PR 40 and 150
(76FR28336)

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International Isotopes Inc.

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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

September 7, 2011

Ms. Annette L. Viette-Cook
Secretary
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville MD 20555-0001

Attn: Rulemaking and Adjudications Staff - *Rulemaking.Comments@nrc.gov*

Subject: Comments on Proposed Rule Language, 10 CFR Parts 40 and 150 "Domestic Licensing of Source Material –Amendments/Integrated Safety Analysis", (RIN 3150-A150) Docket ID NRC-2009-0079

Dear Ms. Viette-Cook:

International Isotopes Inc. (INIS) appreciates the opportunity to provide comments on the Proposed Rule Language, "Domestic Licensing of Source Material –Amendments/Integrated Safety Analysis," which was published in the *Federal Register* on May 17, 2011 (76 FR 28336). INIS is a small business currently in the process of licensing a depleted uranium hexafluoride de-conversion facility to be located in Hobbs, New Mexico that will be directly affected by the Proposed Rule. In a May 26, 2009 letter and consistent with SECY-07-0146, the U.S. Nuclear Regulatory Commission (NRC) directed INIS to submit an integrated safety analysis (ISA) summary and to incorporate an appropriate emergency planning assessment with the license application. In an effort to meet this directive INIS prepared the license application using guidance provided in "Standard Review Plan (SRP) for the Review of a License Application for a Fuel Cycle Facility" (NUREG-1520).

INIS has invested a significant amount of resources in developing the ISA for the proposed Fluorine Extraction Process / Depleted Uranium Hexafluoride De-conversion Plant (FEP/DUP) to be located in Hobbs, New Mexico. As stated above, this ISA was developed in accordance with Part 70 Subpart H and regulatory guide NUREG-1520. It is not clear how a Part 40 licensee that prepared an ISA under Part 70 will transition to the new Part 40 regulations after the FEP/DUP facility is licensed and the rule becomes effective. There needs to be a mechanism in place that acknowledges and accepts an ISA developed and approved in accordance with Part 70 Subpart H as directed by SECY-07-0146 for Part 40 facilities affected by the proposed rule.

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I conducted a thorough review of the Proposed Part 40 rule and, based on INIS's experience in developing an ISA summary for a Part 40 license application along with our engagement with the NRC, the Nuclear Energy Institute (NEI) and other Fuel Cycle Licensees addressing issues regarding Part 70 Subpart H rule requirements, prepared general and specific comments to the proposed rule. I have provided these comments in Attachments 1 and 2 of this letter for consideration by the Staff.

Please contact me by phone at (208) 524-5300 or by email at jjmiller@intisoid.com if you have questions regarding the comments provided with this letter.

Sincerely,

John J. Miller, CHP
Radiation Safety Officer

JJM-2011-48

Enclosures as Stated

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Attachment 1: General Comments to Proposed Part 40 Rule

1. In regards to Question K (Federal Register Vol. 76 No. 95 Page 28340); *Should the NRC use probabilistic risk analyses methodology at 10 CFR Part 40 licensed facilities*? The simple answer would be **No**.

   The ISA methodology has been found to be more than adequate for Part 70 licensed facilities and should be considered equally effective for Part 40 facilities. In addition, International Isotopes Inc. expended a significant amount of resources completing an ISA, as directed by the NRC in accordance with SECY 07-0146, as part of the license application for the Fluorine Extraction Process / Depleted Uranium Hexafluoride De-conversion Plant (FEP/DUP). The PRA methodology does not provide a benefit over the ISA methodology that would warrant negating the effort taken by licensees that had developed ISAs and the additional cost to the licensees associated with conducting a PRA.

2. Portions of the proposed rule as well as the current Part 70 rule contain subjective criteria complicating the ability of the licensee to operate and the NRC to regulate these facilities.

3. There is no mechanism in place that supports the transition from current ISAs to the Part 40 ISA. International Isotopes Inc. has invested a significant amount of resources in developing the ISA for the proposed FEP/DUP facility to be located in Hobbs, New Mexico. This ISA was developed in accordance with Part 70 Subpart H and regulatory guide NUREG-1520. Assuming the FEP/DUP is licensed it is not clear how a Part 40 licensee that prepared an ISA under Part 70 will transition to the new Part 40 regulations.

