SECY-97-137

June 30, 1997

FOR: The Commissioners

FROM: L. Joseph Callan /s/
Executive Director for Operations

SUBJECT: PROPOSED RESOLUTION TO PETITION FOR RULEMAKING FILED BY THE NUCLEAR ENERGY INSTITUTE

PURPOSE:

To obtain Commission approval of staff's proposed resolution to the Petition for Rulemaking (PRM-70-7) filed by the Nuclear Energy Institute (NEI), which includes staff's recommendations to revise 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material" [SNM].

BACKGROUND:

On September 30, 1996, NEI filed a petition for rulemaking on behalf of certain Part 70 licensees and potential licensees. The Petition requests that Part 70, "Domestic Licensing of Special Nuclear Material," be amended by adding three new provisions. On November 26, 1996, a summary of the Petition and a request for public comments were published in the *Federal Register*; five comment letters were received in response to this request.

Before submission of the Petition, staff provided the Commission with a paper, SECY-96-079, "Alternatives for Regulating Fuel Cycle Facilities." Subsequent to the submission of the Petition, staff provided a second paper, SECY-97-097, "Additional Alternative for Regulating the Safety of Fuel Cycle Facilities: Nuclear Energy Institute Petition for Rulemaking." The staff recommendations in this paper supercede the alternatives in the previous papers and are the staff recommended course of action for rulemaking associated with fuel cycle facilities.

DISCUSSION:

The Petition requests that the current Part 70 be amended by adding three new provisions that would:

(1) Add a definition of a uranium processing and fuel fabrication plant;

(2) Require the performance of an integrated safety assessment[(1)], or an acceptable alternative, for uranium processing, fuel fabrication, and enrichment plants, to confirm that adequate controls are in place to protect the public health and safety; and

(3) Require a backfit analysis, under certain circumstances.

Five comment letters were received in response to the *Federal Register* Notice, which requested public comments on the NEI petition. Four letters were from current Nuclear Regulatory Commission fuel cycle facility licensees and the remaining letter was from a current NRC certificate holder. In summary, the comment letters support the Petition's provisions regarding the performance of an integrated safety assessment and backfitting. In addition, one comment letter provided certain suggested changes to the proposed rule text, and another comment letter recommended that NRC should develop supporting guidance, in the form of regulatory guides, which should be available for public comment before a rule is finally promulgated. All the public comments were considered in staff's review and development of the proposed resolution to the Petition. The results of staff's review of the Petition and its recommended resolution are presented in Attachment 1.

RECOMMENDATIONS:

Staff agrees in principle with the Petition and recommends that the Commission direct the staff to proceed with rulemaking, which would include the basic elements of the Petition, with some modifications. Staff's recommendations for the resolution of the Petition, including these modifications, are presented in Attachment 1. These recommendations would establish a risk-informed framework for revising Part 70.[(2)] A summary of staff's recommendations is presented in Attachment 2. Copies of the Petition and the five comment letters received are contained in Attachments 3 and 4, respectively.

In summary, the staff proposes to revise Part 70, as requested by the NEI Petition, with staff's modifications, to include the following major elements:

(1) Performance of a formal ISA, which would form the basis for a facility's safety program. This requirement would apply to all facilities (except reactors and the gaseous diffusion plants) or activities, subject to NRC regulation, that are authorized to possess SNM in quantities sufficient to constitute a potential for nuclear criticality;

(2) Establishment of limits to identify the adverse consequences that licensees must protect against;

(3) Inclusion of the safety bases in a license (i.e., the identification of the potential accidents, the items relied on to prevent or mitigate these accidents, and the measures needed to ensure the continual availability and reliability of these items). (This is in sharp contrast to Petition's approach, where the ISA results would not be included in the license);

(4) Based on the results of an ISA, licensees would be able to make 10 CFR 50.59-type changes as long as such changes do not decrease the effectiveness of the program being changed or involve unresolved safety issues; and

(5) After initial conduct and implementation of the ISA by the licensees, the Commission would consider a qualitative backfitting mechanism to enhance regulatory stability.

There are no significant resource, information technology, or information management impacts that would result from this paper. Resources to conduct this rulemaking are included in budget.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection.

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Attachments:
1. Proposed Resolution to Petition for Rulemaking
2. Summary of Staff's Proposed Resolution to Petition for Rulemaking
3. Copy of Petition
4. Public Comment Letters

ATTACHMENT 1

PROPOSED RESOLUTION TO PETITION FOR RULEMAKING

This attachment presents a discussion of staff's review of, and recommended resolution to, the Petition for Rulemaking (PRM-70-7) filed with the Nuclear Regulatory Commission on September 30, 1996, by the Nuclear Energy Institute, on behalf of certain 10 CFR Part 70 licensees and potential licensees. The Petition requests that Part 70, "Licensing of Special Nuclear Material," be amended by adding three new provisions. These provisions would: (1) add a definition of a uranium processing and fuel fabrication plant; (2) require uranium processing and fuel fabrication plants and enrichment plants to perform an integrated safety assessment,[3] or "... an acceptable alternative integrated approach to safety;" and (3) require a backfit analysis, under certain circumstances.

