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: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is proposing to amend its regulations by adding additional requirements for source material licensees who possess significant quantities of uranium hexafluoride (UF6). The proposed amendments would require such licensees to conduct integrated safety analyses (ISAs) similar to the ISAs performed by 10 CFR part 70 licensees; set possession limits for UF6 for determining licensing authority (NRC or Agreement States); add defined terms; add an additional evaluation criterion for applicants who submit an evaluation in lieu of an emergency plan; require the NRC to perform a backfit analysis under specified circumstances; and make administrative changes to the structure of the regulations. The proposed ISA requirements would not apply to facilities that are currently undergoing decommissioning under the current regulations.

This rulemaking pertains to 10 CFR part 40 licensees and applicants who possess, or plan to possess, significant quantities of UF6. The current regulations do not contain ISA requirements for evaluating the consequences of facility accidents. The proposed amendment would require applicants and licensees who possess or plan to possess significant amounts 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, would address both the radiological and chemical hazards from licensed material and hazardous chemicals produced in the processing of licensed material. Similar hazards that exist at other fuel cycle facilities are addressed by ISA requirements elsewhere in the regulations.

The NRC is also proposing new guidance on the implementation of the additional regulatory requirements for licensees that would be authorized under this rulemaking.

DATES: Submit comments specific to the proposed rule and draft guidance document by August 1, 2011. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date. Submit comments specific to the information collection aspects of this rule by June 16, 2011.

ADDRESSES: Please include the applicable Docket ID in the subject line of your comments. For additional instructions on submitting comments and accessing documents related to this action, see Section I, "Submitting Comments and Accessing Information" in the **SUPPLEMENTARY INFORMATION** section of this document. You may submit comments on the proposed rule (Docket ID NRC–2009–0079) by any one of the following methods:

- *Federal Rulemaking Web Site:* Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2009–0079 for the proposed rule. Address questions about NRC dockets to Carol Gallagher, telephone: 301–492–3668; e-mail: *Carol.Gallagher@nrc.gov.*
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- *E-mail comments to: Rulemaking.Comments@nrc.gov.* If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301–415–1677.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, MD 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays. (Telephone 301–415–1677).
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.

You may submit comments on the proposed guidance document (Docket ID NRC–2011–0080) by any one of the following methods:

- *Federal Rulemaking Web Site:* Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2011–0080. Address questions about NRC dockets to Carol Gallagher, telephone: 301–492–3668; e-mail: *Carol.Gallagher@nrc.gov.*
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.
- *Fax comments to:* RADB at 301–492–3446.

You may submit comments on the information collections by the methods indicated in the Paperwork Reduction Act Statement.

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. Submitting Comments and Accessing Information

Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site, *http://www.regulations.gov.* Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they

should not include any information in their comments that they do not want publicly disclosed.

You can access publicly available documents related to the proposed rule and draft guidance document using the following methods:

• *NRC's Public Document Room (PDR):* The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are available online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–800–397–4209, or 301–415–4737, or by e-mail to *PDR.Resource@nrc.gov.* The proposed rule and draft guidance document are available electronically under ADAMS Accession Numbers ML110890797 and ML102520022, respectively.

• *Federal Rulemaking Web Site:* Public comments and supporting materials related to the proposed rule and draft guidance document can be found at *http://www.regulations.gov* by searching on the applicable Docket ID, NRC–2009–0079 (proposed rule) and NRC–2011–0080 (draft guidance document).

II. 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 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 principle factors on which this proposed 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 would be the sole regulator for future major fuel cycle facilities under 10 CFR part 40. The NRC sent a letter to the Agreement States (ADAMS Accession Number ML071030304) on April 13, 2007, notifying them of the Commission's directive.

In SECY–07–0146 (August 24, 2007), 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 kilograms (or 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 SRM for SECY–07–0146, dated October 10, 2007, 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 and concerns. 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 that this mission does not encompass chemical hazards. Both noted that 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 that 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-based 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 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 the above NEI and Honeywell comments. As discussed above, 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 can be found in the following section in Question E. Therefore, generic ISA requirements to ensure that an adequate level of public health and safety is maintained, are needed for existing and future 10 CFR part 40 facilities handling significant quantities of UF6.

The NRC staff, in later reviewing all 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, 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, "Proposed Rule: Domestic Licensing of Source Material—Amendments/ Integrated Safety Analysis," dated October 1, 2010. In response to SECY–10–0128, the Commission issued an SRM dated November 30, 2010, which directed the staff to publish the draft proposed rule for public comment subject to Commission comments and changes which include:

(1) Adding a backfit provision similar to § 70.76, applicable to any source material licensee authorized to possess 2000 kilograms (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) 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 this 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 in Question E in Section III (Discussion), the staff found there was no need to modify the MOU, and guidance on how MOU Criterion 3 should be evaluated in completing ISAs has been developed. Comments on the draft guidance for this proposed rule may be submitted to the NRC by the methods listed in the **ADDRESSES** section of this document.