4. In the Staff Requirements Memoranda (SRM) to SECY-06-0186, the Commission approved the staff's recommendation to implement maximum license terms of up to 40 years. This term can be considered for new applications which implement an integrated safety analysis (ISA), as required by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, Subpart H, and was used to provide a basis for the approval of a 40 year license term for the International Isotopes Fluorine Products (IIFP) FEP/DUP facility should the facility receive a license. The proposed rule should allow for a 40 year license term for Part 40 facilities that fulfill the requirements of Subpart H of the proposed rule.

5. The Initial Cost of $290,000 from Table A1 of the September 2010 Regulatory Analysis are grossly underestimated. International Isotopes Inc. has incurred costs in excess of $1,000,000 in developing the ISA as part of the FEP/DUP license application and that cost excludes NRC review costs. While we have not yet been licensed we believe the estimated annual cost of $119,000 referenced in the Federal Register is equally underestimated.

Attachment 1: General Comments to Proposed Part 40 Rule

6. Lessons learned and issues that have developed during the implementation of Part 70 Subpart H should be considered in the proposed Part 40 rule making. Specifically the acknowledgement and use of design features inherent to a facility or design that either reduces the likelihood or mitigates the consequence of an internal or external event and reliance on industry to develop quantitative standards for dermal exposures to hazardous materials produced from licensed operations to be utilized to define high or intermediate consequence events.

7. The NRC's regulatory authority in regards to licensees located in Agreement States needs to be clarified. The language of the proposed rule does not suggest the NRC has sole regulatory authority over these facilities.

Attachment 2: Specific Comments to Proposed Part 40 Rule

1. Clarify §40.3a Denial of licensing by Agreement States.

   Basis: The language in §40.3a does not appear to match the intent of the NRC's proposed rule as stated in Section IV. Discussion of Proposed Amendments by Section. Specifically the discussion states:

   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.

   The language used in §40.3a simply prohibits Agreement States from issuing new licenses covering the possession of 2000 kilograms or more of uranium hexafluoride. This language does not equate to granting the NRC sole licensing authority over such a facility. By including the terms "new" and "covering" in the rule language one could argue that existing licensees would be exempt from the rule and that an Agreement State could still issue licenses covering the possession of uranium compounds other than UF_6 and byproduct materials that may be possessed by a facility that is licensed to possess 2000 kg or more of UF_6.

2. §40.4 - Suggest revising the definition of *Defense–in–depth*

   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.~~

   Basis: This text is better suited as a footnote to the definition as is the case in §70.4 or could be included in the guidance document NUREG-1962.

3. §40.4 - Suggest revising the definition of *Hazardous chemicals produced from licensed materials*;

   Hazardous chemicals produced from licensed materials means substances having licensed material as precursor compound(s) or substances that physically or chemically interact with licensed materials; and that are toxic, explosive, flammable, corrosive, or

reactive to the extent that they can endanger life or health if not adequately controlled. These include substances commingled with licensed material, and include substances such as hydrogen fluoride that is produced by the reaction of uranium hexafluoride and water, but do not include substances prior to process addition to licensed material or after process separation from licensed material such that the quantity of residual source material remaining in the hazardous chemical is by weight less than one-twentieth of 1 percent (0.05 percent).

Basis: This addition to the definition removes the ambiguous meaning of "process separation" and is consistent with the exemption currently contained in §40.13 Unimportant quantities of source material.

4. §40.4 - Suggest revising the definition of *Integrated Safety Analysis Summary*;

Integrated safety analysis summary means a document or documents submitted with the license application, license amendment application, license renewal application, or pursuant to §40.82(c)(3)(ii) that provides a synopsis of the results of the integrated safety analysis and contains the information specified in § 40.84(b). ~~The integrated safety analysis summary can be submitted as one document for the entire facility, or as multiple documents that cover all relevant portions and processes of the facility~~.

Basis: The deleted text is more appropriate in the guidance document NUREG-1962.

5. §40.4 - Suggest adding a new definition for *Design feature*;

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.

Basis: The Design Feature concept has been a point of discussion between the industry and the NRC for a number of years. International Isotopes Inc. believes design feature, as defined above, better describes the IIFP facility building design and construction aspects that address natural phenomena hazards. Adding the definition of design feature supports International Isotopes Inc. desire to utilize design features in their Integrated Safety Analysis while maintaining a robust safety program capable of meeting the performance requirements identified in §40.81.