Five comment letters[4] were received in response to a request for public comments published in the *Federal Register* on November 26, 1996. (Copies of these letters are provided in Attachment 4.) Four letters were from current NRC fuel cycle facility licensees, and the fifth letter was from an NRC certificate holder. All five comment letters support the Petition's provisions regarding the performance of an integrated safety assessment and the addition of a backfit provision. In addition, one comment letter provided certain suggested changes to the proposed rule text, and another comment letter also stated support for those proposed rule text changes. Another comment letter stated that NRC should develop supporting guidance and that it should "...be made available for public review and comment before the rule is finally promulgated so that the public has due notice and opportunity to be heard on the features and impact of the rule as it will be interpreted and applied by NRC staff." All public comments were considered in the development of a proposed resolution to the Petition.

The Petition addresses a number of different topics. The following sections present a discussion of the Petition's proposed rule text, along with staff's proposed resolution. The topics addressed include:

1.0 PERFORMANCE OF AN ISA

In the proposed provision under "70.40, Integrated Safety Assessment," Petitioners request that the rule language include the following:

> *"Uranium processing, fuel fabrication, and uranium enrichment plant licensees licensed under 10 CFR Part 70, shall perform an Integrated Safety Assessment (ISA), or provide an acceptable alternative integrated approach to safety, to determine the SSCs [structures, systems, and components] and programs that will be used by the licensee to protect public health and safety...." (NEI petition, p. 10)*[5]

The two issues addressed in this portion of the proposed provision are: (1) the scope of applicability, and (2) the flexibility of licensees to provide an alternative to the ISA, which, as Petitioners stated, "...might not conform to a formal 'hazards analysis' but could still provide the NRC and the licensee with adequate confidence in facility safety." These issues are discussed below.

Scope of Applicability

The Petition requests that Part 70 be revised to require the performance of an ISA and that this requirement be limited to uranium processing, fuel fabrication, and uranium enrichment plants. The basis for the limited scope of applicability is that Petitioners "...do not believe that the 'possibility' that the NRC may be asked to regulate DOE facilities provides an appropriate basis for imposing significant new programmatic changes on an entire industry that has operated successfully under the existing requirements." They also stated that "...it is not clear that the NRC should, or even could at this stage, attempt to develop a set of meaningful regulatory changes given the very wide range of facilities, hazards and operations within the DOE complex." (p. 3)

Resolution:

Staff strongly agrees that "Uranium processing, fuel fabrication, and uranium enrichment plant licensees licensed under 10 CFR Part 70..." should perform an ISA. In addition to the Petition's proposal, staff recommends that the ISA requirements apply to all types of facilities (except reactors and the Gaseous Diffusion Plants) subject to NRC regulation (e.g., existing NRC licensees or potential activities such as atomic vapor laser isotope separation (AVLIS), mixed oxide fuel (MOX), and other proposed Department of Energy (DOE) activities) that are authorized to possess special nuclear material (SNM) in quantities sufficient to constitute a potential for nuclear criticality. Broadening the scope of applicability of the ISA requirement beyond what the Petition proposes will not impose extra burdens on NRC's current fuel cycle licensees (i.e., with or without this broadened scope, the same requirements would apply to fuel cycle licensees). Thus, staff recommends that a risk-informed approach (consistent with Commission policy) for regulating safety be applicable to all facilities and activities that are authorized to possess specific threshold quantities of SNM.(6)

As mentioned above, the Petitioner's expressed concern about "...significant new programmatic changes..." that NRC may impose on industry. However, examples or the specifics of the concerns were not included in the Petition. Staff is not recommending any "...new significant programmatic changes" to address the specific needs associated with the regulation of new facilities. Recommended changes are in response to weaknesses that were identified by numerous sources, which include the recommendations contained in NUREG 1324, "Proposed Method for Regulating Major Materials Licensees."

Certain features of the April 1995 draft rule did include the establishment of "multiple safety programs" (e.g., fire protection, chemical process safety, criticality, management controls, configuration management, quality assurance, maintenance, and training). However, the possibility of licensing or certifying new facilities was not the reason for including these features in the draft rule. At the various 1995 NRC-sponsored public workshops, where proposed revisions to Part 70 were discussed, industry representatives stated that they oppose the proposal of multiple safety programs. In response to licensees' concerns, staff is now proposing that, rather than require multiple safety programs to ensure the continual availability and reliability of items relied on for safety (see SECY-96-079), licensees have the flexibility to determine, based on the ISA results, the specific elements of the safety program that would be needed.

