeting discussions informed our comments which we trust the staff will find useful and informative as it proceeds to draft a final rule for Commission review and approval. In addition, we suggest that the U.S. Nuclear Regulatory Commission (NRC) make the final guidance and related inspection procedures publicly available by the effective date of the final rule.

Industry's comments are grouped into four general categories as presented during the August 17, 2011 public meeting. A copy of our meeting presentation is attached. We offer general comments in the categories of Integrated Safety Analysis (ISA) Implementation, jurisdictional and 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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consistency issues (Enclosure 1), as well as responses to the NRC questions in the Federal Register Notice along with comments and specific edits to the rule (Enclosure 2), the Draft NUREG-1962 and the Draft Regulatory Analysis (Enclosure 3).

As an overview, industry's primary concerns can be summarized, as highlighted below, and discussed in more detail in the enclosures.

Integrated Safety Analysis

- The proposed requirements are silent on how existing ISAs will transition under the new rule. Specifically, there appears to be no mechanism to recognize the ISAs developed to date in accordance with Part 70 Subpart H, as directed by NRC, by Part 40 facilities impacted by this rule.
- The ISA timeline is overly restrictive and based on industry experience to date this approach is not appropriate.
- The NRC estimates for ISA development and implementation costs are significantly underestimated based on industry experience to date. Further, NRC estimates for its ISA Summary review and approval are not recognized in the cost analysis but perhaps should be included in the Regulatory Analysis.

Jurisdictional and Consistency Across the Fuel Cycle Fleet

- There is a lack of clarity on whether the NRC intends to exercise exclusive jurisdiction over existing and new Part 40 facilities possessing or requesting permission to possess UF₆ in quantities equal to or exceeding 2,000 kg. As you are aware, several Agreement State representatives expressed concern with this issue during the public meeting as is captured in the meeting transcript. Also, NEI believes that the Agreement State licensing cases discussed in SECY-10-0128 (*i.e.*, existing Agreement State licenses authorizing possession of equal to or greater than 2,000 kg of UF₆) should be fully resolved and communicated to licensees before the staff forwards the draft final rule to the Commission for approval. Resolving these licensing cases now will provide valuable insights and allow the staff to ensure all subtleties (e.g., uranium compounds other than UF₆) are well understood and can be considered in crafting the final rule.
- Industry suggests a 40-year license term for Part 40 facilities which is consistent with earlier Commission direction and some operating facilities.
- Conforming changes to Part 70 should be considered by NRC to ensure consistency across the fuel cycle fleet.

As stated above, this letter identifies areas where conforming changes to Part 70 should be made to ensure consistency across the fuel cycle fleet. However, industry is not, by this letter, petitioning the NRC to modify Part 70. Rather, we trust that the staff will consider these conforming changes and proceed to propose modifications to Part 70 as opportunities are identified, e.g., Part 70

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rulemaking on the Petition for Rulemaking 70-8. It is also important to state that licensee suggested conforming changes are not intended to imply that there are safety issues which need to be addressed by NRC at this time.

On a related note, industry supports the new "backfit" provision in Section 40.89 that provides requirements similar to those currently in 10 CFR Part 70, Section 70.76. While NEI generally support inclusion of this provision, in Enclosure 1 to this letter we make several recommendations with respect to clarifying the applicability of the compliance exception (10 C.F.R. §§ 40.89(c)(3)(i),(ii)) as well as the requirement that the Commission produce an appropriately documented evaluation for findings made pursuant to section 40.89(c)(3).

Finally and equally important, industry supports the fact that the proposed rule does not contain a provision for conducting or relying on a Probabilistic Risk Analysis (PRA) methodology at Part 40 facilities. Industry's position on this matter as it relates to the question of an ISA versus a PRA at fuel cycle facilities is well documented in NEI letters to NRC dated September 10, 2010, November 19, 2010, and February 8, 2011 as well as the industry presentation at the January 11, 2011, meeting of NRC's Advisory Committee on Reactor Safeguards, Subcommittee on Waste and Materials. In summary, industry strongly believes that a Process Hazards Analyses-based ISA is the most appropriate tool for analyzing the unique operations of fuel facilities and it has been proven to more than adequately demonstrate compliance with applicable NRC requirements.

Should you have any questions about the content of this letter, please feel free to contact me or Andrew Mauer (202-739-8018; anm@nei.org). We look forward to review of the draft final rule for Commission review and approval.

