PART 40

INTERGRATED SAFETY ANALYSIS (ISA) PROPOSED RULE

REGULATORY ANALYSIS

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10 CFR PART 40 ISA AMENDMENT REGULATORY ANALYSIS

1.0 Introduction

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend 10 CFR Part 40, "Domestic Licensing of Source Material," to obtain increased confidence in the margin of safety at 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); (3) the implementation of measures to ensure that the IROFS are available and reliable when needed.

The scope of the proposed rule is limited to applicants or licensees who are authorized to possess, or plan to possess, 2000 kilograms 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 proposed 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 Part 40 fuel cycle facilities authorized to possess significant quantities of UF6 are 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), accidentally generated at Part 40 fuel cycle facilities, has a significant potential for onsite and offsite consequences. 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.”

There are a number of weaknesses with the current 10 CFR Part 40. It does not:

- Contain general design criteria or performance objectives. Unlike 10 CFR Parts 70 and 72, which regulate fuel cycle facilities, 10 CFR Part 40 contains no “general design criteria.”

- Address clearly which facility changes require a license amendment; does not require management review or audits of changes of procedures and methods; and, does not mention managerial controls, including elements of quality assurance.

- Emphasize commitments to a safety basis for Part 40 fuel cycle facilities authorized to possess significant quantities of UF6. Section 40.31(j) allows for an evaluation, in lieu of an emergency plan, that demonstrates the uranium intake by a member of the public due to a release would not exceed 2 milligrams. There is no requirement in this evaluation to account for a release of hazardous chemicals produced from licensed materials that could affect a member of the public offsite.

- Explicitly address licensee safety assessment.

3.0. Objectives

The primary objective is to fix certain weaknesses in the current safety regulations in 10 CFR Part 40 in order to regulate licensees who are authorized to possess 2000 kilograms 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 would retain licensing authority for all other radiological activities at such facilities, regardless of their location in Agreement or non-Agreement States.

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 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 433950). This MOU clarified NRC responsibility for chemical hazards resulting from 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 processing licensed material has not been incorporated specifically into the licensing requirements of 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, 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 licensees that are determined to be consistent causes of serious incidents and precursors. 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 kilograms or more of UF6 that

provides 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 proposed 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 Part 40 do not require establishment of a safety program based on performance of an ISA. There are several requirements in the current 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 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 offsite. It also does not include identification of all the IROFS nor does it comprehensively and systematically address all the hazards, such as chemical and fire that could cause a release of licensed material.

Under the *status quo* no-action alternative, the NRC would retain the current Part 40 as it is. The one licensee currently required by license condition to perform an ISA would continue to do so. In addition, per the Commission's direction in SRM-M070308B, dated March 22, 2007, new applicants are required to meet the performance requirements in 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 be pursued, the ISA standard review plan (SRP) developed for Part 70 facilities would still be used under this alternative, in accordance with NRC policy, to promote licensing consistency and uniformity and provide standards for the quality and completeness of the ISA. The NRC uses SRPs to provide guidance to the staff for review and evaluation of license applications. In addition to promoting uniformity and consistency in licensing reviews, SRPs help make information about regulatory reviews widely available and improve communication and understanding of the staff review process. An SRP provides guidance and compliance is not mandatory.

The SRP acceptance criteria are not considered the only acceptable positions or approaches. Other positions or approaches that are consistent with the regulations may be proposed by an applicant. However, the current regulations are very general (see the discussion above). This allows applicants to dispute the need for performing a comprehensive and systematic ISA, for committing to use the ISA to evaluate changes, and for committing to ensure the continuous availability and reliability of the IROFS, as identified in the ISA. The guidance provided in the SRP could be challenged by the absence of explicit regulatory requirements for protection

against certain chemical and fire hazards, as well as the absence of explicit requirements for an ISA. Furthermore, there would be no explicit regulatory requirement for configuration management and other management measures necessary to ensure that the licensee makes no changes, deliberate or inadvertent, that would decrease the continuous availability and reliability of IROFS.

5.2 Option 2 Description

Option 2 is the NRC's proposal to modify 10 CFR Part 40 by adding a new subpart as described in the proposed rule. This new subpart would include requirements aimed at increasing NRC's confidence in the margin of safety at licensed facilities authorized to possess 2000 kilograms 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; (3) the implementation of management measures to ensure that the IROFS are available and reliable when needed; and (4) adding an additional evaluation criterion for applicants who submit an evaluation in lieu of an emergency plan under § 40.31(j). In addition, in order to ensure confidence in the margin of safety, a licensee would be required to maintain its safety basis by using its ISA to evaluate changes and periodically update its ISA. Also, the summary of the ISA and an emergency plan or evaluation would be docketed and revisions to the ISA summary would be required to be provided to NRC.