Alternative to an ISA

The Petition discussion includes a statement that:

> "The rule should provide flexibility for licensees to offer alternative approaches [to an ISA] for the NRC's consideration. Such approaches might not conform to a formal `hazards analysis,' but could still provide the NRC and the licensee with adequate confidence in facility safety. The rule should allow for such alternative approaches, but would require the licensee to obtain NRC approval of, and complete its efforts, as the rule requires, for formal ISAs." (p. 7)

Within the framework of an ISA, Petitioners stated that "...the AIChE [American Institute of Chemical Engineers] document provides reasonable approaches, and that other formal methods may also be acceptable." They also request that the analyses being performed under the Occupational Safety and Health Administration's (OSHA's) Process Safety Management regulations and the Environmental Protection Agency's (EPA's) Risk Management Program regulation be considered acceptable means of meeting the ISA requirement for evaluating hazards within NRC's jurisdiction.

Resolution:

Staff supports the Petition request to consider alternative approaches for conducting an ISA. However, the staff has concerns about alternative approaches that are not considered a formal and integrated "hazards analysis." Staff's view is that a "formal" hazards analysis, as compared with an informal or unstructured approach to hazards analysis, is one that involves a systematic, comprehensive, and well-documented approach for the conduct of an ISA. In addition, the ISA should consider all types of potential hazards (e.g., criticality, chemical, radiological, fire) in an integrated manner. The ISA will form the basis of a facility's safety program. The process of providing an increased confidence in the margin of safety relies on, among other things, a thorough and comprehensive facility analysis, with licensees' commitments to identify and implement the items relied on for safety and the measures needed to ensure their continual availability and reliability. Thus, staff is concerned that an approach that does not "conform," or correspond, to a "formal" hazards analysis would not provide confidence in the margin of safety. (The Petition did not include examples nor the specifics of what methodology or structure might be used in lieu of that used in the formal hazards analysis.)

Within the ISA framework, licensees should have the flexibility to choose from a variety of hazard evaluation techniques, in particular those that are recognized by AIChE. Reference to the AIChE document, Guidelines for Hazard Evaluation Procedures, Second Edition with Worked Examples, and the AIChE hazard analysis methods are included in the draft NRC ISA Guidance Document, which was distributed and discussed with industry at the August 1993 and September 1994 NRC-sponsored public workshops. The current draft guidance document identifies a number of methods from the AIChE document, as well as other methods that were developed in other industries, that would be suitable, under certain circumstances, for licensees or license applicants to use in performing a detailed analysis of facility hazards.

In addition, other techniques, including those defined by licensees or by license applicants, could be used, but these would be subject to NRC review and approval. Such approval would be based on whether the technique met the objectives of performing an ISA (i.e., to: (1) identify radiological and non-radiological hazards related to the processing of licensed material; (2) determine potential accident sequences and their consequences resulting from such hazards; and (3) identify the items (i.e., SSCs and activities of staff), that are relied on to prevent or mitigate the potential accidents, needed to assure protection of public health and safety.

With regard to hazard analyses performed under other applicable requirements, such as the OSHA's Process Safety Management regulations and EPA's Risk Management Program regulation, such analyses could be used in part to satisfy the NRC requirements. However, licensees' analyses must be extended to include radiological hazards, since these particular OSHA and EPA regulations do not address such hazards. In addition, licensees would need to include all chemicals that may constitute a hazard from the activities associated with the processing of licensed material, and not limit the analyses to those hazardous chemicals where the inventory exceeds a certain limit. (OSHA and EPA only require analyses of hazardous chemicals when large amounts that could lead to catastrophic consequences are present (e.g., 4536 kilograms (10,000 pounds) of anhydrous ammonia). (See section 4.0 of this attachment, "Consequence Limits," for further discussion.)

2.0 CHANGES IN FACILITY OPERATIONS

According to the Petition's proposed rule change, licensees would:

> *"...based on the results of the ISA, implement changes to SSCs or associated licensee programs that provide reasonable assurance that the performance criteria set forth in 70.40(b) are not exceeded." (p. 10)*

In addition, the Petition states that:

> "If the ISA results indicate that relaxation of some controls or reallocation of resources is justified, the licensee may do so, in accordance with applicable license amendment or commitment change procedures." (p. 6)

Resolution:

Staff agrees that licensees will need to make changes to structures, systems, and components or associated licensee programs, if the results of the ISA, conducted in conformity with the revised regulation, indicate that they are needed to ensure adequate protection of public health and safety. On the other hand, if the results of the ISA demonstrate that certain licensee commitments are unnecessarily restrictive, changes to these commitments would be permitted, subject to review in accordance with license amendment procedures. Furthermore, changes could be made through a 10 CFR 50.59-type process as long as the proposed changes do not decrease the effectiveness of the program being changed and do not involve unresolved safety issues. For NRC to have confidence in the margin of safety, it must have the responsibility for reviewing and approving licensee actions involving safety-significant changes in facility operations.