III. Discussion

A. What issues is the NRC seeking public comments on?

In addition to seeking comments in general on the proposed rule, the NRC is seeking specific public comments on the proposed provision to require an additional evaluation criterion in § 40.84(b) for chemical hazards. This criterion is not currently required for any fuel cycle facility. Specific discussion on this issue is located in Question H of this section and in Section IV (Discussion of Proposed Amendments by Section).

Additionally, the NRC is seeking public comments on the potential challenges and impacts of conducting probabilistic risk analyses (PRAs) rather than ISAs for 10 CFR part 40 fuel cycle facilities. This issue is discussed in Question K of this section.

Comments on these issues may be submitted as described in the **ADDRESSES** section of this document.

B. What action is the NRC taking?

The NRC is proposing to amend 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 would be similar to requirements found in 10 CFR part 70 subpart H, which apply to fuel fabrication and enrichment facilities. In the rulemaking, the NRC would assert jurisdiction over all applicants and licensees that may possess 2000 kg or more of UF6.

The rulemaking would add an additional evaluation criterion for applicants or licensees that submit an evaluation in lieu of the emergency plan required by § 40.31(j). The evaluation would have to demonstrate that an acute chemical exposure from licensed material or hazardous chemicals produced from licensed material due to a release would result in neither irreversible nor mild transient health effects to a member of the public offsite. If such an evaluation is not submitted, an emergency plan must be submitted in accordance with § 40.31(j)(3).

The format of the requirements contained in 10 CFR part 40 would be administratively restructured to create subparts. Included in the restructuring would be the addition of a new subpart titled, "Additional Requirements for Certain Licensees Authorized to Possess 2000 kilograms (4400 lb) or More of Uranium Hexafluoride." The rulemaking would also add definitions to § 40.4 that pertain to the proposed ISA requirements.

The rulemaking would add a backfit provision applicable to licensees authorized to possess 2000 kg or more of UF6. This provision would be similar to existing § 70.76.

C. Whom would this action affect?

The proposed amendment would affect current licensees and future applicants that possess or plan to possess 2000 kg or more of UF6. Agreement States and NRC licensees that are currently in the process of decommissioning would be exempt from the new requirements.

All future facilities authorized to possess 2000 kg or more of UF6 would be licensed by the NRC. On April 13, 2007, a letter was sent to all the Agreement States (FSME–07–036) 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."

D. What steps did NRC take to involve the public in this proposed 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.

E. What is the basis for the NRC to regulate the hazardous chemicals produced from licensed materials?

Health and safety risks at uranium 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, and HF. 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 Atomic Energy Act (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 (53 FR 43950) further discusses the radiological and chemical hazards to workers handling radiological materials licensed by 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 thus present an increased radiation risk to workers;

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 by Agreement States to which AEA authority has been delegated) and are within the NRC'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 in the discussion of the proposed § 40.81(a) in Section IV (Discussion of Proposed Amendments by Section) of this document. Guidance on the MOU's Criterion 3 has also been added to the draft guidance, NUREG–1962, developed to support the rulemaking. The draft 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. OSHA, in Appendix A of Title 29 of the CFR (29 CFR) Section 1910.119, identifies threshold quantities of hazardous chemicals that "present a potential for a catastrophic event." The HF is listed in this appendix with a threshold quantity of 1000 lb. In Appendix A to 29 CFR 1910.119, OSHA lists toxic and reactive highly hazardous chemicals which present a potential for a catastrophic event at or above specified threshold quantities. The 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 thus 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 reactive highly hazardous chemicals which present a potential for a catastrophic event at or above the threshold quantity. The regulations at 29 CFR 1910.119 has 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, § 1910.119 does not provide structured risk-informed requirements for evaluating the consequences of facility accidents as an ISA does.

Under the OSHA regulation, facilities that possess hazardous chemicals in quantities greater than listed in Appendix A to 29 CFR 1910.119 must perform a process hazard analysis. This analysis is similar but less comprehensive than the requirements in

the proposed ISA. Additionally, § 1910.119 only addresses chemical hazards. An ISA would address both the radiological and chemical hazards from licensed material and hazardous chemicals produced in the processing of licensed material.