6. §40.4 - Suggest revising the definition of *Configuration management* to include design feature.

Configuration management means a management measure that provides oversight and control of design information, safety information, and records of modifications (both temporary and permanent) that might impact the ability of items relied on for safety or design features to perform their functions when needed.

Basis: Revised definition supports the introduction of the term design feature.

7. §40.4 - Suggest revising the definition of *Integrated safety analysis* to include design feature and to delete last two sentences.

Integrated safety analysis means a systematic analysis to identify facility and external hazards and their potential for initiating accident sequences, the potential accident sequences, their likelihood and consequences, and the items relied on for safety and design features. As used here, integrated means joint consideration of, and protection from, all relevant hazards, including radiological, fire, 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 radioactive material. An integrated safety analysis can be performed process by process, but all processes must be integrated, and process interactions considered.~~

Basis: Revised definition supports the introduction of the term design feature, deleted text more appropriate in the guidance document.

8. Suggest revising §40.81(a) as follows:

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) and (c)~~, and (d)~~ of this section.

Basis: Paragraph (d) does not contain performance requirements.

9. Suggest revising paragraph §40.81(b)(3) as follows:

§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 in soluble form by any individual located outside the controlled area as specified in paragraph (e) of this section; or

Basis: Defining a soluble uranium intake criterion to the worker that coincides with a high consequence event is consistent with identifying a soluble uranium intake to an individual located outside of the controlled area that coincides with a high consequence event. This provides consistency in the regulation and simplifies the burden placed on the licensee and the NRC in developing and approving facility specific worker intake values for soluble uranium that coincide with a high consequence event.

The 100 mg value includes a sufficient level of conservatism and is supported by the Nuclear Energy Institute report provided to the NRC on May 22, 2009 for consideration to Part §70.61 Performance requirements. The report titled, *Acute Chemical Toxicity of Uranium with Application to 10 CFR 70.61* provided a technically sound industry-consensus set of criteria that can be directly applied at any facility as consequence criteria that can be linked to the performance requirements.

The 100 mg value is conservative in regards to the high consequence event classification in that the consequence to the worker resulting from an intake of 100 mg of soluble uranium is best categorized as an "irreversible or other serious long lasting health effect", which in the case of a worker describes the effect associated with an intermediate-consequence event.

Table 4 from the NEI report is provided below for reference.

Table 4. Proposed Toxicological Threshold levels for Acute Intakes of Soluble Uranium¶

Risk	Acute Ingestion Dose* (mg)	Acute Ingestion Dose (mg U/kg)	Acute Inhalation Dose* (mg)	Acute Inhalation Dose (mg U/kg)	Peak concentration in adult kidney (ug U/g)	Comments
Life endangerment	>2500	> 36	>500	>7.1	>18 >52	No reported deaths in humans from calculated kidney concentrations of ≤~380 µgU/g
Irreversible or serious long lasting health effects	>1400	>20	>100	>1.4	>10	No reported permanent kidney damage in humans from calculated kidney concentration of ~50 µgU/g indicating permanent damage may not occur at sub-lethal doses.
Mild transient health effects	410	5.9	30	0.5	3	Totally reversible effects with no acute or long term functional impairment detectable only by urinary biomarkers.

¶ Table reproduced from Kathren and Burklin 2008b.
* Normalized to 70 kg adult male values rounded.

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10. Suggest revising paragraphs §40.81(b)(4) and §40.81(c)(4) as follows:

(4) An acute chemical inhalation exposure to an individual from licensed material or hazardous chemicals produced from licensed material that...

Basis: While it is recognized that there are exposure hazards other than inhalation associated with hazardous chemicals produced from licensed operation the performance requirements should be limited to airborne exposures to hazardous chemicals for the following reasons;

(1) Inhalation is the bounding acute chemical exposure pathway for individuals located outside of the controlled area.

The NRC provides the following example in Section II. Background of the Federal Register Vol. 76, No. 95 28337.

For example, the presence of UF6 in large quantities means that the hazards of hydrogen fluoride (HF) must be considered. The HF gas (and uranyl fluoride) is quickly produced from the chemical reaction that occurs when UF6 is exposed to water, present as humidity in the air, and HF gas may quickly move offsite. The HF is a highly reactive and corrosive chemical that presents a substantial inhalation and skin absorption hazard to both workers and the public.