3.0 GRADED LEVEL OF PROTECTION

The Petition requests a graded approach to safety be applied (i.e., focus on those SSCs and programs that protect against those accidents that have the greatest risks). The following is the Petition's proposed rule language.

> *"Licensees will classify SSCs based on safety significance and will apply controls commensurate with that classification." (p. 10)*

According to the Petition's discussion:

"The anticipated likelihood of an event or accident, as well as its potential impacts would be evaluated by a licensee, in the process of grading the safety programs. Using these criteria, one approach to grading would be to classify SSCs and programs based on safety significance and to apply controls commensurate with that classification. Other approaches may also be appropriate." (p. 6)

In addition, the Petition stated

> "Events or accidents of lesser significance would continue to be prevented and mitigated through existing licensee safety programs." (p. 6)

Resolution:

Staff strongly agrees with the Petition that a graded approach should be followed in identifying the level of protection needed (i.e., items [SSCs] relied on for safety and the measures used to ensure their continual availability and reliability), to prevent potential accidents or to mitigate their consequences. In general, accidents resulting in severe consequences should require a higher level of protection than those having less severe consequences. In addition, the staff agrees with the Petition's proposal that grading take into account the "anticipated likelihood" of an accident, in addition to the consequences of the accident.

Regarding the Petition's statement on the use of existing licensee safety programs to prevent or mitigate the consequences of "events or accidents of lesser significance," staff believes that the effectiveness of these programs will need to be demonstrated by licensees through the ISA process.

4.0 CONSEQUENCE LIMITS

The Petition proposes that "performance criteria"[(7)] be established against which licensees will be required to judge the effectiveness of their safety programs. The following is the Petition's proposed rule text:

"The ISA will identify and evaluate those hazards that could result in not meeting any of the following performance criteria, and will determine whether adequate controls and protective measures are in place to provide reasonable assurance, that: (i) the requirements of Part 20 are satisfied; (ii) accidental criticalities are avoided; and (iii) for accident conditions, it is unlikely that any member of the public offsite will receive a radiation dose of 25 rem total effective dose equivalent, an intake of 30 mg of uranium in soluble form, or an exposure to hydrogen fluoride in air equivalent to immersion for 30 minutes in a concentration of 25 milligrams per cubic meter." (p. 10)

One comment letter stated:

> "The language of the proposed rulemaking should be revised to explicitly clarify the intended use of the performance criteria; namely, that the purpose of the criteria is to guide the Commission and the licensee in their evaluation of the suitability of: (1) the events chosen for evaluation (i.e., those with consequences of concern) and (2) the determination as to the safety significance of SSCs.... The current language of the proposed rulemaking might be interpreted to suggest that the performance criteria are absolute limits, exceedance of which implies that the public health and safety cannot be reasonably assured.... The regulation should provide a mechanism for determining whether there is reasonable assurance of public health and safety and not reasonable assurance that the criteria are not exceeded."

The comment letter also stated that "Because worker safety appears to be a key underlying motive behind the NRC staff's interest in revising 10 CFR 70 and imposing new requirements on fuel cycle facilities, it is essential that this issue be explicitly recognized and considered in this rulemaking proceeding." However, the comment letter does not propose any additional rule language to address worker safety. In addition, a suggestion was made to remove the requirement in the Petition that the ISA "...determine whether adequate controls and protective measures are in place to provide reasonable assurance that (i) the requirements for 10 CFR Part 20 are satisfied...." According to the comment letter, "...analysis is not required to comply with 10 CFR Part 20."

Resolution:

Staff agrees that consequence limits should be established to identify the adverse consequences that licensees must protect against. Further, the ISA will need to identify and consider all radiological and non-radiological hazards related to the processing of licensed material. With regard to non-radiological hazards, the Petition would limit consideration of chemical hazards to those associated with hydrogen fluoride. Staff's view is that chemicals other than hydrogen fluoride will need to be considered. Specific consequence limits will be established during the rulemaking process. In establishing these limits, staff will consider the Petition's recommendations and the relevant requirements of NRC, OSHA, and EPA. Staff agrees that worker safety (i.e., accidental exposure of a worker to radiological or chemical hazards) is an important issue and plans to address it in the proposed rule. The ISA requirement is intended to focus on the identification of potential accidents and the items relied on to prevent or mitigate the consequences of those accidents. It is not intended to focus on the protection of workers during routine operations as currently required under 10 CFR Part 20; the rule language is expected to reflect that position.

Staff believes that all hazards should be identified and considered to determine which hazards could result in accidents that would exceed consequence limits. The Petition stated that only those hazards that "...could result in not meeting" the performance criteria would be identified and evaluated. The Petition did not state how, *a priori*, without identification and consideration of all hazards, licensees could determine that certain hazards would not lead to consequences of concern.