H. Is there an alternative to submitting an emergency plan?

Yes. The current regulations in § 40.31(j) require any licensee or applicant who plans to possess 1000 kg or more of UF6 (or more than 50 kg in a single container) to submit an emergency plan or, per § 40.31(j)(1)(i), an evaluation showing that the maximum intake of uranium by a member of the public due to a release would not exceed 2 milligrams. The proposed rule would add an additional criterion, in addition to § 40.31(j)(1)(i), for licensees or applicants who possess, or plan to possess, 2000 kg or more of UF6, and who opt to submit an evaluation in lieu of submitting an emergency plan. This additional criterion would require a demonstration that an acute chemical exposure from licensed material or hazardous chemicals produced from licensed material due to a release, would result in neither irreversible nor mild transient health effects to a member of the public offsite. An acute exposure guideline level (AEGL) or emergency response planning guidelines (ERPG) standard may be used in making this demonstration. 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. What are ERPG's and AEGLs, and what are they used for?

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, by a number of organizations. A set of chemical consequence criteria, known as 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 AEGLs. The committee, which works under the auspices of the 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.

J. When would these ISA requirements become effective?

Current licensees would have to submit for NRC approval, within 6 months after the rule becomes effective, 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. Unless an alternate schedule is approved, the licensee would submit for NRC approval an integrated safety analysis 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 would have to correct all unacceptable performance deficiencies identified in the ISA. Pending the correction of unacceptable performance deficiencies, the licensee would have to implement appropriate compensatory measures to ensure adequate protection.

K. Should the NRC use probabilistic risk analyses methodology at 10 CFR Part 40 licensed facilities?

A PRA is a systematic methodology to evaluate risks associated with complex technologies, often applied to light water power reactors licensed under 10 CFR part 50. A PRA usually answers three basic questions: What can go wrong, how severe are the consequences, and what are their probabilities or frequencies? The Commission has published a policy statement on the use of PRA entitled "Use of Probabilistic Risk Assessment Methods In Nuclear Regulatory Activities," dated August 10, 1995.

The proposed rule does not contain a provision for using a PRA. However, the Commission has directed the staff to seek public comments on the potential challenges and impacts regarding the use of PRA methodology at facilities licensed under 10 CFR part 40. Additional information on PRA is available in documents related to the review conducted by the Advisory Committee on Reactor Safeguards including:

1. December 15, 2010, staff document entitled "A Comparison of Integrated Safety Analysis and Probabilistic Risk Assessment" (accession number ML103330478); and

2. February 17, 2011, ACRS response letter entitled "Comparison of Integrated Safety Analysis (ISA) and Probabilistic Risk Assessment (PRA) for Fuel Cycle Facilities" (accession number ML110460328).

Comments on this issue may be submitted as described in the **ADDRESSES** section of this document.

L. Has NRC prepared a cost-benefit analysis of the proposed actions?

The NRC staff has prepared a regulatory analysis for this rulemaking. This analysis shows an estimated annual cost of $119,000 for each NRC licensee and $17,000 for the NRC from this proposed rule. The cost to Agreement States to implement this rule was estimated to be minimal; therefore, the cost to Agreement States was not quantified in the regulatory analysis supporting the rule.

M. Has NRC evaluated the paperwork burden to licensees?

This proposed 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 proposed rule will have on reporting and recordkeeping requirements for NRC licenses. There are no reporting or recordkeeping requirements for the Agreement State licensees. The NRC is seeking public comment on these proposed requirements. More information on this subject is in Section X, Paperwork Reduction Act Statement, of this document.

N. What should I consider as I prepare my comments to NRC?

Tips for preparing your comments. When submitting your comments, remember to:

i. Identify the rulemaking (RIN 3150–AI50), Docket ID NRC–2009–0079.

ii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iii. Describe any assumptions and provide any technical information and/or data that you used.

iv. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

v. Provide specific examples to illustrate your concerns, and suggest alternatives.

vi. Explain your views as clearly as possible.

vii. Make sure to submit your comments by the comment period deadline identified.

viii. See Section VII for the request for comments on the use of plain language, Section X for the request for comments on the information collection, and Section XI for the request for comments on the draft regulatory analysis.

IV. Discussion of Proposed Amendments by Section

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

Section 40.3a Denial of Licensing by Agreement States

This new section would specify that Agreement States lack regulatory authority over persons who possess or plan to possess 2000 kg or more of UF6. This section would not apply to facilities in Agreement States that are undergoing decommissioning as of the effective date of this regulation. 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. This proposed 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 proposed requirement is similar to the existing § 72.8 requirement.