Sincerely,



Janet R. Schlueter

Enclosures

c: Mr. John D. Kinneman, NMSS/FCSS, NRC
Ms. Josephine M. Piccone, FSME/DILR, NRC
Mr. Edward M. Lohr, FSME/DILR, NRC

GENERAL COMMENTS – ISA IMPLEMENTATION, JURISDICTION and CONSISTENCY ISSUES

Enclosure 1

1. Integrated Safety Analysis Transition and Implementation

To date, a significant amount of industry resources have been expended to develop an Integrated Safety Analysis (ISA) for NRC approval and implementation. These ISAs were developed in accordance with the only available requirements at the time, i.e., Part 70 Subpart H and related guidance in NUREG-1520, as discussed in SECY-07-0146 for Part 40 facilities affected by the proposed Part 40 rule. The proposed rule and Draft NUREG-1962 are silent on how a Part 40 licensee with an ISA will transition under the proposed Part 40 ISA requirements when the final rule becomes effective. Instead, section 40.82(c)(3) requires existing licensees to take specific steps to develop an ISA plan and make submittals to NRC that do not recognize their efforts to date which have been fully coordinated with NRC. Nor does it address the mechanisms and schedule by which licensee requirements will transition from the current ISA to the new ISA. Therefore, industry strongly suggests that NRC develop, and inform industry of, a mechanism to acknowledge and accept ISAs completed in accordance with Part 70 Subpart H for Part 40 facilities subject to this rule.

It also does not appear that NRC has considered the "lessons learned" by NRC and industry from implementing Part 70 Subpart H. Specifically, Part 70 implementation allowed for a more protracted timeline (e.g., 4 years) for development of the ISA, submittal of the ISA summary, and the correction of deficiencies. Nor does the timeline recognize the necessary sequential nature of some milestones, for example, NRC approval of the ISA plan is needed as a first step. In addition, NRC should clarify when (e.g., before or after the ISA Summary is approved) the Part 40 ISA-related reporting requirements become effective as this was an area of confusion among licensees when Part 70 was implemented.

2. NRC Cost Estimates for ISA Development and Implementation

It appears that the NRC cost estimates, referenced in the Federal Register Notice and the Draft Regulatory Analysis, for development and implementation of an ISA are grossly underestimated based on industry's collective experience to date. Specifically, based on available industry data, NEI estimates that industry costs for developing an ISA range from \$1 million to \$ 9 million. These costs far exceed the NRC estimate of \$290K. In addition, it is also interesting to note that NEI estimates that the NRC billing for reviewing and approving the facility-specific ISA Summaries ranged from \$ 0.5 million to more than \$1 million.

3. NRC and Agreement State Jurisdiction

As stated previously and discussed during the public meeting, the proposed rule is not clear on NRC and Agreement State jurisdiction at Part 40 facilities. Specifically, the Supplementary Information describing the new section 40.3a states "[t]he NRC would be the *sole licensing authority* for all

classes of licensees who possess or plan to possess 2000 kg or more of UF₆ (including generally and specifically licensed activities), and *the NRC would thus hold licensing authority for all radiological activities of such licensees.*" 76 Fed. Reg. 28,341 (emphasis added). But the proposed section 40.3a reads: "After [insert effective date of final rule], Agreement States may not issue new licenses covering the possession of 2000 kg (4400 lb) or more of uranium hexafluoride." This proposed regulatory text is ambiguous because, while it prohibits Agreement States from issuing new licenses allowing possession of the threshold quantity of uranium hexafluoride, it could be read to permit Agreement State licensing of other radiological activities at the same facilities. This reading would contradict the description provided in the section-by-section analysis quoted above and would result in dual regulation of radiological activities at these facilities by both Agreement States and the NRC. The NRC should clarify the proposed regulatory text to remove any ambiguity regarding whether it intends to be the sole regulator of *all radiological activities* at new facilities licensed to possess threshold quantities of uranium hexafluoride.

In addition, the proposed section 40.3a only addresses future licensing activities. It does not resolve cases where Agreement States have already issued licenses allowing possession of threshold quantities of uranium hexafluoride. The NRC staff discussed these cases in SECY-10-0128 (October 1, 2010). Specifically, through interactions with the Agreement States, the staff identified six Agreement State licensees that possess threshold quantities of uranium hexafluoride. See SECY-10-0128, at pg. 4. With regard to these six licensees the staff stated: "Each of these six facilities also holds an NRC Part 70 license. The staff will work with these facilities to either move the UF₆ onto their NRC license, or to reduce their authorized possession limits on their Agreement State licenses below the proposed 2000 kg threshold." *Id.* The staff also pointed out that an average of six licensees per state (of the 13 Agreement States that responded to NRC) are authorized to possess uranium hexafluoride in quantities exceeding the threshold quantity. These facilities do not, however, actually possess uranium hexafluoride in such quantities. With respect to these facilities, the staff stated: "If the proposed Part 40 rule becomes a final rule as now drafted, either (1) the Agreement State licenses which authorized possession of UF₆ in quantities equal to or greater than the 2000 kg threshold will need to be revised below the threshold; or (2) such licensees will have to obtain an NRC Part 40 license for authority to possess UF₆ in quantities greater than the 2000 kg threshold." *Id.* Unlike the section-by-section analysis describing the proposed new section 40.3a, the statements in SECY-10-0128 imply that, for existing facilities, the NRC will only license the threshold quantity of uranium hexafluoride, leaving the Agreement State to regulate possession and use of other radioactive materials at the same facility. The NRC should clarify whether it intends to be the sole regulator of *all radiological activities* at existing facilities that are currently licensed to possess threshold quantities of uranium hexafluoride

Finally, NEI believes that the most efficient course of action would be for the NRC to resolve the jurisdiction issue at the six facilities that currently possess threshold quantities of uranium hexafluoride pursuant to Agreement State licensees prior to submittal of the draft final rule to the Commission for review. Resolution of this issue will require close coordination with Agreement

States and communication with industry and could provide valuable insights when crafting the final rule.