With respect to the comment regarding "reasonable assurance of public health and safety," staff believes it is important to go beyond the abstract concept of protecting "public health and safety" and define in practical terms what such protection would consist of. In essence, if NRC is reasonably assured that the consequence limits will not be exceeded, then NRC should be reasonably assured that the public health and safety will be protected. In addition, staff agrees that the identification, in the ISA, of accidents that could result in exceeding the consequence limits, should not imply that "...the public health and safety cannot be reasonably assured." Staff agrees with the comment letter statement that the performance criteria should not be viewed as "absolute limits." As long as the licensee or applicant provides adequate protection against these potential accidents, NRC will have reasonable assurance of public health and safety.

5.0 TIMEFRAME FOR COMPLETING ISAS

Petitioners request that the rule language include the following provision regarding a timeframe for completing an ISA:

> *"The ISA will be completed before issuance of an initial license to operate, or for existing facilities, within 5 years after the promulgation of the rule and associated implementation guidance." (p. 10)*

Resolution:

An ISA should be completed before operations are allowed to commence at newly constructed facilities or at newly constructed processes at existing facilities. For existing facilities, a reasonable timeframe should be established for licensees to complete their ISAs.

At existing facilities, the timeframe should allow for: (1) the performance of a quality ISA; (2) the correction of vulnerabilities identified in the ISA; and (3) the incorporation of the ISA results in the license. Although the proposed 5-year timeframe appears to be reasonable, staff is not recommending the adoption of a definite timeframe at this time. When the proposed rule revisions are developed, staff will prepare a proposed estimate of time and the 5-year timeframe requested in the Petition will be considered.

With regard to the performance of an ISA at newly constructed facilities or at newly constructed processes at existing facilities, staff recommends that preliminary ISAs be performed and the results submitted to NRC for approval before construction. The preliminary ISA results would facilitate the establishment of the design bases for the facilities (i.e., the safety features, incorporated into the design, that provide protection against credible

accidents or events). Before the commencement of operations at the facilities, licensees would review and update their ISAs to reflect as-built conditions and submit the results to NRC for review and approval as part of the license application.

6.0 PERFORMANCE OF AN ISA AFTER NOTICE OF DECOMMISSIONING

Petitioners request that an ISA not be required for facilities that are being decommissioned. The following is the proposed Petition's rule change:

> *"Licensees who have notified the NRC of plans to decommission their facilities in accordance with the Timeliness Rule (10 CFR 70.38) are not required to perform an ISA per this section." (p. 10)*

Resolution:

Notification of decommissioning by itself would not eliminate the hazards or eliminate a need for an ISA. Once principal activities cease at a facility, the performance of an ISA should not be a prerequisite for routine decommissioning activities. However, for non-routine activities, the determination of whether an ISA would be required would be based on the extent to which special processes, such as chemical treatment of wastes or other hazardous processing, are involved in decommissioning.

NRC's concern regarding hazards during the decommissioning process is recognized in the existing 10 CFR 70.38, which includes a requirement for the submittal of a decommissioning plan if "...the procedures and activities necessary to carry out decommissioning...have not been previously approved by the Commission and these procedures could increase potential health and safety impacts to [on] workers or to [on] the public...." Among other things, the decommissioning plan calls for "...a description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning." For non-routine decommissioning activities, an ISA, if needed, would address the decommissioning process and consider both radiological and non-radiological hazards pertinent to protection of workers and the environment.

7.0 INCORPORATION OF ISA RESULTS INTO LICENSE

The Petition requests that the ISA results remain at each licensee's site. The Petition's proposed rule text is as follows:

> *"The results of the ISA shall be maintained at the licensee's facilities. Licensees will update the ISA for significant facility changes." (p. 10)*

Under the NEI proposed rule change, the ISA results would not become part of the license, and thus licensees would not commit to ensure the continual availability and reliability of items relied on for safety. The Petition proposes that ISA results would be available for review at each licensee's site. The Petition states that the ISA results would include "...a discussion of the controls relied upon to ensure that the performance criteria are not exceeded and the bases for concluding such controls are adequate."

It is also proposed that when "...significant" plant changes are under consideration, licensees should review and update their ISAs and implement any new controls (i.e., items relied on for safety to prevent or mitigate the consequences of accidents) that might be necessitated from these reviews and updates. The updated information would also remain at licensees' sites.

The Petition also expressed concern that the "...incorporation of the ISAs into the license would necessitate significant changes in the current license application format, dramatically expanding the description of the plant site, facilities, equipment, processes, and controls which would form the basis of the license." In addition, "...incorporation of an ISA into an NRC license, in a manner similar to a reactor licensee's Safety Analysis Report (SAR), would represent a fundamental departure from the traditional two-part license format used by many fuel cycle licensees."

Resolution:

Staff strongly believes that the safety bases, including the results of the ISA, should be an essential part of the license. The safety bases consist of the identification of: (1) potential accidents at the facility; (2) items relied on to prevent or mitigate these accidents; and (3) measures that would ensure the continual availability and reliability of these items. Together, this information forms: (a) the basis on which NRC determines that adequate protection is provided; (b) the information from which NRC has on-going confidence in the margin of safety; and (c) the basis for a risk-informed inspection program.

