PART 70 AMENDMENT

REGULATORY ANALYSIS

March 27, 2000

ATTACHMENT 9

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PART 70 AMENDMENT
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1.0 Introduction

The U.S. Nuclear Regulatory Commission (NRC) is amending 10 CFR Part 70, "Domestic Licensing of Special Nuclear Materials," to obtain increased confidence in the margin of safety at major special nuclear material (SNM) facilities. 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; and (3) the implementation of measures to ensure that the items relied on for safety are available and reliable when needed. In addition, to ensure confidence in the margin of safety, the Commission believes that the safety basis for the facility should be docketed with the license application.

The final rule is, in part, NRC's response in resolution of a Petition for Rulemaking (PRM-70-7) submitted by the Nuclear Energy Institute (NEI). The scope of the final rule is limited to applicants or licensees who are authorized to possess greater than a critical mass of SNM and who are or plan to be engaged in enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, fabrication of mixed-oxide fuel or fuel assemblies, scrap recovery, decommissioning of facilities used for these activities, or any other activity that the Commission determines could significantly affect public health and safety.

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

- NRC's decision to issue the final rule is based on adequate information concerning the need for and consequences of the proposal.
- 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

Investigation of a potential criticality incident in May of 1991 determined that 10 CFR Part 70 does not address facility changes nor does it address changes of procedures and methods that could affect the safe operation of the facility. Change reviews were found to be handled on a case-by-case basis during the development of license conditions, with some license conditions stated in a manner that promoted the exercise of discretion on the part of the licensee in establishing the need for change reviews.[1] The investigation found that the licensee's system

[1] Discussed on page 12-4; NUREG-1450, *Potential Criticality Accident ..., May 29, 1991;* published August, 1991.

of criticality safety controls was originally extensive and afforded true defense-in-depth. However, this system of controls deteriorated as operations proceeded and changes accumulated.[2]

This incident prompted the NRC staff to evaluate its safety regulations for licensees that possess and process large quantities of SNM. This evaluation concluded that NRC's existing safety regulations for materials licensees "**...** focus almost exclusively on radiological safety concerns, practically to the exclusion of process safety and managerial controls."[3] Furthermore, the review found that "**...** each licensee needs a strong managerial program of controls and hazard assessments to ensure and maintain the level of safety that existed when it received its initial license."[4] The evaluation also found that "**...** hazards analyses or engineering safety analyses of plant systems and components are not routinely performed"[5] by licensees.

There are a number of weaknesses with the current 10 CFR Part 70:

! It provides neither general design criteria nor performance objectives. Unlike 10 CFR Parts 50 and 72, 10 CFR Part 70 contains no "general design criteria."[6] This would not be a problem if it contained detailed performance requirements in the manner of 10 CFR Part 61 or of 10 CFR 74.51. Unfortunately, the only safety performance objective mentioned in the current 10 CFR Part 70 is the overly general "protect health and minimize danger to life and property."

! It does not address clearly which facility changes require a license amendment;[7] does not require management review or audits of changes of procedures and methods; and, does not mention managerial controls, including elements of quality assurance. Repeatedly, serious events at licensees' facilities can be traced to: a lack of procedures or a failure to follow procedures; poor or no training of staff to conduct assigned duties; insufficient retraining of staff; the staff's conduct of activities without management's knowledge or approval; poor sampling and measurement of health-related, safety-related or environmentally-related media; in some cases, poor sampling and measurement of process streams where the information was not required for material control and accounting purposes, i.e., was not subject to the requirements of 10 CFR 70.57; poor maintenance; a failure by management to follow up on safety-related commitments due to a lack of a safety culture within management, to poor tracking systems and to poor commitment reporting systems; a failure by management to control

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[2] Ibid., page 7-16.

[3] NUREG-1324, *Proposed Method for Regulating Major Materials Licensees*; published February, 1992; page 17.

[4] Ibid., page 18.

[5] Ibid., page 27.

[6] Ibid., pages 17 and 30.

[7] NUREG-1450, page 7-17.

changes; and a failure to properly audit for management effectiveness and to implement corrective actions when audits did occur.

- 10 CFR Part 70 contains no explicit requirements for chemical safety, fire safety, and prevention of criticality accidents.

- 10 CFR Part 70 allows a licensee to continue operating indefinitely past its license expiration date if a renewal application has been received in time. This is referred to as being in "timely-renewal." A licensee in timely-renewal may have little incentive to come to closure on contentious safety issues holding up the license renewal. This delay can allow changes accomplished without a license amendment (see above) to accumulate without NRC licensing review.

- 10 CFR Part 70 does not emphasize commitments to a safety basis. Section 70.22(a)(7) and (8) require the application to contain *descriptions* of equipment. facilities and procedures that will be used to protect health and safety. It does not specify that applications contain *enforceable commitments.* In practice, licensees and applicants for a license or for a license renewal do propose license conditions in Part 1 of their applications. Regulatory Guide 3.52, the Standard Format and Content Guide, specifies a two-part application, with only the first part containing proposed license conditions and the second part containing descriptive material. Licensees frequently have placed important safety information into the non-binding Part 2 of the application. This problem is compounded by the timely-renewal problem.

- 10 CFR Part 70 does not explicitly address licensee safety assessment. In 70.22(f), it does require plutonium processing and fuel fabrication applicants to include a "description and safety assessment of the design bases of the principal structures, systems and components of the plant," but no similar requirements apply to other SNM applicants. In practice, applicants do include safety analyses, as called for in Regulatory Guide 3.52; however, these do not comprehensively and systematically examine all hazards that could result in accidents of concern to the NRC. NUREG-1324 recommended that the regulation be revised to "require that a hazards analysis be performed for each system and component within each process that contains radioactive material or that serves as a barrier to the release of radioactive materials to an unauthorized location."

3.0. Objectives

The primary objective is to fix the weaknesses of the current safety regulations in 10 CFR Part 70 in order to regulate major SNM licensees, without undue burden, in an efficient, fair, and effective way, and in a manner that provides NRC with appropriate confidence in the margin of safety at these facilities. A secondary objective is to implement the resolution of a petition for rulemaking (Docket No. PRM-70-7) from NEI, as proposed in SECY-97-137.[8]

[8] Staff Requirements Memorandum, *SECY-97-137 - Proposed Resolution to Petition for Rulemaking Filed by the Nuclear Energy Institute*, August 22, 1997.

4.0. Background

On January 4, 1986, a worker lost his life during an accidental release of uranium hexafluoride (UF_6) at a facility regulated under 10 CFR Part 40. A Congressional inquiry[9] into this accident criticized NRC's oversight of chemical hazards at NRC-regulated facilities. As a result of this accident, 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 at NRC-regulated facilities.

As a result of the UF_6 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 70. The same is true of branch technical positions on fire safety,[10] management controls,[11] and requirements for operation.[12]

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 need 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 1998.[13] 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. Serious incidents examined included:

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[9] *NRC's Regulation of Fuel Cycle Facilities: A Paper Tiger*, Eighth Report by the Committee on Government Operations, June 18, 1987.

[10] *Branch Technical Position on Fire Protection for Fuel Cycle Facilities*, published in the Federal Register (54 FR 11595-98) dated March 21, 1989. See also NRC Information Notice 92-014, *U Oxide Fires at Fuel Cycle Facilities*, and draft Regulatory Guide DG-3006, *Standard Format & Content For Fire Protection Sections of License Applications for Fuel Cycle Facilities*, issued for comment April 30, 1993.

[11] *Branch Technical Position on Management Controls/Quality Assurance for Fuel Cycle Facilities*, published in the Federal Register (54 FR 11591-92) March 21, 1989.

[12] *Branch Technical Position on Requirements for Operation for Fuel Cycle Facilities*, published in the Federal Register (54 FR 11591-92) March 21, 1989.

[13] Updated from Attachment 3 (Regulatory Concerns from Precursor Events at Fuel Cycle Facilities) to *Improving the regulation of Fuel Cycle Facilities: Overview,* distributed at the NRC Public Workshop on Improving NRC's Regulation of Fuel Cycle Facilities, November, 30, 1995.

a) Sept., 1992: Fire and explosion of 1700 grams of highly enriched uranium (HEU) 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) Uranium contamination at facility due to a chemical explosion and fire in 1992.
d) October, 1992: Improper uranium solution sent to unsafe-geometry vaporization chest.
e) February, 1993: Large (124 Kg) spill of uranium dioxide (UO_2) 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 nonrepresentative sample of uranium dioxide for process measurement step.
g) Oct., 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 UF_6 gas.
i) Sept. 1994: Spill of 188 Kg of enriched UO_2 powder.
j) Several times over the period 1994-95: Accumulation of uranium dust in ventilation ducts exceeding the criticality safety limits.
k) Nov., 1995: Inadequate maintenance program leading to UO_2 powder accumulation inside furnace due to crack in furnace muffle.
l) April, 1996: Site area emergency declared due to fire in process ventilation exhaust duct system.
m) 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.
n) August, 1996: Operations in one process suspended due to flame in high level dissolver tray while dissolving poorly characterized uranium-beryllium material.
o) September, 1996: Second instance of a fire at the same facility in local ventilation duct system because of apparent improper change control.
p) October, 1996: Large spill of material in a licensee's uranium recovery area.
q) Dec., 1996: Calciner tube failure with subsequent accumulation of powder in annulus with loss of two criticality safety controls.
r) March, 1997: Alert declared after low enriched uranium spill from downblending equipment due to inadequate pre-operational testing.
s) April, 1997: Flashback fire in sintering furnace because of loss of process controls.
t) June, 1997: Loss of control on powder granulation hopper results in unacceptable accumulation of UO_2 powder.
u) July, 1997: Quantity of enriched uranium on transfer cart in excess of criticality mass limits.
v) Sept., 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.
w) Jan., 1998: Moderation control in dry conversion process degraded when wrong additive used during a powder blend.

x) June 1998: Failed clamp results in large spill/accumulation of UO2 powder outside of containment.

y) Aug. 1998: Poor configuration control results in large accumulation of UO2 pellets in process equipment.
z) Sept. 1998: Poor configuration control during maintenance of process equipment causes accumulation of material in non-favorable geometry chamber.
aa) June 1999: Inadequate mass controls result in accumulation of UO2 powder in ventilation system HEPA filter housing.
ab) Aug. 1999: Number of containers of enriched uranium in a station violated criticality control limits.
ac) Jan. 2000: Failed clamp results in accumulation of UO2 powder inside enclosure.
ad) Feb. 2000: Large spill of uranium solution contaminates uncontrolled area.

