[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 40 and 150

RIN 3150-AI50

[NRC-2009-0079]

Domestic Licensing of Source Material – Amendments/Integrated Safety Analysis

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is amending its regulations by adding additional requirements for source material licensees that are authorized to possess significant quantities of uranium hexafluoride (UF6). The amendments will require such licensees to conduct integrated safety analyses (ISAs) similar to the ISAs performed by licensees under Title 10 of the *Code of Federal Regulations* (10 CFR) part 70; set possession limits for UF6 for determining regulatory authority (NRC or Agreement States); add defined terms; require the NRC to perform a backfit analysis under specified circumstances; and make administrative changes to the structure of the regulations. The new ISA requirements will not apply to facilities that are currently undergoing decommissioning under the current regulations.

This final rule pertains to 10 CFR part 40 licensees and applicants that are authorized to possess, or plan to possess, significant quantities of UF6. The current source material regulations do not contain ISA requirements for evaluating the consequences of facility accidents. The amendments will require applicants and licensees who possess or plan to

possess 2000 kilogram (kg) or more of UF6 to conduct an ISA and submit an ISA summary to the NRC.

The ISA, which evaluates and categorizes the consequences of accidents at NRC licensed facilities, will address both the radiological and chemical hazards from licensed material and hazardous chemicals produced in the processing of licensed material. Similar hazards present at other fuel cycle facilities are addressed by the existing ISA requirements.

The NRC is also issuing new guidance on the implementation of the additional regulatory requirements for licensees that will be subject to this final rule.

DATES: *Effective Date:* This final rule is effective on **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*].**

ADDRESSES: Please refer to Docket ID NRC-2009-0079 when contacting the NRC about the availability of information for this final rule. You may access information and comment submittals related to this final rulemaking, which the NRC possesses and is publicly available, by the following methods:

- **Federal Rulemaking Web Site:** Go to **http://www.regulations.gov** and search for Docket ID NRC-2009-0079.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may access publicly available documents online in the NRC Library at **http://www.nrc.gov/reading-rm/adams.html**. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to **pdr.resource@nrc.gov**. The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Edward M. Lohr, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-0253, e-mail: *Edward.Lohr@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Health and safety risks at 10 CFR part 40 fuel cycle facilities authorized to possess significant quantities of UF6 are both radiological and chemical in nature. These facilities not only handle radioactive source material but also large volumes of hazardous chemicals that are involved in processing the nuclear material. 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 the 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.

Such hazards were demonstrated in the 1986 accident involving UF6 and HF at Sequoyah Fuels (a 10 CFR part 40 licensed facility). A cylinder of UF6 ruptured and resulted in a worker fatality. The cause of the worker's death was the inhalation of HF gas produced when the cylinder ruptured. The fact that HF can be produced from UF6 under certain conditions and that it has a significant potential for onsite and offsite consequences, are among the principal factors on which this rulemaking is based.

The current 10 CFR part 40 does not contain ISA requirements for evaluating the consequences of facility accidents. Similar hazards, both radiological and chemical, that exist at fuel cycle facilities that are regulated under 10 CFR part 70 are addressed by requirements contained in 10 CFR part 70, subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material."

In March 2007, the NRC staff briefed the Commission on health and safety concerns involving 10 CFR part 40 fuel cycle facilities authorized to possess significant quantities of UF6. Based on these concerns, the Commission issued Staff Requirements Memorandum (SRM)-M070308B, "Staff Requirements – Briefing on NMSS Programs, Performance, and Plans" (March 22, 2007), directing the staff to propose options for rulemaking that would impose ISA requirements (similar to those currently found in 10 CFR part 70, subpart H) on current and future 10 CFR part 40 fuel cycle facilities authorized to possess significant quantities of UF6. The SRM also directed the staff to inform the Agreement States that the NRC will regulate future major fuel cycle facilities licensed under 10 CFR part 40, e.g., uranium conversion and deconversion facilities. The NRC sent a letter to the Agreement States on April 13, 2007 (FSME-07-036, ADAMS Accession No. ML071030304), notifying them of the Commission's directive.

In SECY-07-0146, dated August 24, 2007 (ADAMS Accession No. ML071700584), the staff recommended that the Commission:

1) Approve keeping the Starmet and Aerojet Ordnance facilities under Agreement State jurisdiction and, if similar new facilities are proposed in Agreement States in the future, the NRC would retain jurisdiction of only those facilities that exceed the threshold quantity limits discussed in Recommendation 2.

2) Approve conducting a rulemaking to amend 10 CFR part 40. This would require new applicants and existing licensees for 10 CFR part 40 fuel cycle facilities with UF6 or uranium tetrafluoride (UF4) inventories greater than 10,000 kg (or an alternative threshold quantity) to meet ISA requirements similar to those in 10 CFR part 70, subpart H. These requirements would not apply to existing facilities currently undergoing decommissioning. If new applicants submit license applications before the completion of the rulemaking, the NRC would issue orders establishing the 10 CFR part 70, subpart H, performance requirements as part of the licensing basis for the application review.

The Commission issued an SRM for SECY-07-0146, dated October 10, 2007 (ADAMS Accession No. ML072830536), approving Recommendations 1 and 2. The Commission stated that if new license applications are submitted before the completion of the rulemaking, "the staff shall impose 10 CFR Part 70, Subpart H, performance requirements as part of the licensing basis for the application review." As further directed in the SRM, the NRC held a public meeting on February 22, 2008, at NRC Headquarters in Rockville, Maryland, to discuss the scope of the proposed rulemaking and to seek public input on the proposed threshold quantities for determining when a facility will be regulated by the NRC or an Agreement State. Industry stakeholders that would be impacted by the rulemaking and representatives from four Agreement States attended the meeting either in person or via teleconference. All participants were encouraged to send in written comments within 30 days.

The Nuclear Energy Institute (NEI) and Honeywell Specialty Materials (Honeywell) attended the meeting and both submitted similar written comments. While both supported the

concept of threshold UF6 quantities to determine if ISA requirements analogous to 10 CFR part 70, subpart H, should be required for new licensees, neither supported implementing the proposed ISA requirements at existing facilities. The commenters expressed the opinion that the NRC's mission is to protect public health and safety from the effects of radiological materials, and this mission does not encompass chemical hazards. Both noted the 10 CFR part 70 ISA requirements focus on preventing criticality events, a concern not relevant to source material licensees, and assessing and mitigating the radiological risk of enrichment operations. They felt the primary health and safety concerns from licensed operations are chemical in nature, and since chemical concerns are not the mission of the NRC, the ISA should be narrowly focused to deal only with radiological concerns.

Honeywell further noted that it had already voluntarily submitted a risk-informed ISA to support the license renewal of its Metropolis, Illinois facility, and observed that its plant had only been operating under the ISA since November 2007. It argued that not enough time has passed to assess the effectiveness of the current ISA. Therefore, Honeywell argued that it should be given several years to determine whether its current ISA is adequate before the NRC proceeds with any ISA rulemaking.

The NRC does not agree with these NEI and Honeywell comments. As discussed previously, the Sequoyah Fuels accident that killed one of its employees did not involve a criticality event. The chemical hazard that produced the fatality resulted from the licensed UF6 material that was being handled at the facility, and such hazards are within the NRC's regulatory authority. A more in-depth discussion of the NRC's authority to regulate these specific chemical hazards is provided under Question E in Section II (Discussion) of this document. The NRC continues to find that generic ISA requirements are necessary to ensure that an adequate level of public health and safety is maintained at existing and future 10 CFR part 40 facilities handling significant quantities of UF6.

The NRC staff, in reviewing the data and information available, determined that UF4 did not constitute the same risk as UF6 at 10 CFR part 40 fuel cycle facilities. In a memorandum to the Commission dated June 23, 2009 (ADAMS Accession No. ML091740121), the staff informed the Commission of its findings and intentions not to pursue rulemaking at this time to require an ISA for licensees possessing UF4 in any quantity.

A draft proposed rule was provided to the Commission in SECY-10-0128, dated October 1, 2010 (ADAMS Accession No. ML102380272). In response to SECY-10-0128, the Commission issued an SRM dated November 30, 2010 (ADAMS Accession No. ML103350037), which directed the staff to publish the draft proposed rule for public comment subject to Commission comments and changes which included:

1) Adding a backfit provision similar to § 70.76, applicable to any source material licensee authorized to possess 2000 kg or more of UF6, which becomes effective once such a licensee's ISA summary has been approved by the NRC;

2) Seeking public comment with regard to the potential challenges and impacts on the use of probabilistic risk analyses methodology at 10 CFR part 40 facilities;

3) Publishing concurrently with the proposed rule draft regulatory guidance and a standard review plan related to the proposed rule;

4) Issuing guidance regarding the completion of ISAs to account for differences in the processes or hazards for 10 CFR part 40 facilities, as compared to 10 CFR part 70 facilities; and

5) Providing (from the effective date of the rule) 6 months to develop an ISA plan; 18 months to produce an ISA; and 3 years to correct all performance deficiencies.

Additionally, the SRM directed the staff to determine whether the 1988 Memorandum of Understanding (MOU) (53 FR 43950) between the NRC and the Occupational Safety and Health Administration (OSHA) needs to be modified. If no need to modify the MOU was found,

the SRM directed the staff to provide a clear explanation in the proposed rule and in guidance of how MOU Criterion 3 should be evaluated by a licensee in completing its ISA. The MOU Criterion 3 references plant conditions affecting "the safety of radioactive materials and [which] thus presents an increased radiation risk to workers." As discussed further under Question E in Section II of this document, the staff found there was no need to modify the MOU, and the staff has developed guidance on how MOU Criterion 3 should be evaluated in completing ISAs.

The proposed rule and draft guidance document were published for public comment in the *Federal Register* on May 17, 2011 (76 FR 28336, ADAMS Accession No. ML111380207), and an administrative correction to 76 FR 28336 was published in the *Federal Register* on June 1, 2011 (76 FR 31507). The proposed rule had a public comment period of 75 days, closing on August 1, 2011. The NEI, in a letter dated June 21, 2011 (ADAMS Accession No. ML111950182), requested the NRC to hold a public meeting on the proposed rule and draft guidance document and to extend the public comment period. Based on NEI's request, the NRC published a *Federal Register* notice on July 27, 2011 (76 FR 44865, ADAMS Accession No. ML112092486), extending the comment period to 115 days, closing on September 9, 2011, and announcing a public meeting on August 17, 2011, to seek public input on the proposed rule and its associated draft guidance document.

As a result of the May 17, 2011, *Federal Register* notice (76 FR 28336) soliciting public comments and input received at the public meeting held on August 17, 2011, the NRC received nine comment letters addressing multiple issues. Comment summaries, and responses to the comments, are provided in Section III, Summary and Analysis of Public Comments on the Proposed Rule, of this document.

II. Discussion

A. What action is the NRC Taking?

The NRC is amending 10 CFR part 40 to require applicants or licensees that are, or plan to be, authorized to possess 2000 kg or more of UF6 to conduct an ISA and submit an ISA summary. The new ISA requirements are similar to requirements found in 10 CFR part 70, subpart H, which apply to fuel fabrication and enrichment facilities. In this final rule, the NRC asserts regulatory jurisdiction over all source material at facilities authorized to possess 2000 kg or more of UF6 under its common defense and security authority in the Atomic Energy Act of 1954, as amended (AEA), section 274m. The final rule also adds definitions to § 40.4 that pertain to the proposed ISA requirements and a backfit provision applicable to licensees authorized to possess 2000 kg or more of UF6. This provision is similar to existing § 70.76.

The format of the requirements contained in 10 CFR part 40 is administratively restructured to create subparts. Included in the restructuring is the addition of a new subpart entitled, “Additional Requirements for Certain Licensees Authorized to Possess 2000 Kilograms (4400 lb) or More of Uranium Hexafluoride.”

B. Who Is Affected by this Action?

The amendments will affect current licensees and future applicants that are authorized to possess or plan to possess 2000 kg or more of UF6. The new requirements are not applicable to NRC and Agreement States licensees that are currently in the process of decommissioning. The NRC will regulate all source material at facilities which are authorized to possess 2000 kg or more of UF6. At such facilities, Agreement States will retain authority to regulate byproduct material as defined in 10 CFR 150.3(1) (e.g., byproduct material in gauges, sealed sources, and laboratory materials).

C. What Are the Differences Between the Proposed and Final Rules?

Based on comments from stakeholders, the NRC made several changes to the rule language, and revised the regulatory analysis. These changes are summarized here, and are more fully discussed in Section III, Summary and Analysis of Public Comments on the Proposed Rule, of this document.

The NRC modified the wording of proposed § 40.3a ("Denial of licensing by Agreement States") to clarify the scope of the NRC's regulatory authority at facilities which are authorized, or will be authorized, to possess 2000 kg or more of UF6. Final § 40.3a specifies that the NRC will be the regulatory authority over all source material at facilities authorized to possess 2000 kg or more of UF6. At such facilities, Agreement States will retain authority they now exercise to regulate byproduct material (as defined in § 150.3(1)), such as byproduct material in gauges, sealed sources, and laboratory materials. Further discussion is provided in the response to Comment E2 (Section III of this document), and in Section IV (Discussion of Final Amendments by Section).

Proposed § 40.84(b) contained a provision that would have supplemented the existing emergency planning requirements in § 40.31(j) regarding the potential offsite chemical hazards posed by the operation of UF6 facilities. After considering public comments, the NRC decided there was no need to supplement the existing § 40.31(j) requirements and did not include the proposed provision in the final rule. The wording of final § 40.84 matches the existing requirements in § 70.65. Further discussion of this change is provided in the response to Comment H5.

The wording of the proposed *defense-in-depth* definition in § 40.4, which is based on the footnote in § 70.64(b), has been modified in the final rule. Explanatory text that was included in the definition was removed and placed into the introductory text of final § 40.83(b). Further discussion is provided in the response to Comment C2.

The proposed rule, in §§ 40.81(a) and (b), 40.81(d) and 40.85(c)(2) had erroneous cross-references to performance requirements. The correct cross-references are included in the final rule. Further discussion is provided in the response to Comment H1.

The proposed performance requirements in § 40.81(b) regarding the NRC's preference for the selection of engineered controls over administrative controls was revised in the final rule by removing "subject to § 40.83(b)(1)." Further discussion of this revision is provided in the response to Comment H3.

A provision in the proposed ISA requirements of § 40.82(c)(1)(iii) was removed, as it was redundant to the § 40.82(c)(1)(i) through (ii) ISA requirements. Further discussion of this change is provided in the response to Comment H4.

This final rule also clarifies the Statement of Consideration (SOC) published with the draft rule on May 17, 2011. Four such clarifications are summarized here, and further details are provided in Section III (Summary and Analysis of Public Comments on the Proposed Rule), and Section IV (Discussion of Final Amendments by Section) of this document.

1) The SOC published with the draft rule incorrectly stated that new guidance documents were being developed on the meaning of "unlikely" and "highly unlikely." As discussed in the response to Comment H2, the existing 10 CFR part 70 guidance does not need to be supplemented in this regard.

2) The Section IV discussion of § 40.88(a)(2) inserts "NRC" before "licensed material" to clarify the intended meaning of this reporting requirement. Further discussion is provided in the response to Comment G1.

3) The Section IV discussion of § 40.86(e) clarifies the intended meaning of the requirement to "promptly" update on-site documents when facility changes are made. Further discussion is provided in the response to Comment C10.

4) The Section IV discussion of the § 40.89 backfit requirements now includes an additional explanation of the backfit rule's intent, taken from the SOC for the 1985 Backfit Rule (50 FR 38097, Revision of Backfitting Process for Power Reactors). Further discussion is provided in the response to Comment F2.

The regulatory analysis for the final rule increases the estimated cost for developing an ISA to $2,120,000. Further discussion regarding the changes made to the regulatory analysis is provided in the response to Comment A6.

D. What Steps Did the NRC Take to Involve the Public in this Rulemaking?

The NRC held a public meeting on February 22, 2008, at NRC Headquarters in Rockville, Maryland, to discuss the scope of the proposed rulemaking and to seek public input on the proposed threshold quantities for determining when a facility will be regulated by the NRC or an Agreement State. The NRC announced the meeting on the NRC Web site as well as in a press release sent out by the Office of Public Affairs. The industry stakeholders that would be impacted by the rulemaking attended the meeting. The meeting followed a workshop format, and representatives from Honeywell and NEI gave presentations. All participants were encouraged to send written comments within 30 days.

The proposed rule was published in the *Federal Register* on May 17, 2011 (76 FR 28336), for a public comment period of 75 days, and the draft guidance document was also made available for review and comment at this time. Based on requests made by NEI in its letter dated June 21, 2011, the NRC on August 17, 2011, held a public meeting on the proposed rule and guidance, and the public comment period was extended to 115 days.

Following the May 17, 2011, *Federal Register* notice and the subsequent public meeting, the NRC received 9 comment letters addressing multiple issues. Summaries of the comments,

and the NRC's responses, are provided in Section III, Summary and Analysis of Public Comments on the Proposed Rule, of this document.

E. What is the Basis for the NRC to Regulate the Hazardous Chemicals Produced From Licensed Materials?

Health and safety risks at 10 CFR part 40 fuel cycle facilities authorized to possess significant quantities of UF6 are both radiological and chemical in nature. These facilities not only handle radioactive source material, but also large volumes of hazardous chemicals that are produced from the processing of the nuclear material. As previously explained, chemicals such as HF can be incidentally produced in processes that involve using UF6. Due to its reactive and corrosive qualities, HF has a significant potential to generate harmful onsite consequences to workers, and harmful offsite consequences to the public.

The basis for the NRC's oversight of hazardous chemicals produced from licensed materials is derived from the AEA. Section 161 of the AEA gives the NRC broad authority to establish regulatory requirements necessary to protect the public health and safety, and Chapter 7 of the AEA details the specific statutory bases for NRC licensing and regulating the use of source material, such as UF6. The 1988 MOU between the NRC and OSHA further discusses the radiological and chemical hazards to workers handling radiological materials licensed by the NRC. It defines the general areas of responsibilities for the NRC and OSHA at facilities that have both radiological and chemical hazards.

The NRC-OSHA MOU states that "there are four kinds of hazards that may be associated with NRC-licensed nuclear facilities." It identifies them as:

1. Radiation risk produced by radioactive materials;
2. Chemical risk produced by radioactive materials;

3. Plant conditions which affect the safety of radioactive materials and, therefore, present an increased radiation risk to workers; and
4. Plant conditions which result in an occupational risk, but do not affect the safety of licensed radioactive materials.

The NRC-OSHA MOU states that the "NRC responsibilities cover the first three nuclear facility hazards" and the "NRC does not have statutory authority for the fourth hazard."

The first three hazards and their attendant health and safety risks, involving the possession and use of licensed radioactive materials, are clearly regulated by the NRC (or Agreement State to which the NRC has relinquished, and the State assumed, regulatory authority under a section 274b Agreement pursuant to the AEA) and are within the NRC's (or the Agreement State's) proper jurisdiction. Large quantities of hazardous chemicals, such as HF, can be generated during accidents at NRC-licensed facilities. Chemical hazards can impact radiological safety by incapacitating or causing death of a radiation worker who is performing a critical function in the processing of radioactive material.

As previously discussed, the SRM on SECY-10-0128 directed the staff to evaluate whether the MOU needed to be modified. Feedback from cognizant NRC offices and OSHA indicated the MOU adequately delineates the agencies' respective responsibilities at nuclear facilities. In accordance with the SRM, a clear explanation and example of how to evaluate the MOU's Criterion 3 is provided in Section IV (Discussion of Final Amendments by Section) of this document, where the new § 40.81(a) is discussed. Further guidance on the MOU's Criterion 3 is provided in the guidance document developed to support this rulemaking (NUREG-1962, ADAMS Accession No. ML120950304). The guidance explains how MOU Criterion 3 should be evaluated by a licensee in completing its ISA.

F. Why was 2000 Kilograms of UF6 Chosen as the Threshold for Requiring an ISA and the Threshold for NRC Jurisdiction?

The staff, in SECY-07-0146, recommended that 10,000 kg of UF6 be the threshold quantity for requiring 10 CFR part 40 fuel cycle licensees to perform an ISA and for NRC licensing jurisdiction. The NRC staff subsequently looked at threshold limits and determined that quantities of UF6 greater than 2000 kg represented a significant quantity. This reduction from 10,000 to 2000 kg was based in part on the chemical hazard associated with accident scenarios involving UF6. Specifically, in an accident scenario involving 2000 kg of UF6, approximately 453 kg (1000 lb) of HF vapor could be produced. The OSHA, in Appendix A of 29 CFR 1910.119, identifies threshold quantities of toxic and reactive hazardous chemicals that "present a potential for a catastrophic event" in amounts at or above the threshold quantities. OSHA in this appendix lists HF as having a threshold quantity of 1000 lb. The OSHA regulations also contain requirements for preventing or minimizing the consequences of catastrophic releases of toxic, reactive, flammable, or explosive chemicals that may result in toxic, fire, or explosion hazards.

The NRC believes that chemical quantities exceeding the quantities listed in Appendix A to 29 CFR 1910.119 at 10 CFR part 40 fuel cycle facilities can, and do, affect the safety of radioactive materials and, therefore, present an increased radiation risk to workers.

Although the NRC staff originally recommended that licensees in possession of large quantities of UF4 also be required to submit an ISA, it was determined that UF4 did not pose the same risk as UF6. The UF4 is far less reactive than UF6, requiring days to months to react with moisture in the air. Based on a search of published literature, the staff does not believe there is sufficient information available to establish a threshold of UF4 for requiring an ISA or for the NRC to establish exclusive jurisdiction.

G. What is Appendix A to 29 CFR 1910.119?

Appendix A to 29 CFR 1910.119 is part of an OSHA regulation that contains a listing of toxic and highly reactive hazardous chemicals which present a potential for a catastrophic event at or above the threshold quantity. The regulations at 29 CFR 1910.119 contain requirements for preventing or minimizing the consequences of catastrophic releases of toxic, reactive, flammable, or explosive chemicals that may result in toxic, fire, or explosion hazards. However, 29 CFR 1910.119 does not provide structured risk-informed requirements for evaluating the consequences of facility accidents as does an ISA.

Under the OSHA regulation, facilities that possess hazardous chemicals in quantities greater than those listed in Appendix A to 29 CFR 1910.119 must perform a process hazard analysis. This analysis is similar but less comprehensive than that required by the ISA regulations. Additionally, 29 CFR 1910.119 only addresses chemical hazards. An ISA must address both the radiological and chemical hazards from licensed material, and hazardous chemicals produced in the processing of licensed material.

H. What Are Emergency Response Planning Guidelines and Acute Exposure Guideline Levels, and What Are They Used For?

A set of chemical consequence criteria, known as emergency response planning guidelines (ERPGs), has been developed by the American Industrial Hygiene Association to provide estimates of concentration ranges where defined adverse health effects might be observed because of short exposures to hazardous chemicals. The ERPG criteria are widely used by those involved in assessing or responding to the release of hazardous chemicals. Another organization, the National Advisory Committee for Acute Guideline Levels for Hazardous Substances, is developing acute exposure guideline levels (AEGLs). The committee, which works under the auspices of the U.S. Environmental Protection Agency (EPA)

and the National Academy of Sciences, has identified a priority list of approximately 471 chemicals. Consequence criteria for approximately 200 extremely hazardous substances have been developed, including one for HF. As previously discussed, HF is a significant hazard associated with UF6. 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.

I. When Would These ISA Requirements become Effective?

Current licensees will have to submit for NRC approval, within 6 months after the rule becomes effective, a plan that describes the ISA approach that will be used, the processes that will be analyzed, and the schedule for completing the analysis of each process. Unless an alternate schedule is approved, the licensee will submit for NRC approval an ISA summary within 18 months after the rule becomes effective.

Additionally, within 3 years after the rule becomes effective (unless an alternate schedule is approved), current licensees will have to correct all unacceptable performance deficiencies identified in the ISA. Pending the correction of unacceptable performance deficiencies, the licensee will have to implement appropriate compensatory measures to ensure adequate protection.

J. Has the NRC Prepared a Cost-Benefit Analysis of this Rulemaking?

Yes. A regulatory analysis examines the costs and benefits of the rule and its alternatives. The regulatory analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852, and may be viewed and downloaded electronically via the Federal rulemaking Web site at http://www.regulations.gov by searching for Docket ID NRC-2009-0079.

K. Has the NRC Evaluated the Paperwork Burden to Licensees?

This final rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). The NRC staff has estimated the impact that this rule will have on reporting and recordkeeping requirements for NRC licensees. There are no reporting or recordkeeping requirements for the Agreement State licensees. More information on this subject is in Section X, Paperwork Reduction Act Statement, of this document.

III. Summary and Analysis of Public Comments on the Proposed Rule

Scope and Intent of the 10 CFR Part 40 ISA Rulemaking

The scope and intent of this rulemaking is to revise 10 CFR part 40. Several comments on the proposed ISA rule request that changes be made to the draft regulatory wording in a manner that would make the new ISA requirements inconsistent with the existing ISA regulations in 10 CFR part 70, subpart H – unless these existing ISA regulations were revised. The rulemaking record discussed below provided notice that this rulemaking would be limited to revising 10 CFR part 40. Further, with the exception of existing ISA requirements pertaining to criticality controls, the stated intent of this action has always been to establish ISA requirements that are substantially the same as those set forth in the existing 10 CFR part 70 ISA regulations. Any requested changes that would – absent revisions to 10 CFR part 70 – introduce significant differences between the two sets of ISA regulations, are contrary to the intent of this rulemaking, and raise issues that are outside the scope of this rulemaking.

This rulemaking was initiated by the Commission in an SRM dated March 22, 2007. The Commission requested the NRC staff to propose rulemaking options for requiring 10 CFR part 40 fuel cycle facilities (i.e., those holding source material and engaged in uranium conversion

and deconversion activities) to complete ISAs "similar to" the ISAs required under 10 CFR part 70, subpart H, for facilities holding special nuclear material.

SECY-07-0146, dated August 24, 2007, sets forth the requested options. There, the NRC staff discussed the need to establish accident requirements in 10 CFR part 40 "analogous to those in Part 70, Subpart H." The staff found that such ISA requirements should be made applicable to uranium conversion and depleted uranium deconversion facilities that are or would be licensed under 10 CFR part 40, because although such facilities have "unique and significant hazards," 10 CFR part 40 lacked requirements "for evaluating the consequences" of accidents at such facilities. The staff, therefore, recommended conducting a rulemaking "establishing in Part 40 the analogous requirements in Part 70, Subpart H." The Commission approved this recommendation in its SRM dated October 10, 2007.