By including the safety bases in the license, NRC is assured of specific licensee commitments to maintain adequate protection at its facility. To reflect changes made to facility processes that affect the safety bases, the licensee should provide NRC with revisions to its documented safety bases (including revisions to its ISA) for incorporation into the license. The license would thus become a "living license" in that it would reflect the current configuration of the nuclear process, and safety measures on a continuing basis. This provides a basis for NRC confidence in the margin of safety and would eliminate a major licensee and NRC resource-intensive effort to periodically renew fuel cycle licenses.

With respect to the Petition's concern about incorporating the ISA results into the license "...in a manner similar to a reactor licensee's Safety Analysis Report...," staff's view is that such incorporation is a major cornerstone of the reactor backfit process. Thus, without incorporating the ISA results into the license, the adoption of a backfitting provision for fuel cycle facilities would be precluded.

8.0 BACKFITTING

The Petition requests a backfitting provision for Part 70. The Petition's proposed rule text is similar to that in 10 CFR 50.109, "Backfitting," which applies to power reactors, and defines backfitting as follows:

> *"...the modification of, or addition to, systems, structures, or components of a plant; or to the procedures or organization required to operate a plant; any of which may result from licensee-performed analyses, a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position." (The*

remaining proposed rule text is provided in the Petition.) (p. 11)

The proposed provision would require, except under certain conditions, that NRC perform "...a systematic and documented analysis for backfits which it seeks to impose." Such analysis would need to demonstrate that: (1) the proposed backfit results in a substantial increase in the overall protection of the public health and safety; and (2) the costs of implementing any modifications are justified in view of this increased protection.

A significant difference between the Petition's proposed backfit provision and 10 CFR 50.109 is that, under the proposed provision, NRC-required modifications of SSCs resulting from the initial ISA would be subject to a backfit analysis.

Resolution:

Staff proposes that a qualitative "backfit" mechanism, similar in purpose to a 10 CFR 50.109 provision, be considered after the safety bases, including the results of the ISA, are established and incorporated in the license, and after licensees and staff have gained a few years of experience with implementation of the ISA requirement. This mechanism would *not* apply to modifications identified as a result of the initial ISAs that are needed to assure protection of public health and safety; these modifications would be required for compliance with the revised Part 70.

The Commission's experience with backfitting has been limited to the regulation of power reactors. As noted above, the proposed provision is similar to the reactor backfitting provision in 10 CFR 50.109. However, the information that would be available to NRC staff for fuel cycle facilities, under the Petition's proposal, or even under staff's proposed changes, is less quantitative than the information available to staff through the reactor licensing process.

Before the issuance of a license, reactors must establish well-defined licensing bases. Although all current elements of the required analysis were not available during NRC's initial implementation of a backfit provision, enough elements were present to convey a substantial quantitative understanding of the risks from reactor operations. Currently, the licensing bases for reactors include detailed information in the Final Safety Analysis Report (FSAR), which is developed in accordance with 10 CFR Part 50, its appendices, associated guidance documents, and industry codes (e.g., probabilistic risk assessment [PRA] results, technical specifications, etc.) As a result of this process, NRC and its licensees have a qualitative and quantitative understanding of the risks at reactors. Furthermore, the FSAR is updated on a regular basis, which provides a continuing licensee and NRC understanding of the identification and bases for licensee operations and activities.

In contrast to reactors, fuel cycle facilities do not currently have well-defined safety bases. The performance of an ISA and the incorporation of the ISA results in the license[(8)] would help establish qualitative facility safety bases. However, since the ISA will not be required to provide a quantitative analysis of facility hazards, licensees and NRC staff will have a considerably less quantitative understanding of the risks at fuel cycle facilities, compared with the risks at reactor facilities. For equivalent quantitative information to be available at fuel cycle facilities, the ISA would have to use the PRA approach. (The industry has consistently commented that quantitative-based ISAs [i.e., PRAs] should not be required, and staff draft guidance on ISAs is consistent with that position.) Without the performance of a PRA, it would be difficult, if not impossible, to quantify the benefits of any proposed changes to the facility or its processes. Thus, any backfit analysis not based on the results of a PRA would be primarily qualitative in nature.

Staff agrees with the Petition that some backfit provision should be considered. However, for the reasons explained above, a 10 CFR 50.109 provision would not be suitable. Staff recommends that a qualitative "backfit" mechanism is appropriate to consider after the safety bases, including the results of the ISA, are established and incorporated in the license, and after licensees and staff have gained a few years of experience with the implementation of the ISA requirement.

9.0 SUPPORTING GUIDANCE DOCUMENTS

The Petition mentions supporting guidance documents for Part 70 only in the context of when licensees would be required to complete their ISAs (i.e., within 5 years after the promulgation of the rule and associated guidance). However, specific comments on the need for supporting guidance were provided by two comment letters.

