# 10 CFR PART 40

# INTEGRATED SAFETY ANALYSIS (ISA) FINAL RULE

# REGULATORY ANALYSIS

April 2012

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# REGULATORY ANALYSIS

## 1.0 Introduction

The U.S. Nuclear Regulatory Commission (NRC or the Commission) is amending Title 10 of the *Code of Federal Regulations* (10 CFR) Part 40, "Domestic Licensing of Source Material," to obtain increased confidence in the margin of safety at 10 CFR Part 40 fuel cycle facilities authorized to possess significant quantities of uranium hexafluoride (UF6). The Commission believes that this objective can be best accomplished through a risk-informed, performance-based regulatory structure that includes: (1) the identification of appropriate risk criteria and the level of protection needed to prevent or mitigate accidents that exceed such criteria; (2) the performance of a comprehensive, structured, integrated safety analysis (ISA), to identify potential accidents at the facility and the items relied on for safety (IROFS); and (3) the implementation of measures to ensure that the IROFS are available and reliable when needed.

The scope of the final rule is limited to applicants or licensees who are authorized to possess, or plan to possess, 2000 kilograms (kg) or more of UF6.

The purpose of this Regulatory Analysis is to help ensure that:

- Appropriate alternatives to regulatory objectives are identified and analyzed.
- No clearly preferable alternative is available to the this action.
- The direct and any indirect costs of implementation are justified by its effect on overall protection of the public health and safety.

## 2.0 Statement of the Problem

Health and safety risks at 10 CFR Part 40 fuel cycle facilities authorized to possess significant quantities of UF6 are due to a combination of radiological and chemical hazards. 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, hydrogen fluoride (HF), generated at 10 CFR Part 40 fuel cycle facilities, has a significant potential for onsite and offsite consequences. The HF is a highly reactive and corrosive chemical that presents a substantial inhalation and skin absorption hazard to both workers and the public.

The current 10 CFR Part 40 does not provide structured risk-informed 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."

With respect to regulating facilities authorized to possess 2000 kg or more of UF6, there are a number of weaknesses with the current 10 CFR Part 40. It does not:

- Contain baseline design criteria and performance objectives. Unlike 10 CFR Part 70, which regulates fuel cycle facilities, 10 CFR Part 40 contains no baseline design criteria.

- Provide a risk informed approach to safety.

- Address which facility changes require a license amendment; does not require management review or audits of changes of procedures and methods; and does not require management measures, or otherwise include elements of quality assurance.

## 3.0. Objectives

The primary objective is to improve the current safety regulations in 10 CFR Part 40 in order to regulate licensees who are authorized to possess 2000 kg or more of UF6, without undue burden, in an efficient, fair, and effective way, and in a manner that provides the NRC with appropriate confidence in the margin of safety at these facilities. Additionally, the NRC will regulate all source material at facilities which are authorized to possess 2000 kg or more of UF6. Agreement States will retain authority to regulate byproduct material as defined in 10 CFR 150.3 (e.g., gauges, sealed sources, and laboratory materials) at such facilities.

## 4.0. Background

On January 4, 1986, a worker lost his life during an accidental release of UF6 at a facility regulated under 10 CFR Part 40. A congressional inquiry into this accident criticized the NRC's oversight of chemical hazards at NRC-regulated facilities. As a result of this accident, the NRC established an independent group, the Materials Safety Regulation Study Group (MSRSG), to evaluate regulatory practices at all fuel cycle facilities, including those regulated under 10 CFR Parts 40 and 70. The MSRSG concluded that there was a regulatory implementation gap regarding hazardous chemicals produced from licensed materials at NRC-regulated facilities.

As a result of the UF6 release and the MSRSG conclusions, an interagency Memorandum of Understanding (MOU) between NRC and the Occupational Safety and Health Administration was issued on October 31, 1988 (53 FR 43950). This MOU clarified NRC responsibility for chemical hazards resulting from the processing of licensed radioactive materials. Although a branch technical position on chemical safety was published in 1989 (54 FR 11590), regulation of chemical hazards associated with the processing of licensed material has not been incorporated specifically into the licensing requirements of 10 CFR Part 40. The same is true of branch technical positions on fire safety, management controls, and requirements for operation.

After a near-criticality incident on May 29, 1991, the NRC formed a Materials Regulatory Review Task Force to identify and clarify regulatory issues that needed correction. The Task Force published NUREG-1324, "Proposed Method for Regulating Major Materials Licensees," which identified a number of weaknesses in the regulation of fuel cycle facility licensees in such areas as quality assurance, maintenance, training and qualification, management controls and oversight, configuration management, chemical and criticality safety, and fire protection.

To determine whether the above weaknesses are still a problem, the NRC reviewed the causes of a number of what it considers serious incidents and precursor events at fuel cycle facilities reported between 1992 and 2009. Serious incidents are those involving harm or serious risk of

harm to persons, while precursors are events which place a facility at increased risk of a serious incident. For purposes of this analysis, the NRC did not examine incidents involving only criticality risk concerns. Serious incidents examined included:

a) September 1992: Fire and explosion of 1700 grams of highly enriched uranium contained in dissolver tray.
b) November 1992: Toxic nitrogen oxides released onsite and offsite due to improper addition of process chemicals to licensed material.
c) 1992: Uranium contamination at facility due to a chemical explosion and fire.
d) October 1992: Improper uranium solution sent to unsafe-geometry vaporization chest.
e) February 1993: Large spill of uranium dioxide powder due to unauthorized disabling of automatic limit switches that had not been adequately identified as safety-related component.
f) May 1993: Poor process control and quality assurance leading to obtaining a non-representative sample of uranium dioxide for process measurement step.
g) October 1993: Alert declared due to rooftop fire on plutonium building because of inadequate process controls.
h) January 1994: Alert declared due to ten-minute release of UF6 gas.
i) September 1994: Spill of 188 kilograms of enriched uranium dioxide powder.
j) April 1996: Site area emergency declared due to fire in process ventilation exhaust duct system.
k) August 1996: Exothermic chemical reaction involving enriched uranium leading to fire caused by mixing of chemicals in a uranium recovery operation without appropriate attention to chemical hazards.
l) August 1996: Operations in one process suspended due to flame in high level dissolver tray while dissolving poorly characterized uranium-beryllium material.
m) September 1996: Second instance of a fire at the same facility in local ventilation duct system because of apparent improper change control.
n) October 1996: Large spill of material in a licensee's uranium recovery area.
o) September 1997: Release of radioactive material from stack at levels higher than internal plant action limits, due to inadequate valving arrangement and procedure for kiln startup.
p) August 2001: UF6 release caused hydrofluoric acid burns to onsite workers.
q) December 2003: UF6 release resulted in a site area emergency and evacuation of members of the public in the surrounding area. Four members of the public reported to local hospital for treatment.
r) July 2005: Onsite uranium airborne contamination of building due to filter failure in the vacuum system.
s) March 2009: Onsite uranium airborne contamination caused four individuals to receive acute internal exposures.

These events demonstrated systemic program deficiencies at fuel cycle facilities. These deficiencies are neither rare nor isolated in the industry.

As previously stated, the purpose of the rulemaking is to establish a risk-informed framework for regulating licensees who are authorized to possess 2000 kg or more of UF6 that provides the NRC with increased confidence in the margin of safety. The intent is to establish requirements that strengthen regulatory oversight while minimizing the accompanying regulatory burden.

## 5.0 Alternatives

The alternatives considered are:

- Option 1 -- no action;
- Option 2 -- the final rule and supporting guidance; and
- Option 3 -- a quantitative probabilistic risk analyses (PRA) type requirement.

These alternatives are described more fully in the following paragraphs.

## 5.1 Option 1 Description

The existing regulations in 10 CFR Part 40 do not require establishment of a safety program based on performance of an ISA. There are several requirements in the current 10 CFR Part 40 that specifically address public health and safety. Section 40.32, "General requirements for issuance of specific licenses," requires, among other things, a determination that the applicant's proposed equipment, facilities, and procedures are adequate to protect health and minimize danger to life or property. However, the descriptions are not necessarily comprehensive. In addition, the existing 10 CFR Part 40 does not explicitly require analysis for potential accidents involving source material or the release of hazardous chemicals produced from licensed materials to members of the public. It also does not require the identification of IROFS, and does not address chemical and fire hazards that can result in a release of licensed material.

Under the *status quo* no-action alternative, the NRC would have retained the current 10 CFR Part 40 as it is. The one 10 CFR Part 40 licensee currently required by its license to perform an ISA would have remained subject to its license requirements in this regard. In addition, per the Commission's direction in Staff Requirements Memorandum (SRM)-M070308B, dated March 22, 2007 (ADAMS Accession No. ML070820023), new applicants would continue to be required to meet the performance requirements in 10 CFR Part 70, Subpart H, as part of the licensing basis for the application review. Thus, this option is not entirely no-action. Although no rulemaking would have been pursued, the ISA requirements in 10 CFR Part 70 would have still been used for new facilities which possess significant quantities of UF6 under this alternative in accordance with SRM-M070308B.

## 5.2 Option 2 Description

Option 2 is the NRC's modification of 10 CFR Part 40 which adds a new subpart as described in the final rule. This new subpart includes requirements aimed at increasing the NRC's confidence in the margin of safety at licensed facilities authorized to possess 2000 kg or more of UF6. Option 2 is a risk-informed, performance-based regulatory approach that includes: (1) the identification of appropriate performance criteria; (2) the performance of an ISA to identify potential accidents at the facility and the level of protection needed to prevent or mitigate accidents that exceed such criteria; and (3) the implementation of management measures to ensure that the IROFS are available and reliable when needed. In addition, in order to ensure confidence in the margin of safety, a licensee is required to maintain its safety basis by using its

ISA to evaluate changes and periodically update its ISA. Also, the ISA summary is docketed and revisions to the ISA summary are required to be provided to the NRC.

In brief, revisions to 10 CFR Part 40 include the following major elements:

a) Performance of a formal ISA, which forms the basis for a facility's safety program. This requirement applies to the subset of Part 40 licensees authorized to possess 2000 kg or more of UF6.

b) Establishment of limits to identify the adverse consequences against which licensees must protect.

c) Inclusion of the safety basis, as reflected in the ISA summary, with the license application (i.e., the identification of the potential accidents, the items relied on for safety (IROFS) to prevent or mitigate these accidents, and the measures needed to ensure the availability and reliability of these items when needed).

d) Ability of licensees, based on the results of an ISA, to make certain changes without NRC pre-approval.

e) Modification of Agreement State licenses covering 2000 kg or more of UF6 to exclude the licensing of source material. Note: Facilities which possess this threshold of UF6 and which also process special nuclear material in quantities sufficient to form a critical mass are already subject to the performance requirements in 10 CFR Part 70, Subpart H which provides the basis for this rulemaking.

Also included in Option 2 are new reporting requirements, which are based on consideration of the consequences or risk involved, and are intended to supplement the § 40.60 reporting requirements and those in 10 CFR Part 20.