In brief, staff proposes to revise Part 40 to include the following major elements:

a) Performance of a formal ISA, which would form the basis for a facility's safety program. This requirement would apply to a subset of licensees authorized to possess 2000 kilograms 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 safety items relied on 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) Submittal of either (1) an emergency plan or (2) an evaluation demonstrating 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.

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.

Supporting guidance documents are being developed for the proposed rule, and will be made available in conjunction with this rulemaking. The guidance will pertain to the review and evaluation of license applications, renewals, and amendments. The guidance documents describe ways of complying with the revised 10 CFR Part 40 requirements that are acceptable to 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 is similar to Option 2, except that licensees would be required to perform the ISA using quantitative risk analyses methodology (e.g., probabilistic risk analysis (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:

- 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 guidance for Regulatory Analyses provides a monetary conversion for stochastic exposure to radioactivity, but not for injuries and fatalities due to exposure to hazardous chemicals, which are a primary concern at these Part 40 fuel cycle facilities authorized to possess significant quantities of UF6.
- Available estimates of the likelihood and consequences of an accident at 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 would be required as to 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.

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 NRC's confidence in the margin of safety at 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 obvious 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 would correct the weaknesses identified with the current 10 CFR Part 40 (see section 2 of this Regulatory Analysis). The new § 40.81 would provide explicit safety performance requirements and § 40.83 would provide baseline design criteria for new facilities, or new processes at existing facilities. The risk-informed regulation specifies protection must be provided to limit risk of credible high-consequence and intermediate-consequence events. Proposed § 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 would require a safety program that includes management measures, such as configuration management and quality assurance. It also would require personnel to be trained to ensure they understand the safety features that are relied on to prevent accidents. The required ISA would have to address chemical and fire hazards that affect radiological hazards, as well as direct radiological hazards.

In addition, Options 2 and 3 would reduce the complexity of license renewal reviews because the safety features of the license would be kept up to date resulting in a “living” license. Any changes to the safety basis documentation would be handled by a structured change control process.

The PRA approach (Option 3) would provide additional numerical values associated with the likelihood of accident sequences and would provide 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 would enable the NRC to quantify the benefits of proposed changes to facility requirements. However, on balance, NRC believes that Option 3 would provide only a small incremental benefit compared with Option 2, and Option 3 would be negatively impacted by the unavailability of data and relative immaturity of experience in the chemical industry with quantitative models.

6.1.2 Reduction in Frequency and Severity of Accidents

The processing of uranium at Part 40 fuel cycle facilities licensed to possess 2000 kilograms 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

Deaths of two workers are directly attributable to accidents involving licensed nuclear material at fuel cycle facilities. One death was from a 1964 criticality event at a licensed special nuclear material scrap recovery plant. The second death was from the hydrogen fluoride vapor cloud resulting from the release of UF6 at Sequoyah Fuels in 1986. By contrast, there have been no deaths, because of licensed radioactive material usages, from accidents at U.S. licensed

reactors. Additional worker injuries and health concerns have resulted from radiation and chemical exposures resulting from NRC licensed uranium processing operations.

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 additional potential to reduce the likelihood of accidents.

Options 2 and 3 would be expected to be more effective than Option 1 in reducing the consequences and likelihood of accidents because they would apply generic requirements uniformly to all current and future licensees who possess 2000 kilograms or more of UF6. License conditions and orders requiring an ISA could vary between licensees. Furthermore, Option 1 is considerably more limited than Options 2 or 3 in maintaining ISAs as a tool for evaluating facility changes.

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 has involved 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 opportunities for accidents with 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 have been and continue to be several incidents annually of safety significance. Reporting, investigating, and resolving these incidents cause both the 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 less 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 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 proposed requirements minimize the burden on licensees by not requiring reports of inconsequential or low-risk incidents. Options 2 and 3 would increase 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 proposed rule (Option 2) and from Option 2 to the PRA option (Option 3). Details on supporting cost assumptions are discussed in the Appendix A.

Existing licenses for facilities within the scope of the proposed 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 proposed rule. To a varying degree, some of the other provisions of the proposed rule are required by license condition in existing licenses. These were accounted for in determining the true cost of Option 2.