Section 40.4 Definitions

Definitions of the following 11 terms used in the new subpart H would be added to § 40.4: "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 below, 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 proposed "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) of this section would be amended to add the 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) of this section would be amended to add the 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 would list the types of NRC licensees or applicants who would be subject to the new subpart H. The new requirements would apply to all applicants or licensees that are or plan to be authorized to possess 2000 kg or more of UF6. In general, the 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 proposed NRC requirements would only apply to NRC's areas of responsibility (radiological safety and chemical safety directly related to licensed radioactive material). In this regard, the proposed 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 would not apply to licensees who, as of the effective date of the final 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 should provide 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 would explicitly address 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 proposed changes to 10 CFR part 40 seek to 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 being proposed, 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.

Section 40.81(a). A risk-informed approach must consider not only the consequences of potential accidents, but also their likelihood of occurrence. As mentioned above, 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 proposed 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 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). Guidance documents are being developed to provide examples of acceptable approaches for the meaning of "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 "item relied on for safety" (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 proposed 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. Generally, the NRC covers the first three areas, whereas OSHA covers the fourth area:

(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.

One goal of the proposed 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 proposed 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 have been proposed in this section as a reference value, to be used by licensees in the ISA (a forward-looking analysis) to establish controls (*i.e.,* items relied on for safety (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.

Section 40.81(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.

Section 40.81(b)(1). An acute exposure of a worker to a radiation dose of 1 Sv (100 rem) or greater total effective dose equivalent (TEDE) is considered to be 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."

Section 40.81(b)(2). The exposure of an individual located outside of the controlled area to a radiation dose of 0.25 Sv (25 rem) or greater TEDE is 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.

Section 40.81(b)(3). The intake of 30 mg of soluble uranium by an individual located outside of the controlled area is 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).

Section 40.81(b)(4). An acute chemical 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, is 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 above.

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.

Section 40.81(c). This provision addresses performance requirements for "intermediate-consequence events," which would be of a lower magnitude than high consequence events, and thus 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.

Section 40.81(c)(1). A worker radiation dose between 0.25 Sv (25 rem) and 1 Sv (100 rem) TEDE is 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 (Regulatory Guide 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.

Section 40.81(c)(2). A dose to any individual located outside of the controlled area between 0.05 Sv (5 rem) and 0.25 Sv (25 rem) is 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.

Section 40.81(c)(3). 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, is 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)" [October 12, 2006, 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 $5{,}000 \times 0.5$ mSv/yr $\times$ 1 day $\times$ 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.

Section 40.81(c)(4). An acute chemical 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, is 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 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.

Section 40.81(d). This provision addresses IROFS and management measures. Paragraph (d) would require 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.

Section 40.81(e). This provision addresses the term "controlled area" as defined in 10 CFR part 20 and as used in the performance requirements discussed above. Section 40.81(e) 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 proposed 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 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 would specify the safety program that licensees would be required to implement at covered UF6 facilities, including the performance of an ISA, and 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 would 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.

Section 40.82(a). Each licensee would be required to establish and maintain a safety program that demonstrates compliance with the performance requirements of § 40.81. Although the ISA would be the primary tool in identifying the potential accidents requiring consequence mitigation and accident prevention, process safety information would be used to develop the ISA, and management measures would 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 this section. 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 be implemented to allow easy retrieval of required information.

Section 40.82(b). This provision would require 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.

Section 40.82(c). This provision proposes 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 would 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 proposed rule would be required to develop plans and submit them to the NRC within 3 months of the effective date of the rule. Each plan would identify the processes that would be subject to an ISA, the ISA approach that would be implemented for each process and the schedule for completing the analysis of each process. Licensees would be expected to complete their ISA within the required time, correct any unacceptable vulnerabilities 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 vulnerabilities, licensees would be expected to implement appropriate compensatory measures to ensure adequate protection until the

vulnerability can be more appropriately corrected.

Applicants for licenses to operate new facilities or new processes at existing facilities would be 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 would be 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).

Section 40.82(d). This provision proposes requirements to establish management measures. Although the ISA would play a critical role in identifying potential accidents and the IROFS, the performance of an ISA would not, by itself, ensure adequate protection. Thus, 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 would be required to meet and that licensees of existing UF6 facilities would be required to meet when adding new processes to existing facilities. The BDC are based on the existing criteria in 10 CFR 70.64.

Section 40.83(a). This provision would specify 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. Each proposed BDC is discussed below.

(1) The quality standards and records BDC would need to be developed and implemented in accordance with management measures. Management measures that would 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 would need to be provided as to how appropriate records would be maintained.