4. Reportable Safety Events

As was discussed during the August 2011 public meeting, three of the nine items contained in industry's Part 70 Appendix A Petition for Rulemaking (PRM 70-8) on reportable safety event requirements have been addressed in the proposed Part 40 rule. However, the FRN did not discuss the PRM or its disposition, or whether NRC intends to make conforming changes to Part 70 since the changes were administrative in nature and relatively minor. NRC staff stated during the public meeting that a separate conforming Part 70 rulemaking is in process.

Conforming Changes to Part 70: We support the conforming changes because in their absence, Part 40 and Part 70 facilities would have different reporting timelines for the same reportable safety events. Also, we suggest that NRC include other industry suggested conforming modifications to Part 70, in the PRM related rulemaking, as identified throughout this letter for efficiency and greater industry consistency.

Also, please note the related Part 70, Appendix A comment discussed in the following section.

5. Soluble Uranium Intake Values

It is unclear whether NRC considered industry's white paper on soluble uranium intake values submitted in December 2008 and May 2009 (Revision 1 in response to NRC comments) when drafting the proposed Part 40 rule. Specifically, the suggested increased intake values described in the industry white paper were developed based on discussions by an NRC-industry working group in the context of Part 70 but are relevant to and are proposed for Part 40.

Also, NRC has approved the use of soluble uranium intake values higher than the 30 milligram value contained in the proposed performance requirements in 40.81(b)(3). Specifically, defining a soluble uranium intake value to the worker (e.g., 100 milligram) that coincides with a high consequence event is consistent with using the current soluble uranium intake value of 30 milligram to an individual located outside the controlled area for identifying a high consequence event. This more risk-based approach provides greater alignment with regard to the intent of event reporting. As such, industry proposes in Enclosure 2 to this letter specific rule edits to affect this outcome.

In addition, NRC should consider modifying the related reporting requirements proposed in Section 40.88 to reference the performance requirements in proposed Section 40.81. This approach will help ensure that events which meet or exceed the performance requirements are reported. As such, industry proposes in Enclosure 2 to this letter specific rule changes to affect this outcome.

Conforming Changes to Part 70: It should be noted that Part 70 is also not internally consistent with regard to the performance requirements in Section 70.61 and reportable event requirements in Appendix A. As such, NRC could fully address the soluble uranium intake value issue described above and make conforming changes to Part 70.61 and Appendix A to ensure internal consistency within Part 70 and greater consistency across the fleet assuming that industry's suggested changes to proposed sections 40.81 and 40.88 are adopted.

6. Inhalation Exposure Pathway

Industry suggests that NRC modify proposed Sections 40.81(b)(4) and (c)(4) to add the word, "inhalation" to more accurately reflect the fact that inhalation of UF₆ is the primary concern for high and intermediate consequence event determinations since inhalation is the bounding acute chemical exposure pathway. It is also important to note that no consensus standard for dermal exposure exists so any determination of high or intermediate consequences is very subjective. Such industry concerns have been publicly discussed with NRC and are documented in letters dated September 8, 2008, and February 24, 2009. We believe that the more accurate and efficient approach is to recognize that inhalation is the primary exposure pathway of concern and therefore licensees work to ensure the proper use of personnel protective equipment. As a result, industry proposes in Enclosure 2 to this letter specific rule edits to affect this outcome.

Conforming Changes to Part 70: This is an area where conforming changes could be made to Sections 70.61(b)(4) and (c)(4) to ensure greater consistency across the fuel cycle industry assuming that industry's suggestions to the proposed sections 40.81 are adopted.

7. Use of Design Features

Industry suggests that NRC consider adding a definition of "design features" to Part 40 since this issue is not unique to Part 40 facilities, applies to Part 70 facilities and has been a point of significant discussion between NRC and industry for more than 2 years. As such, industry proposes in Enclosure 2 to this letter specific rule edits to add a definition for design features and make modifications to the proposed definition for "configuration management" and "ISA."

Conforming Changes to Part 70: This is an area where conforming changes to Part 70 could be made to ensure consistency across the fuel cycle industry. It should also be noted that industry also suggested modifications to NUREG-1520 in an NEI letter dated June 7, 2011 to address this issue which complements the industry suggested rule change. This letter was the subject of an August 17, 2011 NRC public meeting.

8. 40-Year License Term

In the staff requirements memorandum for SECY-06-0186, the Commission approved the staff recommendation to implement a maximum license term of up to 40 years. At present, some fuel facilities have been issued a 40 year license term; NRC requires licensees to submit annual updates to facility-specific Integrated Safety Analysis; and NRC has full and immediate access to all licensee program information as part of the inspection and oversight process. For these reasons, industry believes that the final Part 40 rule should allow for a 40 year license term.

9. Chemical Hazards

Section 40.84 contains new and additional criteria for chemical hazards that do not appear necessary and are not currently required for Part 70. Industry believes that this regulatory change is not necessary to address the safety of radioactive materials and thus the radiation risk to workers or members of the public, therefore, it should be deleted.