While there is no question that HF presents an inhalation and skin absorption hazard to an individual exposed in such a manner, the example implies that a release of HF gas that moves offsite presents a substantial skin absorption hazard to a member of the public. This is not entirely accurate; while a plume of HF gas may present a skin absorption hazard to an individual exposed to a plume of highly concentrated HF; the hazard posed to the individual as a result of inhaling the HF gas would be of greater significance. Pursuant to §40.81(b) and (c) controls must be applied that either reduce the likelihood of or consequence associated with the event. Controls put in place to reduce the likelihood of the event, i.e. the release, limit the risk to an individual located outside of the controlled area regardless of exposure pathway. Barring any actions that would be taken by the exposed individual, controls that limit the consequence of the event to an individual located outside of the controlled area would either reduce the source term or limit the duration of the release. In either case, bounding the consequence with the inhalation exposure pathway would thereby reduce the consequence associated with dermal exposure. As such, developing a "quantitative standard" for acute dermal exposure to an individual located outside of the controlled area will not serve any function in regards to complying with the performance requirements of §40.81.

(2) Unlike §40.81(b)(1-3) and §40.81(c)(1-3) the consequences in §40.81(b)(4) and §40.81(c)(4) are subjective and cannot be measured directly. Instead they must be inferred based on some other measurement. On page 28343 of Federal Register Vol. 76, No. 95, the NRC discusses the use of an appropriate quantitative standard such as an AEGL or ERPG as the chemical consequence criteria corresponding to anticipated adverse health effects to humans from acute exposures. In fact the descriptions of the health effects in §40.81(b)(4)(i-ii) and §40.81(c)(4)(i-ii) can be linked directly to those in the definitions of the AEGLs and ERPGs shown below.

§40.81(b)(4)(i)	*could endanger the life*
AEGL-3	*could experience life-threatening health effects or death*
ERPG-3	*without experiencing or developing life-threatening health effects*
§40.81(b)(4)(ii), §40.81(c)(4)(i)	*could lead to irreversible or other serious, long-lasting health effects*
AEGL-2	*could experience irreversible or other serious, long-lasting adverse health effects*
ERPG-2	*without experiencing or developing life-threatening health effects*
§40.81(c)(4)(ii)	*Could cause mild transient health effects*
AEGL-1	*could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure*
ERPG-1	*without experiencing other than mild transient adverse health effects*

Given the similarities in the language cited above it appears that the qualitative consequences described in §40.81(b)(4)(i-ii) and §40.81(c)(4)(i-ii) were intended to be linked to the comparable exposure standard associated with the hazardous chemical of interest.

(3) Compliance with the performance requirements in regards to acute chemical exposures to the worker other than an airborne exposure, specifically a dermal exposure, is problematic because dermal exposure standards for the hazardous chemicals typical of facilities handling large quantities of uranium hexafluoride (UF_6), primarily hydrogen fluoride (HF), do not exist. The last sentence of §40.81(b)(4)(ii) and §40.81(c)(4)(ii) states: *If an applicant or licensee possesses or plans to possess quantities of material capable of such chemical exposures, then the applicant or licensee must propose appropriate quantitative standards for these health effects, as part of the information submitted under §40.84.* Similar language is found in §70.61(b)(4)(ii) and §70.61(c)(4)(ii) which has prompted the NRC to require some Part 70 licensees to develop a standard for dermal exposure to HF.

The discussion provided in the Federal Register, however, focuses on the airborne exposure standards.

The qualitative language in §40.81(b)(4) allows the applicant/licensee to propose and adopt an appropriate standard, which may be an AEGL or ERPG standard. Where no AEGL or ERPG is available, the applicant/licensee may develop or adopt a criterion that is comparable in severity to those that have been established for other chemicals. This approach is currently being used in 10 CFR part 70 for fuel cycle facilities.