The staff submitted the proposed rule to the Commission for its approval in SECY-10-0128, dated October 1, 2010. As stated there, this ISA rulemaking would, in part, add definitions to § 40.4 that are "essentially the same as those used in Part 70, Subpart H." Further, in discussing the guidance supporting this rulemaking, the staff referenced "the identical sections in Part 40 and Part 70," and noted that the differences between the existing 10 CFR part 70, subpart H, and the proposed 10 CFR part 40 requirements "stem primarily from the fact that criticality events at special nuclear material facilities are not credible at Part 40 source material facilities." In its SRM dated November 30, 2010, approving publication of the proposed rule for comment, the Commission reiterated that the proposed 10 CFR part 40 ISAs were to be "similar to the ISAs performed by 10 CFR Part 70 licensees."

Accordingly, the section-by-section discussion of the proposed 10 CFR part 40 requirements in the May 17, 2011, *Federal Register* (76 FR 28336) reflects the close match between these proposed ISA requirements and the existing 10 CFR part 70, subpart H, regulations in the following areas: 1) the § 40.4 defined terms); 2) the § 40.83 baseline design

criteria; 3) the § 40.84 content of application provisions; 4) the § 40.86 change process requirements; and the § 40.89 backfit provisions.

As discussed further in the following responses to specific comments, the commenters have not provided an adequate basis to support their requests that changes be made to the draft regulatory wording in a manner that would create substantive differences between the 10 CFR part 40 ISA requirements and the existing 10 CFR part 70, subpart H, regulations.

Comments on the proposed rule were submitted on behalf of several affected States, and by industry representatives. NRC licensees, and an individual, also submitted comments. The comments and responses have been grouped into eight areas: general, procedural, definitions, performance requirements, jurisdiction/authority, backfitting, reporting, and corrections. To the extent feasible, all of the comments on a particular subject are grouped together.

A. General

Comment A1: In the *Federal Register* (76 FR 28336) notice for the proposed rule (Question K), the NRC sought public comments on the potential challenges and impacts regarding the use of probabilistic risk analyses (PRA) methodology at facilities licensed under 10 CFR part 40. Several industry commenters are against using PRA methodology at 10 CFR part 40 facilities, stating that a process hazards analysis using ISA methods is the most appropriate technique for analyzing the unique operations of fuel cycle facilities, and has been proven to adequately demonstrate compliance with applicable NRC requirements.

Response: On January 5, 2012, the Commission issued SRM-SECY-11-0140, "Enhancements to the Fuel Cycle Oversight Process" (ADAMS Accession No. ML120050322). Regarding the use of PRA methodology in general, the SRM stated only that "for the longer-term, the staff should develop and test the use of focused PRA-like analyses," as was

recommended by the Advisory Committee for Reactor Safeguards. Otherwise, the SRM directed the staff to "continue their interaction with stakeholders, including use of public workshops, to develop the optimal basis for the cornerstones, ultimately recommending the path that is most likely to help ensure safe operations." The SRM further stated that the existing fuel cycle oversight process is effective and ensures safety and security and "consequently, the activities undertaken to enhance the NRC's fuel cycle oversight process are truly that – enhancements – and are a lower funding priority than some other recently emergent, unfunded activities, such as the Commission-approved post-Fukushima response actions."

Based on the public comments and the SRM, the final rule does not include any requirements for using PRA methodology at 10 CFR part 40 facilities.

Comment A2: One commenter states that three of the nine items contained in an industry petition for a 10 CFR part 70 appendix A rulemaking (PRM-70-8, ADAMS Accession No. ML091110449) on reportable safety event requirements have been addressed in the proposed 10 CFR part 40 rule, but that the May 17, 2011, *Federal Register* notice (76 FR 28336) did not discuss PRM-70-8 or its disposition, and did not discuss whether the NRC intends to make conforming changes to 10 CFR part 70.

Response: The NRC acknowledges that the May 17, 2011, *Federal Register* notice (76 FR 28336) for the proposed 10 CFR part 40 ISA rule did not discuss PRM-70-8. This is because PRM-70-8 pertains to the potential amendment of 10 CFR part 70 rather than 10 CFR part 40 requirements. However, as the comment indicates, three of the items discussed in PRM-70-8 have been implemented in this 10 CFR part 40 rulemaking. Consideration of PRM-70-8 will be undertaken in a future action. The NRC does not expect that 10 CFR part 40 and 10 CFR part 70 licensees will be subject to different reporting timelines for the same reportable safety events.

Comment A3: One commenter states that the Agreement States were not adequately informed of the proposed rulemaking.

Response: The NRC disagrees with the comment, in part. In accordance with SRM-M070308B, a letter, dated April 13, 2007 (FSME-07-036), was sent to the Agreement States informing them of this proposed rulemaking action. On February 22, 2008, the NRC conducted a workshop with stakeholders to solicit input on development of the rule, and four Agreement State representatives participated. A second Agreement State Letter (FSME-10-049, ADAMS Accession No. ML101680656) was sent on June 21, 2010, requesting information on Agreement State licensees authorized to possess UF6. The NRC is reviewing its procedures and will make adjustments, as necessary, to ensure that the Agreement States are kept informed in cases where proposed rulemakings could affect the Agreement States.

Comment A4: One commenter states that the conference call with Agreement State representatives, which began at 9 a.m. on August 17, 2011, was held too early in the day for representatives on the West Coast to participate, and that an e-mail sent the day before to schedule the conference call left very little time to prepare and ensure that all affected Agreement States could participate. The commenter states that in the future conference calls need to be arranged with a longer lead time, and that the start time should fall during normal working hours of all the continental United States.

Response: The plan to hold the August 17, 2011 public meeting was announced in the *Federal Register* on July 27, 2011 (76 FR 44865). The August 16, 2011 e-mail was sent to all Agreement States to remind them of the August 17, 2011 meeting, and was not intended to be the primary notification. However, for scheduling purposes, the NRC commits in the future to be more sensitive to the time differences between the East Coast and the West Coast.

Comment A5: One commenter states that the FSME-11-042 letter (ADAMS Accession No. ML111380088) was sent to State Liaison Officers only, and not to Agreement States or the

Radiation Control Program Directors. Not all State Liaison Officers work in the Radiological Health programs, and they do not share this information with these programs. The commenter states that the letter should have been sent to the affected Agreement State programs directly, because its title included the phrase "Proposed Rule to Amend."

Response: The NRC acknowledges that the FSME-11-042 letter, dated May 19, 2011, was only sent to the State Liaison Officers, and that the title of FSME-11-042 ("Opportunity to Comment on the Environmental Assessment and the Proposed Rule to Amend 10 CFR 40 – Domestic Licensing of Source Material – Amendments/ Integrated Safety Analysis") may have been poorly worded. This title is broader than the letter's stated purpose, which was to inform the State Liaison Officers of the opportunity to comment on the Environmental Assessment for this rulemaking. Several Agreement States submitted comments in September 2011 following the May 17, 2011, *Federal Register* notice (76 FR 28336) of the proposed 10 CFR part 40 ISA rule. In retrospect, the NRC recognizes that the draft proposed rule should have been sent to the Agreement State programs prior to May 2011, for their early review and comment, as was done in 2012 for the draft final rule. The NRC is reviewing its procedures and will make adjustments, as necessary, to ensure that future draft proposed rules that could affect the Agreement States are provided for their early review and comment.

Comment A6: Several commenters state that the estimated cost for developing an ISA contained in the draft regulatory analysis ($290,000) was too low. One commenter states that its cost to develop an ISA exceeded $1 million. Another commenter states that its cost was approximately $7 million. A third commenter states that industry costs for developing an ISA range from $1 million to $9 million. These commenters request that the NRC revise the regulatory analysis to include the costs for the number of new licensee staff needed to maintain the ISA, and the cost for the NRC's review of an ISA summary. Additionally, the NRC's assumption that the level of effort associated with a conversion facility ISA is one-fourth that

associated with a 10 CFR part 70 facility is said to be too low, and the regulatory analysis did not contain a basis supporting this assumption.

Response: The draft regulatory analysis has been revised in response to the comments. During the August 2011 public meeting on this proposed rulemaking, the NRC staff asked for data from the stakeholders in attendance to support their concerns that the estimated costs in the regulatory analysis were too low. Several stakeholders then stated that such data was proprietary, and they accordingly did not provide any licensee-specific cost data in their subsequent comment letters. Nonetheless, the final regulatory analysis reflects a re-evaluation of the assumptions used in developing the disputed cost estimates.

The NRC reviewed the assumption that the level of effort associated with an ISA at a 10 CFR part 40 fuel cycle facility authorized to possess significant quantities of UF6 is one-fourth that associated with a 10 CFR part 70 facility. The radiological and chemical hazards are similar at relevant 10 CFR part 40 and 10 CFR part 70 fuel cycle facilities, with the primary difference being the absence of criticality hazards from source material at the 10 CFR part 40 facilities. Since the 10 CFR part 40 and the 10 CFR part 70 ISA requirements to evaluate the chemical and radiological hazards at these facilities are also similar – other than the absence of any 10 CFR part 40 ISA provisions requiring the evaluation of criticality hazards - the licensee's assumed level of effort to conduct an ISA was raised from one-fourth to three-quarters in the final regulatory analysis.

As noted in the comments, the NRC in the draft regulatory analysis did not account for the addition of new staff to develop and implement the ISA regulations, and did not estimate the cost for the NRC's review of an ISA summary. The cost estimates for two new staff members, and for the NRC's review of an ISA summary, are included in the final regulatory analysis. The cost estimates associated with ISA development and implementation was further revised based on recent NRC experience reviewing an ISA summary submitted as part of an application for a

uranium deconversion facility. For the reasons stated in this Response, the estimate in the final regulatory analysis for developing an ISA was revised upwards to $2,120,000.

Comment A7: One commenter states that the NRC's regulatory analysis did not present the case for a safety benefit relative to an existing licensee. The commenter states that the regulatory analysis did not acknowledge that the licensee has implemented an ISA as a condition of its license and that licensee-specific change controls are already in place. The commenter also states that the regulatory analysis unfairly skewed the results towards taking generic action, because it focused only on the proposed regulations, and did not acknowledge that the proposed ISA requirements would affect only one facility.

Response: The NRC disagrees with this comment. Safety benefits of the proposed rule are discussed in Section 6.1.1, Increased Confidence in the Margin of Safety, of the draft regulatory analysis. This section also identifies weaknesses with the current 10 CFR part 40, including the lack of a requirement to perform a comprehensive and systematic ISA. Facilities that process 2000 kg or more of UF6 have significant health and safety hazards for workers and the public. These hazards need to be evaluated in an ISA.

The draft regulatory analysis acknowledges that there is one facility which is required “by license condition to perform an ISA” (Section 5.1 Option 1 Description). Further, the NRC did consider the cost impacts for developing an ISA by license condition. Under this approach, the NRC incorporates ISA requirements directly into the facilities’ licenses. Section 6.2, Cost Impacts, discusses existing licenses for facilities within the scope of the proposed rule that have license conditions that require the performance of an ISA. Although under this approach only a subset of the ISA requirements are incorporated into the facilities’ licenses.

The NRC also disagrees with the assertion that there is only one existing facility which would be impacted by the proposed rule. The NRC is aware of a number of facilities which are

authorized to possess 2000 kg or more of UF6, or that have requested such authorization. These facilities were also considered in the safety basis for the regulatory analysis.

B. Procedural

Comment B1: Several commenters state that various changes should be made to the proposed § 40.82(c)(3) (entitled, "Requirements for existing licensees"). These commenters note that if any of their requested changes in § 40.82(c)(3) are made, conforming changes to § 40.85(a) through (c) would be necessary.

One commenter states that the introductory text to § 40.82(c)(3) should be revised to state:

> 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….

The commenter states that the additional language would provide a mechanism to transition ISAs developed in accordance with SECY-07-0146 and regulatory guide (RG) NUREG-1520 (ADAMS Accession No. ML101390110), as distinct from those developed in accordance with the new 10 CFR part 40 regulations.

Another commenter states that, to date, a significant amount of industry resources have been expended to develop ISAs for NRC approval and implementation, in accordance with 10 CFR part 70, subpart H, and NUREG-1520, as discussed in SECY-07-0146. But, the proposed rule and draft NUREG-1962 are silent on how a 10 CFR part 40 licensee with an ISA will transition under the proposed 10 CFR part 40 ISA requirements when the final rule becomes effective. Instead, proposed § 40.82(c)(3) would require existing licensees to take specific steps to develop an ISA plan and make submittals to the NRC that do not recognize their efforts to date which have been fully coordinated with the NRC. The commenter states that the proposed

rule also does not address the mechanisms and schedule by which licensee requirements will transition from the current ISA to the new ISA.

Another commenter similarly states that the proposed §§ 40.82 and 40.85 do not adequately address existing ISAs that have been performed in accordance with 10 CFR part 70, in cases where licensees would now be subject to the proposed 10 CFR part 40 ISA requirements. The provisions in § 40.82(c)(3)(i) through (v) should, therefore, be modified to eliminate the need to submit an ISA plan for review and approval under paragraph (c)(3)(i), on the grounds that requiring an ISA plan in such cases would constitute "an undue administrative burden." In place of § 40.82(c)(3)(ii) through (iii), the two commenters state that such licensees should be allowed to submit any changes required over a two- to three-year period in accordance with the requirements of 10 CFR 70.72(d), where the change identified is the result of changes in analysis required by the proposed 10 CFR part 40. This commenter further states that the utilization of any performance deficiency corrective options (as referenced in § 40.82(c)(3)(iv) through (v)) should include relief from the reporting requirements of 10 CFR part 70, for issues identified as the result of changes in the analysis required by the proposed 10 CFR part 40 ISA requirements.

Response: No change in the rule text has been made. In response to the comments, the following discussion is provided, and pertains to the set of 10 CFR part 70 licensees who 1) have NRC-approved ISA summaries and 2) will now be subject to the 10 CFR part 40 ISA requirements as well. Those 10 CFR part 70 licensees operating fuel fabrication facilities, who previously obtained NRC approval of their ISA summaries, and who now will also be subject to the part 40 ISA requirements, should describe in their ISA plans the extent to which any existing items relied on for safety (IROFS), safety procedures and license conditions will need to be modified, and the extent to which new IROFS, safety procedures and license conditions will need to be added, to meet the part 40 ISA requirements. For example, such licensees will likely

need to identify new IROFS to address the hazards posed by potential accidents involving UF6 that is being stored onsite before it is introduced into the fuel fabrication process.
The § 40.82(c)(3) requirements are not intended to require licensees to develop, and the NRC to approve, redundant IROFS, safety procedures and license conditions that have already been approved under 10 CFR part 70. Therefore, any existing IROFS, safety procedures and license conditions that can remain in place without modification (i.e., those that already meet the 10 CFR part 70 ISA requirements and will continue to meet the 10 CFR part 40 ISA requirements) need not be submitted for approval, but should be identified in the ISA plan. For example, a 10 CFR part 70 licensee who previously obtained NRC approval of its ISA summary should, in the ISA plan required by § 40.82(c)(3)(i), describe any changes to its existing ISA summary that are necessary to comply with 10 CFR part 40. More specifically, the reference to "licensed activities" in the § 40.82(c)(3) preamble refers to 10 CFR part 40 licensed activities, and the § 40.82(c)(3)(ii) requirement to complete an ISA accordingly pertains only to 10 CFR part 40 licensed activities.

The ISA plan required by § 40.82(c)(3)(i) serves as a mechanism for licensees to describe the development of their ISAs and ISA summaries, and this requirement is similar to existing § 70.62(c)(3)(i). As noted in Section III.J of the proposed rule (76 FR 28336, May 17, 2011), a licensee may, in its ISA plan, propose an alternate time frame for completing the ISA, thereby providing flexibility to avoid any hardship in individual cases. For example, if the licensee has an approved ISA under 10 CFR part 70, subpart H, the ISA plan can be used to notify the NRC of the transition to 10 CFR part 40, subpart H, and to provide a path forward for addressing § 40.82(c)(3)(iv) (i.e., a plan to address any unacceptable performance deficiencies in complying with the new 10 CFR part 40, subpart H). The NRC expects that any such deficiencies would be minimal, due to the similarities between the existing 10 CFR part 70, subpart H, and the proposed 10 CFR part 40, subpart H. Accordingly, the NRC does not agree

that the proposed provisions in § 40.82(c)(3)(i) through (v) constitute “an undue administrative burden,” and does not agree with the other related requests for changes in the proposed requirements as set forth in this comment summary.

Regarding the request to revise the introductory text to § 40.82(c)(3), the proposed revision would exclude ISAs developed in accordance with SECY-07-0146 from all of the § 40.82(c)(3) requirements (e.g., the ISA plan required by § 40.82(c)(3)(i); the need to correct unacceptable performance deficiencies in accordance with § 40.82(c)(3)(iv)). No basis supporting such an exclusion was provided.

Comment B2: Several commenters stated that “lessons learned” and other issues that arose during the implementation of 10 CFR part 70, subpart H, should be considered in the proposed 10 CFR part 40 rulemaking, and the NRC was asked to meet with stakeholders to formally convey these lessons. For example, implementation of the 10 CFR part 70 requirements 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. The NRC was also asked to clarify when (e.g., before or after the ISA Summary is approved) the 10 CFR part 40 ISA-related reporting requirements are to become effective, as this was an area of confusion among licensees when 10 CFR part 70 was implemented.

One of the commenters further states that a discussion of the lessons learned is especially important here, where the NRC is essentially imposing the new 10 CFR part 40 ISA requirements on a single facility that cannot benchmark itself with other similarly-situated facilities. This commenter also states that the NRC should make clear that the new ISA reporting requirements are not effective until the new ISA is approved, and the current ISA is fully dispositioned. This will eliminate uncertainty and avoid potentially conflicting reporting requirements during the period of transition from the current ISA to the ISA required under the proposed rule.

Response: For the reasons discussed in this response, no changes in the rule language or the SOC were made in response to this comment:

The NRC disagrees with the statement suggesting that this rulemaking impacts a single licensee. In addition to the uranium conversion facility licensed by the NRC under 10 CFR part 40, three licensees of existing 10 CFR part 70 facilities are subject to the new 10 CFR part 40 ISA requirements. The statement that the 10 CFR part 40 uranium conversion facility will not be able to benchmark itself with other similarly-situated facilities is unclear, as the NRC is not aware of any cross-comparison between facilities that will be required to comply with the 10 CFR part 40 ISA regulations. Although three out of the four facilities referenced in this response are now licensed under 10 CFR part 70, the new 10 CFR part 40 ISA requirements are similar to the existing ISA requirements, and in this regard NUREG-1520, Rev. 1, provides useful and relevant guidance on developing and implementing an ISA. Additionally, the NRC has published NUREG-1962 with the final rule NUREG-1962, which describes the ISA guidance that is specifically applicable to 10 CFR part 40 facilities. The lessons learned from implementing the 10 CFR part 70, subpart H, requirements are reflected in NUREG-1520, Rev. 1 and NUREG-1962, and this licensing experience was taken into account in developing the proposed rule.

As to when the new ISA performance requirements become effective, starting from the effective date of the final rule, § 40.82(c)(3) provides a timeline for developing an ISA plan (6 months); completing an ISA and submitting an ISA summary (18 months); and correcting any performance deficiencies (3 years). Section 40.82(c)(3) also includes a provision for approval of an alternative schedule, in cases where a licensee shows good cause for extending these deadlines, thereby providing a mechanism to avoid any unwarranted hardship.

The comment that the new ISA reporting requirements need to be clarified to state that they are not effective until the new ISA is approved is contrary to the proposed § 40.88

requirements. The first two sentences in the introductory text to proposed § 40.88 make a clear distinction between those reporting requirements that a licensee must meet upon the effective date of the final rule, and those that a licensee must later meet once it has submitted its ISA summary. Specifically, licensees subject to § 40.88 must comply with the reporting requirements in § 40.88(a)(1), 40.88(a)(2), and 40.88(b)(4) upon the effective date of the final rule, to ensure that these significant safety-related events are reported to the NRC on a timely basis. A licensee must meet the other reporting requirements in § 40.88 once it has submitted its ISA summary, regardless of whether or not the ISA summary has been approved. The first two sentences in the § 40.88 preamble are based on what used to be the introduction to the 10 CFR part 70 appendix A reporting requirements (that introductory language was established in 2000, but has since been revised to reflect the fact that there are no longer any 10 CFR part 70 licensees without an approved ISA summary).

The NRC held a public meeting on the proposed rule on August 17, 2011, and heard comments and suggestions from the public on implementing the 10 CFR part 40 rule, including key lessons from implementing the 10 CFR part 70 ISA requirements.

Comment B3: Two commenters state that proposed § 40.82(c)(3) should be changed so as to be more aligned with the timelines provided to existing 10 CFR part 70 licensees (pursuant to § 70.62(c)(3)). One of these commenters also states that changes should be made to the ISA plan provisions in proposed § 40.82(c)(3)(i), and the compensatory measures provisions in proposed § 40.82(c)(3)(v).

Regarding the § 40.82(c)(3) timelines, the latter commenter compares its licensed 10 CFR part 40 fuel cycle facility to a 10 CFR part 70 facility, stating that even though its operations do not raise criticality issues, its facility is equally complex due to the number of different chemical process lines and areas that must be evaluated (e.g., its Fluorine Building and tank farm). Therefore, the level of ISA effort involved is at least as great as that for a 10 CFR part 70

facility. Accordingly, to the extent that that the 6-month, 18-month, and 3-year periods proposed in § 40.82(c)(3) are shorter than those given to 10 CFR part 70 licensees (compared to the § 70.62(c)(3)(ii) 4-year provision), changes to the implementation period are warranted. Additionally in this regard, the commenter states that in order to meet the proposed 18-month deadline, it will need to be actively working to finalize its ISA, prepare the NRC submittal, and develop compensatory measures. Given the significant cost and resource burden associated with these efforts, extending the implementation period would provide time for the NRC to review the ISA plan and provide feedback, and time for the licensee to incorporate that feedback into its ISA. The commenter therefore requests that the NRC eliminate the 18-month interim deadline, and set all of the § 40.82(c)(3) deadlines at 4 years.

Regarding the ISA plan provisions, the commenter states that the NRC should revise proposed § 40.82(c)(3)(i) as follows:

> Submit for NRC approval, within [insert date six months after the effective date of final rule], a plan that describes the integrated safety analysis approach that will be used, the processes that will be analyzed, and the schedule for completing the analysis of each process. For a licensee that already has an ISA as part of its licensing basis, the plan may also include a proposed approach and schedule for transitioning to the ISA required under Part 40, Subpart H, including the process for removing the prior ISA from the facility licensing basis, and for completing management measures, developing programs and procedures, putting compensatory measures in place, or implementing any necessary enhancements or hardware procurement and installation related to the new ISA.

The commenter states that this change will make clear that the licensee can include information related to its ISA transition in the ISA plan submitted for approval, and that in the absence of such information there would be no clear process for obtaining NRC approval of the approach for transitioning to the new ISA.

The commenter further states in this regard that its existing program cannot be easily or quickly "upgraded" to comply with the proposed new requirements. Although the safety program contains some of the same elements as a 10 CFR part 70 ISA, its existing ISA is different from the ISA that would be required under the proposed 10 CFR part 40 ISA rule in

many fundamental respects. For example, the existing ISA was performed in a relatively short period of time and without the benefit of any explicit regulatory standards or guidance. The existing ISA also relied heavily on pre-existing licensee programs, and the scope of the existing ISA is different than that required by the proposed rule. As a result, the commenter states that it cannot simply "upgrade" its existing ISA because the existing ISA cannot be easily extrapolated to the new ISA requirements, and that its new analysis must therefore be performed "from scratch."

As a result, the commenter states that imposing the proposed ISA requirements on it would result in significant changes to its financial, technical, design change, training, record-keeping, and reporting activities. These changes would, therefore, result in significant impact to its related site procedures. The magnitude of the proposed changes and the resulting burden in a relatively short time period would stress the ability of plant personnel to assimilate new knowledge and requirements, as there would be no clear understanding of the steps involved in transitioning to the new ISA.

The commenter states that the NRC has not addressed how the licensee's existing license commitments should be reported, tracked, or maintained during the period of ISA development or implementation necessary to meet the proposed 10 CFR part 40 ISA rule, and that the rulemaking package does not contain any discussion of the effects of the ISA Summary on the existing safety program. The commenter states that it cannot develop an effective ISA plan without some understanding of the processes and practicalities associated with transitioning to a new ISA.

The commenter also states that the compensatory measures provisions in proposed § 40.82(c)(3)(v) should be revised by making this requirement inapplicable to any licensee that already has an ISA as part of its licensing basis. The commenter requests that § 40.82(c)(3)(v) state that such a licensee may use

"its existing procedures for addressing new information to analyze the results of the ISA required by § 40.82(c)(1)."

In support of this request, the commenter states that proposed § 40.82(c)(3)(v) conflicts with the basis for the proposed 10 CFR part 40 ISA rule, which identifies the benefits of the proposed rule as an increased margin of safety (not minimum levels of safety). The NRC has previously determined that the commenter's license provides adequate protection, so in the commenter's view even if the ISA process resulted in the identification of performance deficiencies, there would still be adequate protection of public health and safety. The proposed approach is also said to conflict with the current ISA, and the commenter states that the NRC should clarify that licensees with an existing ISA should implement a review process for analyzing the results of the new ISA that is consistent with such a licensee's current ISA, meaning that the licensee will perform an analysis to determine if a "Potentially Inadequate Safety Analysis" exists and take appropriate corrective actions. The commenter further states that such an approach would help to ensure regulatory stability relative to the current ISA and the licensee's existing procedures for implementing corrective actions.

Response: The NRC disagrees with the comment, and has made no changes to the § 40.82(c)(3) requirements.