A supporting guidance document, NUREG-1962, “Guidance on the Implementation of Integrated Safety Analysis Requirements for 10 CFR Part 40 Facilities Authorized to Possess 2,000 Kilograms or More of Uranium Hexafluoride” (ADAMS Accession No. ML120950304), has been developed for the final rule, and is available in conjunction with this rulemaking. The guidance pertains to the review and evaluation of license applications, renewals, and amendments. The guidance document describe ways of complying with the revised 10 CFR Part 40 requirements that are acceptable to the NRC, and may be used by applicants who need to determine what information should be presented in an application.

### 5.3 Option 3 Description

Option 3 requires significant effort by the NRC to develop guidance for use by licensees in developing reliability data, including failure rates and modeling of the risk of their unique facilities. Licensees would have been required to perform the ISA using quantitative risk analyses methodology (e.g., PRAs).

## 6.0 Value-Impact Analysis

This section of the Regulatory Analysis discusses the benefits and costs of each action alternative relative to the baseline. Ideally, all costs and benefits would be converted into monetary values. The total of benefits and costs would then be algebraically summed to determine for which alternative the difference between the values and impacts was greatest. However, for this rulemaking, the assignment of monetary values to benefits is not attempted because the staff believes that, for the following reasons, meaningful quantification is not possible:

- There are difficulties in translating the principal health and safety benefit of this rule (increased confidence in the margins of safety) into an estimate of risk reduction.

- Available estimates of the likelihood and consequences of an accident at 10 CFR Part 40 facilities affected by this rulemaking are subject to large uncertainties.

While better estimates may be available from ISAs being performed by fuel cycle facilities licensed under 10 CFR Part 70, non-quantifiable attributes will remain the primary benefits. Subjective judgment still was used to determine which of the alternatives best solves the problems identified in section 2 of this Regulatory Analysis. Thus, in section 6.1 we discuss the benefits of each alternative in a qualitative manner only. In section 6.2 we present estimates of the cost to licensees and to the NRC for implementing each alternative.

The NRC, in the final rule, is reserving licensing authority over all source material at facilities located in Agreement States that are authorized to possess 2000 kg or more of UF6. Licensees of such facilities will either 1) have to obtain an NRC Part 40 license; or 2) obtain an amendment of their State license to reduce their UF6 possession limits to below the 2000 kg UF6 threshold. Agreement States retain their licensing authority to regulate byproduct material.

The NRC will coordinate with the Agreement States regarding any of their facilities that possess 2000 kg or more of UF6, to ensure that all NRC and State licenses are properly revised. The NRC final rule does not apply to facilities located in Agreement States that are undergoing decommissioning. In most cases, licensees in Agreement States that are authorized to possess 2000 kg or more of UF6 do not actually possess this amount of source material. In these cases, the necessary license amendments are expected to be administrative in nature.

Based on Agreement State responses to FSME-10-049, “Request to Provide Information on Source Material Licensees that Authorize Possession of Uranium Hexafluoride Source Material or Uranium in any Form” (ADAMS Accession No. ML101680656), dated June 21, 2010, the estimated cost to Agreement States to implement this rulemaking is minimal. Therefore, Agreement State costs were not quantified in this regulatory analysis.

## 6.1 Benefits

### 6.1.1 Increased Confidence in the Margin of Safety

A comprehensive and systematic hazards analysis, as part of an ISA, together with corrective actions and associated licensee commitments to maintain the IROFS, are key elements for increasing the NRC's confidence in the margin of safety at 10 CFR Part 40 facilities affected by this rulemaking. Safety analyses that consider chemical, fire, and radiation safety separately, as opposed to in an integrated manner, can result in measures that enhance safety in one area but degrade it in another. As an example, water may not be an acceptable fire-suppression medium in an area that is utilizing UF6 since water plus UF6 yields hydrogen fluoride, a poisonous gas. The performance of ISAs will significantly improve licensee and NRC knowledge, regarding potential accidents and the IROFS to prevent or mitigate the consequences of these accidents. Only Options 2 and 3 ensure that: (a) ISAs will be performed by all affected licensees and future applicants in an acceptable manner; (b) IROFS will be identified and reviewed; (c) those items will be reliable and available when needed; and (d) future changes will not significantly decrease safety at the facilities without NRC review.

Options 2 and 3 correct the weaknesses identified with the current 10 CFR Part 40 (see section 2 of this Regulatory Analysis). The new § 40.81 provides explicit safety performance requirements and § 40.83 provides baseline design criteria for new facilities, or new processes at existing facilities. These ISA requirements will limit the risk of credible high-consequence and intermediate-consequence events. Section 40.86 clarifies what changes the licensee may make without submitting an amendment application and ensures that all changes, whether or not an amendment is required, are subjected by the licensee to an appropriate safety review. The rule requires a safety program that includes management measures, such as configuration management and quality assurance. It also requires personnel to be trained to ensure they understand the safety features that are relied on to prevent accidents. The required ISA will have to address chemical and fire hazards that affect radiological hazards, as well as direct radiological hazards.

In addition, Options 2 and 3 reduce the complexity of license renewal reviews because the ISA and ISA summary are updated annually to reflect any facility changes made during the previous year. These annual updates facilitate license renewal reviews, as compared to such reviews performed under Option 1. Any changes to the safety basis documentation would be handled by a structured change control process.

The PRA approach (Option 3) could have provided additional numerical values associated with the likelihood of accident sequences and could have provided a basis for more refined grading of protection, if the data were available to allow the quantitative approach without excessive uncertainty bounds. In addition, the availability of PRAs could have enabled the NRC to quantify the benefits of proposed changes to facility requirements. However, on balance, the NRC believes that Option 3 would have provided only a small incremental benefit compared with Option 2, and Option 3 would have been negatively impacted by the unavailability of reliability data including failure rates for the unique facilities subject to the rule.