10. Backfitting

As stated in the cover letter accompanying these comments, NEI generally supports inclusion of a backfitting provision in the revisions to Part 40 and agrees with NRC's efforts to create a provision that is analogous to the backfitting requirements in 10 C.F.R. § 70.76. However, we believe that the NRC should provide additional clarification in two areas. First, the Supplemental Information published with the final rule should explain further the applicability of the compliance exception provided in sections 40.89(c)(3)(i) and (ii). Specifically, the NRC should include the following language in the section-by-section analysis describing sections 40.89(c)(3)(i) and (ii) (see 76 Fed. Reg. 28,349):

The compliance exception is intended to address situations in which the licensee has failed to meet known and established standards of the Commission because of omission or mistake of fact. It should be noted that new or modified interpretations of what constitutes compliance would not fall within the exception and would require a backfit analysis and application of the standard.

This language is quoted verbatim from the Supplementary Information published with the 1985 final backfitting rule, which modified 10 C.F.R. § 50.109. "Revision of Backfitting Process for Power Reactors: Final Rule," 50 Fed. Reg. 38,097, 38,103 (Sept. 20, 1985). Without this limiting language, the compliance exception has the potential to swallow the backfit rule whole, as most (if not all) backfits have their genesis in "new or modified interpretation of what constitutes compliance."

Second, while NEI supports the requirement that the Commission provide an "appropriately documented evaluation" explaining a finding that one of the exceptions to the backfit rule applies (see proposed § 40.89(c)(3)), we believe that the section-by-section analysis describing this

provision should clarify that: (1) the required documented evaluation should explain why the Commission believes that the exception applies, given the relevant facts and regulatory history (in addition to providing the "objectives and reasons for the modifications when invoking and exception"), and (2) that, when possible, such documented evaluations should be made available for public comment before the backfit is imposed. In situations where adequate protection considerations require that a backfit be imposed prior to public comment, the documented evaluation should be made available for comment as soon as practicable.

RESPONSES TO NRC QUESTIONS and SPECIFIC EDITS TO PROPOSED PART 40

Enclosure 2

Responses to NRC Questions

1. Federal Register Notice (FRN), Section H: Industry supports the inclusion of an alternative to submitting an emergency plan. Specifically, an evaluation demonstrating that the maximum intake by a member of the public due to a release would not exceed 2 milligrams of UF₆.
2. FRN, Section K: Industry supports the fact that the proposed rule does not contain a provision for conducting or relying on a Probabilistic Risk Analysis (PRA) methodology at Part 40 facilities. Industry's position on this matter as it relates to the question of an Integrated Safety Analysis (ISA) versus a PRA at all fuel cycle facilities is well documented in NEI letters to NRC dated September 10, 2010, November 19, 2010, and February 8, 2011 as well as the industry presentation at the January 11, 2011 meeting of NRC's Advisory Committee on Reactor Safeguards, Subcommittee on Waste and Materials. In summary, industry strongly believes that a Process Hazards Analyses-based ISA is the most appropriate tool for analyzing the unique operations of fuel facilities and it has been proven to more than adequately demonstrate compliance with applicable NRC requirements.

Specific Suggested Edits to the Proposed Rule

Section 40.4, Definitions

1. ***Current definition - "Defense-in-depth practices"*** means a design philosophy, applied from the outset and through completion of the design that is based on providing successive levels of protection such that health and safety will not be wholly dependent upon any single element of the design, construction, maintenance, or operation of the facility. ~~The net effect of incorporating defense in depth practices is a conservatively designed facility and system that will exhibit greater tolerance to failures and external challenges. The risk insights obtained through performance of the integrated safety analysis can then be used to supplement the final design by focusing attention on the prevention and mitigation of the higher risk potential accidents."~~

Comment: NRC should delete the text as indicated since this information should be provided in the companion Draft NUREG-1962 as it is not a definition, but rather an explanation of the defined term.

2. ***Current definition - "Items relied on for safety"*** mean structures, systems, equipment, components, and activities of personnel that are controls relied on to prevent potential accidents at a facility that could exceed the performance requirements in § 40.81 or to mitigate their potential consequences. This does not limit the licensee from identifying additional structures, systems, equipment, components, or activities of personnel (*i.e.*,

beyond those in the minimum set necessary for compliance with the performance requirements) as items relied on for safety.”

Comment: NRC should insert the term, “controls” as indicated. The introduction of the term “controls” is consistent with § 40.82(d) current wording; “Each applicant or licensee must establish management measures to ensure compliance with the performance requirements of section 40.81. The measures applied to a particular engineered or administrative control or control system may be graded commensurate with the reduction of the risk attributable to that control or control system. The management measures must ensure that engineered and administrative controls and control systems that are identified as IROFS.....” .

- 3. Comment: “Design Feature”** – A new definition of “design feature,” and corresponding modifications to the existing definitions of “Configuration Management” and “ISA” should be made to address a long standing regulatory matter between NRC and industry. This definition complements the industry-suggested modifications to NUREG-1520 submitted to NRC via an NEI letter dated June 7, 2011 which was also the subject of an August 17, 2011 NRC public meeting.