Regarding the six-month, 18-month, and 3-year periods specified in proposed § 40.82(c)(3), the Commission in SRM-SECY-10-0128, directed the staff to extend the proposed schedule to these times. Note, however, that the provisions in § 40.82(c)(3)(ii), (iii) and (iv) each state that the NRC may, in approving the ISA plan submitted in accordance with § 40.82(c)(3)(i), authorize "an alternative schedule," thereby providing sufficient flexibility in adjusting deadlines should individual circumstances warrant. The SOC for the proposed rulemaking (76 FR 28336; May 17, 2011) discusses the approval of such alternative schedules. Further, when the 4-year provision in § 70.62(c)(3) was promulgated, the NRC and industry had

no ISA experience. Current licensees now have experience with the ISA processes, and NUREG-1520, Rev. 1, reflects the cumulative lessons learned by industry and the NRC in implementing the 10 CFR part 70, subpart H, ISA requirements. These facts warrant the shorter general timeframe set forth in § 40.82(c)(3) as compared to § 70.62(c)(3).

Regarding the requested changes to the § 40.82(c)(3)(i) ISA plan requirements, no explanation is given as to how a licensee "that already has an ISA as part of its licensing basis" would be distinguished from a licensee having an ISA approved under 10 CFR part 70. As discussed in response to Comment B1, the NRC in this document has clarified that the § 40.82(c)(3) requirements are not intended to require licensees to develop, and the NRC to approve, redundant IROFS, safety procedures and license conditions that have already been approved under 10 CFR part 70.

Regarding the compensatory measures provisions in proposed § 40.82(c)(3)(v), this provision matches the wording used in existing § 70.62(c)(3)(iii). The NRC does not agree with the statement that because a particular facility holds an NRC license, adequate protection of public health and safety is automatically ensured "even if the ISA process resulted in the identification of performance deficiencies." No further basis supporting this position is provided, and if it were true there would be no need for the existing § 70.62(c)(3)(iii) requirement.

Comment B4: Several commenters state that proposed § 40.86(c)(4) should be revised by inserting the words "safety aspect" [or alternatively "safety attributes"] into the provision, so that the regulation would state: "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," and "(4) alter the safety aspect of an [or alternatively, safety attributes 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."

One commenter states in this regard that an IROFS could be altered without affecting the safety aspect, such that there would be no change in the ability of the IROFS to perform its intended function. Another states that the proposed § 40.86(c)(4) is overly prescriptive, in that it does not "provide the intended (and necessary) flexibility," and that adding "safety aspect" would "improve efficiency."

Similarly, a third commenter adds that the proposed § 40.86(c)(4) would not be performance-based, as it would not give licensees enough flexibility to effectively manage their facilities. This commenter states that its proposed revision would improve efficiency for both the licensee and the NRC. In noting that proposed § 40.86(c)(4) is based on existing § 70.72(c)(3), the commenter further states that several 10 CFR part 70 licensees "have had significant issues" with the wording of § 70.72(c)(3), as discussed in draft RG 3.74 (that had not been published in final form when the comment was submitted).

In support of the "safety attributes" alternative, a commenter states that minor alterations to a sole IROFS can be made without first obtaining the NRC's approval, because such alterations would have "no bearing on the safety function." For example, proposed § 40.86(c)(4) would prohibit a licensee from painting a section of a passive piece of equipment that is a sole IROFS without first obtaining the NRC's approval, and this requirement would, therefore, impose "an excessive administrative burden on the licensee."

Response: No change to the rule text has been made. The comment provides no basis explaining how insertion of the words "safety aspect" or "safety attributes" into the regulation would either 1) increase flexibility in how licensees effectively manage their facilities; or 2) improve regulatory efficiency. Further, making either of the requested changes would introduce a substantive difference between this 10 CFR part 40 ISA provision and the existing § 70.72(c)(3) requirement, which uses neither the "safety aspect" wording, nor the "safety attributes" wording. In the NRC's view, "safety attributes" and "safety aspect" are equivalent

terms, and adding either one of them to § 40.86(c)(4) would modify the sole IROFS concept by restricting its scope, when compared against the existing § 70.72(c)(3) requirement.

Additionally, section 2.4. of RG 3.74 (entitled "Guidance for Fuel Cycle Facility Change Process" and published in final form in January 2012) addresses the § 70.72 change process, but does not say anything about the "safety aspect" issue where it provides guidance on the sole IROFS requirement in § 70.72(c)(3).

The NRC does not agree that § 40.86(c)(4) would prohibit a licensee from making certain alterations to a sole IROFS -- such as painting a passive piece of equipment -- provided the change does not impact the IROFS safety function. Existing guidance on the equivalent § 70.72(c)(3) requirement regarding the term "alter" states that the term should be read as "meaning any change to the IROFS that will modify, positively or negatively, any of the attributes associated with the safety function of the IROFS." See RG 3.74 at section 2.4(a). The NRC, therefore, does not agree that § 40.86(c)(4) would impose "an excessive administrative burden on the licensee."

Comment B5: One commenter states that the proposed § 40.86(d)(2) and (3) should be revised so that the due dates for the annual facility and ISA change summaries would be 30 days from the anniversary date of the license, rather than 30 days after the end of the calendar year. The commenter states that under its suggested revision, licensee submittals to the NRC would be staggered throughout the calendar year, thereby avoiding the expenditure of licensee and NRC resources during "crunch time" (i.e., during the period of November – February each year).

Response: No change in the rule text has been made. Making the requested changes would introduce differences between § 40.86(d)(2) and (3) and the parallel set of existing requirements in § 70.72 (d)(2) and (3). Further, in the foreseeable future, five licensees will be subject to the § 40.86(d)(2) and (3) update requirements. Three of these licensees already

provide ISA Summary updates 30 days after the end of the calendar year, in accordance with the § 70.72 (d)(2) and (3) requirements. Modifying the submittal date to 30 days after the anniversary date of the license would, therefore, require double reporting for these licensees, and would create an added burden on both the NRC and these licensees.

C. Definitions

Comment C1: Several commenters request the NRC to incorporate the concept of design features into the 10 CFR part 40 ISA regulatory framework. For example, commenters request that "Design feature" be added as a defined term in § 40.4 to read:

> *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.

One commenter requesting this change acknowledges that conforming changes to 10 CFR part 70 would be necessary to ensure that regulations across the fuel cycle industry would be consistent in this regard. Another commenter states that incorporating the concept of design features would provide a mechanism ensuring that design features utilized in new facilities (or incorporated into new processes at existing facilities) would be designed, constructed and manufactured in a manner so that they could be available and reliable to perform their intended function. This commenter states as an example the design and construction of a building utilizing U.S. Department of Energy (DOE) Standard 1020-2002 to meet the performance requirements when the initiating event is a design basis earthquake. After such a building is constructed, there would be no mechanism allowing the components of the building (i.e. rebar, concrete, structural steel) to be inspected or tested to ensure that the building would be able to withstand a design basis earthquake.

Commenters request that the terms "Integrated safety analysis" and "Configuration management" in § 40.4 include a reference to design features as part of their respective

definitions, and that design features be referenced in the regulations regarding: performance requirements (§ 40.81(d)); ISAs (§ 40.82(c)); management measures (§ 40.82(d)); baseline design criteria (§ 40.83(a)); a facility's design and layout (§ 40.83(b)); the ISA summary (§ 40.84(c)); changes to a facility (§ 40.86(c)); and required reports (§ 40.88(a) and § 40.88(b)).

Response: The NRC does not agree with these comments. The NRC finds that issues related to design features are outside the scope of the proposed 10 CFR part 40 rulemaking, and that design features should not now be incorporated into the NRC's regulations. The proposed 10 CFR part 40 rule and its preamble published for comment on May 17, 2011 (76 FR 28336) did not contain any references to design features as being a potential alternative to IROFS, and the NRC did not solicit any input on the various design features issues discussed in the comments. Adopting design features now as part of the final rule would constitute a significant change from the proposed rule, and would be contrary to the notice requirement in section 553(b) of the Administrative Procedure Act (APA). Any final rule authorizing reliance on design features would not be a logical outgrowth of the proposed 10 CFR part 40 rule -- and would be contrary to the APA as interpreted by the federal courts -- unless a further round of notice and comment rulemaking was undertaken to provide the public an opportunity to consider whether the NRC should incorporate design features into the 10 CFR part 40 ISA provisions. See, e.g., *Owner-Operator Independent Drivers v. FMCSA*, 494 F. 3rd 188, 210 (D.C. Cir. 2007)(unless a provision in a final rule is reasonably foreseeable based on the proposed rule, the logical outgrowth test is not met); and *CSX Transportation Inc. v. Surface Transportation Bd.,* 584 F. 3rd 1076, 1080-82 (D.C. Cir. 2009)(citing cases in which the logical outgrowth test is met where federal agencies in their notices of proposed rules had solicited comments on the issue in question).

Further, in licensing-related actions regarding design basis earthquake issues, the NRC has to date refused to designate buildings that are relied on for safety as design features.

See ADAMS Accession No. ML11230A115. Neither the proposed 10 CFR part 40 ISA requirements, nor the existing subpart H regulations in 10 CFR part 70 on which the proposed requirements are based, support the concept of design features as an alternative to IROFS.

Comment C2: Several commenters state that the following sentences should be removed from the proposed *Defense-in-depth* definition in § 40.4:

> 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.

The commenters state that this wording is not a definition, but is instead an explanation of the defined term, and would therefore be more appropriately contained within the proposed NUREG-1962 guidance document. One commenter stated that the proposed § 40.83(b), which uses the *defense-in-depth* term, specifies the application of defense-in-depth principles, but fails to include the clarifying footnote present in the existing § 70.64. This commenter states that the § 70.64 footnote should be included in § 40.83(b).

Response: The NRC agrees in part and disagrees in part with the comments. The wording of the proposed *defense-in-depth* definition in § 40.4 tracks the wording of the footnote in § 70.64(b). This footnote clarifies that the purpose of the defense-in-depth requirements are to build a level of safety margin into the entire facility. This concept is equally applicable to the 10 CFR part 40 facilities that will be subject to ISA requirements, and the footnote's wording, therefore, needs to be included in the 10 CFR part 40 ISA requirements, rather than moving portions of it into the proposed NUREG-1962 guidance document. Accordingly, while the explanatory text will be removed from the definition of *defense-in-depth* in § 40.4 as requested, it will be placed into the introductory text of § 40.83(b). This revision will keep the 10 CFR part 40 and part 70 ISA requirements consistent with each other in this regard, and promotes the goal of avoiding the use of unnecessary footnotes in NRC regulations.

Comment C3: Two commenters state that the NRC should add text to the end of the § 40.4 proposed definition of *Hazardous chemicals produced from licensed materials.* One commenter states that the additional text should be: "such that the quantity of residual source material remaining in the hazardous chemical is by weight less than one-twentieth of one percent (0.05 percent)." Instead of "one-twentieth of one percent (0.05 percent)," the other commenter would specify the quantity of residual source material as "500 ppm." The basis for the proposed additional text is that it would remove "the ambiguous meaning" of the words "process separation" (which are part of the definition), and that using the one-twentieth of one percent figure would be "consistent with" wording used in the existing § 40.13(a) exemption.

Response: No change in the rule text has been made. The proposed definition of *Hazardous chemicals produced from licensed materials* in § 40.4 is the same as the existing definition of this term in § 70.4. No problems arising from the purportedly ambiguous meaning of "process separation" are identified in the comments, and adding the text as requested would introduce an inconsistency between the 10 CFR part 40 and 10 CFR part 70 ISA requirements that contain this defined term. The comments also do not explain why adding the proposed text to the 10 CFR part 40 definition would be consistent with the § 40.13(a) exemption ("Unimportant quantities of source material"). This exemption applies to the net inventory of source materials held at a facility, and specifies thresholds below which an NRC license is not required. Facilities which have an NRC license, therefore, fall outside the § 40.13 exemption thresholds. In addition, the 10 CFR part 40 licensees that will be subject to the definition of *Hazardous chemicals produced from licensed materials* hold amounts of source material far above the § 40.13(a) "unimportant quantities" (even though such material may be mixed with hazardous chemicals). Further, adding a reference in the definition to "residual" source material as proposed by the commenters would be inconsistent with § 40.13, which does not refer to "residual" source material.

Comment C4: One commenter states that the definition of *Integrated Safety Analysis Summary* in § 40.4 should be modified by moving its second sentence ("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") into guidance document NUREG-1962, on the grounds that this text would be "more appropriate" there.

Response: No change in the rule text has been made. The 10 CFR part 40 definition of *Integrated Safety Analysis Summary* is based on the wording of this same term as defined in 10 CFR part 70. Moving the text into guidance would introduce an inconsistency between the 10 CFR part 40 and 10 CFR part 70 ISA requirements in this regard, and an adequate basis for making this change was not provided.

Comment C5: Two commenters request that the proposed definition of *Integrated safety analysis* in § 40.4 should be revised, in part, by deleting its last two sentences, which state:

> 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.

They state that this text should instead be included in the NUREG-1962 guidance document.

Response: No change in the rule text has been made. An adequate basis for moving this text to NUREG-1962 was not provided. The definition's statement that ISA requirements are "limited to consideration of the effects of all relevant hazards on radiological safety or chemical hazards directly associated with NRC licensed material" is important, because it identifies the hazards that the ISA requirements address. Further, the definition's statement that "all processes must be integrated, and process interactions considered" is mandatory, and would, therefore, not properly be part of a guidance document. Other than its lack of references to criticality accidents, the 10 CFR part 40 definition of *Integrated Safety Analysis* closely matches the wording of this same term as defined in 10 CFR part 70. Moving portions of this

definition into guidance as requested would, therefore, introduce an inconsistency between the 10 CFR part 40 and part 70 ISA requirements that contain this defined term.

Comment C6: One commenter states that the proposed definition of "Items relied on for safety" in § 40.4 should be modified by adding the words "management measures" to the first sentence of the definition. The commenter states that a lessons learned during implementation of the 10 CFR part 70 ISA requirements is that "procedure management measures are routinely accepted by NRC staff as appropriate for designation" as an IROFS, but that such acceptance is not always given for other management measures. The commenter gives as an example of a management measure "an inspection required prior to placing a piece of equipment in service, which can only be inspected upon receipt." Such receipt inspections are said to be "routinely performed by licensee Quality Assurance staff and are an integral part of a quality program." In cases where a specific application of a management measure provides the best available and reliable means to prevent or mitigate an accident sequence, such a designation should not be precluded by the regulatory framework.

Response: The requested change to the proposed 10 CFR part 40 definition of "Items relied on for safety" (i.e., revising the definition to include "management measures") has not been made. As discussed further in this response, the regulatory functions of IROFS and management measures differ. Management measures are applied to IROFS to ensure they are available and reliable. The IROFS are applied to accident sequences to help ensure that the performance requirements are met. Therefore, the same item cannot be both an IROFS and a management measure.

"Management measures" is itself a defined term used in the existing 10 CFR part 70 ISA requirements, and the same definition is being made part of the 10 CFR part 40 ISA requirements. The term means, in part, "the functions performed by the licensee, generally on a continuing basis, that are applied to items relied on for safety, to ensure the items are available

and reliable to perform their functions when needed." As stated in the definition, management measures "are applied" to IROFS. By contrast, the proposed definition of "Items relied on for safety" states in part that IROFS are items that "prevent potential accidents at a facility that could exceed the performance requirements in § 40.81, or to mitigate their potential consequences." The IROFS are applied to accident sequences, whereas management measures are applied to IROFS. Management measures therefore cannot be IROFS because their functions are different.

Comment C7: Two commenters state that the proposed definition of "Items relied on for safety" in § 40.4 should be modified by adding "controls" to the first sentence of the definition. One commenter gave as an example of a control an automatic isolation valve that is activated by an instrument monitoring loop upon reaching an established set point value, and states that adding "controls" would be consistent with the proposed § 40.82(d) wording.

Response: No change in the rule text has been made. Since the word "control" is used in § 40.82(d) to describe management measures, it should not be included in the definition of IROFS. The definitions of management measures and IROFS are distinct, as discussed in the response to Comment C6. Further, the NRC's view is that adding "control" to the definition would improperly limit the scope of the definition, and that the meaning of the word control is not well defined and could therefore be interpreted as a synonym for IROFS.

Comment C8: One commenter states that a definition of "credible" should be added to § 40.4. Such a definition needs to be consistent with either the historical usage in industry, with existing guidance provided by national consensus standards, or with the DOE guidance documentation for 10 CFR part 830 (i.e. IOE-6). The commenter states that many sections in the proposed 10 CFR part 40 ISA rules refer to "credible" hazards or "credible" accidents, yet the term is not defined.

Response: No change in the rule text has been made. The proposed § 40.84(c)(9) requires that each licensee's ISA summary contain descriptions of certain definitions used in the ISA for the licensee's facility, including a definition of "credible." This provision is the same as existing § 70.65(b)(9). Adding a generic definition of "credible" as requested would be inconsistent with the facility-specific § 40.84(c)(9), and would introduce inconsistencies between the ISA requirements of 10 CFR parts 40 and 70. Guidance on developing facility-specific definitions of "credible" is provided in NUREG-1520, Rev. 1, Section 3.4.3.2(9).

Comment C9: One commenter states that, to differentiate between the process described and analyzed in the process safety information required by proposed § 40.82(b), and those controls identified as IROFS, a definition of "control" should be added to § 40.4. The commenter states that the definition should be consistent both with the historical usage in industry and with existing guidance provided by national consensus standards, and acknowledges that the word "control" is used in different contexts within the ISA requirements.

Response: No change in the rule text has been made. The comment does not provide any specific information on which a universal definition of "control" could be reasonably based. Although the comment suggests using national consensus standards to develop a definition, the comment does not indicate which such standards are being referenced.

The NRC agrees that the word "control" is used in different contexts within the ISA requirements. Since the meaning of this word is highly dependent on the context in which it is used (e.g., the licensee's controlled area, beyond the control of the licensee, engineered control, administrative control, control systems, etc.), it is impractical to provide a generic regulatory definition.

Comment C10: Two commenters state that proposed § 40.86(e) should clearly define the word "promptly."

Response: No change in the rule text has been made. The wording of § 40.86(e) is based on existing § 70.72(e), which also uses the word "promptly" in describing when on-site documentation of facility changes must be updated. To date, the NRC has not been made aware of any previous difficulties licensees have had in implementing § 70.72(e) in this regard.

Further, use of "promptly" in this context allows for the variability needed for a broad range of applications throughout the fuel cycle industry. The NRC view is that specifying a time in place of "promptly" would be impractical, as the time would be too long in some cases and too short in others. The NRC expects licensees to exercise sound judgment to ensure that on-site documents of facility changes are updated in a timely manner (i.e., without undue delay and consistent with the licensee's documentation procedures).

D. Performance Requirements

Comment D1: Several commenters state that the high consequence event provision in § 40.81(b)(3), which proposes a threshold of 30 mg of soluble uranium intake for a member of the public, should be modified to also define a threshold for a worker of 100 mg of soluble uranium intake. Specifying a worker intake of 100 mg or greater of uranium in soluble form as a high consequence event is said to be consistent with using the 30 mg soluble uranium intake value for an individual located outside of the controlled area (i.e., a member of the public). The commenters state that their requested change would provide regulatory consistency and would simplify the burden placed on the licensee and the NRC in developing and approving facility specific worker intake values for soluble uranium coinciding with a high consequence event. The commenters state that their proposed 100 mg value for workers is conservative, 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.

Response: No change in the rule text has been made. Proposed § 40.81(b)(3) is based on existing § 70.61(b)(3). As previously stated in this document, the scope of the 10 CFR part 40 rulemaking established by SRM-SECY-07-146 is to incorporate the 10 CFR part 70 ISA requirements into 10 CFR part 40. Modifications to the proposed 10 CFR part 40 requirements which would introduce significant differences from the existing 10 CFR part 70 requirements are not consistent with the scope and intent of this rulemaking. Modifying § 40.81(b)(3) as requested would make the requirement significantly different than the parallel requirement in existing § 70.61(b)(3).

However, the NRC recognizes that the soluble uranium exposure issues discussed in the comment need to be addressed. As discussed further in the response to Comment D2 on chemical inhalation exposure issues regarding proposed §§ 40.81(b)(4) and 40.81(c)(4), the NRC is working with a contractor to develop a technical basis document to support a new NRC RG with the proposed title of "Soluble Uranium Exposure Criteria for Integrated Safety Analyses." The projected completion date for this RG is early 2014, subject to budgetary constraints. The primary purpose of the RG will be to establish thresholds for exposure to soluble uranium. This will enable licensees to better identify 1) high and intermediate consequence events for workers; and 2) intermediate consequence events for the public, due to exposures of soluble uranium and hydrogen fluoride.

Comment D2: Several commenters state that the inhalation of UF6 is the primary concern for high and intermediate consequence event determinations, and that the word "inhalation" should therefore be inserted into the introductory text of proposed §§ 40.81(b)(4) and 40.81(c)(4).

Two commenters, while recognizing there are exposure hazards other than inhalation associated with hazardous chemicals produced from licensed operations, state that 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. Controls put in place to reduce the likelihood of hazardous releases limit the risk to an individual located outside of the controlled area regardless of the exposure pathway. Bounding the consequence with the inhalation exposure pathway would reduce the consequence associated with dermal exposure. Since inhalation is bounding, developing an additional "quantitative standard" for acute dermal exposure to an individual located outside of the controlled area will not be useful for complying with the proposed § 40.81 performance requirements; 2) Unlike proposed § 40.81(b)(1) through (3) and § 40.81(c)(1) through (3), the consequences in the proposed subsections of § 40.81(b)(4) and 40.81(c)(4) are subjective, and cannot be measured directly; and 3) Compliance with the proposed performance requirements regarding acute chemical exposures to the worker other than an airborne exposure (i.e., a dermal exposure), is problematic because dermal exposure standards for the hazardous chemicals typical of facilities handling large quantities of uranium hexafluoride (UF6), primarily hydrogen fluoride (HF), do not exist. Because quantitative standards for dermal exposure to HF have not been developed by the chemical industry, or by the agencies regulating the chemical industry, it is unreasonable to expect the small number of NRC licensees affected by the proposed rule to develop quantitative dermal exposure standards to HF.

The two commenters additionally discuss an April 2011 National Institute for Occupational Safety and Health (NIOSH) publication ("NIOSH Skin Notation Profiles Hydrogen Flouride / Hydrofluoric Acid (HF)"), describing the process used in developing Skin Notation profiles for several hazardous chemicals, including a revised Skin Notation profile for HF.

The commenters include the following statements from sections 3 and 5 of the NIOSH publication:

> 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. … 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.

In the commenters' view, the inability to estimate the degree to 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.

A third commenter similarly states that the phrases "irreversible or other serious long lasting health effects" (in proposed § 40.81(b)(4)(ii)), and "mild transient health effects" (in proposed § 40.81(c)(4)(ii)) are subjective, and adds that this wording has been problematic for licensees as well as for the NRC, as evidenced through various inspections. The commenter states that the NRC should therefore consider defining these terms or using less subjective language.

The commenters request that conforming changes be made to proposed §§ 40.84(b), 40.84(c)(7), 40.88(a)(2), and 40.88(b)(3), all of which either reference or use the § 40.81(b)(4) and/or 40.81(c)(4) provisions.

Response: No change in the rule text has been made. The NRC's view is that inserting the word "inhalation" as requested would limit the scope of the performance requirements to inhalation exposures for hazardous chemicals, and that preventing or mitigating the consequences of dermal HF exposures is also important to health and safety and needs to be covered under § 40.81. The general "chemical exposure" wording is used in existing § 70.61(b)(4) and 70.61(c)(4), and § 40.81(b)(4) and 40.81(c)(4) will also use this wording.

The April 2011 NIOSH publication references skin notation values representing both the toxicity (SYS) and corrosivity (COR) for dermal HF exposures, and states that dermal exposure to HF can have a fatal toxicity and is considered corrosive to the skin. Specifically, in spite of the lack of an established dermal exposure threshold, NIOSH in Table 1 found the SYS as fatal – "indicating chemicals are highly or extremely toxic and may be potentially lethal or life-threatening following exposure of the skin". NIOSH also found the COR as corrosive – "indicating the potential for a chemical to be corrosive following exposure of the skin."

The NRC recognizes that there is not a consensus standard for dermal exposures to HF, but notes that the regulations in § 40.81(b)(4) and 40.81(c)(4) do not require the development of an exposure threshold. Rather, these regulations will require licensees to prevent or mitigate high or intermediate consequence events. Based on the published data, the NRC believes certain dermal chemical exposures can result in high or intermediate events (e.g., fatality and dermal corrosion) and must be addressed to comply with the performance requirements in § 40.81.

However, the NRC recognizes that the absence of exposure thresholds for dermal exposure to UF6 and related chemicals makes it difficult to demonstrate compliance with the performance requirements. Accordingly, the NRC has undertaken development of a RG to address inhalation of soluble uranium and related dermal exposures. One of the intended purposes of the proposed RG is to evaluate whether an HF dermal exposure threshold is achievable. The NRC staff discussed the development of the proposed RG during a public meeting on May 12, 2009 (ADAMS Accession No. ML091410118). To inform the development of the guidance, the NRC will use the NEI white paper on soluble uranium dated May 22, 2009, "Acute Chemical Toxicity of Uranium with Application to 10 CFR 70.61 (ADAMS Accession No. ML091490747)," the July 2009 DOE report ("Guide of Good Practices for Occupational

Radiological Protection in Uranium Facilities", DOE-STD-1136-2009); the February 2010 DOE report ("Evaluation of Radiological Versus Chemical Toxicity Limits for Varying Enrichments of Uranium for Department of Energy Facilities," Operational Radiation Safety, Vol. 98, No. 2); and NUREG-1391 ("Chemical Toxicity of Uranium Hexafluoride Compared to Acute Effects of Radiation"). The RG is expected to address, among other things, dermal exposure criteria to HF, and HF inhalation criteria -- topics that were not addressed in the NEI white paper.

The NRC already provides relevant guidance in NUREG-1520, Revision 1, Section 6.4.3.3, under which licensees may use information from the Material Safety Data Sheets (MSDS) to assess chemical consequences. The MSDS contain useful information about toxicity, health effects, first aid, reactivity, protective equipment, and spill or leak procedures. Even though the MSDS do not provide quantitative standards for dermal exposures, Section 6.4.3.3 recommends using the MSDS of the hazardous chemicals held at the NRC-licensed facility when assessing chemical consequences. Due to the wide variety of potential chemicals held by licensees, the NRC relies upon the EPA and OSHA thresholds, as well as on data in the MSDS, to address the broadest possible list of chemicals.