Interpreting the language provided in both the Federal Register discussion and proposed rule as to require the development of dermal exposure standards for hazardous chemicals produced from licensed materials places the licensee in an undesirable position of developing a quantitative dermal exposure standard were supporting data to justify such a standard does not exist. Consider the case of HF; the National Institute for Occupational Safety and Health (NIOSH) recently updated its process of developing Skin Notation profiles for several hazardous chemicals. The revised Skin Notation profile for HF was published in April 2011 (Publication No. 2011-137) and assigned a Skin Notation profile SK: SYS(FATAL) — DIR (COR) to HF. This assignment was based on systemic toxicity via skin absorption and corrosivity (skin burns) as a result of direct contact. These effects have been cited in case reports and a few animal studies NIOSH identified in the literature. The NIOSH publication acknowledges the lack of data and reports the following;

- No in vivo or in vitro toxicokinetic data were identified that would enable estimating the absorption of HF following dermal exposure.
- The human dermal lethal dose ($LD50_{Lo}$) of HF has not been estimated
- No repeat-dose studies following dermal exposure of humans or animals to HF were identified in the literature
- No standard toxicity or specialty studies were identified that evaluated the biological system/function-specific effects (including reproductive and developmental effects and immunotoxicity) following dermal exposure to HF
- No studies were identified that evaluated the potential of HF to be a carcinogen following dermal exposure
- No studies were identified that estimated the degree of HF absorption through the skin

The NIOSH publication states; *It has been reported that the severity of HF skin burns and the degree of pain and systemic effect depend on the concentration of the HF solution, its quick penetration, the area involved, and the duration of exposure.*

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The publication does not develop standards for dermal exposure to HF. The report concludes that "*No studies were identified that estimated the degree to which HF can be absorbed through the skin. However, several case reports and acute dermal studies in animals indicate that HF is absorbed through the skin. Although no repeat-dose dermal studies involving humans or animals were identified, the acute dermal studies indicated that HF can cause systemic toxicity, including fluorosis, leading to cardiac arrhythmia and eventually death. There is sufficient evidence from several case reports and from dermal exposure studies involving animals to show that undiluted HF or diluted HF solution is corrosive to the skin. Available data suggest that concentrations of HF as low as 0.01% applied for as short as 5 minutes could possibly cause injury to the more sensitive areas of human skin*".

The inability to estimate the degree at which HF can be absorbed through the skin does not support the development of a quantitative dermal exposure standard for HF that would prevent a systemic toxicity health effect. Similarly the number of variables associated with the corrosivity of HF and its effect on the skin would require the development of several quantitative standards to address the corrosive effect of HF exposure to the skin.

Quantitative standards for dermal exposure to HF have not been developed by the chemical industry or by the agencies regulating the chemical industry. Instead the chemical industry relies on personnel protection equipment to reduce the potential for dermal exposures and immediate treatment to mitigate the consequence of a dermal exposure should one occur.

A November 2005 report summarizing the use and production capacity of HF indicates uranium fuel processing consumes 2% of the HF as indicated on the table below.

Hydrofluoric Acid Usage	
Fluorocarbons	58%
Miscellaneous	21%
Aluminum production	13%
Metal etching	3%
Alkylation catalyst	3%
Uranium fuel processing	2%
	100%

http://www.icis.com/Articles/2005/11/07/2010992/hydrofluoric-acid.html

Given the number of the fuel cycle facilities and quantity of HF handled at these facilities relative to the chemical industry as a whole it seems unreasonable to expect a handful of NRC licensees affected by the proposed rule to develop quantitative

dermal exposure standards to HF. The health hazards associated with dermal exposure should be controlled in a manner consistent with the chemical industry;

- through the use of engineered controls to prevent release,
- through the use of personnel protective equipment during handling operations to prevent exposure and,
- through immediate treatment should an exposure occur regardless of concentration or area exposed, to mitigate the exposure.

11. Consequences in §40.81(b)(4)(i-ii) and §40.81(c)(4)(i-ii) are subjective.

If the acute chemical exposure referenced in §40.81(b)(4) and §40.81(c)(4) is limited to an inhalation exposure then the health consequence terms can be linked directly to the AEGLs and ERPGs and there is no need to provide additional clarification. If however the acute chemical exposures are interpreted as including dermal (or any other exposure pathway) then these health consequences need to be defined in terms that are not subjective.

12. Suggest revising §40.81(d) as follows:

(d) Each engineered or administrative control or control system necessary to comply with paragraphs (b) or (c)~~, or (d)~~ of this section must be designated as an item relied on for safety or, where appropriate, as a design feature. The safety program, established and maintained under §40.82, must ensure that each item relied on for safety or design feature will be available and reliable to perform its intended function when needed and in the context of the performance requirements of this section.