The details of the costs are provided below and in the Appendix. A summary of the cost impacts is shown in Table A3. For licensees operating under Option 1, i.e. no change option, the estimated annualized incremental cost to implement the rule is $119,000 for Option 2 and $203,000 for Option 3.

6.2.1 Option 1 Costs

6.2.1.1 Option 1 Licensee Cost Impacts

The licensees who are required to perform an ISA under Option 1 (the status quo no-action alternative), are estimated to have total license conditions costs of $35,500 annually (see Table A3).

- Licensee Operational/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 configuration control, quality assurance, training and other measures for ensuring reliability and availability of safety items identified by the ISA. There are also recurring costs associated with facility changes which will require updating the ISA. In total, these recurring costs are estimated to be $33,400 per licensee per year to perform periodic updates of their ISAs and the demonstration sections of their license applications.

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.

- NRC Option 1 Operational/Recurring Costs

The NRC would not incur any additional operational/recurring cost under Option 1. As shown in Table A4, it is estimated that the NRC currently spends about $23,000 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

- Incremental Requirements of Option 2 vs Option 1

Option 2 would include developing and documenting the required ISAs, including the identification of IROFS and measures to ensure their availability and reliability. Only one NRC licensee is performing an ISA under Option 1, and it would have to upgrade its existing analyses to meet the standards required by Option 2.

The current ISA requirements implemented by license condition are considerably less than the requirements of an ISA under Option 2. Changes in the current safety analysis will be significant. Required actions would include:

- Establish or upgrade measures to ensure that IROFS meet quality standards commensurate with their importance, and establish corresponding policies and procedures.

- Establish and maintain configuration control to assure that changes to processes and systems are reviewed, documented, communicated and implemented in a manner which satisfies safety requirements.

- Establish or upgrade any additional measures needed to ensure that IROFS are designed, constructed, inspected, calibrated, tested and maintained as necessary.

- Establish or upgrade training programs to ensure that personnel are trained to ensure they recognize and understand safety concerns.

- Establish records that demonstrate adherence to the foregoing requirements.

- New reporting requirements. (Option 2 also includes strengthening the event reporting requirements for affected licensees.)

Table A2 indicates the estimates of the relative efforts needed to establish measures or bring existing measures into compliance with the Option 2 requirements. The lower the dollar value in the Option 1 column compared to the Option 2 column, the greater the "relative effort needed to achieve compliance." 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 proposed rule.

- Implementation Costs of Option 2 Compared to Option 1

Affected licensees would incur some implementation costs under Option 2, even if the licensee already had conducted an ISA under Option 1. One-time implementation costs for licensees to go from Option 1 to Option 2 would 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 and guidance provisions). This additional estimated cost to upgrade the ISA to ensure reliability and availability of IROFS is estimated to be $248,000 per licensee (annualized to $12,400).

- Incremental Operational Cost Impacts Compared to Option 1

Once these measures were implemented, the licensees would incur recurring operational costs for maintenance and for periodic 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 of configuration management, enhanced maintenance, testing, inspection activities, enhanced quality assurance, maintaining design basis information, and similar ongoing activities. In addition, Option 2 includes strengthening the event reporting requirements for affected licensees.

This additional annual operational costs for licensees performing ISAs under Option 2, as compared to license conditions (Option 1) is estimated to be $106,600.

6.2.2.2 Option 2 NRC Cost Impacts

- NRC Option 2 Implementation Costs

The NRC previously developed a SRP for reviewing ISAs at Part 70 fuel fabrication facilities. New guidance for the proposed rule would be very similar to the existing guidance. Very little refinement of the language in these documents would be necessary in order to apply them to the ISAs in this proposed rule. Not having to expend funds to establish entirely new guidance would be a cost savings in Options 2 and 3 relative to the baseline. This savings is estimated to be about $15,000.

The NRC's incremental implementation activities under Option 2 would consist of initial evaluations of ISA summaries. The costs of ISA reviews will depend on the type of ISA results documentation submitted by licensees. Option 2 would require licensees to submit ISA summaries that would contain the information specified in the rule, in contrast to the very brief submittals that are currently required under Option 1. The summaries are expected to reduce NRC staff expenditures of time and effort associated with reviewing ISAs. Field inspectors, however, still will need to spend some time at licensee sites reviewing ISAs. For the one licensee who would have to upgrade its ISA to the rule standard, the NRC review and onsite evaluation costs with the ISA summaries are estimated at $25,000.

In addition to the ISA evaluations, staff would also review the adequacy of licensee measures to ensure the reliability and availability of IROFS. These incremental implementation costs are assumed to require about $25,000.