### 6.1.2 Reduction in Frequency and Severity of Accidents

The processing of uranium at 10 CFR Part 40 fuel cycle facilities licensed to possess 2000 kg or more of UF6 could result in a number of potential accidents with varying consequences. These accidents could include public or worker intake of uranium: public or worker exposure to radiation; and public or worker exposure to hazardous chemicals that are produced from licensed material.

#### 6.1.2.1 Onsite Consequences

As discussed in section 4 above, a worker was killed by a hydrogen fluoride vapor cloud resulting from the release of UF6 at Sequoyah Fuels in 1986. By contrast, there have been no deaths, due to licensed radioactive material usages, from accidents at U.S. licensed reactors.

Options 1, 2, and 3 have the potential to prevent and mitigate the consequences and reduce the likelihood of accidents through the correction of any vulnerabilities discovered by licensees in their performance of ISAs. To the extent that they enhance plant personnel awareness of their plant's safety features and measures relied on to ensure the continuous reliability and availability of those features, these options have the additional potential to reduce the likelihood of accidents.

Options 2 and 3 are expected to be more effective than Option 1 in reducing the consequences and likelihood of accidents because they apply generic requirements uniformly to all current and future licensees who possess 2000 kg or more of UF6. License conditions and orders requiring an ISA could vary between licensees.

#### 6.1.2.2 Offsite Consequences

Accidents at licensed fuel cycle facilities have resulted in offsite releases of uranium compounds and hazardous chemicals produced from licensed materials which have resulted in contamination of offsite property. The 1986 Sequoyah accident resulted in significant government and licensee effort to track, measure, and account for the material released. The types of accidents that could have the most harm to offsite populations are a release of UF6 to the atmosphere or accidents sending toxic chemicals through the ventilation stacks. As in the case of onsite accidents, Options 2 and 3 offer the greatest potential for reducing the likelihood of accidents having significant offsite consequences. Only Options 2 and 3 provide the offsite consequence criteria against which to judge the adequacy of protection.

### 6.1.3 Reduction in Frequency of Incidents

There are several incidents annually of safety significance at facilities handling 2000 kg or more of UF6. Reporting, investigating, and resolving these incidents cause both licensee and NRC resource expenditures. Reporting has value because it provides the NRC with information needed to perform and focus its oversight responsibilities. Reporting also requires a licensee to consider what went wrong and what steps might be needed to prevent a recurrence of the safety degradation. The net result should be a trend towards fewer incidents and fewer required reports. Under Option 1, reports specific to ISA-related events are not mandated, and the NRC's confidence in the margin of safety would not increase.

Options 2 and 3 expand the reporting required by the current 10 CFR Part 40 to include reporting loss of safety controls. The reporting requirements in these options have been written with consideration of risks associated with the full range of incidents of concern, but the requirements minimize the burden on the licensees by not requiring reports of inconsequential or low-risk incidents. Options 2 and 3 increases NRC confidence in the margin of safety. They should also lead to a reduction in accident precursor incidents due to the requirement to perform ISAs, maintain them and use them to evaluate changes.

## 6.2 Cost Impacts

This section presents the incremental costs of transition from the baseline (Option 1) to the final rule (Option 2) and from Option 2 to the PRA option (Option 3). Details on supporting cost assumptions are discussed in Appendix A.

Existing licenses for facilities within the scope of the final rule (Option 2) contain license conditions that require the performance of an ISA, although not necessarily to the standards that would be established by the final rule. To a varying degree, some of the other provisions of the final rule are required by license condition in existing licenses. These were considered in estimating the cost of Option 2. Licensees under 10 CFR Part 70 whose facilities are within the scope of this 10 CFR Part 40 rulemaking already have met the ISA performance standards in 10 CFR Part 70, Subpart H. This rulemaking will therefore have minimal additional cost impacts on such licensees, and these costs were accordingly not included in estimating the cost in Option 2.

The details of the estimated costs are provided below and in the appendix. A comparison of licensee's total estimated cost is shown in Table A5. Compared to Option 1 (no action), the additional annualized estimated cost (total cost to implement divided by the 40 year license term) to implement Option 2 is $204,175 (Option 2 minus Option 1) and to implement Option 3 is $276,925 (Option 3 minus Option 1).

### 6.2.1 Option 1 Costs

#### 6.2.1.1 Option 1 Licensee Cost Impacts

*Licensee Implementation Costs of Option 1*

The 10 CFR Part 40 licensee who is already required by its license conditions to perform an ISA is estimated to have total annualized costs of $150,825 over an assumed 40 year license term (see Table A5).

*Licensee Annual Recurring Costs of Option 1*

For a licensee with appropriate conditions in its license, the annual operational (recurring) costs of Option 1 include the costs associated with maintaining management measures for ensuring reliability and availability of IROFS identified by the ISA. Licensees also experience recurring costs from maintaining their ISA up to date and submitting required annual updates of the ISA summary to the NRC. In total, these recurring costs are estimated to be $145,900 per licensee per year (see Table A2) to perform periodic ISA updates.

#### 6.2.1.2 Option 1 NRC Cost Impacts

*NRC Option 1 Implementation Costs*

Under Option 1, the NRC would not incur any additional implementation cost. As shown in Table A3, it is estimated that the NRC's total implementation cost was $50,000 for the one uranium conversion facility that performs a limited ISA in accordance with license conditions.