(2) The natural phenomena hazards BDC would have to provide for adequate protection against natural phenomena with consideration of the most severe documented historical events for the site. The criteria would have to 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 would have to provide for adequate protection against fires and explosions. As appropriate, the criteria would need to 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 would have to 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 would have to ensure that IROFS will perform their safety functions under the environmental and dynamic service conditions in which they would be required to function and for the length of time their function would be required. The criteria would also have to include how the design ensures that non-IROFS will not prevent satisfactory accomplishment of safety functions of IROFS.

(5) The chemical protection BDC would have to 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 would have to 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 would also have to 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 would have to 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

would have to address methods to ensure continued operation of essential utilities during emergency events.

(8) The inspection, testing, and maintenance BDC would have to 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 would need to address the possible methods to provide adequate inspection, testing, and maintenance to ensure their availability and reliability. This would need to 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 would have to address the inclusion of these systems in the implementation of IROFS. The criteria would need to 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 would need to be identified and justified.

Section 40.83(b). This new provision requires licensees to base their facility and system design and facility layout on practices. 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 NRC under § 40.31, for a license application, this new section would specify 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.

Section 40.84(a). This provision would require 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.

Section 40.84(b). This new provision supplements the existing requirements in § 40.31(j) to capture the additional hazards posed by operations involving 2000 kg or more of UF6. As previously discussed, accidents involving UF6 can produce HF, a highly reactive and corrosive chemical generated in gaseous form when UF6 interacts with moisture in the air. The HF presents a substantial inhalation and skin absorption hazard to both workers and the public, as clouds of HF can quickly move offsite. Thus, licensees authorized to possess 2000 kg or more of UF6 must either submit an evaluation in accordance with § 40.31(j)(1)(i) and this new provision or an emergency plan pursuant to § 40.31(j)(3). Compliance with this new provision would require the evaluation to also show that an acute chemical exposure from licensed material or hazardous chemicals produced from licensed material due to a release would not result in irreversible or mild transient health effects to a member of the public offsite. In performing such an evaluation, an applicant/licensee may use an AEGL or ERPG standard. This approach is currently being used by fuel cycle facility licensees subject to the 10 CFR part 70 ISA requirements.

Section 40.84(c). This provision would require that an ISA summary be submitted with the license or renewal application (and amendment application as necessary). The ISA summary would not be incorporated in the license.

The ISA summary would have to 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 would be required to 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 would focus on the factors the NRC would use to determine that requirements in §§ 40.80 through 40.85 have been met. These proposed new regulations are in addition to the existing licensing regulations being introduced into 10 CFR part 40 under the new subpart D.

Section 40.85(a). This provision would require the NRC to approve a license application from an applicant subject to the requirements of the proposed 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.

Section 40.85(b). This provision details the criteria that the NRC would 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).

Section 40.85(c). This provision details the criteria the NRC would 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 would specify 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.

Section 40.86(a). This provision would require the licensee to establish a configuration management system documented in written procedures to track operational changes made by the licensee. The system would have to assure that prior to implementing any change, its technical basis, impact on safety and other specified factors are evaluated.

Section 40.86(b). This provision would require the licensee, before implementing any change, to determine whether the change requires NRC pre-approval through the license amendment process.

Section 40.86(c). This provision would specify 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.

Section 40.86(d). For changes that are found not to require NRC pre-approval, the licensee would be 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 would be required to submit to the NRC annually, within 30 days after the end of the calendar year, revised ISA summary pages. These yearly updates would 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).

Section 40.86(e). Licensees who make changes under the provisions of this section would be required to promptly up-date all affected on-site documents.

Section 40.86(f). Records documenting facility changes would be maintained until termination of the license. Such records would 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 would specify 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 proposed § 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 would establish event reporting requirements for licensees required to conduct ISAs. These requirements would become applicable after the ISA summary had been submitted. The required reports would have to be made by a knowledgeable licensee representative in a manner ensuring timely reporting of events, and licensees would have to 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.

Section 40.88(a). This provision would require 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 licensed material or hazardous chemicals produced from 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.

Section 40.88(b). This provision would require 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 licensed material or hazardous chemicals produced from 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.

Section 40.88(c). This provision would pertain to 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. At the same time that the news release (or notification) is given, the licensee would have to also report the situation to the NRC Operations Center.

Section 40.88(d). This provision specifies information licensees would be required to 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 would further require that follow-up information be provided to the NRC Operations Center until all information required to be reported is complete.

Section 40.88(e). This provision would pertain to the written reports submitted under § 40.88(a) and (b). In addition to including the information required by § 40.88(d)(1), written reports would include: A discussion of the probable cause of the event, specific information regarding any equipment that failed or malfunctioned, any corrective actions taken to prevent future similar events, the results of any evaluations or assessments of the event, and a discussion of whether the event was previously identified and evaluated in the ISA.