Under this guidance, licensees may also use EPA and OSHA chemical thresholds (e.g., AEGLs and ERPGs, respectively) for evaluating chemical exposures from inhalation. This is further indicated in Section IV discussion regarding proposed § 40.81(c)(4), that states in pertinent part:

> Two existing standards, AEGL–2 and ERPG–2, can be used to define the concentration level for irreversible health effects, and two existing standards, AEGL–1 and ERPG–1, can be used to define the concentration level for noticeable discomfort. The qualitative language in § 40.81(c)(4) allows the applicant/licensee to adopt and propose an appropriate standard, which may be an AEGL or ERPG standard. Where no such standard exists, the applicant/licensee may develop or adopt a criterion that is comparable in severity to those that have been established for other chemicals (76 FR 28336; May 17, 2011).

This discussion is clarified here by stating that, with respect to § 40.81(c)(4), AEGL–1 and ERPG–1 can be used to define the concentration level for "mild transient health effects which can produce" notable discomfort.

The NRC recognizes that the AEGLs and ERPGs do not provide dermal exposure thresholds. However, to ensure that the performance requirements in § 40.81 are not exceeded, the ISA should evaluate the degree of hazard and the route of entry of the hazardous chemicals. If dermal exposure is credible and not unlikely, and if it could exceed the § 40.81 performance requirements, the applicant/licensee is required to use IROFS to reduce the consequences or the likelihood of the event.

Finally, the introductory text to § 40.81(b)(4) and 40.81(c)(4) is the same as the existing wording in § 70.61(b)(4) and 70.61(c)(4), which specify the credible high and intermediate consequence events that the performance requirements must address. Similarly, the proposed § 40.81(b)(4)(ii) and 40.81(c)(4)(ii) are based on the existing requirements found in § 70.61(b)(4)(ii) and 70.61(c)(4)(ii). As previously stated in this document, the scope of the 10 CFR part 40 rulemaking established by SRM-SECY-07-146 is to incorporate the 10 CFR part 70 ISA requirements into 10 CFR part 40. Modifications to the proposed 10 CFR part 40 requirements which would introduce significant differences from the existing 10 CFR part 70 requirements are not consistent with the scope and intent of this rulemaking. The requested revisions would make the 10 CFR part 40 ISA requirements significantly different than the parallel 10 CFR part 70 ISA requirements.

Comment D3: Two commenters state that proposed § 40.81(e)(2), regarding training requirements, should be modified by removing the phrase "and conspicuously posts and maintains notices stating" from its first sentence. One commenter states that postings are considered by many to be the least effective training and familiarization tool, and requiring them is an unnecessary administrative burden. If postings are indeed an appropriate training tool,

then licensees are in a better position to make that determination based on particular circumstances and, therefore, allowance for posting is more appropriately contained within the proposed NUREG-1962 guidance document. The commenter further states that the term "conspicuously" is subjective and, therefore, reliant on interpretation.

Response: No change in the rule text has been made. Proposed § 40.81(e)(2) is based on existing § 70.61(f)(2), which also contains the "conspicuously posts" wording. The comment does not specify any problems that have arisen to date as a result of this requirement. Further, the posting requirement is not itself a training and familiarization tool but rather an information requirement. The NRC does not believe that this information requirement is an unnecessary administrative burden to licensees. While the term "conspicuously" is not defined in NRC regulations, § 19.11(f) states, in pertinent part, that "documents, notices, or forms posted under this section [§ 19.11] shall appear in a sufficient number of places to permit individuals engaged in NRC-licensed or regulated activities to observe them on the way to or from any particular licensed or regulated activity location."

E. Jurisdiction/Authority

Comment E1: Several commenters cite a 2006 SRM to SECY-06-0186 ("Increasing Licensing Terms for Certain Fuel Cycle Facilities," ADAMS Accession No. ML062700110) in stating that the proposed § 40.87, *Renewal of licenses,* should be revised to authorize 40-year license terms for facilities that will be subject to the 10 CFR part 40 ISA requirements. The commenters state that the reasoning for the Commission's 2006 SRM supports a 40-year renewal period for 10 CFR part 40 facilities, and one requests that the following specific text be added to the proposed § 40.87: "For licensees subject to the regulations in 10 CPR Part 40, Subpart H, the term of the renewal period will be 40 years."

Response: No change in the rule text has been made. The 2006 SRM approved "maximum" license terms of 40 years for license renewals and new applications for facilities required to submit ISA summaries under 10 CFR part 70, subpart H, but did not authorize 40-year terms in all such cases. Rather, the Commission approved license terms for less than 40 years "on a case-by-case basis" where safety concerns exist. Further, in publishing notice of the SRM, the Commission stated it was establishing "a new policy" for the affected 10 CFR part 70 licensees, and noted that it replaced an earlier 10-year license term policy that also had not been "codified in the regulations" (71 FR 70441; December 4, 2006). Accordingly, the SRM did not lead to the revision of the § 70.73 license renewal provision -- which does not authorize any specific term of years.

The wording of proposed § 40.87 closely tracks existing § 70.73. The comment neither addresses these points, nor establishes an adequate basis for treating licensees subject to the 10 CFR part 40 ISA requirements differently in this regard than licensees subject to the 10 CFR part 70 ISA requirements.

Comment E2: As indicated in the following comment summary, the rulemaking record is unclear on the intended meaning of proposed § 40.3a ("Denial of licensing by Agreement States"), and this has led to varying interpretations by several industry and Agreement State commenters. The industry commenters state that proposed § 40.3a is ambiguous because, while it prohibits Agreement States from issuing new licenses authorizing possession of the threshold quantity of UF6, it could be read to permit Agreement States to license other radiation hazards (e.g., those arising from uranium compounds other than UF6, and from byproduct materials) at these same facilities. This reading of proposed § 40.3a would result in dual Agreement State and NRC regulation at these UF6 facilities. One industry commenter approves of the proposed § 40.3a language, assuming that under it the NRC would assert sole licensing authority over UF6 facilities, thereby avoiding dual regulation. In summary, the

industry position is that § 40.3a should more clearly state that the NRC has sole regulatory authority over licensees authorized to possess 2000 kg or more of UF6, to make it consistent with the following statement of intent regarding proposed § 40.3a:

> The 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.

SOC Section IV, "Discussion of Proposed Amendments by Section," (76 FR 28336). An industry commenter states that, contrary to this 2011 SOC statement, the NRC staff's previous discussion in SECY-10-0128, implied that, for existing facilities, the NRC would only license the threshold quantity of UF6, leaving the Agreement State to regulate possession and use of other radioactive materials at the same facility.

An Agreement State commenter cites the description of the rulemaking's general intent (Section III B of the SOC), where the NRC stated that it would "assert jurisdiction over all applicants and licensees that may possess 2000 kg or more of UF6" (76 FR 28336).

The Agreement State commenters object to the proposed § 40.3a on the grounds that: 1) including byproduct material under the NRC license at UF6 facilities will not enhance radiation health and safety of the byproduct material; 2) States would lose licensing fees if the NRC regulates UF6 facilities; and 3) an NRC rulemaking cannot supersede Agreement State agreements. One of these commenters references a Presidential memorandum dated May 20, 2009, and indicates that the NRC would need explicit approval from Congress before taking this rulemaking action.

Response: SECY-07-0146, "Regulatory Options for Licensing New Uranium Conversion and Depleted Uranium Deconversion Facilities", which initiated this rulemaking, discussed the need for the NRC to retain jurisdiction over "major fuel cycle facilities" licensed under 10 CFR part 40 which hold significant quantities of source material (specifically, UF6). The SECY-07-0146 focused on Honeywell's uranium conversion facility (which is discussed separately in this

response), and on new depleted uranium deconversion facilities that potentially will be licensed by the NRC. The following response also discusses fuel fabrication facilities, which are authorized to possess and use 2000 kg or more of UF6 and currently operate under both State and NRC specific licenses.

After considering the comments, the NRC finds, with respect to the fuel fabrication facilities in Agreement States which are authorized to possess 2000 kg or more of UF6, the NRC need not regulate byproduct material at these facilities. There are three fuel fabrication facilities that possess 2000 kg or more of UF6 and that operate under both State and NRC licenses. These facilities also hold special nuclear material (SNM) in quantities sufficient to form a critical mass. Regulation of such SNM is reserved to the NRC in accordance with section 274b(4) of the AEA, and this SNM is, therefore, regulated under 10 CFR part 70 licenses. However, Agreement States currently regulate byproduct and source material at these fuel fabrication facilities.

In response to the comments, the NRC is modifying the wording of § 40.3a in the final rule to clarify the scope of the NRC's regulatory authority at these fuel fabrication facilities. The NRC in this rulemaking is not taking away the authority that Agreement States now exercise to regulate the possession and use of byproduct materials at fuel fabrication facilities. The discussion in the May 2011 SOC pertaining to proposed § 40.3a (76 FR 28336), stating that the NRC would hold licensing authority over "all radiological activities" at all the facilities covered by this rule, was overbroad, and the final SOC has been modified accordingly. The revised § 40.3a wording reflects the need for the NRC to assert and maintain licensing authority over all source material at fuel cycle facilities which are authorized to possess 2000 kg or more of UF6.

Under Section 274m of the AEA, any agreement between the NRC and a State entered into pursuant to Section 274b of the AEA does not affect the ability of the NRC "to issue rules, regulations, or orders to protect the common defense and security" under its broad rulemaking

authority in Section 161b or 161i of the AEA. The NRC finds that there are common defense and security reasons for asserting the NRC's licensing and regulatory authority over all source material at fuel cycle facilities authorized to possess 2000 kg or more of UF6 (referred to as a threshold quantity of UF6), including the fuel fabrication facilities located in Agreement States. As discussed in SECY-07-0146, after 9/11 there is a heightened threat of sabotage and terrorist attacks at nuclear facilities, including those that possess 2000 kg or more of UF6. Any accidents involving the UF6 – regardless of whether the UF6 is being processed or is simply being stored onsite -- can potentially generate hazardous amounts of HF if the UF6 is exposed to moisture in the air. The HF is a highly reactive and corrosive chemical that presents a substantial inhalation and skin absorption hazard to workers and to off-site residents. Additionally, the complex operations at fuel fabrication facilities, and at uranium conversion and deconversion facilities, all involve large volumes of hazardous chemicals and nuclear material. As stated in SECY-07-0136, the nature of these operations makes it difficult to separate common defense and security requirements from those requirements that have a public health and safety basis.

The NRC regulation of the UF6 source material at fuel fabrication facilities authorized to hold a threshold quantity of UF6, and at uranium conversion facilities, ensures that the potential accidents that could generate HF are evaluated in accordance with the § 40.82(c) ISA requirements. Similar HF hazards will be present at any depleted uranium deconversion facility which, if licensed, will, therefore, also be subject to the 10 CFR part 40 ISA requirements. At several fuel fabrication facilities, Agreement States now license "byproduct material" (as defined in § 150.3(1) of the definition), and the Agreement States will retain their authority to regulate such material (e.g., byproduct material in gauges, sealed sources, and laboratory materials). The NRC agrees with the Agreement State comments that, to date, State licensing of byproduct material at fuel fabrication facilities has adequately protected public health and

safety. Agreement States should continue to regulate byproduct material at these facilities because this material is separate from operations involving UF6, and it is distinct from all other source material and SNM that is also present at these facilities. Allowing the Agreement States to continue regulating byproduct material at these fuel fabrication facilities does not interfere with the NRC's common defense and security authority. Accordingly, this final rule reflects a revised approach in which the Agreement States will maintain their existing licensing and regulatory authority they now exercise over byproduct material at fuel fabrication facilities authorized to hold threshold quantities of UF6. This approach grants some regulatory responsibilities to the NRC and maintains others to the Agreement States. Although the NRC understands the dual regulation concerns expressed by the industry commenters, such regulation by the NRC and an Agreement State has been a common practice for many years at fuel fabrication facilities.

At Honeywell's uranium conversion facility in Metropolis, Illinois, the NRC will continue to regulate and license all source and special nuclear material due to common defense and security considerations at this site. In this regard, when Illinois became an Agreement State in 1987, the NRC determined that the Metropolis facility is important to national security because it provided UF6 to the DOE enrichment complex, for military and energy purposes (ADAMS Accession No. ML071910026). As discussed further in SECY-07-0146, in addition to the health and safety risks at uranium conversion facilities (primarily chemical risks from the use of HF), there are common defense and security reasons for maintaining the existing licensing scheme at the Metropolis site, under Section 274m of the AEA. As stated by DOE in a 2007 letter to the NRC staff (Enclosure 4 to SECY-07-0146), uranium conversion facilities are essential to the national interest in maintaining a secure supply of nuclear fuel to critical energy infrastructure facilities. Honeywell's Metropolis facility continues to be the sole domestic supplier of UF6 feed for the nation's uranium fuel cycle industry.

Contrary to the Agreement State comments, the NRC does not need to amend its Agreement States agreements in order to assert licensing and regulatory authority over UF6 activities. As noted previously, under Section 274m of the AEA, any agreement between the NRC and a State entered into pursuant to Section 274b of the AEA does not affect the ability of the NRC "to issue rules, regulations, or orders to protect the common defense and security" under its broad rulemaking authority in Section 161b or 161i of the AEA. Article V of the standard Agreement States agreement contains this Section 274(m) provision, and nothing in an Agreement State agreement can limit the NRC's ability to act in an arena expressly reserved to it by the AEA. Further, the mixture of UF6 source material with SNM that occurs during fuel fabrication creates situations in which the common defense and security concerns cannot be separated from the health and safety concerns.

The comment which references the President's May 2009 memorandum does not establish why the NRC would need explicit approval from Congress before taking this rulemaking action. The May 2009 Presidential Memorandum only applies to situations in which an agency issues a regulation which specifically states that it preempts state law. No provision in this rulemaking contains such a statement. Furthermore, the Memorandum only requires explicit authority from Congress if there is no sufficient basis for preemption under applicable legal principles. There is no preemption concern here because the Supreme Court has stated that "the federal government has occupied the entire field of nuclear safety concerns, except the limited powers expressly ceded to the states," *Pac. Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 212 (1983). The Agreement State agreement can only cede a State that regulatory power which is authorized by the AEA. As noted previously, Section 274(m) expressly reserves the NRC's right "to issue rules, regulations, or orders to protect the common defense and security." Because the May 2009 Presidential Memorandum does not address the situation at hand, and because the NRC fully occupies the arena of

"common defense and security," it does not need explicit preemption authority from Congress to assert its jurisdiction over radiation and chemical hazards at facilities authorized to possess 2000 kg or more of UF6.

With regard to the Agreement State concern about licensing fees, because Agreement States retain the regulatory authority they currently exercise over byproduct material, any existing licensing fees regarding such material are not affected by this rulemaking.

For these reasons, facilities authorized to possess 2000 kg or more of UF6 are within the legitimate scope of the NRC's common defense and security authority under Section 274m of the AEA. The NRC finds that it, rather than the Agreement States, must oversee operations involving source material at facilities which are authorized to possess 2000 kg or more of UF6, both at uranium conversion and depleted uranium deconversion facilities, and at the fuel fabrication facilities discussed in this **r**esponse. All applicants and licensees that are or will be authorized to possess 2000 kg or more of UF6 are subject to the 10 CFR part 40 ISA requirements.

F. Backfitting

Comment F1: A commenter states that adding a backfit provision to 10 CFR part 40 is vital to ensure that a formal, systematic, and disciplined review of new, changed, or differing positions that could backfit existing facilities is applied to increase regulatory certainty. A disciplined approach to backfitting of uranium hexafluoride conversion facilities will improve the overall effectiveness and certainty in the regulatory process, thereby enhancing the NRC's regulatory mission. The proposed backfit provision in § 40.89 provides for this systematic analysis and review process. The commenter, therefore, supports the inclusion of a backfit provision in the proposed rule. Another commenter states, in part, that it generally supports the proposed 10 CFR part 40 backfitting provisions, and agrees they should be analogous to the

existing backfitting requirements in 10 CFR 70.76.

Response: The NRC acknowledges the comment. No further response is necessary.

Comment F2: While generally supporting the proposed 10 CFR part 40 backfitting provisions, a commenter states that the SOC for the final rule should discuss the applicability of the compliance exception (stated in proposed § 40.89(c)(3)(i) and (ii)), and should include the following statement in the final rule's section-by-section discussion:

> 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.

Without this limiting language (quoted from the SOC published with the 1985 final backfitting rule modifying § 50.109), the commenter states that the compliance exception has the potential to swallow the backfit rule, as most (if not all) backfits have their genesis in new or modified interpretations of what constitutes compliance.

Response: The NRC disagrees with the comment's assertion that most (if not all) backfits have their genesis in new or modified interpretations of what constitutes compliance. The comment provides no analysis of NRC backfitting actions supporting this assertion. While many such actions have properly relied upon the compliance exception (e.g., backfitting of degraded voltage at the *Edwin I. Hatch Plant*, *see* September 29, 2011 NRC Response to Backfit Appeal, ADAMS Accession No. ML112730194), the reactor security rule (74 FR 13926; March 27, 2009) is an example where the NRC relied upon the adequate protection exception to the backfit rule. Other actions are taken after preparation of a backfit analysis (e.g., the 2011 Enhancement to Emergency Preparedness Regulations rulemaking, 76 FR 72560; November 23, 2011).

The NRC agrees that the discussion drawn from the SOC for the 1985 Backfit Rule (50 FR 38097; September 20, 1985) should be included in the SOC for the final 10 CFR part 40

rulemaking. The SOC discussion from the 1985 Backfit Rule continues to be an accurate statement of the NRC's interpretation of the "compliance exception" in 10 CFR 50.109(a)(4)(i). The NRC also believes that a consistent interpretation should be applied in both 10 CFR part 50 and part 40 because there is no reason to distinguish between these two parts with respect to the meaning and scope of the compliance exception. The final rule's SOC includes the statement drawn from the 1985 Backfit Rule's SOC with respect to the "compliance exception."

Further guidance on the applicability of the compliance exception as stated in § 40.89(c)(3)(i) and (ii) may prove useful to all stakeholders. However, the NRC believes that, before issuing such guidance, interested stakeholders should have an opportunity to provide comments on a draft of such guidance. This would increase public confidence in the NRC's regulatory activities, and would allow the NRC to increase the quality and usefulness of the guidance based upon significant comments. However, delaying the issuance of the final 10 CFR part 40 rulemaking in order to include such guidance in the SOC for the final rule does not seem prudent, given that the NRC could develop (with external stakeholder input) and issue such guidance separately from the final 10 CFR part 40 rule. If external stakeholders believe that additional guidance, beyond the additional discussion included in the SOC for the final 10 CFR part 40 rulemaking, should be developed by the NRC, they may request such action from the NRC staff.

Comment F3: The section-by-section discussion of § 40.89(c)(3) should clarify that: 1) the required documented evaluation explaining a finding that one of the backfit analysis exceptions applies should include a discussion of the relevant facts and regulatory history; and 2) when possible, such documented evaluations should be made available for public comment before the backfit is imposed. In this regard, the commenter further states that 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.

Response: The NRC agrees that, whenever the NRC decides to rely upon one or more of the backfit analysis exceptions, the NRC must prepare a documented evaluation that clearly explains why the exception applies, and that this explanation must include the "relevant facts and regulatory history." As requested, the section-by-section discussion of § 40.89(c)(3) in this document includes this clarification.

However, the NRC believes that the level of detail to be presented in the documented evaluation with respect to the "relevant facts and regulatory history" will vary depending upon the nature of the backfitting action. If the NRC backfitting action is limited to a single facility -- or to a small set of facilities with largely identical licensing bases in the area which is the subject of the backfitting action -- then the NRC should ordinarily prepare a more specific and detailed discussion of the "relevant facts and regulatory history" for that facility (or a small set of facilities with largely identical licensing bases in the area which is the subject of the backfitting action).

By contrast, for a generic backfitting action (i.e., a rulemaking generally applicable to the entire population of affected entities or facilities, or to a group of facilities whose licensing bases vary among the facilities), the documented evaluation may be based upon a generic identification and determination of the "relevant facts and regulatory history." This would be a level of detail comparable to what would be acceptable to support a rulemaking under the applicable provisions of the APA. The NRC should not ordinarily be required to perform a detailed review of the licensing basis for each facility which is the subject of the generic backfit. The NRC believes that its position on this point is consistent with the principles underlying the APA, and makes practical sense. The licensee is responsible for knowing and complying with its facility's licensing bases. If the NRC's backfitting discussion for a proposed generic action (such as a rule) is not substantially applicable to a facility, then that facility's licensee has the opportunity to bring to the attention of the NRC specific licensing basis information relevant to

the proposed backfitting (e.g., in the public comment opportunity the NRC provides for proposed regulations, and for certain draft documents such as RGs). The NRC considers this approach to be appropriate because the licensee has the most knowledge of its own licensing basis and, therefore, is in the best position to present the backfitting implications of the NRC-proposed action as applied to the licensee's facility.

The NRC does not agree with the comment insofar as it requests that the agency routinely make available for public comment its documented evaluations before backfits (including adequate protection backfits) are imposed. The NRC is reluctant to limit itself in the manner suggested, given the broadly-worded rulemaking authorities accorded to the NRC under various provisions of the AEA (e.g., sections 103.a, 103.b, 161.i, 161.p, 182.a, and 183). Further, the backfit rule in 10 CFR 50.109 (and as proposed in 10 CFR part 40) does not require a "comment period" for any documented evaluation – the NRC simply has to prepare the evaluation and provide it as part of the backfitting action. The NRC notes that, arguably, the backfit rule imposes an even more stringent test than the commenter suggests, because the backfit rule (e.g., 10 CFR 40.89(c)(5)) limits the NRC's ability to delay preparation of the documented evaluation to situations where "immediate[ly] effective regulatory action is required." (This backfit provision is consistent with the NRC's position that an issue may be an "adequate protection" matter but is not one which requires immediately effective action). Accordingly, the NRC ordinarily prepares its documented evaluations before taking backfitting actions (unless immediately effective regulatory action is required).

In any event, even if the NRC agreed that, when possible, its documented evaluations should be made available for public comment before the backfit is imposed, the NRC does not believe that such a position should be adopted at this late stage of the 10 CFR part 40 rulemaking. To ensure consistency and uniformity between 10 CFR part 40 and other parts of this chapter which have backfitting and issue finality restrictions, the NRC would have to change

its practice and guidance with respect to backfitting in those parts. Such changes in practice would require notice and a comparable public comment opportunity, and NRC consideration of the comments, before the 10 CFR part 40 rulemaking could go forward. Such a delay in the 10 CFR part 40 rulemaking is not warranted. For these reasons, the final SOC does not state that, before backfits are imposed, the NRC will make available for public comment its documented evaluations.

G. Reporting

Comment G1: Two commenters state that the proposed reporting requirements in § 40.88 should be modified to take into account the lessons learned from the 10 CFR part 70 implementation, and they cite in this regard the guidance on the 10 CFR part 70 appendix A reporting requirements provided by Division of Fuel Cycle Safety and Safeguards Interim Staff Guidance (FCSS ISG-12, Rev. 0) (ADAMS Accession No. ML102020267). The commenters state that § 40.88 needs to specify that it "applies to NRC licensed materials or hazardous chemicals produced from licensed materials" to avoid a broad interpretation of the reporting requirements.

Response: No change in the rule text has been made. The 1-hour reporting requirements of § 40.88(a)(2) state, in relevant part, that an "acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material" is a reportable event, and § 40.88(b)(3) contains a similar 24-hour reporting requirement. Further, the term "hazardous chemicals produced from licensed materials" is defined in § 40.4 (the definition matches the one used in 10 CFR part 70). Together, the regulatory wording is adequately clear that "licensed material" is referring to NRC-licensed material.

Additionally, the comment does not show how FCSS ISG-12, Rev. 0 (issued in 2010) is relevant to this 10 CFR part 40 rulemaking. As discussed in the proposed rule, some, but not

all, of the § 40.88 reporting requirements are based on the reporting requirements contained in 10 CFR part 70 appendix A. Moreover, to the extent that this ISG document may be relevant here, the comment is not clear on how any of its guidance could be transformed into § 40.88 reporting requirements.

Comment G2: Several commenters state that proposed § 40.88(b)(4) (which sets forth one of the events that must be reported to the NRC within 24 hours of discovery) should be revised as follows:

> (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 commenters state that the phrase “or may have affected” is subjective, unclear, and subject to extremes in interpretation. Two commenters state that 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 the NRC under the emergency plans, this subjective criterion is unnecessary and potentially can result in violations based solely on interpretation. One of these commenters adds that the licensee is in the best position to determine if a natural phenomenon or fire event actually impacts an IROFS safety function. If such an impact actually occurs, that would be the appropriate time to report the event to the NRC, if the event had not already been reported under the licensee’s emergency preparedness program.

A third commenter states that the wording "may have affected the intended safety function or availability or reliability of one or more items relied on for safety" is unclear, because any such event could potentially affect one or more IROFS depending on the potential for the growth of the fire or propagation of the external event. This commenter adds that the requested change would permit licensees, who have the best information regarding the event and the duty of compliance, to make the determination regarding the need to report an event.

Regarding proposed § 40.88(a)(2) and 40.88(b)(4), the third commenter further states that these reporting requirements should not apply until after the ISA summary is submitted, because the quantitative health effects standards referenced in § 40.88(a)(2), and the type of IROFS referenced in § 40.88(b)(4), will not be identified until the ISA summary is submitted. As of the date that the rule will become effective the licensee will not have established such standards, and will not have identified such IROFS.

Response: No change to the rule text has been made. The proposed § 40.88(a)(2) and 40.88(b)(4) match existing reporting requirements in 10 CFR part 70 appendix A, and the comment does not provide an adequate basis to introduce differences between these sets of requirements.

Proposed § 40.88(a)(2) identifies the following as an event that must be reported to the NRC within 1 hour of discovery:

> An acute chemical 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).

This wording matches the reporting requirement in existing 10 CFR part 70, appendix A, subsection (a)(3). The comment does not identify any problems to date that 10 CFR part 70 licensees have had in complying with this reporting requirement. Further, the comment does not address the fact that 10 CFR part 40 licensees are already required by existing § 40.60(a) to report within 4 hours of discovery similar exposure incidents involving releases of licensed material (including releases due to fires, explosions, and toxic gas releases). Accordingly, 10 CFR part 40 licensees should already have in place health standards similar to those required by § 40.88(a)(2), and should not be permitted to wait until the ISA summary is submitted before becoming subject to this requirement. Such a delay could have adverse health consequences to any exposed individuals, should a reportable event occur between the time the rule becomes effective and the time when the ISA summary is submitted.