*NRC Option 1 Annual Recurring Costs*

The NRC would not incur any additional annual recurring cost under Option 1. As shown in Table A4, it is estimated that the NRC's annual recurring cost is $50,000 per year for the one uranium conversion facility that performs a limited ISA in accordance with license conditions.

### 6.2.2 Option 2 Costs

#### 6.2.2.1 Option 2 Licensee Cost Impacts

*Licensee Requirements of Option 2 vs Option 1*

Option 2 included developing and documenting an ISA similar to current 10 CFR Part 70 requirements, including the identification of IROFS and management measures to ensure their availability and reliability. Only one NRC licensee is cost-impacted by having to upgrade its existing analyses to meet the standards required by Option 2.

For this facility, the current requirements implemented by license conditions are considerably less than the requirements of an ISA under Option 2. Changes in the current safety analysis will be significant. Required actions are listed in Table A1.

Table A2 indicates the estimates of the annual recurring costs for maintaining an ISA in compliance with the Option 2 requirements. The judgments of the relative effort needed to achieve compliance are based on NRC fuel cycle licensing staff comparisons of existing license conditions with the requirements of the final rule.

*Licensee Implementation Costs of Option 2 vs Option 1*

Implementation costs for the one existing licensee to transition from Option 1 to Option 2 include upgrading the ISA to Option 2 standards (e.g., to review the ISA and update it where necessary based on the consequences of concern and other rule provisions). This additional cost to upgrade the ISA from Option 1 to Option 2 (Table A1) is estimated to be $1,923,0000 (i.e., $2,120,000 minus $197,000), which on an annualized basis is $48,075 (i.e., $53,000 minus $4,925). Costs for developing an ISA for any new applicants after the rule is in effect will be approximately equal to the Option 2 estimated total cost in Table A1.

*Licensee Annual Cost of Option 2 vs Option 1*

Once these measures are implemented, the licensees will incur annual recurring costs for maintenance and annual updates associated with changes to systems and processes. These costs include updates to ISAs to reflect changes to systems and processes, and recurring costs

associated with additional personnel training, maintenance measures, inspection activities, maintaining design basis information, and similar ongoing activities. In addition, Option 2 includes strengthening the event reporting requirements for affected licensees.

This additional annual recurring costs for licensees performing ISAs under Option 2 (Table 2), as compared to license conditions (Option 1) is estimated to be $156,100 (i.e., $302,000 minus $145,900).

#### 6.2.2.2 Option 2 NRC Cost Impacts

*NRC Option 2 Implementation Costs*

The NRC's implementation activities under Option 2 include updating NUREG-1520, "Standard Review Plan (SRP) for the Review of a License Application for a Fuel Cycle Facility" and any other existing guidance as appropriate, developing new guidance (NUREG-1962), initial evaluations of ISA summaries, and other related activities (see Table A3). Implementation total costs for the NRC's activities under Option 2 compared to Option1 (Table A3) is estimated to be $475,000 (i.e., $525,000 minus $50,000).

*NRC Option 2 Annual Recurring Costs*

Annual recurring NRC activities listed in Option 2 are similar to those in Option 1 but with a reduced overall cost. This cost savings is related to the ISA performance requirements allowing the licensees to make some facility changes without first having to submit a license amendment request, and having the request approved by the NRC. The NRC's annual cost savings is estimated (see table A4) to be approximately $12,500 (i.e., $50,000 minus $37,500).

### 6.2.3 Option 3 Costs

#### 6.2.3.1 Option 3 Licensee Cost Impacts

*Requirements of Option 3 vs Option 1*

Option 3 is identical to Option 2 except that it would require PRA methodology to be used for performance of ISAs. In Option 2, PRA methodology is an option that licensees *may elect* to use for the performance of ISAs, but are not required to use. Option 3 is estimated to have many of the same implementation costs as Option 2, but to be considerably more costly than Option 2 because of the PRA requirement to quantify the numerical risk level to workers and the public (see cost estimates in Tables A1 and A2).

In addition, component or "basic-element" reliability data do not appear to be currently available to perform quantitative ISAs on 10 CFR Part 40 fuel cycle facilities authorized to possess significant quantities of UF6. Fuel cycle facilities employ unique equipment for which failure data may not have been kept. In addition to mechanical failures, many activities at fuel cycle facilities have considerable human interaction, the failure of which, considering both acts of commission and acts of omission, is difficult to model quantitatively. Also, because of the competitive nature of the fuel cycle industry, there is no shared reliability database as there is

for the nuclear power industry. Accordingly, the reliability data needed to perform a quantitative PRA would be difficult and expensive to assemble and evaluate.

*Implementation Costs of Option 3 vs Option 1*

Based on the assumptions discussed in Table A1, the cost increase for implementation of Option 3 compared to Option 1 is $3,033,000 (i.e., $3,230,000 minus $197,000).

*Annual Recurring Costs of Option 3 vs Option 1*

Option 3 has similar annual recurring costs as Option 2, but also additional costs, both because of the requirement to use quantitative ISAs (PRAs) to evaluate changes to facilities and processes and because of the continued need to collect and update reliability data. Based on the assumptions discussed in Table A2, the cost increase for implementation of Option 3 compared to Option 1 is $201,100 (i.e., $347,000 minus $145,900).

#### 6.2.3.2 NRC Cost Impacts

The NRC's total annualized cost for Option 3 would be $11,875 (i.e., $62,500 minus $50,625) higher than Option 2 (see Table 5) because of the cost to develop guidance describing how to collect, maintain, and use the failure rate data.

### 6.2.4 Summary of Cost Impacts

For a licensee to transition from Option 1 to Option 2, the annualized estimate to meet the standards in the rule (Option 2) is $204,175 (i.e., $355,000 minus $150,825 (see Table A5.)