There continues to be a set of 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.

An action plan for remedying deficiencies identified by NUREG-1324, approved by the Commission,[14] in addition to calling for improvements in the regulatory base, fostered an approach to license renewals that encouraged inclusion of a commitment to perform an ISA as a condition of the license.

On September 30, 1996, the NRC docketed a petition for rulemaking (Docket No. PRM-70-7) from NEI. The petitioner wrote:

> Over the past decade, while the formal requirements of Part 70 have not changed significantly, its application has. Licensees' documentation requirements have evolved significantly and additional requirements on the facilities have been imposed through the inspection and licensing processes. Regulatory predictability and stability associated with licensing and oversight of Part 70 facilities [have] suffered as a result. The industry believes that the ISA[15] requirement to evaluate risks (consequences and frequency) and the graded approach to safety (implementation and assurance), coupled with a backfit provision, would help to promote a stable and effective regulatory environment.

Staff submitted a proposed resolution to PRM-70-7 to the Commission (SECY-97-137) on June 30, 1997. That proposed resolution was endorsed by the Commission in an SRM dated August 26, 1997. On July 30, 1998, staff submitted a proposed rule to the Commission in SECY-98-185[16]. In a December 1, 1998 SRM, the Commission disapproved publication of the staff's submittal as a proposed rule. The Commission directed the staff to continue to discuss all relevant documents with stakeholders (Nuclear Energy Institute, Department of Energy, and others) in public, including use of the Internet. Subsequently, staff submitted a revised

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[14]Staff Requirements Memorandum (SRM) on action plan for fuel cycle facilities (SECY-93-128), dated June 7, 1993.

[15]The Petition uses ISA to stand for integrated safety assessment. NRC prefers the term integrated safety analysis.

[16]SECY-98-185, *"Proposed Rulemaking - Revised Requirements for the Domestic Licensing of Special Nuclear Material".*

proposed rulemaking package to the Commission as SECY-99-147, and a proposed rule was published in the Federal Register on July 30, 1999 (FR64:41338). The final rule has been modified in response to the comments obtained during the public comment period. In addition, the accompanying Standard Review Plan has been modified, from that which accompanied the proposed rule, as a result of additional stakeholder interaction, both in public meetings and through use of the Internet. Staff's final rule includes the basic elements of the PRM-70-7, with some modifications.

As previously stated, the purpose of the rulemaking is to establish a risk-informed framework for regulating major[17] SNM licensees 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.

[17] Major SNM licensee, in the context of this rulemaking, means, in general, a licensee whose approved activity involves mechanical or chemical processing of greater than critical quantities of SNM. See the scope of the final rule for more detail.

5.0 Alternatives

The alternatives considered are:

- Option 1 -- no action;
- Option 2 -- the final rule and standard review plan (SRP); 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

Two alternatives, resulting in the establishment of two different baselines, are discussed under this option. The first baseline (1a) represents the Part 70 program as required by regulation and prior to imposition of license conditions resulting from the 1993 action plan (no ISAs). The second baseline (1b) reflects the required program under Part 70 with license conditions resulting from the action plan included in most license renewals. Thus, while both alternatives are considered to be "no action," the frame of reference for each is different. This is necessary to accurately reflect the incremental cost/benefit impact of the final rule.

5.1.1 Option 1a

Option 1a is a so-called "no-action" alternative that corresponds to the *status quo* that existed before initial implementation of the 1993 action plan for fuel cycle facilities. This alternative, which ignores the fact that most licensees are now required by license condition to prepare an ISA, is needed because the existing regulations in Part 70 do not require establishment of a safety program based on performance of an ISA. In the timeframe of Option 1a, NRC was criticized in House Report 100 -167 for concentrating on radiological hazards and largely ignoring other hazards.

There are several requirements in the current Part 70 that specifically address public health and safety. Section 70.23, *Requirements for the approval of applications*, requires, among other things, a determination that the applicant's proposed equipment, facilities, and procedures be adequate to protect health and minimize danger to life or property. Similarly, 10 CFR 70.22 requires the applicant to provide a description of equipment, facilities, and procedures to protect health and minimize danger to life or property. Section 70.22 includes such examples of equipment and facilities as "... handling devices, working areas, shields, measuring and monitoring instruments, devices for the disposal of radioactive effluents and wastes, storage facilities, criticality accident alarm systems, etc." It includes "... procedures to avoid accidental criticality, procedures for personnel monitoring and waste disposal, post-criticality accident emergency procedures, etc." as examples of procedures. However, the descriptions were not necessarily comprehensive nor enforceable license commitments because they were not proposed as, nor incorporated into, the conditions of the licenses. In addition, the existing

Part 70 does not explicitly require fire safety or chemical safety, except that fires and "... any associated chemical hazards directly incident"[18] to an accidental release of SNM are required to be considered in emergency planning for responding to accidents. Although "... procedures to avoid accidental criticality" are included as examples of proposed procedures to be contained in the license application, engineered means of preventing accidental criticality, which generally are more reliable than procedural means, and are preferred for nuclear criticality safety, are not addressed in the regulation.

For plutonium, in addition to the above requirements, 10 CFR 70.22(f) specifically requires:

> Each application for a license to possess and use special nuclear material in a plutonium processing and fuel fabrication plant shall contain, in addition to the other information required by this section, a description of the [plant site], a description and safety assessment of the design bases of the principal structure, systems, and components of the plant, including provisions for protection against natural phenomena, and a description of the quality assurance program to be applied to the design, fabrication, construction, testing and operation of the structures, systems, and components of the plant.

A footnote to 10 CFR 70.23(b) notes that for plutonium facilities, "The criteria in appendix B of part 50 of this chapter will be used by the Commission in determining the adequacy of the quality assurance program."

Regulatory Guide 3.52, *Standard Format and Content for the Health and Safety Sections of License Renewal Applications for Uranium Processing and Fuel Fabrication*, provides the staff position on information that should be included in the application. Because this is a guidance document rather than a regulation, compliance with it is not mandatory. Regulatory Guide 3.52 identifies a two-part license renewal application, i.e., proposed license conditions in Part I and descriptive information (demonstration and performance record) in Part II. The information in Part I is noted to be of major importance to the NRC inspection and enforcement staff and, the Regulatory Guide states that Part I should be written to be inspectable and verifiable. The information in Part II, on the other hand, is stated to be of major importance to the NRC licensing staff, during the review of the license renewal application, and should be written to provide the basis for licensing decisions.[19]

According to Regulatory Guide 3.52:

> In the renewal application, the applicant should analyze the plant in terms of potential hazards and the means, including appropriate margins of safety, employed to protect against these hazards. Sufficient information should be included in Part II to allow the NRC licensing staff to perform independent analyses to confirm conclusions reached by the applicant. These analyses should include but are not limited to (1) the site and its relationship to accidents from natural phenomena, (2) operations involving radiation exposures, releases

[18]10 Section CFR 70.22(I)(1)(ii).

[19]Regulatory Guide 3.52, Revision 1, November, 1986, page vii.

> to the environment, and the application of the principle of as low as is reasonably achievable (ALARA), (3) nuclear criticality safety, (4) operations involving hazardous chemicals, (5) confinement and control of radioactive materials, (6) projected effluent quantities and concentrations and effluent treatment, (7) reliability of the systems essential to safety, (8) prevention and control of fire and explosion, (9) radiological contingency planning, and (10) environmental impact associated with normal operations, abnormal conditions, and accidents.[20]
>
> The application should contain a safety analysis, including radiation safety and nuclear criticality safety, for each step of the process. The analysis should show how the commitments specified in Part I [of the application] will be met.[21]
>
> The types of accidents considered and their potential impact on occupational safety and the environment should be summarized.[22]

However, these analyses did not typically include identification of all the items relied on for safety nor did they comprehensively and systematically address all the hazards, such as chemical and fire hazards, that could cause a release of licensed material.