Similarly, regarding proposed § 40.88(b)(4), should a fire (or other reportable event) occur between the time the rule becomes effective and the time when the ISA summary is submitted, this needs to be reported to the NRC without delay. A comparable issue was addressed when 10 CFR part 70, appendix A, subsection (b)(4) – which matches the proposed § 40.88(b)(4) wording – was established in 2000. In response to a comment regarding these reportable events, the NRC stated in the SOC that it wanted to "be informed when such events occur, regardless of the licensee's determination with respect to the performance requirements." 65 FR 56211; Sept. 18, 2000). The NRC holds the same view today.

Further, the comment does not identify any problems to date that 10 CFR part 70 licensees have had in complying with this reporting requirement, and does not identify any licensee complaints that its requirements are too subjective. Additionally, the comment does not address the fact that 10 CFR part 40 licensees are already required by existing § 40.60(b)(4) to report within 24 hours of discovery any unplanned fire that damages licensed material.

Comment G3: Two commenters state that the proposed § 40.88(a)(1), which specifies one of the events that must be reported to the NRC within 1 hour of discovery, should be based on and limited to high consequence events as described in the performance requirements. They request that this provision be limited to an "acute intake of soluble uranium by an individual" that qualifies as a high consequence event.

One of the commenters states that, as worded, the NRC's proposed § 40.88(a)(1) provision would require a 1-hour report if a worker received an acute intake of 30 mg of soluble uranium, which corresponds to, at most, an intermediate consequence event to the worker.

Response: The requested change to the proposed § 40.88 reporting requirements has not been made. The NRC's proposed wording – including its 30 mg criterion – is the same as that used in existing provision (a)(2) in the 10 CFR part 70, appendix A, reporting requirements.

The 10 CFR part 40 and part 70 reporting requirements for intake incidents apply to all individuals (i.e., to workers employed by the licensee and to members of the public), whereas the 30 mg value in the § 40.81(b)(3) performance requirements applies only to members of the public. Since a 30 mg exposure to soluble uranium would represent a significant safety event to the individual – whether that individual is a worker or a member of the public -- the NRC needs to be informed within 1 hour of any such exposure. In addition, the requested change would represent a significant departure from the existing 10 CFR part 70 appendix A reporting requirements, and the comment neither acknowledges this fact, nor sets forth an adequate basis for doing so.

Comment G4: One commenter noted that § 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 10 CFR part 70, Appendix A, PRM appear to have been addressed in § 40.88(a) and (b), i.e., 60-day written reports. The commenter supported the modifications.

Response: The NRC acknowledges the comment. No further response is necessary.

H. Corrections

Comment H1: Several commenters state that the proposed § 40.81(d) is mischaracterized as containing "performance" requirements. Specifically, §§ 40.81(a), 40.81(d) and 40.85(c)(2) are cited as containing inaccurate references due to "cut and paste" errors made in basing these provisions on similar wording used in the existing 10 CFR part 70 performance requirements. For example, the commenters note that proposed § 40.81(d) contains no performance requirements (rather, it addresses IROFS and management measures), and that its wording is equivalent to that used in the existing § 70.61(e).

Response: The NRC agrees with the comments, and the final rule language has been modified accordingly as discussed in this response.

The wording of proposed § 40.81(a) is based on existing § 70.61(a), the latter of which contains a cross-reference to the § 70.61(d) performance requirements specific to criticality accidents. There are no such performance requirements proposed for 10 CFR part 40 facilities, where criticality accidents are not a concern. Therefore, unlike § 70.61 which contains three paragraphs specifying performance requirements, the proposed § 40.81 requirements have only two paragraphs (i.e., § 40.81(b) and (c)) specifying performance requirements for high-consequence and intermediate-consequence events, respectively. The final rule has been corrected to remove from § 40.81(a) the erroneous cross-reference to paragraph (d) "performance" requirements.

The wording of proposed § 40.81(d) is based on existing § 70.61(e), the latter of which contains a cross-reference to the § 70.61(d) performance requirements. This cross-reference was inadvertently used in proposed § 40.81(d), and the final rule has been corrected so that this provision will correctly refer back to only the § 40.81(b) and (c) performance requirements.

The wording of proposed § 40.85(c)(2) is based on existing § 70.66(c)(2), the latter of which contains a cross-reference to the § 70.61(d) performance requirements. This cross-reference was inadvertently used in proposed § 40.85(c)(2), and the final rule has been corrected so that this provision will correctly refer back to only the § 40.81(b) and (c) performance requirements.

Comment H2: A commenter notes that the May 17, 2011 SOC for the proposed rule contains the following statement, at page 28342 of the *Federal Register* notice (76 FR 28336): "Guidance documents are being developed to provide examples of acceptable approaches for the meaning of "unlikely" and "highly unlikely." The commenter requests the opportunity to review such guidance (of which it was unaware), and suggests that it be made available for review prior to the final rule becoming effective.

Response: The SOC statement quoted in the comment is not accurate, as the NRC is

not developing any new guidance in this regard. Existing guidance on developing facility-specific definitions of the terms “unlikely” and “highly unlikely” is provided in NUREG-1520, Rev. 1, Section 3.4.3.2(9). This guidance can be used by existing 10 CFR part 40 fuel cycle facilities authorized to possess 2000 kg or more of UF6. Further, as discussed in Comment C8, the proposed § 40.84(c)(9) requires that each licensee’s ISA summary contain descriptions of certain definitions used in the ISA for the licensee’s facility, and this provision is the same as the existing § 70.65(b)(9) requirement. Facility-specific definitions of “unlikely” and “highly unlikely” are required.

Comment H3: Two commenters state that the introductory text to proposed § 40.81(b) (pertaining to performance requirements for high consequence events) should be modified by removing the words “subject to § 40.83(b)(1),” because this text is not in the parallel performance requirements of existing § 70.61(b). One commenter adds that the § 40.83 title (“Requirements for new facilities or new processes at existing facilities”) is relevant to the scope of § 40.83(b).

Response: The NRC agrees that § 40.81(b) should be modified by removing the words “subject to § 40.83(b)(1),” and the final rule has been modified as requested.

The proposed rule wording had been intended to reflect the NRC’s preference for the selection of engineered controls over administrative controls. But this preference is stated in the § 40.83(b)(1) requirements (which are the same as those stated in existing § 70.64(b)(1)), making the proposed reference to § 40.83 in § 40.81 unnecessary and redundant. Also, as stated in the comment, the proposed § 40.81(b) is based on the existing § 70.61(b), which does not reference § 70.64(b)(1). Deleting the words “subject to § 40.83(b)(1)” adheres to the overall scope and intent of this rulemaking to make the 10 CFR part 40 and part 70 ISA requirements consistent, as discussed in the introduction to this comment and response section. Further, the NRC now recognizes that the proposed change would have improperly linked § 40.81(b) to

40.83(b)(1), and would have had the unintended consequence of requiring retrofits of existing structures.

The NRC does not agree with the comment that the § 40.83 title ("Requirements for new facilities or new processes at existing facilities") is relevant to the scope of § 40.83(b). The § 40.83(b)(1) requirement that a facility's "system design" incorporate, to the extent practicable, a preference for engineered controls over administrative controls, applies to the design of new facilities and to the design of new processes at existing facilities, consistent with the § 40.83(a) preamble.

Comment H4: Several commenters state that the proposed § 40.82(c)(1)(iii) differs from the existing § 70.62(c)(1)(iii), which states: "Facility hazards that could affect the safety of licensed materials and thus present an increased radiological risk." Two commenters state that any potential hazard which is chemical in nature that could affect the safety of licensed materials would be within the NRC's jurisdiction, and will already have been addressed in the ISA. One commenter states that the proposed language is difficult to interpret and is a significant departure from the language in § 70.62(c)(1)(iii). Another commenter states that the proposed rule wording pertaining to hazardous chemicals will result in subjective interpretation by NRC staff.

Response: The NRC agrees, for the reasons stated in this response, that the wording of § 40.82(c)(1)(iii) should match existing § 70.62(c)(1)(iii), and the final rule has been modified as requested.

The proposed § 40.82(c)(1)(i) through (ii) provisions match those stated in existing § 70.62(c)(1)(i) through (ii), and require that an ISA identify the "radiological hazards related to" the possession or use of "licensed material" at the facility covered by the ISA; the "chemical hazards of licensed material" at the facility covered by the ISA; and the "hazardous chemicals produced from licensed material" at the facility covered by the ISA. Proposed § 40.82(c)(1)(iii)

added to the existing § 70.62(c)(1)(iii) provision by describing the risks to be evaluated as those "due to licensed material or hazardous chemicals produced from licensed material." This additional text is redundant to the proposed § 40.82(c)(1)(i) through (ii) provisions.

Further, the *Federal Register* notice for the proposed rule (76 FR 28336) discussed the proposed § 40.82(c) in general, but provided no explanation or rationale for departing from the wording used in existing § 70.62(c)(1)(iii). As stated in the comment, the proposed additional text in § 40.82(c)(1)(iii) is a significant departure from the language in § 70.62(c)(1)(iii). Matching § 40.82(c)(1)(iii) to existing § 70.62(c)(1)(iii) adheres to the overall scope and intent of this rulemaking, which is to make the 10 CFR part 40 and part 70 ISA requirements consistent, as discussed in the introduction to this comment and response section.

Comment H5: Two commenters state that proposed § 40.84(b) should not be included in the final rule. One states that these proposed emergency planning requirements (which would have supplemented the existing § 40.31(j) requirements) would increase regulatory burden without increasing public health and safety, and are inconsistent with the intent of the 1989 rule that first established NRC emergency planning requirements.

The other commenter states that proposed § 40.84(b) is not necessary to address the safety of radioactive materials, and that its new and additional criteria for chemical hazards are not necessary and are not currently required under 10 CFR part 70.

Response: For the following reasons, the NRC has decided not to include proposed § 40.84(b) in the final rule. The wording of § 40.84 will, accordingly, match the existing § 70.65 requirements.

The existing emergency planning provisions in § 40.31(j) (and the similar set of requirements in § 70.22(i)) require that the potential offsite chemical hazards posed by the operation of UF6 facilities be addressed in their emergency plans, and there is no need to supplement the ISA requirements in this regard.

As stated in the section-by-section discussion of § 40.84(b) in the May 17, 2011, SOC for the proposed rule (see 76 FR 28347), the new requirement was intended to supplement the existing emergency planning requirements in § 40.31(j), to capture the additional hazards posed by operations involving 2000 kg or more of UF6, which include the hazardous HF chemical that UF6 can generate when exposed to air. The NRC's primary concern was that a cloud of HF may rapidly move offsite, while the uranium settles on site. The proposed § 40.84(b) would accordingly have required the licensee to either show that members of the public offsite would not be seriously affected by a UF6 accident that produces HF, or submit an emergency plan pursuant to § 40.31(j)(3).

In response to the comment, the NRC staff reconsidered the need for the proposed § 40.84(b). The NRC staff used modeling software (RASCAL) to evaluate the release of UF6 and exposure to soluble uranium and HF. The modeling reveals that an accident involving 2000 kg or more of UF6 would produce enough HF to pose an offsite hazard. Additionally, such an accident would potentially generate an intake of soluble uranium to a member of the public at the fence line exceeding the 2 mg criterion in existing § 40.31(j)(1)(i), thereby triggering the requirement to submit an emergency plan in accordance with § 40.31(j)(3). This is why the existing and proposed UF6 facilities that will be subject to the 10 CFR part 40 ISA requirements have already developed NRC emergency plans.

The NRC staff also reviewed the 1989 rulemaking (54 FR 14051) which established the emergency planning requirements in § 40.31(j), and finds that these existing requirements are comprehensive and need not be supplemented in this rulemaking. The chemical hazards arising from accidents at UF6 facilities were well-recognized, as airborne releases from such accidents "are likely to occur rapidly with little warning," and the highly soluble uranium from UF6 releases is chemically toxic. Accordingly, 10 CFR part 40 licensees authorized to possess significant amounts of UF6 (i.e., amounts exceeding 1000 kg, as stated in § 40.31(j)(1)) were

made subject to the emergency planning requirements. Further, even if a licensed facility is not required to have an NRC-approved emergency plan under § 40.31(j), the NRC noted that the Emergency Planning and Community Right-To-Know Act of 1986 (EPCRA) (Title III, Pub. L. 99-499), administered by the EPA, is complementary to the NRC's requirements, as the EPCRA applies to a broad range of NRC materials licensees. The SOC states in pertinent part that UF6 facilities are covered by the EPCRA because they "possess hydrogen fluoride and fluorine," both of which are on the EPA's list of hazardous chemicals. The 10 CFR part 40 licensees authorized to possess significant amounts of UF6 are required by § 40.31(j)(3)(xiii) to certify as part of their emergency planning that they are in compliance with the EPCRA. Such licensees are also required by § 40.31(j)(3)(viii) to promptly notify local government officials as soon as a UF6 accident having the potential to cause a release is detected.

The similar set of emergency planning requirements in § 70.22(i) contains the same provisions as those discussed previously (i.e., § 70.22(i)(1) makes the requirements applicable to licensees authorized to possess amounts of UF6 exceeding 1000 kg; such licensees are required by § 70.22(i)(3)(xiii) to certify as part of their emergency planning that they are in compliance with the EPCRA; and such licensees are required by § 70.22(i)(3)(viii) to promptly notify local government officials as soon as a UF6 accident having the potential to cause a release is detected). No additional emergency planning requirements were established in the 10 CFR part 70 ISA requirements (e.g., § 70.65), and the NRC has decided to take the same approach here. This decision keeps the 10 CFR part 40 ISA requirements consistent with the 10 CFR part 70 ISA requirements, thus meeting one of the primary goals of this rulemaking.

IV. Discussion of Final Amendments by Section

The format of the requirements contained in 10 CFR part 40 is administratively restructured to conform with the structures of other parts in the chapter. Currently, 10 CFR part 40 has undesignated subject headings preceding related sections. This final rule replaces the undesignated subject headings with specific lettered and titled subparts. In addition to this administrative restructuring, a new subpart H is added to 10 CFR part 40, entitled "Additional Requirements for Certain Licensees Authorized to Possess 2000 Kilograms (4400 lb) or more of Uranium Hexafluoride." The new 10 CFR part 40 subpart H is similar to the existing subpart H of 10 CFR part 70.

Section 40.3a Denial of licensing by Agreement States

This new section specifies that Agreement States lack regulatory authority over persons who are authorized to possess or plan to possess 2000 kg or more of UF6. The § 40.3a requirements do not apply to facilities in Agreement States that are undergoing decommissioning as of the publication date of this rule. The wording of the proposed requirement has been revised in the final rule to specify that the NRC will be the regulatory authority over all source material at facilities which are authorized, or will be authorized, to possess 2000 kg or more of UF6. Agreement States will retain authority they now exercise to regulate byproduct material at such facilities. This requirement is consistent with the Commission's direction in SRM-M070308B, dated March 22, 2007, and the letter that the NRC sent to all the Agreement States (FSME-07-036), dated April 13, 2007, informing them that the NRC "will regulate future major fuel cycle facilities licensed under 10 CFR part 40, e.g., uranium conversion and deconversion facilities." The revised § 40.3a wording, by specifying "source material," also helps to focus the requirement on the Agreement States that have issued

licenses for possession of UF6 above the 2000 kg threshold, as noted in SRM-10-0022. The revised wording is consistent with the Commission's statement in SRM-10-0128 that for all "source material licensees possessing significant amounts" of UF6 the rule should "set possession limits for UF6 to determine whether the NRC or Agreement States have licensing authority." As stated in response to Question E2 (Section III, Summary and Analysis of Public Comments on the Proposed Rule), to the extent that Agreement States now license "byproduct material" (as defined in § 150.3(1) of the definition) at facilities affected by this rulemaking, the Agreement States will retain their authority to regulate such material (e.g., byproduct material in gauges, sealed sources, and laboratory materials).

Section 40.4 Definitions

The definitions of 11 terms used in the new subpart H are added to § 40.4 and include: ''Acute,'' ''Available and reliable to perform their function when needed,'' ''Configuration management,'' ''Defense-in-depth practices,'' ''Hazardous chemicals produced from licensed materials,'' ''Integrated safety analysis,'' ''Integrated safety analysis summary,'' ''Items relied on for safety,'' ''Management measures,'' ''Unacceptable performance deficiencies,'' and ''Worker."

Except as specified, these terms are defined the same as those used in 10 CFR part 70, subpart H. Language referencing criticality events was removed from the definitions for "integrated safety analysis" and "unacceptable performance deficiencies" because 10 CFR part 40 licensees do not possess special nuclear material in concentrations where criticality events are possible. The "defense-in-depth" definition originates from the footnote in § 70.64 that describes what defense-in-depth means.

Section 40.8 Information collection requirements: OMB approval

Paragraph (b) is amended to update the list of applicable sections in the new subpart H and to reflect the administrative renumbering of 10 CFR part 40.

Section 40.26 General license for possession and storage of byproduct material as defined in this part

Paragraph (c)(1) is amended to update the list of applicable sections in the new subpart H and to reflect the administrative renumbering of 10 CFR part 40.

Section 40.80 Applicability

This new section lists the types of NRC licensees or applicants who are subject to the new subpart H. The new requirements apply to all applicants or licensees that are or plan to be authorized to possess 2000 kg or more of UF6. In general, this new subpart is intended to ensure that significant accidents, that are possible at 10 CFR part 40 fuel cycle facilities authorized to possess 2000 kg or more of UF6 have been analyzed in advance and that appropriate controls or measures are established to ensure adequate protection of workers, the public, and the environment.

The requirements and provisions in subpart H are in addition to, and not a substitute for, other applicable requirements, including those of the EPA and the U.S. Department of Labor, OSHA. The new NRC requirements only apply to NRC's areas of responsibility (radiological safety and chemical safety directly related to licensed radioactive material). In this regard, the new requirements for hazards and accident analyses are intended to complement but not supersede any parallel OSHA and EPA regulations.

The new requirements in subpart H do not apply to licensees who, as of the effective date of this rule, are undergoing decommissioning under the provisions of § 40.42. The NRC

notes that existing § 40.42(g)(4)(iii) states that a proposed decommissioning plan (DP) must include ‘‘a description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning.’’ Because the DP is submitted for NRC approval before initiation of procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area, the DP will continue to be the vehicle for regulatory approval of the licensee’s practices for protection of health and safety during decommissioning. The ISA provides valuable information with respect to developing the DP and the use of the ISA in this manner is encouraged.

Section 40.81 Performance requirements

This new section explicitly addresses potential radiological and chemical exposures to workers or members of the public and environmental releases as a result of accidents. The requirements in 10 CFR part 20 continue to be NRC’s general standard for protection of workers and the public from licensed activities during normal operations and accidents. Although it is the NRC’s intent that the regulations in 10 CFR part 20 also be observed to the extent practicable during an emergency, it is not the NRC’s intent that the 10 CFR part 20 requirements apply as the design standard for all possible facility accidents, irrespective of the likelihood of those accidents. Because accidents are unanticipated events that usually occur over a relatively short period of time, the changes to 10 CFR part 40 assure adequate protection of workers, members of the public, and the environment by limiting the risk (combined likelihood and consequence) of accidents.

Two risk-informed performance requirements are included in this final rule, both of which are set out in § 40.81: 1) Paragraph (b) states that high-consequence events must meet a likelihood standard of highly unlikely; and 2) paragraph (c) states that intermediate-consequence events must meet a likelihood standard of unlikely. The term

‘‘performance requirements’’ thus considers together consequences and likelihood. For regulatory purposes, each performance requirement is considered an equivalent level of risk. For example, the acceptable likelihood of intermediate-consequence events is allowed to be greater than the acceptable likelihood for high-consequence events.

Paragraph (a). This paragraph requires each applicant or licensee to evaluate, in the ISA, its compliance with the performance requirements in paragraphs (b) and (c). A risk-informed approach must consider not only the consequences of potential accidents, but also their likelihood of occurrence. The performance requirements rely on the terms ‘‘unlikely’’ and ‘‘highly unlikely’’ to focus on the risk of accidents. However, the NRC has decided not to include in the final rule quantitative definitions of the terms ‘‘unlikely’’ and ‘‘highly unlikely,’’ because a single definition for each term that would apply to all the facilities regulated by 10 CFR part 40 may not be appropriate. Depending on the type of facility and its complexity, the number of potential accidents and their consequences could differ markedly. Therefore, to ensure that the overall facility risk from accidents is acceptable for different types of facilities, the final rule requires applicants to develop, for NRC approval, the meaning of ‘‘unlikely’’ and ‘‘highly unlikely’’ specific to their processes and facility (see discussion of § 40.84 in this document). NUREG-1520, Rev. 1, Section 3.4.3.2(9) provides guidance on developing facility-specific definitions of the terms “unlikely” and “highly unlikely” that can be applied to existing 10 CFR part 40 fuel cycle facilities authorized to possess 2000 kg or more of UF6. The general approach for complying with the performance requirements is that, at the time of licensing, each hazard (e.g., fire, chemical, electrical, industrial) that can potentially affect either radiological health and safety, or chemical safety associated with hazardous chemicals produced from licensed material, is identified and evaluated by the licensee or applicant in an ISA. The impact of accidents, both internal and external, associated with these hazards is compared with the two performance requirements. Any (and all) structures, systems,

components, or human actions, for which credit is taken in the ISA for mitigating (reducing the consequence of) or preventing (reducing the likelihood of) the accident such that the two performance requirements are satisfied, must be identified as an IROFS. Under this approach, the licensee or applicant has a great deal of flexibility in selecting and identifying the actual ''items.'' For example, IROFS can be defined at the systems-level, component-level, or sub-component level. ''Management measures'' (see discussion of § 40.82(d) in this document) are applied to IROFS in a graded fashion to ensure that the item will perform its safety function when needed. The combination of the set of ''items relied on for safety'' and the ''management measures'' applied to each item will determine the extent of the licensee's programmatic and design requirements, consistent with the facility risk, and will ensure that at any given time, the facility risk is maintained safe and protected from accidents.

The new performance requirements also address certain hazardous chemicals produced from licensed nuclear material. The question of the extent of NRC's authority to regulate chemical hazards at its fuel cycle facilities was raised after the Sequoyah Fuels accident discussed above, which resulted in a worker fatality. The cause of the worker's death was the inhalation of HF gas, which was produced from the chemical reaction of UF6 and water (present as humidity in air). Partly as a result of the coordinated Federal response and resulting Congressional investigation into that accident, the NRC and the OSHA entered into an MOU in 1988 that clarified the agencies' interpretations of their respective responsibilities for the regulation of chemical hazards at nuclear facilities. The MOU identified the following four areas of responsibility:

1) Radiation risk produced by radioactive materials;

2) Chemical risk produced by radioactive materials;

3) Plant conditions that affect the safety of radioactive materials; and

4) Plant conditions that result in an occupational risk, but do not affect the safety of

licensed radioactive materials.

Generally, the NRC covers the first three areas, whereas OSHA covers the fourth area.

One goal of the new performance requirements in § 40.81 is to be consistent with the NRC–OSHA MOU. Therefore, the performance requirements in § 40.81 include explicit standards for the MOU's first two areas of responsibility. In addition, the third MOU area of responsibility is specifically evaluated by licensees under the ISA requirements of § 40.82(c)(1)(iii). As an example of the third MOU area, if the failure of a chemical system adjacent to a nuclear system could affect the safety of the nuclear system such that the radiation dose (and associated likelihood of that accident) exceeded a performance requirement, the chemical system failure would be within the scope of the ISA and the means to prevent the chemical system failure from impacting the nuclear system would be within the NRC's regulatory purview.

Within each performance requirement, the NRC recognizes that the new radiological standards are more restrictive, in terms of acute health effects to workers or the public, than the chemical standards for a given consequence (high or intermediate). This is consistent with the NRC's current regulatory practice. The choice of each criterion is discussed in a paragraph-by-paragraph discussion of § 40.81(b) through (e) in this document.

The use of any of the performance requirements is not intended to imply that the specified worker or public radiation dose or chemical exposure constitutes an acceptable criterion for a maximum allowed dose to a worker or the public. Rather, these values in this section are reference values, to be used by licensees in the ISA (a forward-looking analysis) to establish controls (i.e., IROFS and associated management measures) necessary to protect workers from potential accidents with low or exceedingly low probabilities of occurrence that are not expected to occur during the operating life of the facility.

Paragraph (b). This provision addresses performance requirements for

"high-consequence events." Such events include accidental radiological or chemical exposure of a worker or an individual located outside of the controlled area, and would involve exposure to high levels of radiation or hazardous chemicals produced from licensed materials. A high-consequence radiological accident, if it occurred, would produce radiation doses to a worker or an individual located outside of the controlled area at levels causing clinically observable biological damage. A high-consequence chemical accident would involve concentrations of hazardous chemicals produced from licensed material, and would be severe enough to cause death or life-threatening injury. The goal is to ensure an acceptable level of risk by limiting the combination of the likelihood of occurrence and the identified consequences. Thus, high-consequence events must be sufficiently mitigated to a lower consequence or prevented such that the event is highly unlikely to occur. The application of ''items relied on for safety'' provides this prevention or mitigation function.

Paragraph (b)(1). This paragraph requires that an acute exposure of a worker to a radiation dose of 1 Sv (100 rem) or greater total effective dose equivalent (TEDE) be considered a high-consequence event. According to the National Council on Radiation Protection and Measurements (NCRP, 1971), life-saving actions—including the "search for and removal of injured persons, or entry to prevent conditions that would probably injure numbers of people'' - should be undertaken only when the ''planned dose to the whole body shall not exceed 100 rems.'' This is consistent with a later NCRP position (NCRP, 1987) on emergency occupational exposures, that states ''when the exposure may approach or exceed 1 Gy (100 rad) of low-LET [linear energy transfer] radiation (or an equivalent high-LET exposure) to a large portion of the body, in a short time, the worker needs to understand not only the potential for acute effects but he or she should also have an appreciation of the substantial increase in his or her lifetime risk of cancer.''