Section 40.89 Backfitting

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

Section 40.89(a). This provision would make the backfit requirements applicable to licensees authorized to possess 2000 kilograms (4400 lb) or more of UF6, and its terms would become effective once such a licensee's ISA summary has been approved by the NRC. The proposed backfit requirements would not be applicable to 10 CFR part 40 licensees who are not authorized to possess 2000 kilograms or more of UF6.

Section 40.89(b). This provision would define backfitting as 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 proposed definition is substantially similar as the one in existing § 70.76(a)(1).

Section 40.89(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 would be 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.

Other provisions in proposed § 40.89(c): (1) Would 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) would 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) would 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.

Section 40.89(d). This provision would require the Commission, in the 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 would require the Commission to consider specific information relevant 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.

Section 40.89(e). This provision would prohibit withholding a license during the backfit analyses and is the same as existing § 70.76(c).

Section 40.89(f). This provision is the same as existing § 70.76(d) and would designate the Executive Director for Operations as the party responsible for its implementation. Additionally, it would require 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 would be re-designated as § 40.102. Additionally, Paragraph (b) of this section would be 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) would be added to support the NRC's determination that licensees who possess or plan to possess 2000 kg or more of UF6 would be exclusively 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. Criminal Penalties

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

VI. Agreement State Compatibility

This proposed rule applies only to NRC licensees and therefore contains no components that have Agreement State compatibility.

VII. Plain Language

The Presidential Memorandum "Plain Language in Government Writing" published June 10, 1998 (63 FR 31883), directed that the Government's documents be in clear and accessible language. The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the **ADDRESSES** section of this document.

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 proposed rule, the NRC would add 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. The NRC is not aware of any voluntary consensus standards that address the proposed subject matter of this proposed rule. The NRC will consider using a voluntary consensus standard if an appropriate standard is identified. If a voluntary consensus standard is identified for consideration, the submittal should explain why the standard should be used.

IX. Environmental Impact: Categorical Exclusion

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 proposed rule, because the Commission has concluded on the basis of an environmental assessment that this proposed rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment.

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. Implementation of the proposed amendments, including the requirement to protect against events that could damage the environment, is expected to result in a significant improvement in licensees', NRC's, other governmental agencies', and the public's understanding of the risks at these facilities and licensees' ability to ensure that those risks are appropriately controlled. For existing licensees, any deficiencies identified in the ISA would need to be promptly addressed. For new licensees, operations will not begin unless licensees demonstrate an adequate level of protection against potential accidents identified in the ISA. As a result, the safety and environmental impact of the new amendments is positive. There would be less potential adverse impact on the environment from licensed operations carried out under the final rule than if those operations were carried out under the existing 10 CFR part 40 regulation.

The determination of this environmental assessment is that there will be no significant impact to the public from this action. However, the general public should note that the NRC welcomes public participation. Comments on any aspect of the Environmental Assessment may be submitted to the NRC by the following methods: (1) Mail comments to Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff; (2) e-mail comments to *Rulemaking.Comments@nrc.gov;* (3) hand deliver comments to 11555 Rockville Pike, Rockville, MD 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays (telephone 301–415–1677); or (4) fax comments to Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.

The NRC has sent a copy of the Environmental Assessment and this proposed rule to every State Liaison Officer and requested their comments on the Environmental Assessment. The Environmental Assessment may be examined at the NRC's PDR, O–1F21, 11555 Rockville Pike, Rockville, MD 20852. The environmental assessment is available electronically under ADAMS Accession Number ML102380248.

X. Paperwork Reduction Act Statement

This proposed 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*). This rule has been submitted to the Office of Management and Budget (OMB) for approval of the information collection requirements.

Type of submission, new or revision: Revision.

The title of the information collection: 10 CFR part 40—Integrated Safety Analysis, Proposed Rule.

The form number if applicable: N/A.

How often the collection is required: One hour, 24 hours, 60 days and annually.

Who will be required or asked to report: Licensees Authorized to Possess 2000 Kilograms (4400 lb) or More of Uranium Hexafluoride.

An estimate of the number of annual responses: 7.4.

The estimated number of annual respondents: 1.

An estimate of the total number of hours needed annually to complete the requirement or request: 295.