“Design Feature means a passive engineered feature or component of a facility or process system that has an insignificant possibility of failure, its safety aspect is not easily altered, it is not subject to degradation or routine replacement, and does not require and may not support periodic testing or verification to ensure it remains available and reliable to perform its intended function.”

“Configuration Management means a management measure that might impact the ability of items relied on for safety or design features to perform their functions when needed.”

“Integrated Safety Analysis means a systematic analysis to identify.....and the items relied on for safety and design features. As used here, integrated means.....and chemical. ~~The NRC’s ISA requirement is limited to consideration of the effects of all relevant hazards on radiological safety or chemical hazards directly associated with NRC licensed material. An integrated safety analysis can be performed process by process, but all processes must be integrated, and process interactions considered.~~

Deleted text should be included in NUREG-1962.

4. Section 40.81(a)

Proposed 40.81(a) states, “Each applicant or licensee must evaluate in the integrated safety analysis performed in accordance with 40.82, its compliance with the performance requirements in paragraphs (b), (c), and (d) of this section.”

Comment: The NRC should remove section (d) from inclusion as it does not contain performance requirements. Also, page 76 FR 28342 of the FRN states: "Guidance documents are being developed to provide examples of acceptable approaches for the meaning of "unlikely" and "highly unlikely." Industry is unaware of such guidance, would like the opportunity to review it, and suggests that it be made available prior to the final rule becoming effective.

5. Section 40.81(b)

Proposed 40.81(b) states, "The risk of each credible high-consequence event must be limited. Engineered controls, administrative controls, or both, subject to §40.83(b)(1), must be applied to the extent needed to reduce the likelihood of occurrence of the event so that, upon implementation of such controls, the event is highly unlikely or its consequences are less severe than those in paragraphs (b)(1) through (b)(4) of this section."

Comment: The NRC should remove the phrase "subject to 40.83(b)(1)" from this section. Section 40.81 applies to all existing licensees, in addition to applicants. In contrast, section 40.83 applies to existing licensees only to the extent that they are designing "new processes at existing facilities that require a license amendment under § 40.86." Further, section 40.83 states that "[t]he baseline design criteria must be applied to the design of new facilities and new processes, but do not require retrofits to existing facilities or existing processes. . . ." 10 C.F.R. § 40.83(a). Although the same qualifying language is not repeated in paragraph 40.83(b), the title for the entire Section "Requirements for new facilities and *new processes at existing facilities*," supports reading the limitation in paragraph (a) as also being applicable to paragraph (b). Including the "subject to 40.83(b)(1)" language in section 40.81 could effectively require retrofits to existing facilities and processes by applying the design and layout requirements to all existing facilities. This change would directly conflict with the limiting language in section 40.83(a) and is inconsistent with the analogous provisions of 10 C.F.R. Part 70 (see section 70.61(b)).

6. Section 40.81(b)(3)

This section should be edited as follows to provide for a consistent regulatory approach to the licensee identification of high consequence events based on soluble uranium intake values for the worker and individual located outside the controlled area. Conforming changes to Part 70 could be considered for consistency.

40.81(b)(3): "An intake of 100 mg or greater of uranium in soluble form to a worker or an intake of 30 mg or greater of uranium....."

7. Section 40.81(b) and (c)

Comment: The performance requirements of this section should allow for the treatment of Standard Industrial Hazards within the existing programs used by the licensees. Such programs work to preclude dermal exposures based on the use of properly identified and utilized personnel protective equipment without the extensive burden placed upon the licensee of such techniques being subject to interpretation as an IROFS.

This comment can be addressed by rewording sections 40.81(b)(4) & (c)(4) to include the term "inhalation" so that they read "(4) An acute chemical exposure from inhalation by an individual....."

The basis for this is already provided in the section III H and I of the FRN, in that, a consensus standard upon which a licensee can make a determination of high or intermediate consequences exists for inhalation of toxic chemicals can be based on ERPGs or AEGLs. No such consensus standards are available for dermal exposures due to the lack of scientific data and studies and, as such, any such determination is highly subjective. (See April 2011 report by Centers for Disease Control NIOSH Skin Notation Profiles for Hydrogen Fluoride/Hydrofluoric Acid(HF)).

Finally, the phrases "irreversible or other serious long lasting health effects" and "mild transient health effects" are subjective and have been problematic for licensees as well as for NRC as has been evidenced through various inspections. NRC should consider defining these terms or using less subjective language.

Conforming Changes to Part 70: NRC should consider making conforming changes to Part 70, sections 70.61(b) and (c) to ensure consistency across the fuel cycle industry assuming that industry's suggested modifications are adopted.

8. Section 40.81(d)

Proposed 10 CFR 40.81(d) states, "Each engineered or administrative control or control system necessary to comply with paragraphs (b), (c), or (d) of this section must be designated as an item relied on for safety."

Comment: The NRC should remove section (d) from inclusion. Again, this is in reference to 70.61(d) and does not have any applicability to 40.81.