Paragraph (b)(2). This paragraph requires that the exposure of an individual located

outside of the controlled area to a radiation dose of 0.25 Sv (25 rem) or greater TEDE be considered a high-consequence event. This is generally consistent with the criterion established in 10 CFR 100.11, ‘‘Determination of exclusion area, low population zone, and population center distance,’’ and 10 CFR 50.34, ‘‘Contents of applications; technical information,’’ in which a whole-body dose of 0.25 Sv (25 rem) is used to determine the dimensions of the exclusion area and low-population zone required for siting nuclear power reactors.

Paragraph (b)(3). This paragraph requires that the intake of 30 mg of soluble uranium by an individual located outside of the controlled area be considered a high-consequence event. This value is consistent with the performance requirements in § 70.61 which applies to fuel cycle facilities. Additionally, the use of this value is consistent with the selection of 30 mg of uranium as a criterion during the 10 CFR part 76 rulemaking (59 FR 48944; September 23, 1994).

Paragraph (b)(4). This paragraph requires that an acute exposure to hazardous chemicals produced from licensed material at concentrations that either 1) could cause death or life-threatening injuries to a worker; or 2) could cause irreversible health effects to an individual located outside of the controlled area, be considered a high-consequence event. Chemical consequence criteria corresponding to anticipated adverse health effects to humans from acute exposures (i.e., a single exposure or multiple exposures occurring within a short time-24 hours or less) have been developed, or are under development, as discussed in Section II, question H.

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.

Paragraph (c). This provision specifies performance requirements for "intermediate-consequence events," which would be of a lower magnitude than high consequence events because they do not involve risk of death or life-threatening injury. Intermediate-consequence events include accidental radiological or chemical exposure of a worker or an individual located outside of the controlled area and would involve exposure to levels of radiation or hazardous chemicals produced from licensed materials that generally correspond to permanent injury to a worker or transient injury to a non-worker. An intermediate-consequence event is also specified as including significant releases of radioactive material to the environment.

The goal is to ensure an acceptable level of risk by limiting the combination of the likelihood of occurrence and the identified consequences. Thus, ''intermediate consequence events'' must be sufficiently mitigated to a lower consequence or prevented such that the event is unlikely to occur. The application of ''items relied on for safety'' provides this prevention or mitigation function.

Paragraph (c)(1). This paragraph requires that a worker radiation dose between 0.25 Sv (25 rem) and 1 Sv (100 rem) TEDE be considered an intermediate-consequence event. This value was chosen because of the use of 0.25 Sv (25 rem) as a criterion in existing NRC regulations. For example, in 10 CFR 20.2202, ''Notification of incidents,'' immediate notification is required of a licensee if an individual receives ''…a total effective dose equivalent of 0.25 Sv (25 rem) or more.'' Also, in 10 CFR 20.1206, ''Planned special exposures,'' a licensee may authorize an adult worker to receive a dose in excess of normal occupational exposure limits if a dose of this magnitude does not exceed 5 times the annual dose limits [i.e., 0.25 Sv (25 rem)] during an individual's lifetime. In addition, EPA's Protective Action Guides (U.S. Environmental Protection Agency, 1992) and NRC's regulatory guidance (RG 8.29, "Instruction Concerning

Risks from Occupational Radiation Exposure," 1996) identify 0.25 Sv (25 rem) as the whole-body dose limit to workers for life-saving actions and protection of large populations. The NCRP has also stated that a TEDE of 0.25 Sv (25 rem) corresponds to the once-in-a-lifetime accidental or emergency dose for workers.

Paragraph (c)(2). This paragraph requires that a dose to any individual located outside of the controlled area between 0.05 Sv (5 rem) and 0.25 Sv (25 rem) be considered an intermediate-consequence event. The NRC has used a 0.05-Sv (5-rem) exposure criterion in a number of its existing regulations. For example, 10 CFR 72.106, ''Controlled area of an ISFSI or MRS,'' states that ''Any individual located on or beyond the nearest boundary of the controlled area shall not receive a dose greater than 5 rem to the whole body or any organ from any design basis accident.'' In addition, in the regulation of the above-ground portion of a proposed geologic repository, 10 CFR 60.136, "Preclosure controlled areas," states that ''for [accidents], no individual located on or beyond any point on the boundary of the preclosure controlled area will receive a total effective dose equivalent of 5 rem.'' A TEDE of 0.05 Sv (5 rem) is also the upper limit of EPA's Protective Action Guides of between 0.01 to 0.05 Sv (1 to 5 rem) for emergency evacuation of members of the public in the event of an accidental release that could result in inhalation, ingestion, or absorption of radioactive materials.

Paragraph (c)(3). This paragraph requires that the release of radioactive material to the environment outside the restricted area in concentrations that, if averaged over a period of 24 hours, exceed 5000 times the values specified in Table 2 of Appendix B to 10 CFR part 20, be considered an intermediate-consequence event. In contrast to the other consequences criteria that directly protect workers and members of the public, the intent of this criterion is to minimize the environmental impacts. The value established for this consequence criterion is identical to the NRC Abnormal Occurrence (AO) criterion that addresses the discharge or dispersal of radioactive material from its intended place of confinement (Section 208 of the Energy

Reorganization Act of 1974, as amended, requires that AOs be reported to Congress annually). In particular, the AO reporting Criterion 1.B requires the reporting of an event that involves ‘‘…the release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceed 5000 times the values specified in Table 2 of Appendix B to 10 CFR part 20, unless the licensee has demonstrated compliance with 10 CFR 20.1301 using 10 CFR 20.1302(b)(1) or 10 CFR 20.1302(b)(2)(ii)’’ (71 FR 60199). The concentrations listed in Table 2 of Appendix B to 10 CFR part 20 apply to radioactive materials in air and water effluents to unrestricted areas. The NRC established these concentrations based on an implicit effective dose equivalent limit of 0.5 mSv/yr (50 mrem/yr) for each medium, assuming an individual was continuously exposed to the listed concentrations present in an unrestricted area for a year. If an individual were continuously exposed for 1 day to concentrations of radioactive material 5000 times greater than the values listed in Appendix B to 10 CFR part 20, the projected dose would be about 6.8 mSv (680 mrem), or 5000 x 0.5 mSv/yr x 1 day x 1 yr/365 days. In addition, a release of radioactive material, from a facility, resulting in these concentrations, would be expected to cause some contamination of property in the area affected by the release, with a resultant potential for further adverse health effects and loss of use. This contamination would pose a longer-term hazard to members of the public until it was properly remediated. Depending on the extent of contamination caused by such a release, the contamination could require considerable licensee resources to remediate. For these reasons, the NRC considered the existing AO reporting criterion for discharge or dispersal of radioactive material as an appropriate consequence criterion in this rulemaking.

Paragraph (c)(4). This paragraph requires that an acute exposure to hazardous chemicals produced from licensed material at concentrations that either 1) could cause irreversible health effects to a worker, or 2) could cause notable discomfort to an individual located outside of the controlled area, be considered an intermediate-consequence event. As

stated in the § 40.81(b)(4) discussion, effects on humans from acute exposures to chemicals are being developed by a number of organizations. Two existing standards, AEGL–2 and ERPG – 2, can be used to define the concentration level for irreversible health effects, and two existing standards, AEGL–1 and ERPG–1, can be used to define the concentration level for mild transient health effects which can produce notable discomfort. The qualitative language in § 40.81(c)(4) allows the applicant/licensee to adopt and propose an appropriate standard, which may be an AEGL or ERPG standard. Where no such standard exists, the applicant/licensee may develop or adopt a criterion that is comparable in severity to those that have been established for other chemicals.

Paragraph (d). This paragraph requires that each engineered or administrative control or control system that is needed to meet the performance requirements be designated as an item relied on for safety. This means that any control or control system that is necessary to maintain the acceptable combination of consequence and likelihood for an accident is designated an item relied on for safety. The importance of this section is that, once a control is designated as an item relied on for safety, it falls into the envelope of the safety program required by § 40.82. For example, records will be kept regarding the item, and management measures such as the configuration control program are applied to the item and to changes that affect the item, to ensure that the item will be available and reliable to perform its function when needed. The failure of an item relied on for safety does not necessarily mean that an accident will occur which will cause one of the consequences listed in the performance requirements to be exceeded.

Some control systems may have parallel (redundant or diverse) control systems that would continue to prevent the accident. The need for such defense-in-depth and single-failure resistance would ideally be based on the severity and likelihood of the potential accident. In other cases, the failure of an item may mean that the particular accident sequence is no longer

‘‘highly unlikely,’’ or ‘‘unlikely.’’ In these cases, the performance requirement is not met, and the expectation would be that a management measure would exist (possibly in the form of an operating procedure) that ensured that the facility would not operate in a condition that exceeds the performance requirement. For example, a facility that relies on emergency power could not operate for an extended time in the absence of an emergency power source even if grid power is available. In this manner, the IROFS and the management measures complement each other to ensure adequate protection from accidents at any given time.

Paragraph (e). This provision addresses the term ‘‘controlled area’’ as defined in 10 CFR part 20 and as used in the performance requirements discussed in this response. This paragraph requires licensees to identify a controlled area consistent with the use of that term in 10 CFR part 20, and provides clarification regarding the activities that may occur inside the controlled area. The function of this term is to delimit an area over which the licensee exercises control of activities. Control includes the power to exclude individuals, if necessary.

The size of the controlled area is not specified in the regulation because it will be dependent upon the particular activities that are conducted at the site and their relationship to the licensed activities. Individuals who do not receive an “occupational dose” (as defined in 10 CFR part 20) in the controlled area will be subject to the dose limits for members of the public in 10 CFR 20.1301. However, the Commission recognizes that certain licensees may have ongoing activities at their site (i.e., within the controlled area) that are not related to the licensed activities. For example, a non-nuclear facility may be adjacent to the nuclear facility but both are within the controlled area (which may be defined similar to the site boundary). This raises a question regarding the appropriate accident standard for these individuals.

Protection of members of the public within the controlled area boundary (e.g., individuals working at a co-located non-nuclear facility) must consider that the fast-acting nature of many potential accidents at a UF6 facility covered by these new requirements is such that there will

not be sufficient time to evacuate such individuals from the controlled area. Therefore, for purposes of the ISA accident evaluation, the final rule explicitly contains two options to adequately protect these individuals (as well as an implicit third option). For the first option in § 40.81(e)(1), the licensee must demonstrate, in the ISA, that the risk to members of the public within the controlled area boundary does not exceed the performance requirements. For the second option in § 40.81(e)(2), the licensee must ensure that members of the public within the controlled area boundary are aware of the risks posed by potential accidents at the nuclear facility, and have received appropriate training and access to information. The NRC views the § 40.81(e) requirement as being consistent with the 10 CFR part 50 definition of ''Exclusion area,'' which states in relevant part that: ''Activities unrelated to operation of the reactor may be permitted in an exclusion area under appropriate limitations, provided that no significant hazards to the public health and safety will result.''

The implied third option is to define (or redefine) a controlled area, such that within it, only activities associated with the licensed nuclear facility are permitted. The NRC's intent is that the ISA need not evaluate compliance with the accident standards for individuals who make infrequent visits to the controlled area and restricted area (e.g., visitors). Use of the ISA to determine the risks to these individuals would need to consider second-order effects such as the probability of the individual being present at the time that the unlikely (or highly unlikely) accident occurred. This level of detail is unnecessary to accomplish the purpose of this rule (viz., to document and maintain the safety basis of the facility design and operations). Application of the 10 CFR part 20 regulations provides adequate protection for these individuals. In addition, the provisions (i.e., performance requirements) to protect workers and non-workers during accidents should, implicitly, provide a degree of protection to the infrequently present individuals.

Section 40.82 Safety program and integrated safety analysis

This new section specifies the safety program that licensees are required to implement at covered UF6 facilities, including the performance of an ISA, and the establishment of management measures. The performance of an ISA and the establishment of measures to ensure the availability and reliability of IROFS when needed are the means by which licensees will demonstrate an adequate level of protection at their UF6 facilities. The ISA is a systematic analysis to identify plant and external hazards and their potential for initiating accident sequences; the potential accident sequences and their consequences; and the site, structures, systems, equipment, components, and activities of personnel relied on for safety. As used here, an ‘‘integrated’’ analysis means joint consideration of, and protection from, all relevant hazards, including radiological, fire, and chemical. The structure of the safety program recognizes the critical role that the ISA plays in identifying potential accidents and the IROFS. However, it also recognizes that the performance of the ISA, by itself, will not ensure adequate protection. Instead, an effective management system is needed to ensure that the IROFS are available and reliable to perform their function when needed. Detailed requirements for each part of the safety program are included in this section.

Paragraph (a). This paragraph requires each licensee to establish and maintain a safety program that demonstrates compliance with the performance requirements of § 40.81. Although the ISA will be the primary tool in identifying the potential accidents requiring consequence mitigation and accident prevention, process safety information will be used to develop the ISA, and management measures will be used to ensure the availability and reliability of IROFS identified through the ISA. The management measures may be graded according to the risk importance associated with an IROFS.

The licensee is also required to establish and maintain records demonstrating that it has met, and continues to meet, the requirements of § 40.82. These records serve two major

purposes. First, they can supplement information that has been submitted as part of the license application. Second, records are often needed to demonstrate licensee compliance with applicable regulations and license commitments. It is important, therefore, that an appropriate system of recordkeeping is implemented to allow easy retrieval of required information.

Paragraph (b). This provision requires the licensee to maintain process-safety information pertaining to the hazards of the materials used or produced from licensed materials, the technology of the process, and the equipment in the process. The NRC's confidence in the margin of safety at its licensed facilities depends, in part, on the ability of licensees to maintain a set of current, accurate, and complete records available for NRC inspection. The process-safety information should be used in support of development of an ISA.

Paragraph (c). This provision contains the requirements for conducting an ISA. There are four major steps in performing an ISA:

1) Identify all hazards at the facility, including both radiological and non-radiological hazards. Hazardous materials, their location, and quantities, should be identified, as well as all hazardous conditions, such as high temperature and high pressure. In addition, any interactions that could result in the generation of hazardous materials or conditions should be identified.

2) Analyze the hazards to identify how they might result in potential accidents. These accidents could be caused by process deviations or other events internal to the plant, or by credible external events, including natural phenomena such as floods, earthquakes, etc. To accomplish the task of identifying potential accidents, the licensee needs to ensure that detailed and accurate information about plant processes is maintained and made available to the personnel performing the ISA.

3) Determine the consequences of each accident that has been identified. For an accident with consequences at a ‘‘high’’ or ‘‘intermediate level,’’ as defined in § 40.81, the

likelihood of such an accident must be shown to be commensurate with the consequences, as required in § 40.81.

4) Identify the IROFS (i.e., those items that are relied on to prevent accidents or to mitigate their consequences, identified in the ISA). These IROFS are needed to reduce the consequences or likelihood of the accidents to acceptable levels. The identification of IROFS is required only for accidents with consequences at a high or intermediate level, as defined in § 40.81.

It is expected that the licensee or applicant will perform the ISA using a ‘‘team’’ of individuals with expertise in engineering and process operations related to the system being evaluated. The team should include persons with experience in radiation safety, fire safety, and chemical process safety, as warranted by the materials and potential hazards associated with the process being evaluated. At least one member of the ISA team should be an individual who has experience and knowledge that is specific to the process being evaluated. Finally, at least one individual in the team must be knowledgeable in the specific ISA methodology being used.

Current 10 CFR part 40 licensees covered by the rule are required to develop plans and submit them to the NRC by **[DATE THAT IS 6 MONTHES AND 30 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Each plan shall identify the processes that are subject to an ISA, the ISA approach that will be implemented for each process and the schedule for completing the analysis of each process. Licensees are expected to complete their ISA within the required time, correct any unacceptable performance deficiencies identified, and submit the results to the NRC for approval in the form of an ISA summary that contains the information required by § 40.84(b). Pending the correction of any unacceptable performance deficiencies, licensees are expected to implement appropriate compensatory measures to ensure adequate protection until the performance deficiency can be more appropriately corrected.

Those 10 CFR part 70 licensees operating fuel fabrication facilities, who previously obtained NRC approval of their ISA summaries, and who now will also be subject to the 10 CFR part 40 ISA requirements, should describe in their ISA plans the extent to which any existing IROFS, safety procedures and license conditions will need to be modified, and the extent to which new IROFS, safety procedures and license conditions will need to be added, to meet the 10 CFR part 40 ISA requirements. For example, such licensees will likely need to identify new IROFS to address the hazards posed by potential accidents involving UF6 that is being stored onsite before it is introduced into the fuel fabrication process. The § 40.82(c)(3) requirements are not intended to require licensees to develop, and the NRC to approve, redundant IROFS, safety procedures and license conditions that have already been approved under 10 CFR part 70. Therefore, any existing IROFS, safety procedures and license conditions that can remain in place without modification (i.e., those that already meet the 10 CFR part 70 ISA requirements and will continue to meet the 10 CFR part 40 ISA requirements) need not be submitted for approval, but should be identified in the ISA plan. For example, a 10 CFR part 70 licensee who previously obtained NRC approval of its ISA summary should, in the ISA plan required by § 40.82(c)(3)(i), describe any changes to its existing ISA summary that are necessary to comply with 10 CFR part 40. More specifically, the reference to "licensed activities" in the § 40.82(c)(3) preamble refers to 10 CFR part 40 licensed activities, and the § 40.82(c)(3)(ii) requirement to complete an ISA thus pertains to 10 CFR part 40 licensed activities. Similarly, the § 40.82(c)(3)(iii) requirement to submit for approval an ISA summary pertains to part 40 licensed activities, and the § 40.82(c)(3)(iv) requirement to correct any unacceptable performance deficiencies pertains to 10 CFR part 40 licensed activities. Applicants for licenses to operate new facilities or new processes at existing facilities are expected to design their facilities or processes to protect against the occurrence of the adverse consequences identified in § 40.81, using the baseline design criteria specified in § 40.83(a).

Before operation, applicants are expected to update their ISAs, based on as-built conditions and submit the results to the NRC as ISA summaries, along with the applications, following the requirements in § 40.84(b).

Paragraph (d). This provision contains requirements to establish management measures. Although the ISA plays a critical role in identifying potential accidents and the IROFS, the performance of an ISA will not, by itself, ensure adequate protection. Therefore, in addition to performing an ISA, management measures need to be established to ensure that an effective management system is in place such that IROFS will be available and reliable to perform their function when needed.

As indicated, management measures are functions performed by the licensee, in general on a continuing basis that are applied to IROFS. Management measures address topics such as: a) configuration management, b) maintenance, c) training and qualifications, d) procedures, e) audits and assessments, f) incident investigations, g) records management, and h) other quality assurance elements. For example, changes in a UF6 facility's configuration need to be carefully controlled to ensure consistency among the facility design and operational requirements, the physical configuration, and the facility documentation. Maintenance measures must be in place to ensure the availability and reliability of all IROFS. Training measures must be established to ensure that all personnel relied on for safety are appropriately trained to perform their safety functions. Periodic audits and assessments of licensee safety programs must be performed to ensure that facility operations are conducted in a manner that will adequately protect the worker, the public health and safety, and the environment. When abnormal events occur, investigations of those events must be carried out to determine the root cause and identify corrective actions to prevent their recurrence; this will better ensure that such events do not lead to more serious consequences. To demonstrate compliance with NRC regulations, records that document safety program activities must be maintained for the life of

the facility.

The phrase ‘‘when needed’’ is used in § 40.82(d) to acknowledge that a particular safety control need not be continuously functioning. For example, such a control may not be operational during maintenance or calibration testing or may not be required when the process is not operational. But this “when needed” concept does not relieve a licensee from compliance with the performance requirements. For example, if a particular component is out for maintenance, the licensee must consider credible event sequences which may occur under the new conditions, when developing the ISA and identifying IROFS.

Section 40.83 Requirements for new facilities or new processes at existing facilities

This new section specifies the baseline design criteria (BDC) that licensees of new UF6 facilities will be required to meet and that licensees of existing UF6 facilities are required to meet when adding new processes to existing facilities. The BDC are based on the existing criteria in 10 CFR 70.64.

Paragraph (a). This provision specifies nine initial safety design considerations: 1) quality standards and records; 2) natural phenomena hazards; 3) fire protection; 4) environmental and dynamic effects; 5) chemical protection; 6) emergency capability; 7) utility services; 8) inspection, testing, and maintenance; and 9) instrumentation and controls.

1) The quality standards and records BDC must be developed and implemented in accordance with management measures. Management measures that will be applied include the development and implementation of the design to provide adequate assurance that the IROFS are adequate and available when called upon. References to specific, definitive, and adequate commitments in other parts of the submittal, such as management measures, industry programs, or consensus standards may be sufficient. Information will need to be provided as to how appropriate records will be maintained.

2) The natural phenomena hazards BDC must provide for adequate protection against natural phenomena with consideration of the most severe documented historical events for the site. The criteria must specifically address how natural phenomena such as earthquakes and volcanoes, stream flooding, coastal flooding, winds (including tornadoes), ice and snow loadings, and temperature extremes were considered in designing the new facility, or adding to an existing facility.

3) The fire protection BDC must provide for adequate protection against fires and explosions. As appropriate, the criteria must address how the design considered a) the use of fire hazards analyses in the ISA and pre-fire planning; b) the facility design in regard to building construction, fire areas, life safety, and ventilation; c) process fire safety including explosion protection; d) fire protection systems including detection and suppression; and e) manual fire suppression capability.

4) The environmental and dynamic effects BDC must address adequate protection from environmental conditions and dynamic effects associated with normal operations, maintenance, testing, and postulated accidents that could lead to the loss of safety functions. The design must ensure that IROFS will perform their safety functions under the environmental and dynamic service conditions in which they will be required to function and for the length of time their function will be required. The criteria must also include how the design ensures that non-IROFS will not prevent satisfactory accomplishment of safety functions of IROFS.

5) The chemical protection BDC must address adequate protection against chemical risks produced from licensed material, facility conditions which affect safety of licensed material, and hazardous chemicals produced from licensed material.

6) The emergency capability BDC must address how the design of the new facility or process provides for the emergency capability to maintain control of licensed material and hazardous chemicals produced from licensed material during an event. It must also address the

evacuation of on-site personnel including the design of the facility to allow personnel to evacuate (e.g., time, dose, ease of egress) as well as onsite emergency facilities and services that facilitate the use of available offsite services.

7) The utility services BDC must address how the design of the new facility or process provides for the continued operation of essential utility services. Essential utilities are the support systems that provide for the safety function of the IROFS; e.g., power, air supply, ventilation. The BDC must address methods to ensure continued operation of essential utilities during emergency events.

8) The inspection, testing, and maintenance BDC must address how the design of the new facility or process provides for adequate inspection, testing, and maintenance of IROFS to ensure their availability and reliability to perform their function when needed. The criteria must address the possible methods to provide adequate inspection, testing, and maintenance to ensure their availability and reliability. This must include the capability for periodic testing and inspection to assess the operability and performance of IROFS, the capability to test the functions of IROFS such as active engineered controls as a completed functioning system and under appropriate design conditions, and the capability to perform needed maintenance actions or to identify system or component maintenance needs to assure availability of IROFS features that are relied upon in the ISA to meet § 40.81 performance requirements.

9) The instrumentation and controls BDC must address the inclusion of these systems in the implementation of IROFS. The criteria must include methods to monitor the behavior of IROFS such as failure detection diagnostics (e.g., information read-out in the control room or locally for variables) and when the bypass indication for IROFS is intentionally rendered inoperable.

The BDC are generally an acceptable set of initial design safety considerations, which may not be sufficient to ensure adequate safety for all new processes and facilities. The BDC

do not provide relief from compliance with the safety performance requirements of § 40.81. The ISA process is intended to identify additional safety features that may be needed. On the other hand, the NRC recognizes that there may be processes or facilities for which some of the BDC may not be necessary or appropriate, based on the results of the ISA. For these processes and facilities, any design features that are inconsistent with the BDC must be identified and justified.

Paragraph (b). This new provision requires licensees to base their facility and system design and facility layout, to the extent practicable, on 1) a preference for the selection of engineered controls over administrative controls and 2) features that enhance safety by reducing challenges to IROFS. The facility and system design must incorporate, to the extent practicable: 1) preference for the selection of engineered controls over administrative controls to increase overall system reliability, and 2) features that enhance safety by reducing challenges to IROFS. Using the BDC and defense-in-depth practices when building new facilities or adding to existing facilities should result in designs that provide successive levels of protection such that health and safety will not be wholly dependent on 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 for failures and external challenges. The risk insights obtained through performance of the ISA can then be used to supplement the final design by focusing attention on the prevention and mitigation of potential high-risk accidents.

Section 40.84 Additional content of applications

In addition to the information that currently must be submitted to the NRC under § 40.31 for a license application, this new section specifies additional information that must be submitted to demonstrate compliance with the proposed performance requirements. This additional information includes a description of the applicant's safety program and management measures

established under § 40.82, and an ISA summary.

Paragraph (a). This provision requires an applicant to submit, as part of the license application, a description of the applicant's safety program established under § 40.82. This is in addition to what is currently required in § 40.31, Application for specific license.

Paragraph (b). This provision requires that an ISA summary be submitted with the license or renewal application (and amendment application, as necessary), and specifies what an ISA summary must contain. The ISA summary will not be incorporated into the license.

The ISA summary must contain all the items specified below:

1) Site: The site description in the ISA Summary will focus on those factors that could affect safety, such as meteorology (e.g., high winds and flood potential) and seismology.

2) Facility: The facility description in the ISA Summary will focus on areas that could affect safety, and will identify the controlled area boundaries.

3) Processes, Hazards and Accident Sequences: The process description in the ISA Summary must address each process that was analyzed as part of the ISA. This description must include a list of the hazards for each process and the accident sequences that could result from such hazards.

4) Demonstration of Compliance with § 40.81: The ISA Summary must demonstrate compliance with the performance requirements, and describe the management measures.

5) Team Qualifications and ISA Methods: The ISA Summary must discuss the applicant’s ISA team qualifications and ISA methods.

6) List of IROFS: The ISA Summary must describe the IROFS for all intermediate- and high-consequence accidents in sufficient detail to permit an understanding of their safety function.

7) Chemical Consequence Standards: The ISA Summary must describe the proposed quantitative standards for assessing the chemical consequence levels specified in § 40.81.

8) List of Sole IROFS: The ISA Summary must identify those IROFS that are the sole item preventing or mitigating an accident for which the consequences could exceed the performance requirements of § 40.81.

9) Definitions of "Unlikely", "Highly Unlikely" and "Credible": The ISA Summary must define the terms "unlikely," "highly unlikely," and "credible," as used in the ISA.