Basis: Paragraph (d) appears to be a "cut and paste" error carried over from §70.62(e). Inclusion of the term design feature supports International Isotopes Inc. desire to utilize design features in their Integrated Safety Analysis program.

13. Suggest revising §40.82(c)(1)(iii) as follows:

(iii) Facility hazards that could affect the safety of licensed materials and thus present an increased radiological risk. ~~due to licensed material or hazardous chemicals produced from licensed material~~.

Basis: The proposed language is difficult to interpret and is a significant departure from the language in §70.62(c)(iii). Table 2 in NUREG 1962 does not identify this difference between §40.82 and §70.62, yet there is a significant change in the scope of the requirement.

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14. Suggest revising §40.82(c)(1)(vi) as follows:

(vi) Each item relied on for safety and design feature as specified in §40.81(d), the characteristics of its preventive, mitigative, or other safety function, and the assumptions and conditions under which the item is relied upon to support compliance with the performance requirements of §40.81.

Basis: Inclusion of the term design feature supports International Isotopes Inc. desire to utilize design features in their Integrated Safety Analysis program.

15. Suggest revising §40.82(c)(3) as follows:

Requirements for existing licensees. Individuals holding an NRC license [insert effective date of final rule] shall, with regard to existing licensed activities that are not currently governed by an ISA prepared in accordance with SECY-07-0146:

Basis: Additional language provides a mechanism to transition ISAs developed as ordered by the NRC in accordance with SECY-07-0146 from an NRC Order to regulation.

16. Suggest revising §40.82(d):

(d) *Management measures.* Each applicant or licensee must establish management measures to ensure compliance with the performance requirements of §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 items relied on for safety or design features pursuant to §40.81(d) are designed, implemented, and maintained, as necessary, to ensure they are available and reliable to perform their function when needed, to comply with the performance requirements of §40.81.

Basis: Inclusion of the term design feature supports International Isotopes Inc. desire to utilize design features in their Integrated Safety Analysis program and recognizes that design features normally associated with accepted engineering practices are designed, implemented and maintained utilizing management measures.

17. Suggest revising §40.83(a)(1):

(1) *Quality standards and records.* The design must be developed and implemented in accordance with management measures, to provide adequate assurance that items relied on for safety and design features will be available and reliable to perform their function

when needed. Appropriate records of these items must be maintained by or under the control of the licensee throughout the life of the facility.

Basis: Inclusion of the term design feature supports International Isotopes Inc. desire to utilize design features in their Integrated Safety Analysis program.

18. Suggest revising §40.83(a)(8) to read:

(8) *Inspection, testing, and maintenance.* The design must:

(i) provide for the adequate inspection, testing, and maintenance of items relied on for safety to ensure their availability and reliability to perform their function when needed; and

(ii) ensure that design features are designed, constructed or manufactured utilizing codes, standards and engineering practices that result in a robust structure or component that is easily maintained such that they remain available and reliable to perform their intended function without the need for inspection or testing.

Basis: Provides a mechanism to ensure that design features utilized in new facilities or new processes at existing facilities are designed, constructed and manufactured in a manner that ensures they can be maintained so that they are available and reliable to perform their intended function. An example would be designing and constructing a building utilizing DOE Standard 1020-2002 to meet the performance requirements when the initiating event is the design basis earthquake. After the building is constructed there is no mechanism in place to inspect the components of the building i.e. rebar, concrete, structural steel or test the building to ensure it can perform its intended function – in this example withstanding a design basis earthquake.

19. Suggest revising §40.83(b)(2) as follows:

(2) Features that enhance safety by reducing challenges to items relied on for safety and design features.

Basis: Inclusion of the term design feature supports International Isotopes Inc. desire to utilize design features in their Integrated Safety Analysis program.

20. Suggest revising §40.84(b) as follows:

In any evaluation submitted under 40.31(j)(1)(i), licensees and applicants must also show that, in the event of a release, an acute chemical inhalation exposure from licensed material or hazardous chemicals produced from licensed materials would not result in irreversible or mild transient health effects to a member of the public offsite. If such an

evaluation is not submitted, licensees and applicants must submit an emergency plan pursuant to §40.31(j)(3).

Basis: Consistent with comment 10.