There is nothing in the current Part 70 that explicitly requires a licensee to notify NRC of changes it makes to its facility and procedures that could make the description in Part II of the application in need of update. As noted by an NRC Incident Investigation Team:

> The regulations in 10 CFR [Part] 70 do not address facility changes and changes of procedures and methods; i.e., there is no regulation comparable to that specified in 10 CFR 50.59, 'Changes, tests, and experiments.' Although the regulations in Part 70 do not explicitly address change reviews, they are handled on a case-by-case basis during the development of license conditions.[23]

5.1.2 Option 1b

Under Option 1b, the actual *status quo* no-action alternative, NRC would retain the current Part 70 as it is. Licensees required by license condition to perform an ISA would continue to do so. It is not entirely no-action, however. Although no rulemaking would be pursued, an SRP still would need to be developed 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. 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

[20] Ibid., page viii.

[21] Ibid., page 29 (Section 15.2).

[22] Ibid., page 30 (Chapter 16).

[23] NUREG-1450

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. Under Option 1b, however, the current regulations are very broad and general (see the discussion in Option 1a, 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 items relied on for safety, as identified in the ISA. The guidance provided in the SRP could be challenged by the absence of explicit regulatory requirements for protection against criticality, and 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 items relied on for safety. (The regulatory basis could be said to exist currently in 10 CFR 70.32(b), which states that the Commission may incorporate in any license additional conditions and requirements necessary to protect the public health and safety. However, invoking that provision of the regulation for a generic requirement applicable to all of a class of applicants and licensees is more properly done through rulemaking.)

Option 1b also includes continuation of reporting criticality events under NRC Bulletin 91-01, *Reporting Loss of Criticality Safety Controls*, without making this reporting a regulatory requirement or expanding it to include reporting the loss of safety controls other than criticality safety controls.

5.2 Option 2 Description

Option 2 is the NRC's proposal to modify 10 CFR Part 70 by adding, *inter alia*, a new subpart as described in the final rule. This new subpart includes requirements aimed at increasing NRC's confidence in the margin of safety at certain licensed facilities authorized to possess greater than a critical mass of special nuclear material. Option 2 is a risk-informed, performance-based regulatory approach that includes: (1) the identification of appropriate performance criteria and the level of protection needed to prevent or mitigate accidents that exceed such criteria; (2) the performance of an ISA to identify potential accidents at the facility and the items relied on for safety; and (3) the implementation of measures to ensure that the items relied on for safety are available and reliable when needed. 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 in evaluation of changes and periodically updating its ISA. Also, the summary of the ISA would be docketed with the license application, and revisions to the ISA summary would be required to be provided to NRC.

In brief, staff proposes to revise Part 70 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 greater than a critical mass of SNM based on their risk of operations. The performance of an ISA will be required of applicants or licensees who are authorized to possess greater than a critical mass of SNM and who are or plan to be engaged in enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched

uranium hexafluoride conversion, plutonium processing, fabrication of mixed-oxide fuel or fuel assemblies, scrap recovery, decommissioning of facilities used for these activities, or any other activity that the Commission determines could significantly affect public health and safety. .

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.

Also included in Option 2 are new reporting requirements, which are based on consideration of the consequences or risk involved, and are intended to replace and expand on the approach licensees have currently been using for reporting criticality events under Bulletin 91-01. The new approach is generic, i.e., it covers all types of potential incidents (not just criticality incidents) and items relied on for safety identified and described in the ISA summary, and establishes a time frame for reporting that is scaled according to the risk. The new reporting requirements would supplement the reporting requirements currently in the existing 10 CFR Part 70 and elsewhere in the regulations (e.g., 10 CFR Part 20).

An SRP, which has been developed for the final rule and is being made available in conjunction with this rulemaking, would be issued to provide guidance to the staff for the review and evaluation of license applications, renewals, and amendments. The SRP acceptance criteria describe ways of complying with the revised 10 CFR Part 70 requirements that are acceptable to NRC. The SRP also serves as regulatory guidance for applicants who need to determine what information should be presented in an application.

To assist license reviewers in determining that the applicant's proposed protection is sufficient to reduce the likelihood or mitigate the consequences of potential accidents to levels specified in the proposed §70.6, the SRP includes a risk matrix of consequence categories and likelihood categories. This matrix shows which combinations the staff would find acceptable.

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. 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 essentially chemical processing facilities.
- ! There also are no monetary criteria to use for injuries or fatalities due to high radiation doses from criticality accidents, because the Regulatory Analysis guidelines of $2000 per person-rem "...is not applicable to deterministic health effects, including early fatalities."[24]
- ! Furthermore, available estimates of the likelihood and consequences of an accident at any of these facilities are subject to large uncertainties.

While better estimates may be available after the completion of the ISAs being performed by most fuel fabrication facilities as a condition of their last license renewal, non-quantifiable attributes will remain the primary benefits. Subjective judgement still would be required as to which of the alternatives best solves the problems identified in section 2 of this report. 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 an average licensee and to the NRC for implementing each alternative.

6.1 Benefits

6.1.1 Increased Confidence in the Margin of Safety

The performance, by fuel fabrication and enrichment applicants and licensees, of a comprehensive and systematic hazards analysis, as part of an ISA, together with implementation of any corrective actions identified by the ISA, and associated licensee commitments to maintain the items relied on for safety, are key elements for increasing NRC's confidence in the margin of safety at these facilities. Safety analyses that consider chemical, fire, criticality, 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 moderator-controlled for nuclear criticality safety. But other examples may not be so obvious. For instance, installation of a drip pan under a valve, to confine radioactive contamination, could constitute a criticality safety concern if its shape was not a safe geometry. The performance of ISAs will significantly improve licensee and NRC knowledge, regarding potential accidents and the items relied on for safety, 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 in an

[24] NUREG-1530, *Reassessment of NRC's Dollar per Person-Rem Conversion Factor Policy,* December, 1995. NUREG-1530 explains that applying cost to non-stochastic fatalities is inconsistent with the Commission's *Safety Goal Policy* wherein the Commission made clear that no death will ever be "acceptable" in the sense that the Commission would regard it as a routine or permissible event.

acceptable manner; (b) items relied on for safety 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 70 (see section 2 of this Regulatory Analysis). The new section 70.61 would provide explicit safety performance requirements as well as, in §70.64, baseline design criteria for new facilities. The risk-informed regulation specifies protection must be provided to limit risk of credible high-consequence and intermediate-consequence events. Proposed section 70.72 clarifies what changes the facility 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 requires 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 criticality hazards, and those chemical and fire hazards that affect radiological hazards, as well as direct radiological hazards.

In addition, Options 2 and 3 would mitigate the timely-renewal issue, because the safety features of the license would be kept up to date making it a “living” license. Any changes to the safety basis documentation will 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, with the availability of PRAs, it may be possible, for NRC to quantify the benefits of proposed changes to requirements on these facilities. Thus, any backfit analysis performed in accordance with new section 70.76, could be based on the results of a PRA. Otherwise, backfit analyses would have to be primarily qualitative and, hence, subjective, in nature. However, on balance, NRC believes that Option 3 would provide only a small incremental benefit compared with Option 2, and Option 3 is beset with problems associated with 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 SNM at facilities licensed to possess greater than a critical mass of SNM could result in a number of potential accidents with varying consequences. These accidents could include an inadvertent criticality; public or worker intake of uranium or plutonium; 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.[25] (In 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 SNM processing operations.

Options 1b, 2 and 3 have the potential to prevent and mitigate the consequences and reduce the likelihood of accidents, compared with Option 1a, 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 1b in reducing the consequences and likelihood of accidents because they would apply uniformly to all major SNM licensees. Under Option 1b not all licensees have license conditions that require performance of ISAs and there is considerable variability in the license conditions regarding maintenance of the safety features. Furthermore, Option 1b 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 fabrication facilities have resulted in offsite releases of uranium compounds and contamination of offsite property. At least one 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 population are a release of UF_6 to the atmosphere, a major fire resulting in loss of confinement of SNM, or accidents sending SNM or 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 of these incidents to NRC causes both licensee and NRC resource expenditures to investigate and resolve such incidents. This reporting has value in that it provides the NRC with information needed for it to perform and focus its oversight responsibility and requires a licensee to consider what went wrong and what steps might be needed to prevent a recurrence of this safety degradation, but the trend should be toward fewer incidents happening so that they do not require reporting. Under Option 1b, Bulletin 91-01 requests licensees to report loss of one or more criticality safety controls, but does not mandate those reports and does not address loss of other safety controls. Under Option 1b the NRC's confidence in the margin of safety would remain the same, and the annual number of incidents would also be unchanged.

[25] One death from a criticality at a licensed SNM scrap recovery plant, July 24, 1964, and one from the hydrogen fluoride vapor cloud resulting from release of UF_6 at Sequoyah Fuels Gore, Oklahoma, conversion plant, January 4, 1986.

Reversion to Option 1a, which does not include Bulletin 91-01, would cause a decrease in NRC confidence in the margin of safety. Option 1a would also not require any ISAs, and, therefore:

a) Plant and external hazards and their potential for initiating accident sequences would not be required to be identified;
b) The potential accident sequences, their likelihood, and consequences would not be required to be identified; and
c) The site structures, systems, equipment, components, and activities of personnel relied on to prevent or mitigate potential accidents at a facility would not be required to be identified.