The IROFS must be clearly and unambiguously listed in the ISA summary. This list of items is then managed and controlled by the applicant/licensee through the management measures required by § 40.82(d) to ensure that the IROFS continue to perform the safety function required. The NRC's review includes evaluating the ISA methodology, and the ISA summary, and may be supplemented by reviewing the ISA and other information, as needed, at the licensee's facility. This enables the NRC to better understand the potential hazards at the facility, how the applicant plans to address these hazards, and thereby have confidence in the safety basis supporting the license.

As previously indicated, the ISA summary must be submitted on the docket in conjunction with the license application but would not be considered part of the license. The ISA, on which the ISA summary is based, would be maintained current at the licensee's facility and available for NRC review, but it would not be submitted and docketed. Although the ISA summary will be on the docket, it is not part of the license and can be changed without a license amendment, unless it reflects a change that cannot be made without prior approval, as specified in § 40.86(c) (discussed later in this document). However, the information used to perform the ISA, and the ISA summary, both form integral parts of the safety basis for issuance of the license and therefore must be maintained to adequately represent the current status of the facility.

Section 40.85 Additional requirements for approval of license application

This new section focuses on the factors the NRC will use to determine that the requirements in §§ 40.80 through 40.85 have been met. These regulations are in addition to the existing licensing regulations that are under the subpart D heading (§§ 40.31 through 40.38).

Paragraph (a). This provision requires the NRC to approve a license application from an applicant subject to the requirements of subpart H if the NRC determines that the applicant has complied with the requirements of subpart D of 10 CFR part 40 and §§ 40.80 through 40.85.

Paragraph (b). This provision details the criteria that the NRC will use for approving ISA-related submissions by existing licensees (i.e., such submissions will be approved if the integrated safety analysis approach and the schedule meet the specified requirements).

Paragraph (c). This provision details the criteria the NRC will use for approving ISA summaries. These include determining if the requirements of § 40.84(b) are satisfied and based on the information in the ISA summary and if the performance requirements in § 40.81(b), (c) and (d) are satisfied.

Section 40.86 Facility changes and change process

This new section specifies the process for making changes to a UF6 facility's site, structures, systems, equipment, components, and activities of personnel after a license application has been approved. Past incidents at NRC-licensed facilities have been the result of improperly analyzed changes that were not authorized by licensee management or changes that were not adequately understood by facility personnel. Effective control of changes to a facility's site, structures, systems, equipment, components, and activities of personnel is a key element in better ensuring safe operation. Under this process, the licensee can make certain changes without NRC pre-approval. All changes made pursuant to this section must be reflected promptly in on-site documents. This approach is the one now applicable to fuel cycle facilities licensed under 10 CFR part 70.

Paragraph (a). This provision requires the licensee to establish a configuration management system documented in written procedures to track operational changes made by the licensee. The system must assure that prior to implementing any change, its technical basis, impact on safety and other specified factors are evaluated.

Paragraph (b). This provision requires the licensee, before implementing any change, to determine whether the change requires NRC pre-approval through the license amendment process.

Paragraph (c). This provision specifies five types of changes that could not be implemented without prior NRC approval. Generally, such changes could have a significant impact on health and safety.

Paragraph (d). This paragraph specifies the facility changes and ISA summary changes that must be submitted to the NRC within 30 days after the end of the calendar year. For changes that are found not to require NRC pre-approval, the licensee is required to submit to the NRC annually, within 30 days after the end of the calendar year, a brief summary of all such changes. For changes that affect the ISA summary, the licensee is required to submit to the NRC annually, within 30 days after the end of the calendar year, revised ISA summary pages. These yearly updates allow the NRC staff to maintain relatively current facility and safety information on the docket and to ensure that the ISA summary reflects the current configuration of the facility, thus facilitating the license renewal process (as discussed further in this document).

Paragraph (e). The NRC expects licensees to exercise sound judgment, to ensure on-site documents are updated in a timely manner (i.e., without undue delay and consistent with the licensee's documentation procedures.

Paragraph (f). Records documenting facility changes must be maintained until termination of the license. Such records must include a written evaluation providing the bases

for the determination that the changes do not require prior NRC pre-approval.

Section 40.87 Renewal of licenses

This new section specifies that license renewal applications may incorporate by reference information contained in previous applications, statements, or reports filed with the NRC, provided that these references are clear and specific. In the past, the license renewal process was burdensome to the NRC and the licensee, because all changes made to the facility since the last license renewal would be reviewed at one time. However, maintaining a ‘‘living license,’’ as required by § 40.86, is expected to make the review of license renewal applications less burdensome since previously approved information could be incorporated with minimal re-evaluation.

Section 40.88 Additional reporting requirements

This new section is based in part on existing appendix A to 10 CFR part 70 and establishes event reporting requirements for licensees required to conduct ISAs. These requirements become applicable after the ISA summary is submitted. The required reports must be made by a knowledgeable licensee representative in a manner ensuring timely reporting of events, and licensees must provide reasonable assurance that a reliable communication link with the NRC Operations Center is maintained.

The reporting of events supports the NRC’s need to be aware of conditions that could result in an imminent danger to the worker or to public health and safety or to the environment. In particular, the NRC needs to be aware of licensee efforts to address potential emergencies. Further, once safe conditions have been restored after an event, the NRC has an interest in disseminating information on the event to the nuclear industry and other interested parties, to reduce the likelihood that the event will occur in the future. Also, in the event of an accident, the

NRC must be able to respond accurately to requests for information by the public and the media. Event reporting helps the NRC evaluate the performance of individual licensees and the industry as a whole in order to fulfill its statutory mandate to protect the health and safety of the worker and the public.

Paragraph (a). This provision requires licensees to report specified events to the NRC Operations Center within 1 hour of their discovery. These events would be: 1) An acute intake by an individual of 30 mg or greater of uranium in a soluble form; 2) An acute chemical exposure to an individual from NRC licensed material or hazardous chemicals produced from NRC licensed material that are high-consequence events under the performance requirements; and 3) An event or condition in which no IROFS remain available and reliable to perform their function. One-hour reports must be supplemented with additional information as it becomes available, and must be followed up by a written report to the NRC within 60 days.

Paragraph (b). This provision requires licensees to report specified events to the NRC Operations Center within 24 hours of their discovery. These events are ones which result in: 1) the facility being in a state that was not analyzed, was improperly analyzed, or is different from that analyzed in the ISA, and which causes a failure to meet the performance requirements; 2) the loss or degradation of one or more IROFS that causes a failure to meet the performance requirements; and 3) an acute chemical exposure to an individual from NRC licensed material or hazardous chemicals produced from NRC licensed materials that is an intermediate consequence event under the performance requirements. Additional events that must be reported within 24 hours of their discovery are fires that have affected or may have affected one or more IROFS. Twenty-four hour reports must be supplemented with additional information as it becomes available, and must be followed up by a written report to the NRC within 60 days.

Paragraph (c). This provision requires that in situations involving a planned news

release (or notification to another government agency) by the licensee, which relates to the health and safety of the public or onsite personnel the licensee report the situation to the NRC Operations Center at the same time that the news release (or notification) is given.

Paragraph (d). This provision specifies information licensees must include in their reports called in to the NRC Operations Center, such as: the caller's name; the date, time, and exact location of the event being reported; a description of the event; actions taken in response to the event; and whether the event is ongoing or has been terminated. The provision further requires that follow-up information be provided to the NRC Operations Center until all information required to be reported is complete.

Paragraph (e). This provision specifies the information that the written reports submitted under § 40.88(a) and (b) must contain.

Section 40.89 Backfitting

This new section establishes backfit requirements similar to those in § 70.76. These requirements apply to the subset of 10 CFR part 40 licensees authorized to possess significant quantities (2000 kg or more) of UF6. The backfit provision is added in accordance with the Commission SRM dated November 30, 2010.

Paragraph (a). This provision makes the backfit requirements applicable to licensees authorized to possess 2000 kg (4400 lb) or more of UF6, and its terms become effective for a particular licensee once the licensee’s ISA summary has been approved by the NRC. The final backfit requirements are not applicable to 10 CFR part 40 licensees that are not authorized to possess 2000 kg or more of UF6.

Paragraph (b). This provision defines the term “backfitting” as it applies to this subpart. Backfitting means the modification of, or addition to: 1) systems, structures, or components of a facility of a licensee subject to ISA requirements; or 2) the procedures or organization required

to operate such a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position. This definition is substantially similar to the one in existing § 70.76(a)(1).

Paragraph (c). This provision contains identical backfit analysis requirements as in the existing § 70.76(a)(2) through (a)(7). Exceptions to requiring a backfit analysis are also listed in this provision and include: 1) modifications necessary to bring a facility into compliance with subpart H, a license, the rules or orders of the Commission, or into conformance with written commitments by the licensee; 2) regulatory action necessary to ensure adequate protection to the health and safety of the public and is in accord with the common defense and security; or 3) the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security should be regarded as adequate.

Whenever the NRC decides to rely upon one or more of these backfit analysis exceptions, the NRC will prepare a documented evaluation that includes a clear explanation of why the exception applies, any relevant facts of the action at issue, and the applicable regulatory history. To help stakeholders understand the applicability of the "compliance exception," the NRC reiterates here its interpretation of the "compliance exception" that the NRC provided in the statement of considerations for the 1985 Backfit Rule:

> 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.
> (50 FR 38097, September 20, 1985).

Other provisions in § 40.89(c): 1) require the Commission to require backfitting of a facility if it is necessary to ensure adequate protection to the health and safety of the public; 2) require the Commission to include a statement of the objectives and reasons for modifications when invoking the exception under § 40.89(a)(3); and 3) allow, in most cases, for

the licensee to choose its own way to achieve compliance with a license or the rules or orders of the Commission, or with written license commitments provided that the objective of compliance or adequate protection is met.

Paragraph (d). This provision requires the Commission, in the backfit determinations required by paragraph (a)(2) of this section, to consider how the backfit would be scheduled in light of other ongoing regulatory activities at the facility, and follows the existing requirements in § 70.76(b). Additionally, this provision requires the Commission to consider specific relevant information specific to the backfit. These factors include: 1) the potential change in the risk to the public from the accidental release of radioactive material and hazardous chemicals produced from such material, and 2) the potential impact on facility employees from exposure to radioactive material and to hazardous chemicals produced from such material.

Paragraph (e). This provision is the same as § 70.76(c), and prohibits withholding a license during the pendency of backfit.

Paragraph (f). This provision is the same as existing § 70.76(d) and designates the Executive Director for Operations as the party responsible for the implementation of the requirements of § 40.89. Additionally, it requires that all backfit analyses be approved by the Executive Director for Operations or his or her designee.

Section 40.102 Criminal penalties

Existing § 40.82 is re-designated as § 40.102. Additionally, paragraph (b) of this section is amended to add the applicable sections in the new subpart H and to reflect the administrative renumbering of 10 CFR part 40.

Section 150.15 Persons not exempt

A new paragraph (a)(10) is added to support the NRC's determination that all source

material held by licensees that possess or plan to possess 2000 kg or more of UF6 would be under the NRC's jurisdiction. Since the events of September 11, 2001, major nuclear facilities with hazardous radioactive or chemical materials have received increased security oversight to address the potential heightened threat of sabotage and terrorist attacks. The complex procedural operations at these facilities involve hazardous chemicals as well as nuclear material, making it difficult to separate the additional common defense and security requirements from the program requirements designed to protect public health and safety. The NRC is the only regulatory agency, under the AEA, that is authorized to implement such a unified program.

V. Section by Section Analysis

The 10 CFR part 40 is administratively restructured to conform with the format of other parts in the chapter. This final rule replaces the undesignated subject headings with specific lettered and titled subparts. In addition, a new subpart H is added to 10 CFR part 40, entitled "Additional Requirements for Certain Licensees Authorized to Possess 2000 Kilograms (4400 lb) or More of Uranium Hexafluoride."

Section 40.3a Denial of licensing by Agreement States

This new section specifies that Agreement States lack regulatory authority over persons who are authorized to possess or plan to possess 2000 kg or more of UF6, and does not apply to facilities in Agreement States that are undergoing decommissioning as of the publication date of this rule.

Section 40.4 Definitions

The definitions of 11 terms used in the new subpart H are added to § 40.4 and include:

‘‘Acute,’’ ‘‘Available and reliable to perform their function when needed,” ‘‘Configuration management,’’ ‘‘Defense-in-depth practices,’’ ‘‘Hazardous chemicals produced from licensed materials,’’ ‘‘Integrated safety analysis,’’ ‘‘Integrated safety analysis summary,’’ ‘‘Items relied on for safety,’’ ‘‘Management measures,’’ ‘‘Unacceptable performance deficiencies,’’ and ‘‘Worker.”

Section 40.8 Information collection requirements: OMB approval

Paragraph (b) is amended to update the list of applicable sections in the new subpart H and to reflect the administrative renumbering of 10 CFR part 40.

Section 40.26 General license for possession and storage of byproduct material as defined in this part

Paragraph (c)(1) is amended to updated the list of applicable sections in the new subpart H and to reflect the administrative renumbering of 10 CFR part 40.

Section 40.80 Applicability

This new section lists the types of NRC licensees or applicants who are subject to the new subpart H. This new subpart is intended to ensure that significant accidents, that are possible at 10 CFR part 40 fuel cycle facilities authorized to possess 2000 kg or more of UF6 have been analyzed in advance and that appropriate controls or measures are established to ensure adequate protection of workers, the public, and the environment.

Section 40.81 Performance requirements

This new section explicitly addresses potential radiological and chemical exposures to workers or members of the public and environmental releases as a result of accidents.

Paragraph (a). This paragraph requires each applicant or licensee to evaluate, in the

ISA, its compliance with the performance requirements in paragraphs (b) and (c).

Paragraph (b). This provision addresses performance requirements for "high-consequence events."

Paragraph (b)(1). This paragraph requires that an acute exposure of a worker to a radiation dose of 1 Sv (100 rem) or greater total effective dose equivalent (TEDE) be considered a high-consequence event.

Paragraph (b)(2). This paragraph requires that the exposure of an individual located outside of the controlled area to a radiation dose of 0.25 Sv (25 rem) or greater TEDE be considered a high-consequence event.

Paragraph (b)(3). This paragraph requires that the intake of 30 mg of soluble uranium by an individual located outside of the controlled area be considered a high-consequence event.

Paragraph (b)(4). This paragraph requires that an acute exposure to hazardous chemicals produced from licensed material at concentrations that either 1) could cause death or life-threatening injuries to a worker; or 2) could cause irreversible health effects to an individual located outside of the controlled area, be considered a high-consequence event.

Paragraph (c). This provision specifies performance requirements for "intermediate-consequence events," which would be of a lower magnitude than high consequence events because they do not involve risk of death or life-threatening injury.

Paragraph (c)(1). This paragraph requires that a worker radiation dose between 0.25 Sv (25 rem) and 1 Sv (100 rem) TEDE be considered an intermediate-consequence event.

Paragraph (c)(2). This paragraph requires that a dose to any individual located outside of the controlled area between 0.05 Sv (5 rem) and 0.25 Sv (25 rem) be considered an intermediate-consequence event.

Paragraph (c)(3). This paragraph requires that the release of radioactive material to the environment outside the restricted area in concentrations that, if averaged over a period of 24

hours, exceed 5000 times the values specified in Table 2 of Appendix B to 10 CFR part 20, be considered an intermediate-consequence event.

Paragraph (c)(4). This paragraph requires that an acute exposure to hazardous chemicals produced from licensed material at concentrations that either 1) could cause irreversible health effects to a worker, or 2) could cause notable discomfort to an individual located outside of the controlled area, be considered an intermediate-consequence event.

Paragraph (d). This paragraph requires that each engineered or administrative control or control system that is needed to meet the performance requirements be designated as an item relied on for safety.

Paragraph (e). This paragraph requires licensees to identify a controlled area consistent with the use of that term in 10 CFR part 20, and provides clarification regarding the activities that may occur inside the controlled area.

Section 40.82 Safety program and integrated safety analysis

This new section specifies the safety program that licensees are required to implement at covered UF6 facilities, including the performance of an ISA, and the establishment of management measures.

Paragraph (a). This paragraph requires each licensee to establish and maintain a safety program that demonstrates compliance with the performance requirements of § 40.81, and establish and maintain records demonstrating that it has met, and continues to meet, the requirements of this section.

Paragraph (b). This provision requires the licensee to maintain process-safety information pertaining to the hazards of the materials used or produced from licensed materials, the technology of the process, and the equipment in the process.

Paragraph (c). This provision contains the requirements for conducting an ISA.

Paragraph (d). This provision contains requirements to establish management measures.

Section 40.83 Requirements for new facilities or new processes at existing facilities

This new section specifies the BDC that licensees of new UF6 facilities will be required to meet and that licensees of existing UF6 facilities are required to meet when adding new processes to existing facilities.

Paragraph (a). This provision specifies nine initial safety design considerations.

Paragraph (b). This new provision requires licensees to base their facility and system design and facility layout to the extent practicable, on 1) a preference for the selection of engineered controls over administrative controls and 2) features that enhance safety by reducing challenges to IROFS.

Section 40.84 Additional content of applications

In addition to the information that currently must be submitted to the NRC under § 40.31 for a license application, this new section specifies additional information that must be submitted to demonstrate compliance with the proposed performance requirements.

Paragraph (a). This provision requires an applicant to submit, as part of the license application, a description of the applicant's safety program established under § 40.82.

Paragraph (b). This provision requires that an ISA summary be submitted with the license or renewal application (and amendment application, as necessary), and specifies what an ISA summary must contain.

Section 40.85 Additional requirements for approval of license application

This new section focuses on the factors the NRC will use to determine that the

requirements in §§ 40.80 through 40.85 have been met.

Paragraph (a). This provision requires the NRC to approve a license application from an applicant subject to the requirements of subpart H if the NRC determines that the applicant has complied with the requirements of subpart D of 10 CFR part 40 and §§ 40.80 through 40.85.

Paragraph (b). This provision details the criteria that the NRC will use for approving ISA-related submissions by existing licensees.

Paragraph (c). This provision details the criteria the NRC will use for approving ISA summaries.

Section 40.86 Facility changes and change process

This new section specifies the process for making changes to a UF6 facility's site, structures, systems, equipment, components, and activities of personnel after a license application has been approved.

Paragraph (a). This provision requires the licensee to establish a configuration management system documented in written procedures to track operational changes made by the licensee.

Paragraph (b). This provision requires the licensee, before implementing any change, to determine whether the change requires NRC pre-approval through the license amendment process.

Paragraph (c). This provision specifies five types of changes that could not be implemented without prior NRC approval.

Paragraph (d). This paragraph specifies the timeframes for the submission of changes.

Paragraph (e). This paragraph requires licensees to promptly update on-site documentation to reflect any changes.

Paragraph (f). This paragraph requires the licensee to maintain records of any changes.

Section 40.87 Renewal of licenses

This new section specifies that license renewal applications may incorporate by reference information contained in previous applications, statements, or reports filed with the NRC, provided that these references are clear and specific.

Section 40.88 Additional reporting requirements

This new section is based in part on existing appendix A to 10 CFR part 70 and establishes event reporting requirements for licensees required to conduct ISAs. These requirements become applicable after the ISA summary had been submitted.

Paragraph (a). This provision requires licensees to report specified events to the NRC Operations Center within 1 hour of their discovery followed by a supplemental, written report within 60 days.

Paragraph (b). This provision requires licensees to report specified events to the NRC Operations Center within 24 hours of their discovery followed by a supplemental, written report within 60 days.

Paragraph (c). This provision requires that the licensee report the situation to the NRC Operations Center at the same time the news release (or notification) is given.

Paragraph (d). This provision specifies the information licensees must include in their reports called into the NRC Operations Center.

Paragraph (e). This provision specifies the information that the written reports submitted under § 40.88(a) and (b) must contain.

Section 40.89 Backfitting

This new section establishes backfit requirements similar to those in § 70.76. These

requirements apply to the subset of 10 CFR part 40 licensees authorized to possess significant quantities (2000 kg or more) of UF6.

Paragraph (a). This provision makes the backfit requirements applicable to licensees authorized to possess 2000 kg (4400 lb) or more of UF6.

Paragraph (b). This provision defines the term “backfitting.”

Paragraph (c). This provision contains backfit analysis requirements. Exceptions to requiring a backfit analysis are also listed in this provision.

Paragraph (d). This provision requires the Commission, in the backfit determinations required by paragraph (a)(2) of this section, to consider how the backfit would be scheduled in light of other ongoing regulatory activities at the facility. Additionally, this provision requires the Commission to consider relevant information specific to the backfit.

Paragraph (e). This provision prohibits withholding a license during the pendency of backfit.

Paragraph (f). This provision designates the Executive Director for Operations as the party responsible for the implementation of the requirements of § 40.89.

Section 40.102 Criminal penalties

Existing § 40.82 is re-designated as § 40.102. Additionally, paragraph (b) of this section is amended to add the applicable sections in the new subpart H and to reflect the administrative renumbering of 10 CFR part 40.

Section 150.15 Persons not exempt.

A new paragraph (a)(10) is added to support the NRC’s determination that all source material held by licensees that possess or plan to possess 2000 kg or more of UF6 would be exclusively under the NRC’s jurisdiction.

VI. Criminal Penalties

For the purpose of Section 223 of the AEA, the Commission is proposing to amend 10 CFR parts 40 and 150 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

VII. Agreement State Compatibility

There are no Agreement State compatibility issues because the NRC, in the final rule, is reserving licensing authority over all source material at facilities located in Agreement States that are authorized to possess 2000 kg or more of UF6. Licensees of such facilities will either 1) have to obtain an NRC part 40 license; or 2) be granted an amendment of their State license to reduce the authorized UF6 possession limit to below the 2000 kg threshold. Any such amendments to Agreement State licenses would be conducted as part of the State's licensing process. Licensees of facilities in Agreement States that are authorized to possess, but do not in fact possess, 2000 kg or more of UF6, will need to amend their State license possession limits to below the 2000 kg UF6 threshold. Regarding any facilities in Agreement States that possess 2000 kg or more of UF6, the NRC will act in coordination with the Agreement States to ensure that all necessary license amendment actions are taken on a timely basis. This final rule is not applicable to facilities located in Agreement States that are undergoing decommissioning.

VIII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113)

requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies, unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC adds performance requirements to fuel cycle facilities regulated by 10 CFR part 40 similar to the performance requirements for fuel cycle facilities regulated by 10 CFR part 70. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

IX. Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, not to prepare an environmental impact statement for this final rule. The Commission has concluded on the basis of an environmental assessment that this final rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment. This conclusion was published in the environmental assessment that was posted to the NRC rulemaking website, http://www.regulations.gov, for 115 days after publication of the proposed rule. No comments were received on the environmental assessment. The determination of this environmental assessment is that there will be no significant impact to the public from this action.

Licensees are required to protect against the occurrence of, or to mitigate the consequences of, accidents that could adversely affect workers, the public, or the environment. The ISA requirements, including the requirement to protect against events that could damage the environment, are expected to result in a significant improvement in understanding the risks at fuel cycle facilities, and in a licensee’s or applicant’s ability to ensure that those risks are adequately controlled. As a result, the safety and environmental impact of this rulemaking action is positive.

The environmental impact statement for this final rule is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852. It may also be viewed and downloaded electronically via the Federal rulemaking portal at http://www.regulations.gov by searching for Docket ID NRC-2009-0079.

X. Paperwork Reduction Act Statement

This final rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval number 3150-0020.

The burden to the public for these information collections is estimated to average 39.86 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS.RESOURCE@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0020), Office of Management and Budget(OMB), Washington, DC 20503. You may also e-mail comments to Chad_S_Whiteman@omb.eop.gov or comment by telephone at (202) 395-4718.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XI. Regulatory Analysis

The Commission has prepared a regulatory analysis on this final regulation (ADAMS Accession No. ML12095A037). The analysis examines the costs and benefits of the alternatives considered by the Commission.

The analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852. The analysis may also be viewed and downloaded electronically via the Federal rulemaking portal at http://www.regulations.gov by searching for Docket ID NRC-2009-0079.

XII. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule would not, if promulgated, have a significant economic impact on a substantial number of small entities. The majority of companies that own these plants do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

XIII. Backfit Analysis

The backfit rule (which is found in the regulations at §§ 50.109, 70.76, 72.62, 76.76, and in 10 CFR part 52) does not apply to this final rule. The regulations at 10 CFR part 40 do not contain a backfit requirement. Therefore, a backfit analysis is not required.

XIV. Congressional Review Act

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects

10 CFR Part 40

Criminal penalties, Government contracts, Hazardous materials transportation, Nuclear materials, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 150

Criminal penalties, Hazardous materials transportation, Intergovernmental relations, Nuclear materials, Reporting and recordkeeping requirements, Security measures, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR parts 40 and 150.

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

1. The authority citation for part 40 continues to read as follows:

Authority: Atomic Energy Act secs. 11(e)(2), 62, 63, 64, 65, 81, 161, 181, 182, 183, 186, 193, 223, 234, 274, 275 (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2231, 2232, 2233, 2236, 2243, 2273, 2282, 2021, 2022); Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109-59, 119 Stat. 594 (2005).

Section 40.7 also issued under Energy Reorganization Act sec. 211, Pub. L. 95-601, sec. 10, as amended by Pub. L. 102-486, sec. 2902 (42 U.S.C. 5851). Section 40.31(g) also

issued under Atomic Energy Act sec. 122 (42 U.S.C. 2152). Section 40.46 also issued under Atomic Energy Act sec. 184 (42 U.S.C. 2234). Section 40.71 also issued under Atomic Energy Act sec. 187 (42 U.S.C. 2237).

2. Remove the undesignated center headings preceding §§ 40.1, 40.11, 40.20, 40.31, 40.41, 40.51, 40.60, 40.71, and 40.81.