With regard to guidance for performing an ISA, one comment letter stated that "Guidance should be promulgated on the required format and content of the analysis required." In addition, "The AIChE 'Guidelines for Hazard Evaluation Procedures, Second Edition with Worked Examples,' 1992, is representative of the types of analysis that should be required."

The other comment letter stated that once the rule is formalized "...implementation and review documentation guidance must be developed that tracks the rule and results in effective and efficient implementation...." The comment letter also stated that the guidance "...must be available for public review and comment before the rule is finally promulgated so that the public has due notice and opportunity to be heard on the features and impact of the rule as it will be interpreted and applied by NRC staff."

Resolution:

Staff agrees with the comment letters' requests for supporting guidance documents to reflect the revised Part 70 and the need for these documents to be published for public comment before implementing a final rule.

Concurrent with developing the April 1995 draft revised Part 70 rule, a number of guidance documents were developed related to the performance of an ISA, the format and content of license applications, and acceptance criteria for staff review of license applications. (These documents were distributed to the public for review and comment at several of the NRC-sponsored workshops that discussed the proposed rule revisions.) Once the proposed rule text is finalized, the draft documents will be modified to be consistent with the rule revisions and published for public comment concurrent with the proposed

rule. In addition, a Regulatory Impact Analysis will be performed and considered in the development of the proposed rule. This analysis will be made available to the public.

With regard to the ISA, Draft NUREG 1513, "Integrated Safety Analysis Guidance Document," was developed to provide guidance to license applicants on how to perform an ISA and document the results. This guidance also defines an ISA, identifies its role in a facility's safety program, identifies and describes several generally accepted ISA methods, and provides guidance in choosing an acceptable method. As mentioned in the discussion of the "ISA Requirement" in this attachment, reference is made to the AIChE document, Guidelines for Hazard Evaluation Procedures, Second Edition with Worked Examples. The AIChE ISA methods are included in the draft NRC ISA Guidance Document, which was distributed and discussed with industry at the August 1993 and September 1994 NRC-sponsored public workshops. The current draft guidance document identifies a number of methods from the AIChE document, as well as other methods that were developed in other industries, that would be suitable, under certain circumstances, for licensees or license applicants to use in performing a detailed analysis of facility hazards.

In addition, draft guidance documents will be revised to address the type and depth of information required for the license applications submitted under the revised rule, and to provide acceptance criteria to support a standardized approach for staff's review of license applications submitted under the revised rule.

10.0 DEFINITIONS

The Petition requests that the following definition of a "uranium processing and fuel fabrication plant" be added to Section 70.4, "Definitions":

> *"Uranium processing and fuel fabrication plant means a plant in which the following operations or activities are conducted: (1) Operations for manufacture of reactor fuel containing uranium including any of the following: (i) Preparation of fuel material; (ii) formation of fuel material into desired shapes; (iii) application of protective cladding; (iv) recovery of scrap material; and (v) storage associated with such operations; or (2) Research and development activities involving any of the operations described in item (1) of this definition except for research and development activities utilizing insubstantial amounts of uranium." (p. 10)*

The Petition's proposed definition of "uranium processing and fuel fabrication plant" is intended to provide clarification as to the applicability of the Petition's proposed requirement to perform an ISA. It is proposed that the ISA requirement apply to only those facilities identified in this definition and to enrichment plants. (The ISA requirement is discussed in section 1.0.)

In addition to the above definition, one comment letter requested that a definition of "double contingency" be included in the proposed revisions to Part 70.

Resolution:

The selection of terms to be included in the "Definitions" section will be determined from the text of the proposed rule.

ATTACHMENT 2

SUMMARY OF STAFF'S PROPOSED RESOLUTION TO PETITION FOR RULEMAKING

Based on the recognized needs for improving the regulatory process at fuel cycle facilities and staff's review of the Petition for Rulemaking (PRM-70-7), which presents a proposed amendment to 10 CFR Part 70, and of the public comments received, staff proposes that Part 70 be revised. These proposed revisions would be the development of a risk-informed regulation, consistent with Commission policy, that could be used as a core regulation for the licensing and certifying of any fuel cycle facility (including enrichment facilities) and other types of facilities that possess special nuclear material (SNM) in quantities sufficient to constitute a potential for nuclear criticality.

The following is a summary of staff's recommended changes to Part 70; these recommendations are discussed in Attachment 1.

- **Performance of an Integrated Safety Analysis (ISA)**

  The performance of a formal ISA would be required for all types of facilities (except reactors and the gaseous diffusion plants) or activities, subject to Nuclear Regulatory Commission regulation, that are authorized to possess SNM in quantities sufficient to constitute a potential for nuclear criticality.
  The ISA would consider all types of hazards (e.g., criticality, chemical, radiological, fire) in an integrated manner with licensees' commitments to identify and implement the items relied on for safety and the measures needed to ensure their continual availability and reliability.