As a result, more accident precursor incidents could be expected by a reversion to Option 1a.

Options 2 and 3 include a requirement that expands the reporting required by the current Part 70 to include reporting criticality incidents (Bulletin 91-01 incidents) as well as loss of other safety controls. The reporting requirements in these options have been written with consideration of risks associated with the full range of incidents of concern, to ensure that safety incidents in addition to criticality are included, but at the same time, to minimize the burden on licensees of reporting inconsequential or low-risk events. 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 that all major licensees 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 1b) to the final rule (Option 2) and from Option 2 to the PRA option (Option 3). It also discusses the sunk cost that was involved in the transition from the pre-1993 action plan (Option 1a) to Option 1b. Details on supporting cost assumptions are discussed in the Appendix.

Most 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 and the guidance provided by the SRP. To a varying degree, some of the other provisions of the final rule and SRP are required by license condition in existing licenses. Following the usual practice for NRC Regulatory Analyses, no credit is given as sunk costs for licensee practices that can be discontinued by the licensee without a license amendment. On the other hand, licensee practices that are commitments included in a license application, provisions of a safety evaluation report (SER), provisions of a license condition, or provisions of a regulation, are considered to be part of the cost baseline (i.e., sunk costs).

The details of the costs are provided below and in the Appendix. A summary of the cost impacts is shown in Table 6.2-1. For licensees that have already implemented a set of license conditions that most nearly approaches the requirements of the final rule (Option 2), the range of estimated average incremental costs to implement the final rule are about $140,000 to $400,000 one-time costs and $20,000 to $40,000 per year. For those licensees with fewest changes in their license conditions under Option 1b, the per licensee range of estimated

average incremental costs to implement Option 2 are about $700,000 to $2,200,000 one-time costs and $150,000 to $230,000 per year.

6.2.1 Option 1 Costs

6.2.1.1 Option 1 Licensee Cost Impacts

- Licensee Incremental Requirements of Option 1b vs Option 1a

Option 1a assumes a reversion to the licensing basis before the action plan was adopted. Incremental changes in requirements due to the action plan (i.e, Option 1b) varies by licensee, but for most licensees (5 of the current 7), included a license condition requiring the performance of an ISA. The standards for the ISA are not defined, and neither are the consequences of concern. Those licensees required by license condition to perform an ISA were all assumed to have to update their design basis documents to as built conditions before beginning the ISA. To varying degrees, Option 1b required establishing or upgrading existing configuration control, quality assurance, training and other measures for ensuring continuous reliability and availability of safety items identified by the ISA. There is considerable nonuniformity in these measures from one licensee to another under Option 1b. Option 1b also includes a license condition requiring 4 of the 7 current licensees to periodically update the demonstration part of their license applications. To account for these individual variations, weighted averages were used for the average costs of licensees already required to perform much of the final rule under Option 1b and those licensees currently required to perform little of the final rule.

- Implementation Costs of Option 1b Compared to Option 1a

Most of the cost involved in going from Option 1a to the Option 1b baseline has already been expended or is in the process of being expended, and is considered sunk cost. Costs that licensees have already expended or will spend in complying with license conditions on establishing configuration management programs, in updating piping and instrumentation drawings to match as-built and as-modified equipment, including the performance of ISAs, are

Table 6.2-1 Summary of Incremental Cost Impacts

	Costs for Current Licensees ($1,000)			
	Costs for average licensee preparing ISA under Option 1b		Costs for average licensee not preparing ISA under Option 1b	
	Low average	High average	Low average	High average
Incremental Sunk Cost of Option 1b Compared to 1a				
Average licensee one time cost ($[26]/licensee)	$700	$2,200	$80	$110
Average licensee recurring costs ($/licensee- year)	$170	$240	$40	$40
Average NRC one time cost ($/licensee)	$60	$140	$0	$140
Average NRC recurring costs ($/licensee- year)	($24)[27]	($23)	$0.7	$1.7
Incremental Cost of Option 2 Compared to Option 1b				
Average licensee one time cost ($/licensee)	$140	$400	$700	$2,200
Average licensee recurring costs ($/licensee- year)	$20	$40	$150	$230
Average NRC one time cost ($/licensee)	($9)	$10	$50	$120
Average NRC recurring costs ($/licensee- year)	($19)	($16)	($11)	($8)
Incremental Cost of Option 3 Compared to Option 1b[28]				
Average licensee one time cost ($/licensee)	$350	$1,400	$800	$3,200
Average licensee recurring costs ($/licensee- year)	$60	$100	$200	$300

[26] Licensee costs in this Regulatory Analysis were originally estimated in terms of 1997 dollars and rounded off. Licensee costs could be adjusted upward by 2.6% to account for inflation between 1997 and 1999. However, this was not done because the difference was small compared to roundoff errors and estimate uncertainty.

[27] Savings are indicated as negative values, shown in parentheses.

[28] No difference in NRC cost was estimated for Option 3 versus Option 2.

considered as the licensee sunk implementation costs for no-action baseline Option 1b. They are part of the baseline for this Regulatory Analysis. The licensees who are required to perform an ISA under Option 1b, implement measures to ensure the reliability and availability of items relied on for safety, are estimated to have license conditions costing on average[29] about $700,000 to $2,200,000 per licensee, with variations depending on several factors.

One factor is the number of complex systems the licensee has to analyze (i.e., the complexity of a licensee's facility and processes), and the labor hours required for each system. As discussed in the Appendix, this Regulatory Analysis presents cost averages based on information from a standard reference on hazards analysis published by the American Institute of Chemical Engineers (AIChE), and also presents cost averages based on communications from two major licensees regarding their cost experience.

Another factor affecting average costs is whether or not the license conditions for a licensee required to perform an ISA include associated requirements for implementation of new measures or upgrading of existing measures to assure the reliability and availability of items relied upon for safety. For example, only 2 of the 7 licensees are required to update their quality assurance of items relied on for safety, 3 have additional record keeping requirements, and 4 have new configuration management requirements. Furthermore, additional Option 1b requirements pertaining to staff training and to self-inspection and maintenance of items relied on for safety were imposed on 6 of the 7 licensees, not just the 5 required to perform an ISA.

Those licensees not performing an ISA under Option 1b are assumed to have incurred some incremental costs compared to Option 1a as a result of their last license renewal. These costs are associated with required enhancements or improvements to staff training, configuration management, quality assurance, and similar measures intended to better ensure safe operations. Average implementation costs for such actions for these licensees are estimated to be in the range of $80,000 to $110,000 per licensee.

- Licensee Operational/Recurring Costs of Option 1b Compared to Option 1a

For a licensee with appropriate conditions in its license, the annual operational (recurring) sunk costs of Option 1b 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 average about $170,000 to $240,000 per licensee per year for those licensees required by license conditions to perform periodic updates of their ISAs and the demonstration sections of their license applications. Other licensees, with minimal requirements for improving Option 1a measures, are also assumed to expend, on average, about $40,000 per licensee-year more under their existing Option 1b requirements than under Option 1a.

[29] In addition to variation in the average cost per licensee, individual licensees can expect to have cost variations about an average.

6.2.1.2 Option 1 NRC Cost Impacts

- NRC Option 1b Implementation Costs

Additional NRC implementation costs are assumed to be required to develop an SRP for Option 1b, because the SRP draft that has been developed assumes the proposal of Option 2 is adopted as a regulation. Not having to expend those funds would be a cost savings in Options 2 and 3 relative to the baseline. These savings for Options 2 and 3 compared to Option 1b are estimated to be approximately 1 FTE (full-time equivalent), or about $150,000[30].

Under Option 1b, the NRC would incur implementation costs in reviewing ISAs for the five licensees required to performing an ISA and in evaluating the actions taken to better assure the availability and reliability of items relied on for safety. These NRC reviews and evaluations are estimated to require, on average, about 900 to 2000 staff-hours per licensee, or incremental NRC expenditures on the order of $60,000 to $140,000 per licensee for the five licensees performing ISAs under Option 1b.

- NRC Option 1b Operational/Recurring Costs

As discussed below, it is estimated that the NRC will have recurring net savings averaging about $24,000 per year per licensee over the long term under Option 1b compared to Option 1a.

The NRC incurs operational costs with Option 1b compared to Option 1a in reviewing periodic updates to the demonstration sections of the license applications. Four fuel cycle facility licensees are required to provide these periodic updates to the NRC. The review costs are estimated to be about $8,000 per licensee per year.

The NRC also expends additional time reviewing the increased number of event reports submitted by licensees as a result of the Bulletin 91-01 requests (and which are assumed to be part of the overall changes from Option 1a to Option 1b). These additional event report reviews are estimated to cost the agency between $4,800 and $12,000 per year, or between $700 and $1,700 per year per licensee.

On the other hand, the NRC's costs associated with performing license renewal reviews are expected to be reduced for those licensees submitting periodic updates to the demonstration sections of their license applications. With Option 1b, four licensees are required to provided these updates. The estimated savings to the agency from reduced license renewal review expenditures is estimated to be about $33,000 per year per each of the four licensees.