- NRC Option 2 Operational/Recurring Costs

Incremental recurring NRC activities with Option 2 include reviews of ISA updates and reviews of additional licensee event reports expected under Option 2. Costs associated with license renewals are expected to be different with Option 2 compared to Option 1.

Licensees would be required to submit updates to their ISA summaries annually to reflect changes to systems and processes. NRC review of ISA annual updates for the one licensee compared to Option 1 is estimated to cost the NRC about $5,000 under Option 2.

The NRC also expects to spend additional time reviewing the event reports submitted by licensee as a result of this rulemaking (Option 2). These additional event report reviews are estimated to cost the agency about $10,000 per year

NRC costs associated with Option 2 license renewal efforts are expected to be reduced compared to those experienced with Option 1, because all licensees will be required to periodically update safety basis licensing information. These updates will enable the NRC to better keep abreast of changes made to licensee processes, systems, and facilities on an ongoing basis, which will reduce the review burden for license renewal applications. Also, processing license amendments are expected to be reduced for those licensees submitting periodic updates to the demonstration sections of their license applications and being allowed to make certain changes under the ISA without having to submit a license amendment. These savings are estimated to amount to about $25,000 per licensee per year.

6.2.3 Option 3 Costs

6.2.3.1 Option 3 Licensee Cost Impacts

- Incremental 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 have many of the same implementation costs as Option 2, but to be considerably more costly than Option 2 because of the PRA requirement.

Component or "basic-element" reliability data, however, do not appear to be currently available to perform quantitative ISAs on 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 A2, the cost increase for implementation of Option 3 compared to Option 1 is $185,000 per licensee.

- Operational/Recurring Costs of Option 3 Compared to Option 1

Option 3 would have similar incremental operational costs as Option 2, but also additional costs, both because of the requirement to use quantitative ISAs (PRAs) to evaluate changes and additions to facilities and processes and because of the continued need to collect and update reliability data.

6.2.3.2 NRC Cost Impacts

No additional NRC costs or savings are attributed to the incremental requirement from Option 2 to Option 3.

6.2.4 Summary of Cost Impacts

For the licensee that has a set of license conditions that require an ISA (Option 1), the estimate to meet the standards in the rule (Option 2) is $119,000 (see Table A3). The estimated cost for the NRC to regulate Option 2 is $17,000 (see Table A4).

7.0. Decision Rationale

a) Option 1 provides some of the desired improvements in 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 renewals, if licensees resist imposition of ISA license conditions. Option 2 corrects these shortcomings.

b) The distinction between Option 2 and Option 3 is that Option 3 would require licensees to use a PRA methodology in performing the ISAs. It is clear however, that this alternative would entail significant additional licensee costs, in comparison to Option 2. 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 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, NRC believes that the proposed rule would provide the needed 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 would be enacted through publication in the *Federal Register* of a Notice of Final Rulemaking.

The NRC staff has developed guidance documents 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 would become effective 30 days after its publication as a Final Rule.

Regulatory Analysis - Appendix

Cost Assumptions

A1 Estimating Cost of Performing an ISA

The cost of performing an ISA at a Part 40 fuel cycle facility authorized to possess significant quantities of UF6 was estimated on the basis of the NRC's experience with eight Part 70 fuel cycle licensees who have implemented ISA requirements since 2000. Although there are major differences between the Part 70 fuel cycle facilities that currently conduct ISAs and Part 40 fuel cycle facilities authorized to possess significant quantities of UF6, the similarities in the performance requirements (ISAs) and underlying cost to implement and maintain an ISA (IROFS, training, maintenance, etc.) are sufficient to extract good estimates of cost. The Part 70 fuel cycle facilities are much more complex (due to criticality issues) while a Part 40 fuel cycle facility authorized to possess significant quantities of UF6 is much simpler (no criticality issues). A simple system is estimated to require about one-fourth the effort of a complex system.

In developing these estimates the NRC utilized the regulatory analysis dated March 27, 2000, for the final rule that amended Part 70 to add ISA requirements for fuel cycle facilities licensed under 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.

A2 Estimating Annual Cost of Operations

Operational costs for each option were estimated using incremental annual operational costs. Costs that occur less frequently than annually were prorated to an annual basis using the assumption of a 20-year remaining plant life. Initial costs for implementing an ISA such as establishing training, IROFS, configuration control, management measures, and compiling safety information, and other factors are summarized in Table A1. The initial cost of implementing an ISA was estimated to be $290,000 and was averaged over the expected remaining facility life of 20 years to yield an annual cost of $14,500 per year.