3. Designate §§ 40.1 through 40.10 as Subpart A, and add a heading for Subpart A preceding § 40.1 to read as follows:

Subpart A – General Provisions

4. Designate §§ 40.11 through 40.14 as Subpart B, and add a heading for Subpart B preceding § 40.11 to read as follows:

Subpart B – Exemptions

5. Designate §§ 40.20 through 40.28 as Subpart C, and add a heading for Subpart C preceding § 40.20 to read as follows:

Subpart C – General Licenses

6. Designate §§ 40.31 through 40.38 as Subpart D, and add a heading for Subpart D preceding § 40.31 to read as follows:

Subpart D – License Applications

7. Designate §§ 40.41 through 40.46 as Subpart E, and add a heading for Subpart E preceding § 40.41 to read as follows:

Subpart E – Licenses

8. Designate §§ 40.51 through 40.56 as Subpart F, and add a heading for Subpart F preceding § 40.51 to read as follows:

Subpart F – Transfer of Source Material

9. Designate §§ 40.60 through 40.67 as Subpart G, and add a heading for Subpart G preceding § 40.60 to read as follows:

Subpart G – Records, Reports, and Inspections

10. Designate §§ 40.71 through 40.82 as Subpart I, and add a heading for Subpart I preceding § 40.71 to read as follows:

Subpart I – Enforcement

11. Add a new § 40.3a to read as follows:

§ 40.3a Denial of licensing by Agreement States.

After **[INSERT DATE THAT IS 30 DAYS AFTER THE DATE OF PUBLICATION IN THE**

***FEDERAL REGISTER*]**, the NRC asserts regulatory and licensing authority over all source material at facilities in Agreement States which are or will be authorized to possess 2000 kilograms (4400 lb) or more of uranium hexafluoride.

12. In § 40.4, add the definitions *Acute, Available and reliable to perform their function when needed, Configuration management, Defense-in-depth practices, Hazardous chemicals produced from licensed material, Integrated safety analysis, Integrated safety analysis summary, Items relied on for safety, Management measures, Unacceptable performance deficiencies*, and *Worker* in alphabetical order to read as follows:

§ 40.4 Definitions.

* * * * *

Acute, as used in this part, means a single radiation dose or chemical exposure event or multiple radiation dose or chemical exposure events occurring within a short time (24 hours or less).

* * * * *

Available and reliable to perform their function when needed, as used in subpart H of this part, means that, based on the analyzed, credible conditions in the integrated safety analysis, items relied on for safety will perform their intended safety function when needed, and management measures will be implemented that ensure compliance with the performance requirements of § 40.81, considering factors such as necessary maintenance, operating limits, common-cause failures, and the likelihood and consequences of failure or degradation of the items and measures.

* * * * *

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 to perform their functions when needed.

* * * * *

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.

* * * * *

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.

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. 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.

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.

Items relied on for safety mean structures, systems, equipment, components, and activities of personnel that are 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.

* * * * *

Management measures mean the functions performed by the licensee, generally on a continuing basis, that are applied to items relied on for safety, to ensure the items are available and reliable to perform their functions when needed. Management measures include configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance elements.

* * * * *

Unacceptable performance deficiencies mean deficiencies in the items relied on for safety or the management measures that need to be corrected to ensure an adequate level of protection as defined in § 40.81(b) or (c).

* * * * *

Worker, when used in subpart H of this part, means an individual who receives an occupational dose as defined in § 20.1003 of this chapter.

13. In § 40.8, revise paragraph (b) to read as follows:

§ 40.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 40.9, 40.23, 40.25, 40.26, 40.27, 40.31, 40.35, 40.36, 40.41, 40.42, 40.43, 40.44, 40.51, 40.60, 40.61, 40.64, 40.65, 40.66, 40.67, 40.80, 40.81, 40.82, 40.83, 40.84, 40.86, 40.87, 40.88, 40.89, and appendix A to this part.

* * * * *

14. In § 40.26, revise paragraph (c)(1) to read as follows:

§ 40.26 General license for possession and storage of byproduct material as defined in this part.

* * * * *

(c) * * *

(1) The provisions of parts 19, 20, and 21 of this chapter, and §§ 40.1, 40.2a, 40.3, 40.4, 40.5, 40.6, 40.41, 40.46, 40.60, 40.61, 40.62, 40.63, 40.65, 40.71, and 40.101; and

* * * * *

§ 40.71 [Redesignated as § 40.101]

15. Redesignate § 40.71 as § 40.101.

§§ 40.81 and 40.82 [Redesignated as §§ 40.102 and 40.103]

16. Sections 40.81 and 40.82 are redesignated as §§ 40.102 and 40.103, respectively.

17. In the newly redesignated § 40.103, revise paragraph (b) to read as follows:

§ 40.103 Criminal penalties.

* * * * *

(b) The regulations in part 40 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 40.1, 40.2, 40.2a, 40.4, 40.5, 40.6, 40.8, 40.11, 40.12, 40.13, 40.14, 40.20, 40.21, 40.31, 40.32, 40.34, 40.43, 40.44, 40.45, 40.71, 40.85, 40.87, 40.101, and 40.102.

18. Add a new subpart H after § 40.67 to read as follows:

Subpart H − Additional Requirements for Certain Licensees Authorized to Possess 2000 Kilograms (4400 lb) or More of Uranium Hexafluoride

§ 40.80 Applicability.

The regulations in this subpart apply, in addition to other applicable Commission regulations, to each applicant or licensee that is or plans to be authorized to possess 2000 kilograms (4400 lb) or more of uranium hexafluoride. The regulations in this subpart do not apply to licensees that are undergoing decommissioning under the provisions of § 40.42 on **[INSERT DATE THAT IS 30 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].**

§ 40.81 Performance requirements.

(a) 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).

(b) The risk of each credible high-consequence event must be limited. Engineered controls, administrative controls, or both, 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. High consequence events are those internally or externally initiated events that result in:

(1) An acute worker dose of 1 Sv (100 rem) or greater total effective dose equivalent;

(2) An acute dose of 0.25 Sv (25 rem) or greater total effective dose equivalent to any individual located outside the controlled area as specified in paragraph (e) of this section;

(3) 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

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

(i) Could endanger the life of a worker; or

(ii) Could lead to irreversible or other serious, long-lasting health effects to any individual located outside the controlled area as specified in paragraph (e) of this section. 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.

(c) The risk of each credible intermediate-consequence event must be limited. Engineered controls, administrative controls, or both must be applied to the extent needed so that, upon implementation of such controls, the event is unlikely or its consequences are less than those in paragraphs (c)(1) through (c)(4) of this section. Intermediate consequence events

are those internally or externally initiated events that are not high consequence events that result in:

(1) An acute worker dose of 0.25 Sv (25 rem) or greater total effective dose equivalent;

(2) An acute dose of 0.05 Sv (5 rem) or greater total effective dose equivalent to any individual located outside the controlled area as specified in paragraph (e) of this section;

(3) A 24-hour averaged release of radioactive material outside the restricted area in concentrations exceeding 5000 times the values in Table 2 of Appendix B to part 20 of this chapter; or

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

(i) Could lead to irreversible or other serious, long-lasting health effects to a worker; or

(ii) Could cause mild transient health effects to any individual located outside the controlled area as specified in paragraph (e) of this section. 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.

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

(e) Each licensee must establish a controlled area, as defined in § 20.1003 of this chapter. In addition, the licensee must retain the authority to exclude or remove personnel and property from the area. For the purpose of complying with the performance requirements of this section, individuals who are not workers, as defined in § 40.4, may be permitted to perform on

going activities (e.g., at a facility not related to the licensed activities) in the controlled area, if the licensee:

(1) Demonstrates and documents, in the integrated safety analysis, that the risk for those individuals at the location of their activities does not exceed the performance requirements of paragraphs (b)(2), (b)(3), (b)(4)(ii), (c)(2), and (c)(4)(ii) of this section; or

(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, and conspicuously posts and maintains notices stating where these individuals may examine the information contained in § 19.11(a) of this chapter. Under these conditions, the performance requirements for workers specified in paragraphs (b) and (c) of this section may be applied to these individuals.

§ 40.82 Safety program and integrated safety analysis.

(a) Safety program. (1) Each licensee or applicant must establish and maintain a safety program that demonstrates compliance with the performance requirements of § 40.81. The safety program may be graded such that management measures applied are graded commensurate with the reduction of the risk attributable to that item. Three elements of this safety program, namely, process safety information, integrated safety analysis, and management measures, are described in paragraphs (b) through (d) of this section.

(2) Each licensee or applicant must establish and maintain records that demonstrate compliance with the requirements of paragraphs (b) through (d) of this section.

(3) Each licensee or applicant must maintain records of failures readily retrievable and available for NRC inspection, documenting each discovery that an item relied on for safety or management measure has failed to perform its function upon demand or has degraded such

that the performance requirements of § 40.81 are not satisfied. These records must identify the item relied on for safety or management measure that has failed and the safety function affected, the date of discovery, date (or estimated date) of the failure, duration (or estimated duration) of the time that the item was unable to perform its function, any other affected items relied on for safety or management measures and their safety function, affected processes, cause of the failure, whether the failure was in the context of the performance requirements or upon demand or both, and any corrective or compensatory action that was taken. A failure must be recorded at the time of discovery and the record of that failure updated promptly upon the conclusion of each failure investigation of an item relied on for safety or management measure.

(b) Process safety information. Each licensee or applicant must maintain process safety information to enable the performance and maintenance of an integrated safety analysis. This process safety information must include information pertaining to the hazards of the materials used or produced in the process, information pertaining to the technology of the process, and information pertaining to the equipment in the process.

(c) Integrated safety analysis. (1) Requirements. Each licensee or applicant shall conduct and maintain an integrated safety analysis that is of appropriate detail for the complexity of the process and identifies:

(i) Radiological hazards related to possessing or processing licensed material at its facility;

(ii) Chemical hazards of licensed material and hazardous chemicals produced from licensed material;

(iii) Facility hazards that could affect the safety of licensed materials and thus present an increased radiological risk;

(iv) Potential accident sequences caused by process deviations or other events internal

to the facility and credible external events, including natural phenomena;

(v) The consequence and the likelihood of occurrence of each potential accident sequence as specified in paragraph (c)(1)(iv) of this section, and the methods used to determine the consequences and likelihoods; and

(vi) Each item relied on for safety 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.

(2) Integrated safety analysis team qualifications. To assure the adequacy of the integrated safety analysis, the analysis must be performed by a team with expertise in engineering and process operations. The team must include at least one person who has experience and knowledge specific to each process being evaluated, and persons who have experience in radiation safety, fire safety, and chemical process safety. One member of the team must be knowledgeable in the specific integrated safety analysis methodology being used.

(3) Requirements for existing licensees. Individuals holding an NRC license on **[INSERT DATE THAT IS 30 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** shall, with regard to existing licensed activities:

(i) Submit for NRC approval, within **[INSERT DATE THAT IS 6 MONTHS AND 30 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*],** a plan that describes the integrated safety analysis approach that will be used, the processes that will be analyzed, and the schedule for completing the analysis of each process.

(ii) Complete an integrated safety analysis within **[INSERT DATE THAT IS 18 MONTHS AND 30 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, unless an approved plan submitted under paragraph (c)(3)(i) of this section, authorizes an alternative schedule.

(iii) Submit for NRC approval, an integrated safety analysis summary within **[INSERT**

DATE THAT IS 18 MONTHS AND 30 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], unless an approved plan submitted under paragraph (c)(3)(i) of this section, authorizes an alternative schedule. The integrated safety analysis summary must include a description of the management measures identified in this section.

(iv) Correct all unacceptable performance deficiencies within **[INSERT DATE THAT IS 3 YEARS AND 30 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The Commission may approve a request for an alternative schedule for completing the correction of unacceptable performance deficiencies if the Commission determines that the alternative is warranted by consideration of the following:

(A) Adequate compensatory measures have been established;

(B) Whether it is technically feasible to complete the correction of the unacceptable performance deficiencies within the required time;

(C) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis and that are beyond the control of the licensee.

(v) Pending the correction of unacceptable performance deficiencies identified during the conduct of the integrated safety analysis, the licensee must implement appropriate compensatory measures to ensure adequate protection.

(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 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.

§ 40.83 Requirements for new facilities or new processes at existing facilities.

(a) Baseline design criteria. Each prospective applicant or licensee must address the following baseline design criteria in the design of new facilities. Each existing licensee must address the following baseline design criteria in the design of new processes at existing facilities that require a license amendment under § 40.86. The 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 (e.g., those housing or adjacent to the new process); however, all facilities and processes must comply with the performance requirements in § 40.81. Licensees must maintain the application of these criteria unless the analysis performed as specified in § 40.82(c) demonstrates that a given item is not relied on for safety or does not require adherence to the specified criteria.

(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 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.

(2) Natural phenomena hazards. The design must provide for adequate protection against natural phenomena with consideration of the most severe documented historical events for the site.

(3) Fire protection. The design must provide for adequate protection against fires and explosions.

(4) Environmental and dynamic effects. The design must provide for adequate protection from environmental conditions and dynamic effects associated with normal operations, maintenance, testing, and postulated accidents that could lead to loss of safety functions.

(5) Chemical protection. The design must provide for adequate protection against chemical risks produced from licensed material, facility conditions which affect the safety of licensed material, and hazardous chemicals produced from licensed material.

(6) Emergency capability. The design must provide for emergency capability to maintain control of:

(i) Licensed material and hazardous chemicals produced from licensed material;

(ii) Evacuation of on-site personnel; and

(iii) Onsite emergency facilities and services that facilitate the use of available offsite services.

(7) Utility services. The design must provide for continued operation of essential utility services.

(8) Inspection, testing, and maintenance. The design of items relied on for safety must provide for adequate inspection, testing, and maintenance, to ensure their availability and reliability to perform their function when needed.

(9) Instrumentation and controls. The design must provide for inclusion of instrumentation and control systems to monitor and control the behavior of items relied on for safety.

(b) Design and layout. Facility and system design and facility layout must be based on defense-in-depth practices. 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. The design must incorporate, to the extent practicable:

(1) Preference for the selection of engineered controls over administrative controls to

increase overall system reliability; and

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

§ 40.84 Additional content of applications.

(a) In addition to the contents required by § 40.31, each license application must include a description of the applicant's safety program established under § 40.82.

(b) The integrated safety analysis summary must be submitted with the license or renewal application (and amendment application as necessary), but will not be incorporated in the license. However, changes to the integrated safety analysis summary are subject to the § 40.86 requirements. The integrated safety analysis summary must contain:

(1) A general description of the site with emphasis on those factors that could affect safety (i.e., meteorology, seismology);

(2) A general description of the facility with emphasis on those areas that could affect safety, including an identification of the controlled area boundaries;

(3) A description of each process (defined as a single reasonably simple integrated unit operation within an overall production line) analyzed in the integrated safety analysis in sufficient detail to understand the theory of operation; and, for each process, the hazards that were identified in the integrated safety analysis as specified in § 40.82(c)(1)(i) through (c)(1)(iii) and a general description of the types of accident sequences considered for that process;

(4) Information that demonstrates the licensee’s compliance with the performance requirements of § 40.81, including a description of the management measures and, if applicable, the requirements of § 40.83;

(5) A description of the team, qualifications, and the methods used to perform the integrated safety analysis;

(6) A list briefly describing each item relied on for safety 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;

(7) A description of the proposed quantitative standards used to assess the consequences to an individual from acute chemical 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);

(8) A descriptive list that identifies all items relied on for safety that are the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of § 40.81; and

(9) A description of the definitions of unlikely, highly unlikely, and credible as used in the evaluations in the integrated safety analysis.

§ 40.85 Additional requirements for approval of license application.

(a) A license application from an applicant subject to the requirements of this subpart will be approved if the Commission determines that the applicant has complied with the license requirements (subpart D) of this part and §§ 40.80 through 40.85.

(b) Submittals by existing licensees in accordance with § 40.82(c)(3)(i) will be approved if the Commission determines that:

(1) The integrated safety analysis approach is in accordance with the requirements of §§ 40.81, 40.82(c)(1), and 40.82(c)(2); and

(2) The schedule is in compliance with § 40.82(c)(3)(ii).

(c) Integrated safety analysis summaries submitted by licensees will be approved if the Commission determines that:

(1) The requirements of § 40.84(b) are satisfied; and

(2) The performance requirements in §§ 40.81(b) and (c) 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.

§ 40.86 Facility changes and change process.

(a) The licensee must establish a configuration management system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel. This system must be documented in written procedures and must assure that the following are evaluated prior to implementing any change:

(1) The technical basis for the change;

(2) Impact of the change on safety and health or control of licensed material;

(3) Modifications to existing operating procedures including any necessary training or retraining before operation;

(4) Authorization requirements for the change;

(5) For temporary changes, the approved duration (e.g., expiration date) of the change; and

(6) The impacts or modifications to the integrated safety analysis, integrated safety analysis summary, or other safety program information, developed in accordance with § 40.82.

(b) Any change to site, structures, processes, systems, equipment, components, computer programs, and activities of personnel must be evaluated by the licensee as specified in paragraph (a) of this section, before the change is implemented. The evaluation of the change must determine, before the change is implemented, if an amendment to the license is required to be submitted in accordance with § 40.44.

(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:

(1) Create new types of accident sequences that, unless mitigated or prevented, would exceed the performance requirements of § 40.81 and that have not previously been described in the integrated safety analysis summary;

(2) Use new processes, technologies, or control systems for which the licensee has no prior experience;

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

(4) Alter 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

(5) Violate the requirements of this section, or any license condition, or order.

(d)(1) For changes that require pre-approval under this section, the licensee must submit an amendment request to the NRC in accordance with §§ 40.44 and 40.84.

(2) For changes that do not require pre-approval under this section, the licensee must submit to the NRC annually, within 30 days after the end of the calendar year during which the changes occurred, a brief summary of all changes to the records required by § 40.82(a)(2).

(3) For all changes that affect the integrated safety analysis summary, the licensee must submit to the NRC annually, within 30 days after the end of the calendar year during which the changes occurred, revised integrated safety analysis summary pages.

(e) If a change covered by this section is made, the affected on-site documentation must be updated promptly.

(f) The licensee must maintain records of changes to its facility carried out under this section. These records must include a written evaluation that provides the bases for the

determination that the changes do not require prior Commission approval under paragraph (c) or (d) of this section. These records must be maintained until termination of the license.

§ 40.87 Renewal of licenses.

Applications for renewal of a license must be filed in accordance with § 2.109 of this chapter, and §§ 40.43 and 40.85. Information contained in previous applications, statements, or reports filed with the Commission under the license may be incorporated by reference, provided that these references are clear and specific.

§ 40.88 Additional reporting requirements.

Licensees who are required to conduct an integrated safety analysis must comply with the following reporting requirements (except for paragraphs (a)(1), (a)(2), and (b)(4) of this section), after they have submitted an integrated safety analysis summary. Licensees must comply with paragraphs (a)(1), (a)(2), and (b)(4) of this section after **[INSERT DATE THAT IS 30 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].** Reports must be made by a knowledgeable licensee representative and by any method that will ensure compliance with the required time period for reporting. Licensees must provide reasonable assurance that reliable communication with the NRC Operations Center is available during events that trigger these reporting requirements.

(a) <u>One-hour reports</u>. In addition to the events described in § 40.60(a) that must be reported within 4 hours of discovery, the following events must be reported to the NRC Operations Center within 1 hour of discovery, supplemented with the information described in paragraph (d)(1) of this section as it becomes available, followed by a written report within 60 days:

(1) An acute intake by an individual of 30 mg or greater of uranium in a soluble form.

(2) An acute chemical 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).

(3) An event or condition such that no items relied on for safety, 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).

(b) Twenty-four hour reports. In addition to the events described in § 40.60(b), the following events must also be reported to the NRC Operations Center within 24 hours of discovery, supplemented with the information described in paragraph (d)(1) of this section as it becomes available, followed by a written report within 60 days:

(1) Any event or condition that results in the facility being in a state that was not analyzed, was improperly analyzed, or is different from that analyzed in the integrated safety analysis, and which results in failure to meet the performance requirements of § 40.81.

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

(3) An acute chemical 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).

(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.

(c) Concurrent reports. Any event or situation, related to the health and safety of the public or onsite personnel, or protection of the environment, for which a news release is planned or notification to other government agencies has been or will be made, must be reported to the NRC Operations Center concurrent to the news release or other notification.

(d) Follow-up reports to the NRC Operations Center. (1) To the extent that the information is available at the time of notification, all reports called in to the NRC Operations Center must include:

(i) Caller's name, position title, and call-back telephone number;

(ii) Date, time, and exact location of the event;

(iii) Description of the event, including:

(A) Radiological or chemical hazards involved, including isotopes, quantities, and chemical and physical form of any material released;

(B) Actual or potential health and safety consequences to the workers, the public, and the environment, including relevant chemical and radiation data for actual personnel exposures to radiation or radioactive materials or hazardous chemicals produced from licensed materials (e.g., level of radiation exposure, concentration of chemicals, and duration of exposure);

(C) The sequence of occurrences leading to the event including degradation or failure of structures, systems, equipment, components, and activities of personnel relied on to prevent potential accidents or mitigate their consequences; and

(D) Whether the remaining structures, systems, equipment, components, and activities of personnel relied on to prevent potential accidents or mitigate their consequences are available and reliable to perform their functions;

(iv) External conditions affecting the event;

(v) Additional actions taken by the licensee in response to the event;

(vi) Status of the event (e.g., whether the event is on-going or was terminated);

(vii) Current and planned site status, including any declared emergency class;

(viii) Notifications, related to the event, that were made or are planned to any local, State, or other Federal agencies; and

(ix) Status of any press releases related to the event that were made or are planned.

(2) Follow-up information in the reports called in to the NRC Operations Center must be provided until all information required to be reported is complete.

(e) Written reports. Written reports required by paragraphs (a) and (b) of this section are subject to the following requirements:

(1) These written reports must be sent to the NRC's Document Control Desk, using an appropriate method listed in § 40.5(a), with a copy to the appropriate NRC regional office listed in Appendix D to part 20 of this chapter.

(2) The reports must include the following:

(i) Complete applicable information required by paragraph (d)(1) of this section;

(ii) Probable cause of the event, including all factors that contributed to the event and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(iii) Corrective actions taken or planned to prevent occurrence of similar or identical events in the future and the results of any evaluations or assessments; and

(iv) Whether the event was identified and evaluated in the integrated safety analysis.

§ 40.89 Backfitting

(a) Applicability. The requirements in this section apply with respect to those facilities of licensees who are authorized to possess 2000 kilograms (4400 lb) or more of uranium hexafluoride, and are applicable once such a licensee’s ISA summary has been approved by the NRC pursuant to § 40.85.

(b) Definition of backfiting. Backfitting is defined as the modification of, or addition to, systems, structures, or components of a facility of a licensee subject to ISA requirements; or to the procedures or organization required to operate such a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC

staff position.

(c) Backfit analysis. (1) Except as provided in paragraph (c)(3) of this section, the Commission shall require a systematic and documented analysis for backfits which it seeks to impose.

(2) Except as provided in paragraph (c)(3) of this section, the Commission shall require the backfitting of a facility only when it determines, based on the analysis described in paragraph (d) of this section, that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.

(3) The provisions of paragraphs (c)(1) and (c)(2) of this section are inapplicable and, therefore, backfit analysis is not required and the standards in paragraph (c)(2) of this section do not apply where the Commission finds and declares, with appropriately documented evaluation for its finding, any of the following:

(i) That a modification is necessary to bring a facility into compliance with subpart H of this part;

(ii) That a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee;

(iii) That regulatory action is necessary to ensure that the facility either provides adequate protection to the health and safety of the public, or is in accord with the common defense and security; or

(iv) That the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security should be regarded as adequate.

(4) The Commission shall always require the backfitting of a facility if it determines that

the regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security.

(5) The documented evaluation required by paragraph (c)(3) of this section must include a statement of the objectives of and reasons for the modification and the basis for invoking the exception. If immediate effective regulatory action is required, then the documented evaluation may follow, rather than precede, the regulatory action.

(6) If there are two or more ways to achieve compliance with a license or the rules or orders of the Commission, or with written license commitments, or there are two or more ways to reach an adequate level of protection, then ordinarily the licensee is free to choose the way that best suits its purposes. However, should it be necessary or appropriate for the Commission to prescribe a specific way to comply with its requirements or to achieve adequate protection, then cost may be a factor in selecting the way, provided that the objective of compliance or adequate protection is met.

(d) Considerations to be addressed in backfit analysis. In reaching the determination required by paragraph (c)(2) of this section, the Commission will consider how the backfit should be scheduled in light of other ongoing regulatory activities at the facility and, in addition, will consider information available concerning any of the following factors as may be appropriate and any other information relevant and material to the proposed backfit:

(1) Statement of the specific objectives that the proposed backfit is designed to achieve;

(2) General description of the activity that would be required by the licensee in order to complete the backfit;

(3) Potential change in the risk to the public from the accidental release of radioactive material and hazardous chemicals produced from licensed material;

(4) Potential impact on facility employees from radiological exposure or exposure to hazardous chemicals produced from licensed material;

(5) Installation and continuing costs associated with the backfit, including the cost of facility downtime;

(6) The potential safety impact of changes in facility or operational complexity, including the relationship to proposed and existing regulatory requirements;

(7) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;

(8) The potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed backfit; and

(9) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

(e) Prohibition on withholding license amendment or ISA approval. No license amendment or ISA approval will be withheld during the pendency of backfit analyses required by the Commission's rules.

(f) Authority of the EDO. The Executive Director for Operations shall be responsible for implementation of this section, and all analyses required by this section shall be approved by the Executive Director for Operations or his or her designee.

PART 150 – EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

19. Revise the authority citation for part 150 to read as follows:

Authority: Atomic Energy Act sec. 161, 181, 223, 234(42 U.S.C. 2201, 2021, 2231, 2273, 2282); Energy Reorganization Act sec. 201 (42 U.S.C. 5841); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 594 (2005).

Sections 150.3, 150.15, 150.15a, 150.31, 150.32 also issued under Atomic Energy Act secs. 11e(2), 81, 83, 84 (42 U.S.C. 2014e(2), 2111, 2113, 2114). Section 150.14 also issued under Atomic Energy Act sec. 53 (42 U.S.C. 2073).

Section 150.15 also issued under Nuclear Waste Policy Act secs. 135 (42 U.S.C. 10155, 10161). Section 150.17a also issued under Atomic Energy Act sec. 122 (42 U.S.C. 2152). Section 150.30 also issued under Atomic Energy Act sec. 234 (42 U.S.C. 2282).

20. In § 150.15, add paragraph (a)(10) to read as follows:

§ 150.15 Persons not exempt.

(a) * * *

(10) The possession of 2000 kilograms (4400 lb) or more of uranium hexafluoride.

* * * * *

Dated at Rockville, Maryland, this _____, day of _____ __ , 2012.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.