[30] The NRC labor rates used in this Regulatory Analysis are discussed in the "Costs per Hour" portion of the Appendix to this Regulatory Analysis.

6.2.2 Option 2 Costs

6.2.2.1 Option 2 Licensee Cost Impacts

- Incremental Requirements of Option 2 vs Option 1b

If a licensee were not required to do so for the Option 1b baseline alternative (two of the seven current licensees are not presently required to perform ISAs), Option 2 would include developing and documenting the required ISAs, including the identification of items relied on for safety and measures to ensure their availability and reliability. Those licensees performing an ISA under Option 1b would likely have to upgrade their existing analyses to meet the standards required by Option 2.

The safety of all existing operating licensees is considered to be adequate, and the licensees are considered competent to safely perform operations with SNM. Accordingly, it is expected that the changes in the current safety basis will not be dramatic, but rather a matter of refinement. It is assumed that for some licensees Option 2 would involve merely a review of their existing measures that ensure the reliability and availability of their safety items, while other licensees may have to establish some new, or upgrade existing, measures. Required actions would include:

- Establish or upgrade measures to ensure that items relied upon for safety 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 items relied upon for safety are designed, constructed, inspected, calibrated, tested and maintained as necessary.

- Establish or upgrade training programs to ensure that personnel are trained to assure 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 6.2-2 indicates the number of current Part 70 licensees judged likely to incur cost impacts by the foregoing provisions of the final rule with Option 2. Also shown are estimates of the relative efforts needed to establish measures or bring existing measures into compliance with the Option 2 requirements. The “relative effort needed to achieve compliance” is indicated as a fraction. A low value indicates that licensees in that group already have measures which are expected to largely satisfy the final rule requirements, and that the remaining effort to achieve full compliance is relatively small. A high value (1.0 is the maximum) indicates that existing

measures are expected to need substantial improvement to comply with the final rule. A value of 1.0 assumes that affected licensees would be given essentially no credit for existing measures, and that an entirely new program would have to be established. The judgments of the relative effort needed to achieve compliance are based on NRC fuel cycle licensing staff suggestions and on comparisons of existing license conditions with the requirements of the final rule and with acceptance criteria of the draft Standard Review Plan.

Table 6.2-2 Relative Impact of Final Rule Reliability and Availability Requirements on Affected Part 70 Licensees

Measures Needed to Assure Reliability and Availability of Items Relied on for Safety	Number of Licensees in Affected Group	Relative Effort Needed to Achieve Compliance with Final Rule
Quality assurance	2	0
	5	1.0
Design[31], construction, inspection, calibration, testing and maintenance measures for items relied upon for safety	6	0.25
	1	1.0
Additional personnel training	6	0.3
	1	0.8
Configuration control	4	0.1
	3	0.75
Additional record keeping	3	0
	4	0.6
Additional event reporting	7	1.0

- Implementation Costs of Option 2 Compared to Option 1b

Each affected applicant or licensee would incur some implementation costs under Option 2, even if the licensee already had conducted an ISA under Option 1b. One time implementation costs that licensees already required to perform an ISA would expend to go from Option 1b to Option 2 could include upgrading of 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 SRP provisions). Weighted average incremental costs for upgrading existing ISAs to Option 2 standards and for measures to ensure reliability and availability of items relied on for safety are estimated at $140,000 to $400,000 per licensee for licensees already required to perform ISAs under Option 1b.

[31] Replacement components are required to be of the correct design and materials.

The licensees who have not committed to perform an ISA under Option 1b would have to do so under Option 2. Weighted average costs to perform an ISA and for measures to ensure reliability and availability of items relied on for safety are estimated to range from $700,000 to $2,200,000 per licensee for licensees who had minimal license conditions imposed under Option 1b.

- Incremental Operational Cost Impacts Compared to Option 1b

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.

The incremental annual recurring or operational costs per licensee are estimated at $20,000 to $40,000 for an average licensee already required by Option 1b to do much of Option 2 requirements. The average annual cost for other licensees is estimated at $150,000 to $230,000.

6.2.2.2 Option 2 NRC Cost Impacts

- NRC Option 2 Implementation Costs

The NRC's incremental implementation activities under Option 2 would consist of initial evaluations of ISA summaries and on-site review of selected ISA details for those licensees who did not commit to perform an ISA under Option 1b, as well as reviews of revised ISAs for the other licensees. 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 or no submittals that are expected under Option 1b. The summaries are expected to reduce NRC staff expenditures of time and effort associated with reviewing ISAs. License reviewers, however, still will need to spend some time at licensee sites reviewing ISAs. For each of the two licensees performing an ISA for the first time, the NRC review and onsite evaluation costs with the ISA summaries are estimated at from $13,000 to $40,000 less than the comparable costs would have been under Option 1b, or an average cost of $47,000 to $100,000 per licensee.[32] For the five licensees whose initial ISAs were reviewed under Option 1b, the NRC's review of the revised ISAs under Option 2 is estimated to average about 120 to 360 staff hours, or about $8,500 to $26,000 per licensee.

Associated with the ISA evaluations would be reviews to assess the adequacy of licensee measures to ensure the reliability and availability of items relied upon for safety. These incremental implementation costs are assumed to require about 80 to 120 staff hours, or about

[32] It is assumed that reviews of ISAs prepared under Option 1b are completed prior to implementation of Option 2. Otherwise, the NRC cost of reviews would show a savings of $5,000 to $13,000 for each of the licensees preparing ISAs under Option 1b.

$6,000 to $9,000 per licensee for licensees required to perform an ISA under Option 1b and on the order of $27,000 to $40,000 per licensee for the two licensees who did not perform an ISA under Option 1b.

- 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 1b.

Licensees would be required to submit updates to their ISA summaries as their ISAs are modified to reflect changes to systems and processes. NRC review of ISA updates for the three licensees not required to provide updates to the demonstration part of their license applications under Option 1b is estimated to cost the NRC about $4,900 per licensee per year under Option 2. On the other hand, NRC review of the ISA updates provided by the other four licensees is expected to require less labor effort per review than the update reviews under Option 1b, because the licensee summaries under Option 2 are expected to be more comprehensive, and hence easier to review, than under Option 1b. This is estimated to be a savings of about $2,700 per licensee per year. With a savings of $10,800 per year for four licensees and an additional cost of $14,700 per year for three licensees, the net cost to the NRC is $3,900 per year, or an average of $600 per year per licensee.

The increased number of licensee event reports expected with Option 2 are estimated to increase NRC operational costs by $13,300 to $33,200 annually compared to the cost of reviews under Option 1b, or $1,900 to $4,700 per licensee,

NRC costs associated with Option 2 license renewal efforts are expected to be reduced compared to those experienced with Option 1b, 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. These savings are estimated to amount to about $18,000 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 1b

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. In general, NRC would not expect any licensees to elect to use PRA methodology under Option 2.

- Implementation Costs of Option 3 Compared to Option 1b

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. According to the Center for Chemical Process Safety:

> Although elements of the CPQRA[33] are being practiced today in the [chemical process industry], only a few organizations have integrated this process into their risk management program. …The reason that these methods are not in more widespread use is that detailed CPQRA techniques are complex and cost-intensive, and require special resources and trained personnel.[34]

Component or "basic-element" reliability data, however, do not appear to be currently available to perform quantitative ISAs on fuel cycle facilities. Fuel cycle facilities may 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.

Based on the assumptions discussed in section A5 of the Appendix, the cost increase for implementation of Option 3 compared to Option 1b ranges from $350,000 to $1,400,000 for the average licensee required to perform an ISA under Option 1b and from $500,000 to $3,200,000 for the average licensee not required to perform an ISA under Option 1b.

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

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

Incremental implementation and operational costs for each alternative are shown in Table 6.2-1 for two "average" licensees, one that was required under Option 1b to perform an ISA and one

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[33] The Center for Chemical Process Safety states, "The term 'Chemical Process Quantitative Risk Analysis' (CPQRA) is used to emphasize the unique character of this methodology as applied to the [chemical process industry]." For the purposes of this Regulatory Analysis, the more familiar term PRA has been used for chemical process quantitative risk analysis.

[34] *Guidelines for Chemical Process Quantitative Risk Analysis*, Center for Chemical Process Safety of the American Institute of Chemical Engineers, 1989, page xvii.

that was not. The differences in high and low costs for each situation reflect, among other things, differences between AIChE estimates and licensee estimates of the cost of performing an ISA.

For licensees that have already implemented a set of license conditions that most nearly approaches the requirements of the Final Rule (Option 2), the range of estimated average incremental costs to implement the Final Rule are about $140,000 to $400,000 one-time costs and $20,000 to $40,000 per year. For those licensees with fewest changes in their license conditions under Option 1b, the per licensee range of estimated average incremental costs to implement Option 2 are about $700,000 to $2,200,000 one-time costs and $150,000 to $230,000 per year. Option 3 implementation costs are estimated to be considerably higher.