9. Section 40.81(e)(2)

Comment: Consider removing the phrase "and conspicuously posts and maintains notices stating" from the first sentence and reword the sentence to read:

(2) Provides training to these individuals that satisfies the requirements of 19.12(a)(1) through (a)(5) of this chapter and ensures that they are aware of the risks associated with accidents involving the licensed activities as determined by the integrated safety analysis, including where these individuals may examine the information contained in 19.11(a) of this chapter.

Mandating postings, which many consider the least effective training and familiarization tool, results in an unnecessary administrative burden. Also the term "conspicuously" is subjective and therefore reliant on interpretation. If postings are indeed the appropriate training tool then the licensee is in a better position to make that determination based on particular circumstances. There are numerous methods available to better inform and disseminate information and thus allowance for posting is more appropriately contained within the proposed companion NUREG-1962.

10. Section 40.82(c)(1)(iii)

Comment: This section should be reworded to state: "(iii) Facility hazards that could affect the safety of licensed materials and thus present an increased radiological risk."

This revised language is more aligned with the current Part 70 language. The proposed rule wording pertaining to hazardous chemicals will result in subjective interpretation by NRC staff. Any potential hazard which is chemical in nature that could affect the safety of licensed materials, and thus under NRC jurisdiction, will have already been addressed in the ISA. To introduce wording that conflicts with the currently established regulatory wording requires further justification than that provided in FRN Section III F where a statement is provided that "The NRC believes that chemical quantitiesand do affect the safety of radioactive materials....".

11. Section 40.82(c)(3)

Comment: Proposed 10 CFR 40.82(c)(3) should be changed to be more aligned with the timelines provided to existing Part 70 licensees or should be changed to the proposed phrasing provided above.

12. Section 40.82(c)(3)(i-v)

Comment: These sections do not adequately address existing ISAs performed in accordance with Part 70 that would be, or are potentially, subject to the proposed Part 40. As such, provisions should be established to:

- a) Exempt licensees who are currently operating under a NRC approved Part 70 ISA Summary
- b) Eliminate the need to submit a plan for review and approval under (i) which is an undue administrative burden, and
- c) In place of (ii) and (iii) of this section as worded, such licensees should be allowed to submit any changes required over a two to three year period in accordance with the requirements of 70.72(d) where the change identified is the result of changes in analysis required by the proposed Part 40.
- d) Further, utilization of any performance deficiency corrective options allowed by (iv) and (v) of this section should also include relief from reporting requirements of Part 70 for issues identified as the result of changes in analysis required by the proposed Part 40.

13. Section 40.83(b)

Comment: Item 40.83(b) specifies the application of defense-in-depth principles but fails to include the clarifying footnote given in 70.64. This footnote should be included.

14. Section 40.85 (a) (b) &(c)

Comment: Suggested changes to 40.82(c)(3)(i-v) should also be reflected in section 40.85 to address licensees or applicants that have already performed an ISA but would be subject to the proposed Part 40.

15. Section 40.85(c)(2)

Comment: Proposed 10 CFR 40.85(c)(2) should, again, remove section (d) from inclusion.

16. Section 40.86

Comment: This section should be reworded to take into account the lessons learned from the Part 70 implementation. After several reports on this criteria for non-radiological related items, NRC issued guidance in FCSS ISG-12, Rev. 0 (ML102020267) that clarified what reports were actually necessary to make under the comparable provision in Part 70. This section of the rule should be written clearly to identify this section applies to NRC licensed materials or hazardous chemicals produced from licensed materials. NRC does not need to be informed if a permit daily limit for Total Suspended Solids is exceeded for an onsite Sanitary Waste Treatment System; however, the current wording would allow such a broad interpretation.

17. Section 40.86(c)

Comment: Industry believes that the current language is too prescriptive and is not performance-based in that it does not give the licensee enough flexibility to effectively manage the facility. In order to improve efficiency for both the licensee and the NRC, it is proposed that 40.86(c) be revised to state:

40.86(c): "The licensee may make changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, without prior Commission approval if the change does not alter any safety aspect of an item relied on for safety, listed in the integrated safety analysis summary, that is the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of §40.81."

Many Part 70 licensees have had significant issues with the wording that is presented in 40.86(c), which is verbatim to §70.72(c)(ii)(3). As such, NRC staff drafted an Interim Staff Guidance (ISG) (not yet published) to provide a more thorough explanation of this section of Subpart H. Industry recommends the NRC revise the rule and issue the clarifying guidance.

18. Section 40.86 (c)(4)

Comment: Suggest that this section be reworded to state: "(4) Alter the safety attributes of any item relied on for safety, listed in the integrated safety analysis summary, that is the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of § 40.81; or...."

Alterations to an IROFS or design feature could be altered without affecting the safety aspect such that there is no change in the item's ability to perform its intended function.

19. Section 40.86(d)(2) and (3)

Comment: Based on previous discussions with NRC, industry suggests that the due dates for the annual facility and ISA change summaries be modified to state that the required submittals are due within 30 days of the anniversary date of the license. As a result, licensee submittals to NRC would be staggered throughout the calendar year and resources expended accordingly avoiding the "crunch time" by licensees and NRC during the period of November – February each year.