The estimated annualized cost for the NRC to regulate Option 2 is $50,625 (i.e., annualized cost of Option 2 in Table A3 plus the annual total cost for Option 2 in Table A4.)

## 7.0. Decision Rationale

a) Option 1 provides some of the desired improvements related to the confidence in the margin of safety, but in an uneven and incomplete manner. It lacks a satisfactory mechanism for ensuring that changes between license renewals do not result in decreased safety, and hence it prevents the Commission from having continued confidence in the margins of safety. In addition, this option does not satisfactorily address degradation of margins of safety in future license renewals. Option 2 corrects these shortcomings.

b) The distinction between Option 2 and Option 3 is that Option 3 requires licensees to use a PRA methodology to quantify the numerical risk to individuals in performing the ISAs. It is clear however, that this alternative would entail significant additional licensee costs, in comparison to Option 2 (see cost estimates in Tables A1 and A2). The NRC does not consider the benefits of Option 3 to be significantly greater than those of Option 2. Therefore, Option 2 is preferred to Option 3 when the significant additional costs of Option 3 are considered.

c) For the reasons stated in (a) and (b) above, Option 2 is superior to Options 1 (the no-action alternatives) and Option 3.

Based on the above analysis, the NRC believes that the final rule will provide the necessary increase in the confidence in the margin of safety, at affected facilities, in the least costly manner.

## 8.0 Implementation

The action evaluated in this regulatory analysis will be enacted through publication in the *Federal Register* of a Notice of Final Rulemaking.

The NRC staff has developed guidance which will be used by NRC staff for evaluating submittals from applicants and licensees for assurance of adequate safety and compliance with the regulation.

The rule will become effective 30 days after its publication as a Final Rule.

# REGULATORY ANALYSIS – APPENDIX
# COST ASSUMPTIONS

## A1 Basis for Estimating Costs of Performing an ISA

The cost of performing an ISA at a 10 CFR Part 40 fuel cycle facility authorized to possess 2000 kg or more of UF6 was estimated on the basis of the NRC's experience with one 10 CFR Part 40 applicant and eight 10 CFR Part 70 fuel cycle licensees who have implemented ISA requirements since 2000. Although there are differences between the 10 CFR Part 70 fuel cycle facilities that currently conduct ISAs and 10 CFR Part 40 fuel cycle facilities authorized to possess 2000 kg or more of UF6, the similarities in the performance requirements (ISAs) and underlying costs to implement and maintain an ISA (IROFS, training, maintenance, etc.) are sufficient to extract estimates of cost. In addition, the NRC recently reviewed a 10 CFR Part 40 application for a depleted uranium deconversion facility which conducted an ISA under 10 CFR Part 70, consistent with the Commission's direction for new facilities in SRM-SECY-07-0146.

The costs to implement 10 CFR Part 40 ISA and 10 CFR Part 70 ISA requirements are similar. When compared to 10 CFR Part 40 facilities covered by this rulemaking, the 10 CFR Part 70 fuel cycle facilities have additional accident sequences to evaluate due to criticality issues arising from their use of special nuclear material. The 10 CFR Part 40 fuel cycle facilities authorized to possess 2000 kg or more of UF6 do not have criticality issues arising from their use of source material. The level of effort associated with conducting an ISA at a 10 CFR Part 40 facility is thus estimated to be 75 percent of conducting an ISA at a 10 CFR Part 70 facility (due to the absence of criticality hazards at 10 CFR Part 40 facilities).

In developing these estimates the NRC utilized the regulatory analysis dated March 27, 2000, for the final rule that amended 10 CFR Part 70 to add ISA requirements for fuel cycle facilities licensed under 10 CFR Part 70. The numbers taken from this analysis were adjusted for inflation and then further refined based on the NRC's experience with the fuel cycle facilities that have performed ISAs since 2000. The cost estimates reflect in part the NRC's recent experience reviewing a license application for a uranium deconversion facility.

## A2 Estimating Implementation and Annual Costs

Costs for options 1, 2 and 3 were estimated using one time implementation costs and recurring annual operational costs. These costs for the licensee are estimated in Table A1 (implementation costs) and Table A2 (annual costs). The costs for the NRC are estimated in Table A3 (implementation costs) and Table A4 (annual costs). Table A5 represents the addition of the implementation costs, annualized over 40 years, combined with the annual costs for both the licensee and the NRC.

As indicated, cost estimates are annualized over 40 years. The period of 40 years is based on the NRC policy established in 2006 (71 FR 70441), authorizing renewed license terms of up to 40 years for fuel cycle facilities with approved ISA summaries. Similarly, for new fuel cycle facilities with approved ISA summaries, the 2006 policy authorizes an initial license term of up to 40 years.

Implementation Costs:

The costs for implementing the rule involve the onetime costs of developing the ISA. There are costs to both the licensee and to the NRC, which are estimated separately. The implementation costs for the licensee include conducting analyses of accident sequences, identifying IROFS, applying management measures, preparing and submitting the ISA Summary to the NRC, and supporting the NRC's review of the ISA Summary. The implementation costs for the NRC include reviewing the ISA Summary, reviewing the ISA onsite, developing requests for additional information, and documenting the reviews in safety evaluation reports. Detailed estimates of the implementation costs for the licensee and NRC are provided Tables A1 and A3, respectively.