7.0. Decision Rationale

a) Option 1b, the actual or *de facto* no-action alternative, 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, as one licensee did in the last round of license renewals.

b) Option 1a would result in a reduction in NRC confidence in the margin of safety. Although the direct licensee costs of this option are considerably lower than for the other options, some of this savings is illusory because the licensees have already expended effort (i.e., Option 1b) that they do not recover by ceasing efforts at developing ISAs. Furthermore, this option would not ensure that licensees have adequate knowledge of the safety basis for their facilities, which likely would lead to more incidents and subsequent NRC investigations, with a greater likelihood of an accident. Hence, Option 1b is preferred to Option 1a.

c) 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.

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

Based on the above analysis, NRC believes that the Final Rule, if adopted, 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 a Standard Review Plan, 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.

The Final Rule states:

> Individuals holding an NRC license on [the date of publication of the final rule] shall, with regard to existing licensed activities:

(i) By <the effective date of the final rule plus 6 months>, submit for NRC approval, a plan that describes the integrated safety analysis approach that will be used, the processes that will be analyzed, and the schedule for completing the analysis of each process.

(ii) By <the effective date of the final rule plus 4 years>, or in accordance with the approved plan submitted under Sec. 70.62(c)(3)(i), complete an integrated safety analysis, correct all unacceptable performance deficiencies, and submit, for NRC approval, an integrated safety analysis summary, including a description of the management measures, in accordance with Sec. 70.65 The Commission may approve a request for an alternative schedule for completing the correction of unacceptable performance deficiencies if the Commission determines that the alternative is warranted by consideration of the following:

(A) Whether it is technically feasible to complete the correction of the unacceptable performance deficiency within the allotted 4 year period;

(B) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis.

Regulatory Analysis - Appendix

Cost Assumptions and Averaging Approach

A1 Estimating Cost of Performing an ISA

The cost of performing an ISA was estimated on the basis of three factors, namely, the labor hours to analyze a single complex system, the cost per hour of that labor loaded with overhead factors, and the equivalent number of complex systems to be analyzed. A simple system is estimated to require about one-fourth the effort of a complex system.

A1.1 Labor Hours

With regard to the factor of labor hours per system, the information obtained from licensees implies that most of their ISA efforts to date consisted of HAZOP[35] analyses, and What-If was used to a lesser extent. An evaluation of the total projected ISA effort of one licensee indicated that a split of 2/3 HAZOP, 1/3 What-If may be a reasonable assumption. The labor required to accomplish these analyses can vary widely, depending on the type of analysis performed, the complexity of the target systems, and the number of people making up the evaluation team.

Guidance in the AIChE document on qualitative hazards analysis[36] was used to estimate the range in the labor requirements for HAZOP and What-if analyses. The estimate is based on the following assumptions:

- the minimum team size would be 5 people, and the maximum size would be 8 people.
- the documentation efforts would be performed by only two members of the team.
- the estimates apply to complex systems.

The results are shown in Table A.

Using the above HAZOP/What-if split with the foregoing "mean" efforts, and noting that not all team members are needed to perform certain of the activities, gives an estimate of 800 labor-hours for analysis of one complex system. This value was used as one basis for estimating ISA efforts.

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[35] A description of HAZOP and What-If analysis methodologies may be found in the draft NUREG-1513, *Integrated Safety Analysis Guidance Document,* which is included in this rulemaking package and is available at the NRC Public Document Room. A more detailed description is available in *Guidelines for Hazard Evaluation Procedures, Second Edition with Worked Examples,* Center for Chemical Process Safety of the American Institute of Chemical Engineers (AIChE), 1992. This is one of the chemical industry references cited by the Occupational Safety and Health Administration in its rulemaking on Process Safety Management rulemaking (10 FR 6356, February 24, 1991.)

[36] Ibid.

In addition to the labor effort included above for documenting the ISA, an additional effort by licensees was assumed to be needed for those options requiring the submittal of comprehensive summaries of ISA results to the NRC. The effort to prepare these ISA submittals was estimated to require about two person-weeks (80 hrs) per system to prepare.

A1.2 Costs per Hour

Average industry labor rates for skill categories assumed to be representative of the work required were estimated based partially on information obtained from fuel fabrication licensees. Licensee actions and activities involved in performing work that might be required by alternatives under consideration in this Regulatory Analysis were assumed to be accomplished by two types of work groups. Group 1 could be used to perform analytical efforts which were not overly complex, and could include activities such as creating or revising procedures. Group 2 would be needed to perform more complex evaluations such as performing ISAs and determining measures needed to assure the reliability and availability of items relied on for safety. Each group was assumed to include management, engineers, and clerical staff. Somewhat different mixes were assumed for each group. For example, Composite Group 1 was assumed to require 15% management, 70% engineering staff, and 15% clerical support, while Composite Group 2 had 15 % management, 75% senior engineering staff, and 10% clerical support. The resulting composite labor rate as generated accounted for basic wages, applicable overheads, fringe benefits, and profit. The resulting loaded labor rates for licensees were $50.50 for Composite Group 1 and $57.00 for Composite Group 2. (These labor rate estimates may be somewhat overestimated, because chemical industry experience applying HAZOP and What-if is that teams need someone trained in the hazards analysis methodology but usually need no management member, only a single engineer, and the balance are typically process operators and maintenance personnel.)

NRC labor rates were derived from NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook", which gives $67.50 as the NRC labor rate for 1996. . The resulting NRC composite labor rate was taken to be $73 per hour for 1999. Following standard practice for NRC Regulatory Analyses, this rate is not fully burdened, but represents base wages for staff plus an allowance for management efforts and for efforts by support staff.

A1.3 Number of Systems

The third factor in determining the cost of performing an ISA is the number of complex and simple systems at an average facility. A major fuel fabrication facility generally includes the process steps listed in Table B. Following AIChE guidelines, this type of facility can be considered to consist of four complex and six simple systems.

Of the current seven major fuel cycle licensees that would be subject to this rulemaking, four can be characterized as equivalent to the above plant description. One only loads pellets into fuel rods and assembles rods into fuel bundles, so has no complex process systems, and therefore its ISA should require much less effort. Another facility is also primarily involved in mechanical rather than chemical processes, except for wet scrap recovery operations. It is estimated to have about three complex and a dozen simple systems. The seventh current major licensee is estimated to have about 12 complex systems.

The AIChE guidelines indicate that an ISA for a simple system, using HAZOP and What-If analysis, can be performed for about one-quarter of the effort required for a complex system. On average then, it could be assumed that a typical major fuel cycle licensee has the equivalent of about 6 complex systems.

However, information from one major fuel fabrication licensee is that it has 28 systems in its ISA (complexity not specified), which implies a different breakdown than indicated in Table B. Using 28 systems, 18 of which conservatively are assumed to be complex, for the four licensees whose operations may be roughly characterized by Table B, it was estimated that the seven major fuel cycle licensees averaged the equivalent of 15.5 complex systems per licensee. The same licensee provided an estimate of its cost to perform an ISA, from which it was estimated that they used about 1780 labor hours per system. Licensee opinion that the AIChE estimates may be too low was also stated by a second major licensee, who could not provide cost of performing an ISA but did claim that the AIChE labor estimates per system were a factor of three too low.

A1.4 Error Sources in Estimates of Performing an ISA

The AIChE estimates may be somewhat low because they neither include criticality as a hazard nor include any accident analyses that might be necessary. The possibility is also recognized that information provided by licensees could include costs that may not be solely attributable to the performance of an ISA, such as the cost of criticality analyses that would be done even if an ISA was not performed, and the cost of bringing plant diagrams up to date, which we are considering as a cost separate from the ISA. The true costs of performing an ISA probably lies somewhere between these two extremes.

A2 Estimating Costs of Related Measures

In addition to the costs of preparing for, performing, and documenting the ISA, there are several related activities that may have cost impacts. Licensees that expended resources in upgrading measures (e.g., training) under Option 1b requirements, but that were considered not to fully meet the standards to be imposed by Option 2, were assumed to expend the balance of the resources under Option 2 needed to achieve a complete program (i.e., to meet acceptance criteria in the SRP). For example, if a licensee expended 70% of the resources under Option 1b needed to establish a suitable employee training program, that licensee was assumed to expend 30% under Option 2 to achieve a fully compliant program (0.7 + 0.3 = 1.0). The only exception to this approach was that the five licensees performing an ISA under Option 1b were assumed on average to expend 15% of the full ISA development costs under Option 2 to bring their ISAs up to Option 2 standards.

Table C indicates the level of effort estimated for these upgrade or implementation actions. Estimated implementation costs for these activities are also shown.

Most of the activities listed in Table C had their implementation efforts estimated on a per-system basis. The exception is the staff training/retraining. The training efforts assumed that training manuals would be upgraded based on ISA results and that affected staff members would be required to take enhanced training. The number of affected staff members per facility was based on the number of individuals at fuel facilities with measurable doses (see

NUREG-1272). Record keeping expenditures assumed that new storage space and new storage equipment (I.e., new filing cabinets, new computer data storage systems) would have to be provided, and were assumed to be dependent on the number of systems characterizing the facility.

The implementation costs to establish or upgrade the measures needed to assure the reliability and availability of items relied on for safety were assumed to affect all licensees to some degree under Option 2, depending on the quality and comprehensiveness of their existing measures. The relative impacts for various licensee groups were noted in Table 6.22. Table D indicates the associated cost ranges for upgrading these existing measures or establishing needed measures.