20. Section 40.86(e)

Comment: Proposed 40.86(e) should clearly define the word "promptly" or, at minimum, clarifying guidance should be included in NUREG-1962.

21. Section 40.88(a)(1)

Comment: The reporting requirements should be based on the performance requirements. Assuming that industry's suggested modifications to the performance requirements are adopted, section 40.88(a)(1) should be revised to state: "An acute intake of soluble uranium by an individual that exceeds the performance requirement specified in 40.81(b)(3)."

22. Section 40.88(b)

Section 40.88 is new and modeled after 10 CFR 70, Appendix A with the exception that 3 of the 9 items raised in industry's Part 70, Appendix A Petition for Rulemaking appear to have been addressed in sections 40.88(a) and (b), i.e., 60-day written reports.

Comment: Industry supports these modifications and understands that based on discussions during the August 2011 public meeting that NRC intends to make conforming changes to Part 70 in the near term.

23. Section 40.88 (b) (4)

Comment: Industry suggests that this section be revised to state: "(4) Any natural phenomenon or other external event, including fires internal and external to the facility that has affected the intended safety function or availability or reliability of one or more items relied on for safety."

The subjective term "may" has been removed to improve rule clarity. A fire anywhere near a given site can unrealistically be considered in a "may" statement to spread and eventually impact the structure and equipment inside that structure. Since an uncontrolled fire not contained within a given amount of time is already reported to NRC under the emergency plans, this subjective criterion is unnecessary and potentially can result in violations based solely on interpretation.

COMMENTS ON DRAFT NUREG-1962 and DRAFT REGULATORY ANALYSIS
Enclosure 3

DRAFT NUREG-1962

Industry suggests that NRC include language in this guidance document to address the following text which industry suggests be deleted from the proposed section 40.4 definition of ISA.

~~"Integrated Safety Analysis means a systematic analysis to identify.....and the items relied on for safety including design features. As used here, integrated means.....and chemical. The NRC's ISA requirement is limited to consideration of the effects of all relevant hazards on radiological safety or chemical hazards directly associated with NRC licensed material. An integrated safety analysis can be performed process by process, but all processes must be integrated, and process interactions considered.~~

NRC should include the deleted text as indicated in Enclosure 2, Specific Suggested Edits to the Proposed Rule, item 1, for the definition of defense-in-depth practices since this information is most appropriate for NUREG-1962 as it is not a definition, but rather an explanation of the defined term.

NRC should include the deleted text as indicated in Enclosure 2, Specific Suggested Edits to the Proposed Rule, item 3, regarding design feature in NUREG-1962.

As noted in Enclosure 2, Specific Suggested Edits to the Proposed Rule, item 9, regarding proposed section 40.81(e)(2), mandating postings, which many consider the least effective training and familiarization tool, results in an unnecessary administrative burden. Also the term "conspicuously" is subjective and therefore reliant on interpretation. If postings are indeed the appropriate training tool then the licensee is in a better position to make that determination based on particular circumstances. There are numerous methods available to better inform and disseminate information and thus allowance for posting is more appropriately contained within NUREG-1962.

As noted in Enclosure 2, Specific Suggested Edits to the Proposed Rule, item 20, the proposed section 40.86(e) should clearly define the word "promptly" or, at minimum, clarifying guidance should be included in NUREG-1962.

Abstract, Page 3

Item 3 – This example represents an abnormal condition which should be addressed within an emergency plan and not an ISA.

Item 5 – This example is confusing. The connection between a crane lift accident producing a forklift fire and the resulting impact upon licensed material is not readily apparent. A rewording of the example to state, "A radioactive material container rupture due to a puncture produced by a crane lift accident drop or a forklift fire" would be reasonable and appropriate.

Item 6 – The example and the explanatory text seems to contradict the chlorine tank example provided in Item 3 of this section. If this example need not be evaluated in the ISA, what mechanism allows for this distinction? This example could also have the potential to prevent an operator from taking any actions needed to ensure radiological safety. The guidance provided in items 3 and 6 also appear to be very subjective and broad which will lead to numerous interpretations by both NRC and industry.

Last paragraph under Item 6 – The first sentence denotes that all the preceding examples “must” be evaluated during the ISA process; however, in the paragraph above the statement is made that certain scenarios “would need to be evaluated.” This is confusing and should be clarified.

DRAFT REGULATORY ANALYSIS

It appears that the NRC cost estimates, referenced in the Federal Register Notice and the Draft Regulatory Analysis, for development and implementation of an ISA are grossly underestimated based on industry’s collective experience to date. Specifically, based on available industry data, NEI estimates that industry costs for developing an ISA range from \$1 million to \$ 9 million. These costs far exceed the NRC estimate of \$290K. In addition, it is also interesting to note that NEI estimates that the NRC billing for reviewing and approving the facility-specific ISA Summaries ranged from \$ 0.5 million to more than \$1 million.