Abstract: The NRC is proposing to amend its regulations to amend 10 CFR part 40 to require current licensees and future applicants who are authorized to possess 2000 kilograms or more of uranium hexafluoride to perform an ISA. The proposed amendments would require licensees to submit several one-time reports including a plan of action and an ISA summary. Annual reporting

requirements would be reduced by this proposed rulemaking by allowing the licensees to amend aspects of their licenses through the ISA process without a formal amendment request to the NRC. Record keeping burden would be increased by the requirement to perform an ISA and document changes to it as well as records of training and other necessary actions. Event reporting under this proposed rule would require licensees to report at 1 hour, 24 hours, and 60 day intervals. The information included in the applications, reports and records required by the proposed rule would be mandatory and would be reviewed by the NRC staff to assess the adequacy of the applicant's or licensee's physical plant, equipment, organization, training, experience, procedures and plans for protection of public health and safety.

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the estimate of burden accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

The public may examine and have copied, for a fee, publicly available documents, including the draft supporting statement, at the NRC's PDR, One White Flint North, 11555 Rockville Pike, Room O–1 F21, Rockville, Maryland 20852. The OMB clearance package and rule are available at the NRC's Web site, *http://www.nrc.gov/public-involve/doc-comment/omb/index.html,* for 60 days after the signature date of this notice.

Send comments on any aspect of these proposed regulations related to information collections, including suggestions for reducing the burden and on the issues previously discussed in this section, by June 16, 2011 to the Records and FOIA/Privacy Services Branch (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by Internet electronic mail to *Infocollects.Resources@NRC.gov* and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–10202 3150–0020, Office of Management and Budget, Washington, DC 20503. Comments on the proposed information collections may also be submitted via the Federal rulemaking Web site, *http://www.regulations.gov,* Docket ID NRC–2009–0079. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

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 draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission.

The Commission requests public comment on the draft regulatory analysis. Comments on the draft regulatory analysis may be submitted to the NRC by the following methods: (1) Mail comments to Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff; (2) e-mail comments to *Rulemaking.Comments@nrc.gov;* (3) hand deliver comments to 11555 Rockville Pike, Rockville, MD 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays (telephone 301–415–1677); or (4) fax comments to Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.

The analysis is available for inspection in the NRC's PDR, One White Flint North, 11555 Rockville Pike, Room O–1 F21, Rockville, Maryland 20852. The draft regulatory analysis is available electronically under ADAMS Accession Number ML102380248.

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 proposed rule. Title 10 of the CFR part 40 does not contain a backfit requirement. Therefore, a backfit analysis is not required.

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. 553; the NRC is proposing to adopt 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: Secs. 62, 63, 64, 65, 81, 161, 182, 183, 186, 68 Stat. 932, 933, 935, 948, 953, 954, 955, as amended, secs. 11e(2), 83, 84, Pub. L. 95–604, 92 Stat. 3033, as amended, 3039, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2232, 2233, 2236, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688 (42 U.S.C. 2021); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 275, 92 Stat. 3021, as amended by Pub. L. 97–415, 96 Stat. 2067 (42 U.S.C. 2022); sec. 193, 104 Stat. 2835, as amended by Pub. L. 104–134, 110 Stat. 1321, 1321–349 (42 U.S.C. 2243); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109–59, 119 Stat. 594 (2005).

Section 40.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851). Section 40.31(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 40.46 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 40.71 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

Subpart A—General Provisions

2. The undesignated subject heading that precedes § 40.1 is designated as "Subpart A–General Provisions".

3. A new § 40.3a is added to read as follows:

§ 40.3a Denial of licensing by Agreement States.

After [insert effective date of final rule], Agreement States may not issue new licenses covering the possession of 2000 kilograms (4400 lb) or more of uranium hexafluoride.

4. In § 40.4, 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* are added 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. 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.

* * * * *

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.

5. In § 40.8, paragraph (b) is revised 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.

* * * * *

Subpart B—General Licenses

6. The undesignated subject heading that precedes § 40.20 is designated as "Subpart B—General Licenses".

7. In § 40.26, paragraph (c)(1) is revised 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

* * * * *

Subpart C—License Applications

8. The undesignated subject heading that precedes § 40.31 is designated as "Subpart C—License Applications".

Subpart D—Licenses

9. The undesignated subject heading that precedes § 40.41 is designated as "Subpart D—Licenses".

Subpart E—Transfer of Source Material

10. The undesignated subject heading that precedes § 40.51 is designated as "Subpart E—Transfer of Source Material".

Subpart F—Records, Reports, and Inspections

11. The undesignated subject heading that precedes § 40.60 is designated as "Subpart F—Records, Reports, and Inspections".

Subpart G—Modification and Revocation of Licenses

12. The undesignated subject heading that precedes § 40.71 is designated as "Subpart G—Modification and Revocation of Licenses".

Subpart I—Enforcement

§ 40.81 and 40.82 [Redesignated as §§ 40.101 and 40.102].