A3 Estimating Annual Cost of Operations

Operational costs for each alternative were estimated using incremental annual operational costs associated with the alternative. Costs that occur less frequently than annually were prorated to an annual basis, using the assumption of a 20 year remaining plant life. To convert to present value, a discount rate of 7% was used. The 7% discount rate is suggested in NUREG/BR-0058, Rev. 2.

Incremental licensee operational costs associated with alternatives may include maintaining system and process safety information current, retraining and testing personnel, maintaining configuration control records, and updating process safety information. Table E shows the estimated licensee efforts and costs associated with these activities.

In addition, past history indicates that changes are frequently made to systems and facilities licensed under Part 70, or new processes are added to existing facilities. The data accumulated by the NRC over the past several years 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 three years, or about two thirds of a major modification per year. Major modifications require license amendments. The cost of demonstrating the safety of a proposed amendment will possibly be less with an ISA available to help provide a basis for demonstrating safety, but no credit for such savings was taken in this Regulatory Analysis. Table E includes the annual estimated hours for updating ISAs for minor process modifications. The effort needed to update an ISA for these types of modifications was estimated to be about 20% of the effort needed to evaluate a complex system. Thus, the annual ISA updating effort was assumed to be the equivalent of each licensee performing an ISA of slightly more than one complex system.

The estimates provided in Table E do not give credit for existing measures that could partially or completely satisfy the specified requirements. Such existing measures and measures already required by current license conditions could reduce the actual cost impacts to licensees. Accordingly, the estimates in Table E were multiplied by indicated factors to arrive at the cost estimates reported in section 6.2.

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 the remaining plant life (assumed to be 20 years) is estimated to average a present value of $580,000 to $860,000 per licensee, or about $55,000 to $80,000 (savings) per licensee per year.

Table F summarizes the estimated recurring cost impacts of Option 2 compared to Option 1b. The licensee groups with the lower costs are those that, under Option 1b, are already performing some or all of the required actions called for with Option 2; the converse is true for the licensee groups with the higher cost ranges.

A4 New Reporting Costs

The assumption was made that the issuance of new reporting requirements under Options 2 and 3 would result in event reporting trends analogous to what was experienced with the issuance of Bulletin 91-01. That trend showed a several-fold increase in the number of event reports per year for the first 3-4 years after issuance of the bulletin, and then subsequently decreasing to a level about two and one-half times the number of event reports experienced prior to issuance of the bulletin. The current average number of these reports in recent years has been about 2.1 per licensee-year for major licensees. The estimate of incremental reporting costs assumed that this historical trend will be repeated, starting from the current level of event reports. The number of such events was assumed to be proportional to the number of equivalent complex systems characterizing fuel cycle facilities. To estimate costs, it was further assumed that licensees would expend about one person-week in preparing each event report and responding to NRC inquiries. The resulting average incremental reporting cost is estimated to be in the range of $4,000 to $11,000 per licensee per year (averaged over remaining facility lifetime).[37]

A5 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. In addition, the quantitative ISA is assumed to require a reliability data collection effort to support the analysis. The qualitative ISAs already committed to by licensees could be helpful for the PRAs, and credit was given for these commitments. This basis resulted in estimated incremental quantitative ISA costs of $185,000 to $1.1 million per licensee, on average, for licensees performing a qualitative ISA under Option 1b. Licensees not performing an ISA under Option 1b would incur costs, on average, of between $400,000 and $2.4 million per licensee to perform the quantitative analysis. (This is the incremental cost from Option 1b, rather than the incremental cost from

[37] Event reporting is assumed to increase by a factor of about 5 over baseline values for the first 3-4 years after the new requirements are issued, and then to about 2.5 times the pre-change level for the balance of the facility life. Thus, the reporting expenditures are not constant over the remaining life of a facility. Averaging over remaining facility life is a way of presenting the equivalent annual costs without getting into the complexity of the early year costs versus the later year costs.

Option 2.) In addition, the initial data collection efforts (e.g., failure rates) necessary for PRAs are estimated to cost an additional $60,000 to $160,000 per licensee. Other implementation costs for Option 3 would be the same as those noted for Option 2.

Operational costs would also be higher. The annual data collection efforts are estimated to cost between $2,000 and $6,000 per licensee. For licensees with ISA commitments under Option 1b, the efforts associated with performing quantitative ISA updates are in the range of $50,000 to $120,000 more per licensee annually than those for qualitative ISAs. Licensees without ISA commitments under Option 1b would be expected to expend about $75,000 to $160,000 annually per licensee to update quantitative ISAs.

A6 Cost Summaries

Table 6.2-1 itemizes estimated cost impacts to licensees in transitioning from one option to another. Costs are shown for the transitions from Option 1a to Option 1b (considered to be sunk costs), from Option 1b to Option 2, and from Option 1b to Option 3. Estimates are provided for both implementation and operational/recurring activities. All costs are on a per-licensee basis. Table 6.2-1 provides estimates for two categories of licensees: those which, in the context of the transition being considered, have already been required to implement a license condition that encompasses the proposed requirement to some significant degree, and those which have either not previously had such a license condition or whose implementation of the license condition is expected to need substantial improvement to satisfy the proposed alternative.

As shown in Table 6.2-1, there are large variations in the costs to each licensee, because of variations in licensees processes, variations in the current licensing basis for the licensees, and uncertainties in the cost estimates.

To summarize these cost estimates, the low and high average costs for each cost element were added. In addition, Table G shows total costs to the seven current licenses and "average costs." The values in Table G were rounded off in Table 6.2-1, so as not to imply a high degree of certainty in the estimates.

Table A. AIChE Labor Estimates for Performing a Complex System ISA

ISA Activity	HAZOP Analysis Complex System		What-If Analysis Complex System	
	Low	High	Low	High
Preparation	2d	4d	1d*	3d*
Modeling	-	-	-	-
Evaluation	1w	3w	3d	5d
Documentation	2w*	6w*	1w*	3w*
Labor with 5 member team, hrs	440	1,240	216	488
Labor with 8 member team, hrs	608	1,696	288	608
"Mean" Effort, labor-hrs/system	996		400	

d=day, w=week

*Activity typically performed by 2 team members

Table B. Systems Characterizing Typical Full Scope Fuel Fabrication Facilities

System	Segment	
Shipping/Receiving	1 - UF_6 receiving	S
	2 - UF_6 cylinder washing	
	3 - Shipping container refurbishment	
UF_6 conversion	4 - UF_6 vaporization	C
	5 - formation of UO_2F_2	
	6 - Calcination to produce UO_2	
	7 - Offgas system	
	8 - HF recovery	
	9 - waste handling	
UO_2 powder production	10 - blending	S
	11 - refining	
UO_2 pellet formation	12 - pressing	C
	13 - sintering	
	14 - grinding	
Fuel rod loading	15 - pellet loading and end plugs	S
Fuel bundle assembly	16 - mechanical process of joining fuel and poison rods together. with spacers and end plates	S
Scrap recovery	17 - Dissolution	C
	18 - Solvent extraction	
Waste treatment & handling	19 - liquid wastes	C
	20 - solid wastes	
	21 - gaseous wastes/effluents	
Laboratory operations	22 - product quality and accountability measurements	S
Ventilation systems	23 - ducts and filters	S
Estimated number of complex (C) systems		4
Estimated number of simple (S) systems		6

Table C. ISA-Related Implementation Activities

Implementation Activity	Burden per Licensee[38]		
	Hours	Cost (in 1997 dollars)	Hourly rate ($/hr)
Compile and update baseline process safety information (if existing baseline process safety information is out of date).	1,200-3,100 hrs	$60,000 - $160,000	$50.50
Establish or upgrade measures that ensure that items relied on for safety are designed, constructed, inspected, calibrated, tested and maintained as necessary	600-1,550 hrs	$35,000 - $90,000	$57.00
Establish or upgrade training programs to ensure that personnel are trained, tested, and retested to assure they recognize and understand safety concerns	24 hrs/ staff; ~350 affected staff/licensee	$295,00 - $320,000	$33.00 per student-hr
Establish and maintain configuration control to ensure that changes are reviewed, documented, and adequately communicated to affected staff and parties	350-540 hrs	$30,000 - $60,000	$57.00
Establish or upgrade measures to ensure that items relied on for safety meet quality standards commensurate with their importance, and establish corresponding policies and procedures	620-1,000 hrs	$90,000 - $140,000	$57.00
Establish and maintain records that demonstrate adherence to new regulatory requirements	-	$30,000 - $75,000	-
Cost per Licensee (in 1997 dollars)	$540,000 - $840,000		

[38] The estimated per licensee costs in this table account for cost differences due to differences in the number of systems assumed for affected facilities. The range does not account for uncertainties in the individual estimates. The labor efforts and costs shown do not give credit for existing measures to which licensees may already be committed. Adjustments for sunk costs for existing commitments are discussed in section 6.2.1.