21. Suggest revising §40.84(c)(6) as follows:

(6) A list briefly describing each item relied on for safety and design feature which is identified as specified in §40.81(d) in sufficient detail to understand their functions in relation to the performance requirements of §40.81;

Basis: Inclusion of the term design feature supports International Isotopes Inc. desire to utilize design features in their Integrated Safety Analysis program

22. Suggest revising §40.84(c)(7) as follows:

(7) A description of the proposed quantitative standards used to assess the consequences to an individual from acute chemical inhalation exposure to licensed material or chemicals produced from licensed materials which are on-site, or expected to be on-site as described in §§ 40.81(b)(4) and (c)(4);

Basis: Consistent with comment 10

23. Suggest revising §40.85(c)(2) as follows:

(2) The performance requirements in §§ 40.81(b) and (c) ~~and (d)~~ are satisfied, based on the information in the integrated safety analysis summary, together with other information submitted to the NRC or available to the NRC at the licensee's site.

Basis: §40.81(d) is not a performance requirement.

24. Suggest revising §40.86(c)(3) as follows:

(3) Remove, without at least an equivalent replacement of the safety function, an item relied on for safety or design feature that is listed in the integrated safety analysis summary and is necessary for compliance with the performance requirements of § 40.81;

Basis: Inclusion of the term design feature supports International Isotopes Inc. desire to utilize design features in their Integrated Safety Analysis program.

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25. Suggest revising §40.86(c)(4) as follows:

(4) Alter the safety aspect of any item relied on for safety or design feature, 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

Basis: An IROFS or design feature could be altered without affecting the safety aspect such that there is no change in the ability of the IROFS or design feature to perform its intended function. Inclusion of the term design feature supports International Isotopes Inc. desire to utilize design features in their Integrated Safety Analysis program.

26. Suggest revising §40.88(a)(1) as follows:

(1) An acute intake of soluble uranium by an individual that exceeds the performance requirement specified in §40.81(b)(3) .

Basis: The one-hour reporting requirement should be limited to high consequence events. As proposed a one- hour report would be required if a worker received an acute intake of 30 mg of soluble uranium, which corresponds to a health effect that would be lower than an intermediate consequence to the worker.

27. Suggest revising §40.88(a)(2) as follows:

(2) An acute chemical inhalation exposure to an individual from licensed material or hazardous chemicals produced from licensed material that exceeds the quantitative standards established to satisfy the requirements in § 40.81(b)(4).

Basis: Consistent with comment 10.

28. Suggest revising §40.88(a)(3) as follows:

(3) An event or condition such that no items relied on for safety or design feature, as documented in the integrated safety analysis summary, remain available and reliable, in an accident sequence evaluated in the integrated safety analysis, to perform their function in the context of the performance requirements in §§ 40.81(b) and (c).

Basis: Inclusion of the term design feature supports International Isotopes Inc. desire to utilize design features in their Integrated Safety Analysis program

Attachment 2: Specific Comments to Proposed Part 40 Rule

29. Suggest revising §40.88(b)(2) as follows:

(2) Loss or degradation of an items relied on for safety or design feature that results in failure to meet the performance requirement of §40.81.

Basis: The term "items relied on for safety" suggests that more than one IROFS must fail before a report is made. Inclusion of the term design feature supports International Isotopes Inc. desire to utilize design features in their Integrated Safety Analysis program.

30. Suggest revising §40.88(b)(3) as follows:

(3) An acute chemical inhalation exposure to an individual from licensed material or hazardous chemicals produced from licensed materials that exceeds the quantitative standards that satisfy the requirements of §40.81(c)(4).

Basis: Consistent with comment 10.

31. Suggest revising §40.88(b)(4) as follows:

(4) Any natural phenomenon or other external event, including fires internal and external to the facility that has affected ~~or may have affected~~ the intended safety function or availability or reliability of one or more items relied on for safety or design features.

Basis: the phrase "or may have affected" is subjective and does not warrant a report. Inclusion of the term design feature supports International Isotopes Inc. desire to utilize design features in their Integrated Safety Analysis program.

Rulemaking Comments

From: John Miller [jjmiller@intisoid.com]
Sent: Wednesday, September 07, 2011 9:59 AM
To: Rulemaking Comments
Cc: Bartlett, Matthew
Subject: Comments Part 40 Proposed Rule RIN 3150-A150
Attachments: JJM-2011-48_Part 40_comment letter_RIN 3150-A150.pdf

Please find the attached letter submitting comments on the proposed Part 40 rule.

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