Past history, before the 2000 rulemaking that added ISA requirements to Part 70 fuel cycle facilities, indicates that changes were frequently made to systems and facilities or new processes are added to existing facilities. The data accumulated by the NRC indicated that, on average, fuel fabrication licensees had roughly five minor modifications per year, and also had the equivalent of two substantial modifications or additions every 3 years. While major modifications require license amendments under the criteria in the ISA, minor modifications are allowed without submitting a license amendment. The cost of demonstrating the safety of a proposed amendment will be less with an ISA available to help provide a basis for demonstrating safety.

Table A2 summarizes the estimated recurring annual operational costs associated with ISA activities. The cost estimate include updating the ISA, training, event reporting, record keeping, license renewal, and other factors. The maintenance of ISAs and the requirement to keep licensing basis information current are expected to reduce considerably the effort expended by

licensees in preparing license renewal submittals. The NRC currently expends in excess of three staff years in renewing the license of a typical fuel cycle facility. The assumption was made that licensees probably expend about three times this amount in preparing their renewal applications. The assumption was also made that licensee efforts associated with license renewals would be reduced by about a factor of three under the Final Rule conditions compared to the situation that exists today. The value of these savings over a 10 year renewal interval is estimated to average a present value of $470,000 per licensee, or about $47,000 (savings) per licensee per year. Credit for such savings was taken in this Regulatory Analysis.

A3 PRA Cost Analysis

It is estimated that implementation of a quantitative ISA based on PRA methodology would be at least 1.5 times more expensive than a qualitative ISA. Cost for training of personnel and record keeping would be similar with an ISA. In addition, the quantitative ISA is assumed to require a reliability data collection effort to support the analysis.

A4 Cost Summaries

The estimated annual recurring costs plus the initial cost annualized for each option is summarized in Table A3 and are based on the totals of Tables A1 and A2.

Table A1 - Option Comparison for Initial Costs				
ISA Implementation Activity	Current license condition (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	50,000	75,000	
Establish or upgrade measures that ensure that IROFS are designed, constructed, inspected, calibrated, tested and maintained as necessary	7,000	35,000	52,500	
Establish or upgrade training programs to ensure that personnel are trained, tested, and retested to assure they recognize and understand safety concerns	24,000	120,000	120,000	Training cost should be similar under both and ISA and PRA
Establish and maintain configuration control to ensure that changes are reviewed, documented, and adequately communicated to affected staff and parties	4,000	20,000	30,000	
Establish or upgrade measures to ensure that IROFS meet quality standards commensurate with their importance, and establish corresponding policies and procedures	7,000	35,000	52,500	
Establish and maintain records that demonstrate adherence to new regulatory requirements	0	30,000	30,000	Record keeping cost should be similar under both and ISA and PRA
Estimated Total Cost	42,000	290,000	360,000	
Estimated Annualized Cost	2,100	14,500	18,000	Based on 20 year expected life of facility
Estimated True Cost for Option 2		12,400		

Table A2 - Option Comparison for Annual Recurring Costs				
ISA Recurring Activity	Current license condition (Option 1)	Cost for ISA requirement (Option 2)	Cost for PRA requirement	Notes
Update 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 and 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 and ISA and PRA
License renewal/year amendments	0	(47,000)	(47,000)	Based on 10 year license renewal
Estimated Total Cost	33,400	140,000	185,000	
Estimated True Cost for Option 2		106,600		

Table A3 – Summary of Annual Cost of Options		
Current license condition (Option 1)	Cost for ISA requirement (Option 2)	Cost for PRA requirement (Option 3)
35,500	119,000	203,000

Table A4 – NRC Estimated Costs			
Activity	Current license condition (Option 1)	Cost for ISA and PRA requirements (Option 2)	Notes
Guidance documents update and refinements	0	(15,000)	Guidance documents already exists under Option 1 and would only need updated and refined for reviewing a more comprehensive ISA
License renewal/year amendments	10,000	(25,000)	Reduced license amendments and renewal costs under ISA
ISA periodic updates	3,000	5,000	
Event reporting	0	10,000	
ISA review and on site inspection	10,000	25,000	Increase due to more comprehensive ISA
Review of IROFS	0	25,000	IROFS are not part of the Option 1 ISA
Estimated Total Cost	23,000	40,000	
Estimated True Cost for Option 2 and 3		17,000	