Table D. Cost Impacts of Final Rule Reliability
and Availability Requirements on Affected Part 70 Licensees

Measures Needed to Assure Reliability and Availability of Items Relied on for Safety	Number of Licensees in Affected Group	Cost Impacts to Achieve Compliance with Final Rule
Quality assurance	2	0
	5	$18,000 - $30,000
Design[39], construction, inspection, calibration, testing and maintenance measures for items relied upon for safety	6	$10,000 - $22,000
	1	$35,000 - $90,000
Personnel training	6	$90,000 - $100,000
	1	$235,000 - $260,000
Configuration management	4	$3,000 - $6,000
	3	$22,000 - $42,000
Record keeping	3	0
	4	$18,000 - $45,000

[39] Replacement components are required to be of the correct design and materials.

Table E Estimated Incremental Operational Activities Burden Per Licensee Per Year

Incremental Operational Activity	Average Annual Burden per Licensee		
	Hours	$	Rate, $/hr
Maintaining process safety information up to date	120-310 hrs	$6,000 - $15,000	$50.50
Personnel training/retraining	5,700 hrs	$185,000	$33/ student -hr
Configuration management	520-675 hrs	$26,000 - $34,000	$50.50
Updating ISA for process and system changes	750-1,660 hrs	$50,000 - $110,000	$57.00
Estimated Annual Costs for All Foregoing Activities, per licensee	$280,000-$345,000		

Table F. Licensee Recurring Cost Impacts of Option 2 Relative to Option 1b

Affected Area or Activity	Number of Licensees in Affected Group	Recurring Cost Impacts to Achieve Compliance with Final Rule, $/licensee-year
Update ISA	4	$10,000 - $20,000
	3	$50,000 - $110,000
Maintaining design basis documentation	6	$2,000 - $5,000
	1	$5,000 - $12,000
Personnel training	6	$55,000
	1	$150,000
Design, construction, inspection, calibration, testing and maintenance, quality assurance, recordkeeping	4	$3,000 - $4,000
	3	$20,000 - $25,000
Event reporting	7	$4,000 - $11,000
License renewals	4	($55,000)
	3	($80,000)

Table G - Incremental Cost Impacts
(In thousands of 1997 dollars)

G-1 Incremental Cost of Option 1.b Compared to 1a

Cost1`Item	Number of lic. already with req.	Cost to a licensee already with requirement		Number of lic. needing to add req.	Cost to a licensee to add requirement		Sum of costs to all licensees already with requireme		Sum of costs to all licensees previously without requirement	
		Low	High		Low	High	Low	High	Low	High
One time Cost										
Update design basis documents to as-built conditions	5	$60	$160	2	0	$0	$300	$800	$0	$0
Perform initial ISA	5	$275	$1,575	2	0	$0	$1,375	$7,875	$0	$0
Design, construction, inspection, calibration, testing and maintenance	6	$25	$65	1	0	$0	$150	$390	$0	$0
Enhanced staff training	6	$210	$225	1	$60	$65	$1,260	$1,350	$60	$65
Configuration control	4	$25	$50	3	$10	$15	$100	$200	$30	$45
Quality assurance	2	$35,	$60	5	0	$0	$70	$120	$0	$0
Record keeping	3	$30	$75	4	$10	$30	$90	$225	$40	$120
Total Cost of Elements		**$660**	**$2,210**		**$80**	**$110**				
Average number of licensees	4.4286			2.5714						
Total industry one time cost for Option 1b							$3,345	$10,960	$130	$230
Average licensee one time cost for Option 1b							**$755**	**$2,475**	**$51**	**$89**
Recurring Costs per Year										
Update design basis documents to as-built conditions (re changes)	6	$4	11	1	0	$0	$24	$66	$0	$0
Update ISAs for modifications	4	$40	90	3	0	$0	$160	$360	$0	$0

Table G - Incremental Cost Impacts (cont.)

Staff training	6	$130	130	1	$35	$35	$780	$780	$35	$35
Configuration control, quality assurance, inspection, test, maintenance	4	$25	30	3	$6.5	$8.5	$100	$120	$20	$26
License renewals	4	($25)	($25)	3	$0	$0	($100)	($100)	$0	$0
Total Cost of Elements		**$174**	**$236**		**$42**	**$44**				
Average number of licensees	4.8			2.2						
Total industry annual recurring cost for Option 1b							$964	$1,226	$55	$61
Average licensee annual recurring cost for Option 1b							**$201**	**$255**	**$25**	**$27**

Table G - Incremental Cost Impacts (cont.)

G-2 Incremental Cost of Option 2 Compared to Option 1b

Cost Item	Number of lic. already with req.	Cost to a licensee already with requirement		Number of lic. needing to add req.	Cost to a licensee to add requirement		Sum of costs to all licensees already with requireme		Sum of costs to all licensees previously without requirement	
		Low	High		Low	High	Low	High	Low	High
One time Cost										
Update design basis documents to as-built conditions	5	0	0	2	$60	$160	$0	$0	$120	$320
Cost of performing ISA or refining earlier ISA	5	$40	$240	2	$275	$1,575	$200	$1,200	$550	$3,150
Design, construction, inspection, calibration, testing and maintenance	6	$10	$22	1	$35	$90	$60	$132	$35	$90
Enhanced staff training	6	$90	$100	1	$235	$260	$540	$600	$235	$260
Configuration control	4	$3	$6	3	$22	$42	$12	$24	$66	$126
Quality assurance	2	0		5	$18	$30	$0	$0	$90	$150
Record keeping	3	0	0	4	$18	$45	$0	$0	$72	$180
Total Cost of Elements		**$143**	**$368**		**$663**	**$2,202**				
Average number of licensees	4.4286			2.5714						
Total industry one time cost for Option 2							$812	$1,956	$1,168	$4,276
Average licensee one time cost for Option 2							**$183**	**$442**	**$454**	**$1,663**
Recurring Costs per Year										
Update design basis documents to as-built conditions	6	$2	$5	1	$5	$12	$12	$30	$5	$12
Updates to ISA	4	$10	$20	3	$50	$110	$40	$80	$150	$330

Table G - Incremental Cost Impacts (cont.)

Recurring training	6	$55	$55	1	$150	$150	$330	$330	$150	$150
Configuration control, quality assurance, inspection, test, maintenance	4	$3	$4	3	$20	$25	$12	$16	$60	$75
Enhanced event reporting requirements	4	$4	$11	3	$4	$11	$16	$44	$12	$33
License renewals	4	**($55)**	**($55)**	3	**($80)**	**($80)**	**($220)**	**($220)**	**($240)**	**($240)**
Total Cost of Elements		**$19**	**$40**		**$149**	**$228**				
Average number of licensees	4.6667			2.3333						
Total industry annual recurring cost for Option 2							$190	$280	$137	$360
Average licensee annual recurring cost for Option 2							**$41**	**$60**	**$59**	**$154**

Table G - Incremental Cost Impacts (cont.)

G-3 Incremental Cost of Option 3 Compared to Option 1b

Cost Item	Number of lic. already with req.	Cost to a licensee already with requirement		Number of lic. needing to add req.	Cost to a licensee to add requirement		Sum of costs to all licensees already with requireme		Sum of costs to all licensees previously without requirement	
		Low	High		Low	High	Low	High	Low	High
One time Cost:										
Update design basis documents to as-built conditions	5	0	0	2	$60	$160	$0	$0	$120	$320
Establish reliability data base	5	$60	160	2	$60	$160	$300	$800	$120	$320
Cost of performing PRA or additional cost for converting qualitative ISA to PRA	5	$185	$1,100	2	$400	$2,400	$925	$5,500	$800	$4,800
Design, construction, inspection, calibration, testing and maintenance	6	$10	$22	1	$35	$90	$60	$132	$35	$90
Enhanced staff training	6	$90	$100	1	$235	$260	$540	$600	$235	$260
Configuration control	4	$3	$6	3	$22	$42	$12	$24	$66	$126
Quality assurance	2	0	0	5	$18	$30	$0	$0	$90	$150
Record keeping	3	0	0	4	$18	$45	$0	$0	$72	$180
Total Cost of Elements		**$348**	**$1,388**		**$848**	**$3,187**	$1,837	$7,056	$1,538	$6,246
Average number of licensees	4.5			2.5						
Total industry one time cost for Option 3							$1,837	$7,056	$920	$5,120
Average licensee one time cost for Option 3							**$408**	**$1,568**	**$368**	**$2,048**
Recurring Costs per Year										
Maintaining reliability data	5	$2	$6	2	$2	$6	$10	$30	$4	$12
PRA updates for changes	5	$50	$120	2	$75	$160	$250	$600	$150	$320

Table G - Incremental Cost Impacts (cont.)

Update design basis documents to as-built conditions	6	$2	$5	1	$5	$12	$12	$30	$5	$12
Recurring training	6	$55	$55	1	$150	$150	$330	$330	$150	$150
Configuration control, quality assurance, inspection, test, maintenance	4	$3	$4	3	$20	$25	$12	$16	$60	$75
Enhanced event reporting requirements	4	$4	$11	3	$4	$11	$16	$44	$12	$33
License renewals	4	($55)	($55)	3	($80)	($80)	($220)	($220)	($240)	($240)
Total Cost of Elements		**$61**	**$146**		**$176**	**$284**	$410	$830	$141	$362
Average number of licensees	4.8571			2.1429						
Total industry annual recurring cost for Option 3							$410	$830	$141	$362
Average licensee annual recurring cost for Option 3							**$84**	**$171**	**$66**	**$169**