Annual Costs:

Annual costs involve keeping the ISA and ISA Summary up to date and within compliance with the regulations. There are annual costs to both the licensee and to the NRC. The annual costs for the licensee include annual updates to the ISA Summary, establishing and maintaining documentation regarding facility changes, and submitting license amendment requests for changes that impact IROFS. The annual costs for the NRC include reviewing submittals from the applicant such as reports, ISA Summary updates, license amendment requests, and conducting inspections. In the years following the establishment of the 10 CFR Part 70 ISA requirements in 2000, the NRC staff has observed a reduction in the number of license amendment requests for 10 CFR Part 70 facilities which have an ISA, due in part to the flexibility provided by the 10 CFR 70.72 change process. Fewer license amendment requests save both the licensee and the NRC time and money, resulting in an estimated annual cost savings of $30,000. This and other estimates of the annual costs for the licensee/applicant and NRC are provided in tables A2 and A4, respectively.

Costs that are not incurred annually, such as those related to license renewals, are also included in tables A2 and A4. The estimated cost of license renewals was prorated to an annual basis using an assumed 40-year license renewal term, based on the 2006 NRC policy authorizing renewed license terms of up to 40 years for facilities with approved ISA summaries. Under this policy, the number of license renewal requests over a 40-year period is potentially reduced to zero, as reflected in tables A2 and A4. Additionally, the maintenance of ISAs and the requirement to keep licensing basis information current are expected to reduce the effort expended by licensees in preparing license renewal submittals.

## A3 PRA Cost Analysis

As discussed in section 6.2.3 above, it is estimated that implementation of a quantitative ISA based on PRA methodology would be more expensive than an ISA under Option 2 (see cost estimates in Tables A1 and A2). A PRA methodology would require the compilation of statistically significant reliability data including failure rates for safety significant equipment used at the facility. The licensee's compilation of this data would require significant effort and an estimate of the associated costs have been incorporated into Table 2. In addition, the NRC would have extensive costs to develop guidance defining how to collect, use, and maintain the data. Cost for training of personnel and record keeping would be similar with an ISA.

## A4 Cost Summaries

The total annual recurring costs (Table A2) plus the total initial cost annualized for each option (Table A1) are summarized in Table A5.

## A5 Present-worth Calculations

The present-worth calculation (Table A6) is simply determining how much society would need to invest today to ensure that the designated dollar amount is available in a given year in the future. By using present-worth, costs, regardless of when averted in time, are valued equally. Based on Office of Management and Budget (OMB) guidance (OMB Circular No. A-4, September, 17, 2003), present-worth calculations are presented using both 3 percent and 7 percent real discount rates. The 3 percent rate approximates the real rate of return on long-term government debt which serves as a proxy for the real rate of return on savings. This rate is appropriate when the primary effect of the regulation is on private consumption. Alternatively, the 7 percent rate approximates the marginal pretax real rate of return on an average investment in the private sector, and is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector.

In order to make calculations regarding the costs for license renewal, the NRC staff had to estimate a license term for each option. A 10-year license renewal term was assumed for option 1 because under existing 10 CFR Part 40, there are no ISA requirements and the 2006 license renewal policy does not apply. A 40-year license renewal term was assumed for options 2 and 3 because under the 2006 policy, license renewal terms of up to 40 years are authorized on a case by case basis.

| Table A1 - Option Comparison for Licensee's Initial Implementation Costs | | | | |
|---|---|---|---|---|
| ISA Implementation Activity | Costs for ISA license conditions (Option 1) | Cost for ISA requirement (Option 2) | Cost for PRA requirement (Option 3) | Notes |
| Compile and update baseline process safety information (if existing baseline process safety information is out of date). | 0 | 150,000 | 225,000 | |
| Establish or upgrade measures that ensure that IROFS are designed, constructed, inspected, calibrated, tested and maintained as necessary | 10,500 | 105,000 | 157,500 | |
| Establish or upgrade training programs to ensure that personnel are trained, and qualified to perform a safety analysis. | 36,000 | 360,000 | 360,000 | Training cost should be similar under both an ISA and PRA. |
| Establish and maintain configuration control to ensure that changes are reviewed, documented, and adequately communicated to affected staff and parties | 6,000 | 60,000 | 90,000 | |
| Establish or upgrade measures to ensure that IROFS meet quality standards commensurate with their importance, and establish corresponding policies and procedures | 10,500 | 105,000 | 157,500 | |
| Establish and maintain records that demonstrate adherence to new regulatory requirements | 9,000 | 90,000 | 90,000 | Record keeping cost should be similar under both an ISA and PRA. |
| Develop safety analysis methodology | 5,000 | 50,000 | 75,000 | Applicant must determine whether to use qualitative or quantitative methodology and must develop definitions to credible, unlikely, highly unlikely etc. Requires assessing the potential hazards and the types of quantitative information is available on potential hazards. |

| Table A1 - Option Comparison for Licensee's Initial Implementation Costs (Continued) | | | | |
|---|---|---|---|---|
| ISA Implementation Activity | Costs for ISA license conditions (Option 1) | Cost for ISA requirement (Option 2) | Cost for PRA requirement (Option 3) | Notes |
| Conduct analysis on existing/proposed facility to identify accident sequences and assess them against the performance requirements. | 25,000 | 250,000 | 375,000 | The methodology is established to identify the accident sequences throughout the facility. Since a trained and knowledgeable ISA team is involved in identifying and assessing every potential accident sequence at the facility, the NRC estimates significant initial costs. |
| Establish or upgrade IROFS to ensure accident sequences meet performance requirements | 25,000 | 250,000 | 375,000 | Once the accident analyses have been identified, the ISA team must develop IROFS to prevent or mitigate each intermediate or high consequence event. Considerable analysis is required to develop the IROFS and assess the risks before and after the IROFS is applied. |
| Establish or upgrade management measures to apply to IROFS | 25,000 | 250,000 | 375,000 | The regulations require the development of management measures which are applied to IROFS to ensure they remain available and reliable to meet the performance requirements. |
| Development of reliability data including failure rates | 0 | 0 | 500,000 | Costs of collecting dependable reliability data for unique operations |
| Approximate NRC direct billable costs for reviewing the ISA and ISA Summary | 45,000 | 450,000 | 450,000 | Review cost should be similar under both an ISA and PRA. |
| Total Cost | 197,000 | 2,120,000 | 3,230,000 | |
| Annualized Cost | 4,925 | 53,000 | 80,750 | Based on an assumed license term (or renewal term) of 40 years. |