13. Sections 40.81 and 40.82 are redesignated as §§ 40.101 and 40.102, respectively.

14. The undesignated subject heading that precedes the newly designated § 40.101 is designated as "Subpart I—Enforcement".

15. In the newly redesignated § 40.102, paragraph (b) is revised to read as follows:

§ 40.102 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.

16. A new subpart H is added after § 40.71 to read as follows:

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

Sec.

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 the effective date of this regulation].

§ 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), (c), and (d) of this section.

(b) The risk of each credible high-consequence event must be limited. Engineered controls, administrative controls, or both, subject to § 40.83(b)(1), must be applied to the extent needed to reduce the likelihood of occurrence of the event so that, upon implementation of such controls, the event is highly unlikely or its consequences are less severe than those in paragraphs (b)(1) through (b)(4) of this section. 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), (c), or (d) 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 ongoing 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 risk due to licensed material or hazardous chemicals produced from licensed material;

(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 effective date of final rule] shall, with regard to existing licensed activities:

(i) 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.

(ii) Complete an integrated safety analysis within [insert date 18 months after effective date of final rule], 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 18 months after effective date of final rule], 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 3 years after effective date of final rule]. 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 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) In any evaluation submitted under § 40.31(j)(1)(i), licensees and applicants must also show that, in the event of a release, an acute chemical exposure from licensed material or hazardous chemicals produced from licensed materials would not result in irreversible or mild transient health effects to a member of the public offsite. If such an evaluation is not submitted, licensees and applicants must submit an emergency plan pursuant to § 40.31(j)(3).

(c) 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), (c) and (d) are satisfied, based on the information in the integrated safety analysis summary, together with other information submitted to the NRC or available to the NRC at the licensee's site.

§ 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 effective date of final rule]. 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) *One-hour reports.* 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

17. The authority citation for part 150 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended, sec. 274, 73 Stat. 688 (42 U.S.C. 2201, 2021); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109–58, 119 Stat. 594 (2005).

Sections 150.3, 150.15, 150.15a, 150.31, 150.32 also issued under secs. 11e(2), 81, 68 Stat. 923, 935, as amended, secs. 83, 84, 92 Stat. 3033, 3039 (42 U.S.C. 2014e(2), 2111, 2113, 2114). Section 150.14 also issued under sec. 53, 68 Stat. 930, as amended (42 U.S.C. 2073).

Section 150.15 also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 150.17a also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 150.30 also issued under sec. 234, 83 Stat. 444 (42 U.S.C. 2282).

18. In § 150.15, paragraph (a)(10) is added to read as follows:

§ 150.15 Persons not exempt.

(a) * * *

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

* * * * *

Dated at Rockville, Maryland, this 6th day of May 2011.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2011–11927 Filed 5–16–11; 8:45 am]

BILLING CODE 7590–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 349

RIN 3064–AD81

Retail Foreign Exchange Transactions

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of proposed rulemaking.

SUMMARY: The FDIC is proposing regulations that would impose requirements for foreign currency futures, options on futures, and options that an insured depository institution supervised by the Federal Deposit Insurance Corporation engages in with retail customers. Pursuant to section 742(c) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, such transactions will be prohibited as of July 16, 2011, in the absence of the proposed requirements. The proposed regulations would also impose requirements on other foreign currency transactions that are functionally or economically similar to futures, options on futures, or options. These similar transactions include so-called "rolling spot" transactions that an individual enters into with a foreign currency dealer, usually through the Internet or other electronic platform, to transact in foreign currency. The regulations would not apply to traditional foreign currency forwards or spot transactions that a depository institution engages in with business customers to hedge foreign exchange risk.

DATES: Comments must be received by June 16, 2011.

ADDRESSES: You may submit comments by any of the following methods:

- *Agency Web Site: http:www.fdic.gov/regulations/laws/federal/propose.html.* Follow instructions for submitting comments on the Agency Web Site.
- *E-mail: Comments@FDIC.gov.* Include "Retail Foreign Exchange Transactions" in the subject line of the message.
- *Mail:* Robert E. Feldman, Executive Secretary, Attention: Comments, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.
- *Hand Delivery/Courier:* Guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7 a.m. and 5 p.m. (EDT).
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Public Inspection:* All comments received will be posted without change to *http://www.fdic.gov/regulations/laws/federal* including any personal information provided. Paper copies of public comments may be ordered from the Public Information Center by telephone at (877) 275–3342 or (703) 562–2200.

FOR FURTHER INFORMATION CONTACT: Nancy W. Hunt, Associate Director, (202) 898–6643, Bobby R. Bean, Chief,