Fuel Cycle Industry Comments on Proposed Part 40*

**Fuel Facility Representatives
NEI Representatives**

August 17, 2011 NRC Public Meeting

* Comments are illustrative and not all inclusive



Overview

- **ISA Implementation & Costs**
- **Jurisdictional & Consistency Concerns**
- **Examples of Rule Edits**
- **Conclusion**

ISA Implementation & Costs

- **Regulatory Stability** - Transition of Existing ISAs not Addressed; Coordination with New ISA Effective Dates not Clear
- **Schedule** - ISA Schedule is Overly Restrictive and Does not Consider Transition from Existing ISA
- **Costs** - ISA Development & Implementation Costs Significantly Underestimated by NRC Based on Industry Experience

Jurisdictional Concerns

- **NRC's Jurisdiction Needs to be Clarified**
- **SOC, p. 28341: NRC to be “Sole Licensing Authority” (≥ 2000 kg UF₆) and “Hold Licensing Authority for All Radiological Activities of Such Licensees”**
 - **Licensing of (and Scope of ISAs for) Uranium Compounds other than UF₆ under Part 40, 70 or Agreement States not Clear**
 - **Part 40 Should Exempt Part 70 Licensees Possessing Natural or Depleted UF₆**

Consistency Needed

- **Consistency Across Fuel Facility Fleet Needed**
 - 40-Year License Term
 - Conforming Changes to Part 70, Appendix A, Reportable Safety Events (PRM 70-8)
 - Recognition of Higher Soluble Uranium Intake Values Allowed by NRC and Presented in Industry Consensus White Paper
 - ISA Approach Consistent with Part 70

Examples of Suggested Rule Edits

- **40.4: Considering definition of Design Features and Conforming Modifications to Definitions of Configuration Management and ISA**
- **40.81(b)(4)&(c)(4): Add “inhalation” for Worker Exposure Standard**
- **40.82: Modify to Consider Sequential Nature of Submittals (e.g. Timelines Experienced by Part 70 facilities)**
- **40.82: Exempt Current Part 70 Licensees from a Part 40 ISA**
- **40.86: Modify to Require Annual Submittal of ISA Summary Updates within 60 Days of License Anniversary Instead of 30 Days After the End of the Calendar Year**

Conclusion

- **ISA:**
 - **Implementation & Costs Concerns**
 - **Efficient and Effective Transition of Existing ISAs**
- **NRC's Jurisdiction Not Clear**
- **Fuel Facility Fleet Consistency Needed, e.g., Reportable Events & Soluble Uranium Intake**

From: Vietti-Cook, Annette
Sent: Friday, September 09, 2011 5:37 PM
To: Ngbea, Evangeline
Cc: Mike, Linda; Lewis, Antoinette; Champ, Billie
Subject: FW: REVISED: Industry Comments on Domestic Licensing of Source Material - Amendments/Integrated Safety Analysis, Proposed Part 40
Attachments: 09-09-11_NRC_Industry Comments on Domestic Licensing of Source Material.pdf; 09-09-11_NRC_Industry Comments on Domestic Licensing of Source Material_Attachment.pdf

From: SCHLUETER, Janet [<mailto:jrs@nei.org>]
Sent: Friday, September 09, 2011 5:34 PM
Subject: REVISED: Industry Comments on Domestic Licensing of Source Material – Amendments/Integrated Safety Analysis, Proposed Part 40

Please disregard the previous e-mail forwarded. This e-mail correspondence forwards a revised copy of the attachment. We apologize for any inconveniences.

September 9, 2011

Ms. Annette L. Vietti-Cook
Secretary to the Commission
Attention: Rulemakings and Adjudications Staff
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Industry Comments on Domestic Licensing of Source Material – Amendments/Integrated Safety Analysis, Proposed Part 40; RIN 3150-A150; NRC Docket 2009-0079 (76FR28336, May 17, 2011)

Project Number: 689

Dear Ms. Vietti-Cook:

On behalf of the fuel cycle industry, the Nuclear Energy Institute (NEI)^[1] submits the following industry comments on the proposed Part 40 rule applicable to certain fuel cycle facilities. We appreciated the favorable agency response to our June 21, 2011, letter request for a public meeting on the proposed rule that was held on August 17, 2011, and an extension of the comment period for the rule and Draft NUREG-1962 until September 9, 2011. The meeting discussions informed our comments which we trust the staff will find useful and informative as it proceeds to draft a final rule for Commission review and approval. In addition, we suggest that the U.S. Nuclear Regulatory Commission (NRC) make the final guidance and related inspection procedures publicly available by the effective date of the final rule.

Industry's comments are grouped into four general categories as presented during the August 17, 2011 public meeting. A copy of our meeting presentation is attached. We offer general comments in the categories of

Integrated Safety Analysis (ISA) Implementation, jurisdictional and industry consistency issues (Enclosure 1), as well as responses to the NRC questions in the Federal Register Notice along with comments and specific edits to the rule (Enclosure 2), the Draft NUREG-1962 and the Draft Regulatory Analysis (Enclosure 3).

As an overview, industry's primary concerns can be summarized, as highlighted below, and discussed in more detail in the enclosures.

Enclosures

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Director, Fuel and Materials Safety

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