| Table A2 - Option Comparison for Licensee's Annual Recurring Costs | | | | |
|---|---|---|---|---|
| ISA Recurring Activity | Costs for ISA license conditions (Option 1) | Cost for ISA requirement (Option 2) | Cost for PRA requirement (Option 3) | Notes |
| Update and maintain ISA | 2,000 | 10,000 | 15,000 | |
| Maintain design basis documentation | 0 | 5,000 | 7,500 | |
| Personnel training | 10,000 | 55,000 | 55,000 | Training cost should be similar under both an ISA and PRA. |
| Design, construction, inspection, calibration, testing and maintenance, quality assurance | 5,000 | 25,000 | 37,500 | |
| Event reporting | 0 | 10,000 | 15,000 | |
| Quality assurance | 3,600 | 18,000 | 27,000 | |
| Configure management | 4,400 | 22,000 | 33,000 | |
| Record keeping | 8,400 | 42,000 | 42,000 | Record keeping cost should be similar under both an ISA and PRA. |
| Additional staff | 0 | 100,000 | 100,000 | Adding 2 permanent staff to maintain ISA and conduct other activities to support licensee implementation of ISA requirements. |
| Amendments | 45,000 | 15,000 | 15,000 | Reduced number of administrative license amendments. |
| License renewals | 67,500 | 0 | 0 | Reduced number of renewals over a 40-year period due to extended license terms (up to 40 years). |
| Total Cost | 145,900 | 302,000 | 347,000 | |

| Table A3 – Option Comparison for NRC Implementation Costs | | | | |
|---|---|---|---|---|
| Activity | Costs for ISA license conditions (Option 1) | Cost for ISA requirement (Option 2) | Cost for PRA requirement (Option 3) | Notes |
| Guidance documents update and refinements | 0 | 25,000 | 500,000 | Add new and update existing guidance documents to address the new Part 40 Subpart H. (PRA would require development of significant guidance describing how to collect, maintain, and use the failure rate data.) |
| ISA Summary Review | 30,000 | 300,000 | 300,000 | Review of the ISA Summary to assure adequate IROFS and management measures are applied to meet the performance requirements for the accident sequences. |
| Request for Additional Information | 10,000 | 100,000 | 100,000 | The initial submittal of the ISA Summary must often be augmented by additional review to demonstrate compliance with the regulations. |
| Onsite review of ISA Documents | 5,000 | 50,000 | 50,000 | NRC staff conduct onsite review of the ISA documents. |
| Safety Evaluation Report | 5,000 | 50,000 | 50,000 | The NRC's findings on the review of the ISA and ISA Summary are published in a safety evaluation report. |
| Total Cost | 50,000 | 525,000 | 1,000,000 | PRA cost are assumed to be approximately equal to ISA cost except as noted. |
| Annualized Cost | 1,250 | 13,125 | 25,000 | Based on an assumed license term (or renewal term) of 40 years. |

| Table A4 – Option Comparison for NRC Annual Recurring Costs | | | | |
|---|---|---|---|---|
| Activity | Costs for ISA license conditions (Option 1) | Cost for ISA requirements (Option 2) | Cost for PRA requirement (Option 3) | Notes |
| Amendments | 15,000 | 5,000 | 5,000 | Reduced number of administrative license amendments due to ISA's focus on safety significant systems. |
| License renewals | 22,500 | 0 | 0 | Reduced number of renewals over a 40-year period due to extended license terms (up to 40 years). |
| ISA periodic updates | 3,000 | 5,000 | 5,000 | Increase due to more comprehensive ISA. |
| Event reporting | 2,000 | 5,000 | 5,000 | Higher potential for reporting due to more comprehensive ISA and additional IROFS. |
| Inspections | 7,500 | 12,500 | 12,500 | Inspectors review implementation of IROFS and management measures. |
| Total Cost | 50,000 | 37,500 | 37,500 | PRA cost are assumed to be approximately equal to ISA cost. |

| Table A5 – Comparison of Annualized Total Cost | | | |
|---|---|---|---|
| | Current license condition (Option 1) | Cost for ISA requirement (Option 2) | Cost for PRA requirement (Option 3) |
| Licensee Total Costs | 150,825 | 355,000 | 427,750 |
| NRC Total Costs | 51,250 | 50,625 | 62,500 |

| Table A6 – Present-worth Calculation | | | | |
|---|---|---|---|---|
| Industry Costs | Estimated Total Initial Cost (Table A1) | Estimated Total Annual Cost (Table A2) | Total combined Implementation and Annual Cost for 40-year period at 3% | Total combined Implementation and Annual Cost for 40-year period at 7% |
| Option 1 | 197,000 | 154,900 | 3,777,478 | 2,262,082 |
| Option 2 | 2,120,000 | 302,000 | 9,100,661 | 6,146,176 |
| Option 3 | 3,230,000 | 347,000 | 11,250,826 | 7,856,103 |