  Licensees or license applicants could propose, for NRC approval, alternative approaches for performing an ISA. These approaches should conform or correspond to a "formal" hazards analysis (i.e., a systematic, comprehensive, and well-documented approach) that considers all hazards in an integrated manner.

  A single comprehensive safety program would be established to ensure the continual availability and reliability of items relied on for safety.

- **Incorporation of ISA Results into License**

The safety bases, including the results of the ISA, would be included in a facility's license and would consist of identification of: (1) potential accidents at the facility; (2) the items relied on to prevent or mitigate these accidents; and (3) measures that would ensure the continual availability and reliability of these items.

Revisions to the documented safety bases (including revisions to the ISA) would be provided to NRC for incorporation into the license. (The license would reflect the current configuration of the nuclear process and overall safety program.)

- **Changes in Facility Operations**

NRC review and approval, in accordance with license amendment procedures, would be required before licensees could make safety significant changes to facility operations. Licensees could also make changes through a 10 CFR 50.59-type process as long as the proposed changes do not decrease the effectiveness of the program and do not involve unresolved safety issues.

- **Graded Level of Protection**

A graded approach would be used to provide the level of protection needed, commensurate with the risk (i.e., items (structures, systems, and components) relied on for safety, and the measures used to ensure their continual availability and reliability), to prevent potential accidents, or to mitigate their consequences. In general, accidents resulting in severe consequences would require a higher level of protection than those having less severe consequences.

The graded approach would also take into consideration "the anticipated likelihood" of an accident, in addition to the consequences of the accident.

- **Consequence Limits**

Consequence limits would be established to identify the adverse consequences that licensees must protect against. The relevant requirements of NRC, the Occupational Safety and Health Administration's Process Safety Management regulations, and the Environmental Protection Agency's Risk Management Program regulation will be considered in establishing these limits.

Criteria for hazardous chemicals, which are not limited to hydrogen fluoride, will be included in these limits, along with criteria that address accidental exposure of a worker to radiological or chemical hazards (i.e., worker safety).

- **Timeframe for Completing ISAs**

An ISA would be completed before construction and operations are allowed to begin at newly constructed facilities or at newly constructed processes at existing facilities. For existing facilities, a reasonable timeframe should be established for licensees to complete their ISAs.

At existing facilities, the timeframe would allow for: (1) the performance of a quality ISA; (2) the correction of vulnerabilities identified in the ISA; and (3) the submission of the ISA results to NRC for review and approval, and inclusion in the license.

- **Performance of an ISA during Decommissioning**

Once principal activities cease at a facility, the requirement to perform an ISA would not apply to routine decommissioning activities. However for non-routine activities, the determination of whether an ISA is required would be based on the extent to which special processes, such as chemical treatment of wastes or other hazardous processing, are involved in decommissioning.

- **Backfitting**

A qualitative "backfit" mechanism, similar in purpose to a 10 CFR 50.109 provision, would be considered after the safety bases are established and incorporated in the license, and after licensees and staff have gained a few years of experience with implementation of the ISA requirement. The mechanism would *not* apply to modifications identified as a result of the initial ISAs, and required for compliance with the revised Part 70.

- **Reporting Requirements**

Although the Petition did not address revisions to the current Part 70 reporting requirements, staff believes that revisions are needed in light of the recommended rule changes, in particular the reporting of events related to the loss or degradation of items relied on for safety (e.g., reporting of loss of criticality controls as currently reported under the provision of NRC Bulletin 91-01).

- **Format of Revised Part 70**

To minimize any confusion licensees would have in understanding the applicable requirements in Part 70, staff

proposes that the safety requirements applying to licensees who are authorized to possess SNM in quantities sufficient to constitute a potential for nuclear criticality be organized into a new section within Part 70. The requirements applying to facilities that are authorized to possess SNM in quantities not sufficient to constitute a potential for nuclear criticality would remain unchanged. This would avoid any impact on Agreement State programs.

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1. Terminology used by staff is integrated safety analysis (ISA).

2. Note that a Regulatory Impact Analysis would be performed and considered in the development of a proposed rule. The revision of Part 70 would not be subject to NRC backfit requirements in 10 CFR 50.109 which only apply to reactor facilities.

3. Terminology used by staff is integrated safety analysis (ISA).

4. Letters were received from ABB Combustion Engineering, Incorporated; GE Nuclear Energy; Siemens Power Corporation; Westinghouse Electric Corporation; and United States Enrichment Corporation.

5. Italics are used to denote Petition's proposed rule language. Page references refer to the NEI petition.

6. Bold text highlights the major elements of the staff's proposed resolution.

7. Petition uses the term "performance criteria" in the same sense that the staff uses the term "consequence limits."

8. As indicated above (Section 7.0), the petition proposes not to incorporate the ISA results in the license. Thus, the safety basis for the facility would not be formally established and committed to by the licensee.