May 2, 1997

FOR: The Commissioners

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

SUBJECT: ADDITIONAL ALTERNATIVE FOR REGULATING THE SAFETY OF FUEL CYCLE FACILITIES:NUCLEAR ENERGY INSTITUTE PETITION FOR RULEMAKING

PURPOSE:

To provide the Commission with information on an additional alternative for regulating the safety of fuel cycle facilities (Attachment 1). This additional alternative reflects the basic features of the Nuclear Energy Institute (NEI) Petition for Rulemaking (PRM-70-7) (Attachment 2). This alternative is in addition to the alternatives in SECY-96-079, "Alternatives for Regulating Fuel Cycle Facilities," dated April 16, 1996, and is provided in response to a December 4, 1996, Staff Requirements Memorandum (SRM).

BACKGROUND:

SECY-96-079 presented the Commission, for consideration and decision, six alternatives for regulating the safety of fuel cycle facilities, along with the pros and cons for each alternative. The alternatives range from no change to the current rule, to a restructure and rewrite of the rule.

On July 2, 1996, the Commission was briefed by the staff and industry on the proposed alternatives. At the briefing, industry representatives stated that the U.S. Nuclear Regulatory Commission's and industry's mutual goal of maintaining and improving the margin of safety at fuel cycle facilities would best be served if some carefully designed regulatory changes were implemented. Although industry representatives had opposed revisions to 10 CFR Part 70 in the past, they stated that certain additions to the existing rule could be potentially beneficial and, "They could embrace a specific change to the existing Part 70 that would require licensees to address plant safety hazards using an integrated safety assessment or an acceptable alternative." Since industry representatives concluded that certain rule changes would be beneficial, the Commission encouraged them to present their proposed changes to NRC in the form of a petition for rulemaking (PRM). On September 30, 1996, NEI filed a PRM on behalf of certain Part 70 licensees and potential licensees. On December 4, 1996, an SRM was issued that requested staff to "...evaluate the effect, if any, that the NEI petition has on its analysis presented in SECY-96-079."

DISCUSSION:

The PRM requests that Part 70 be amended by adding three new provisions. These provisions include: (1) a requirement to perform an integrated safety assessment (ISA), or an acceptable alternative, for uranium processing and fuel fabrication plants and enrichment plants, to confirm that adequate controls are in place to protect the public health and safety; (2) the addition of a backfitting provision; and (3) the addition of a definition of a uranium processing and fuel fabrication plant. (Petitioners request that the requirement to perform an ISA be limited to uranium processing and fuel fabrication plants and enrichment plants. They do not believe that the "possibility" that NRC may be asked to regulate U.S. Department of Energy facilities provides an appropriate basis for imposing significant new programmatic changes on an entire industry that has operated successfully under the existing requirements.)

Staff has reviewed the PRM and reexamined the six alternatives in SECY-96-079. It concludes that the proposed amendment could be considered as an additional alternative for Commission consideration and that no changes are needed to the alternatives in SECY-96-079.

Although the PRM includes many recommendations similar to features of Alternative 3 addressed in SECY-96-079, there are important differences when these features are examined in detail. A summary of the major features of the PRM and of how they relate to similar features addressed in SECY-96-079 is provided in Attachment 1. The final analysis of the proposed revisions in the PRM, a summary of public comments received, and a proposed formal resolution to the PRM will be provided in a separate Commission Paper by June 30, 1997.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. There is no information technology or financial impact that would result from this paper.

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Attachments: As stated (2)

ATTACHMENT 1

ADDITIONAL ALTERNATIVE FOR REGULATING FUEL CYCLE FACILITIES

The proposed amendment to 10 CFR Part 70 that was submitted by the Nuclear Energy Institute (NEI) in a Petition for Rulemaking (PRM-70-7) can be considered as an additional alternative to those presented in SECY-96-079, "Alternatives for Regulating Fuel Cycle Facilities."

The topics relevant to this petition are: (1) the performance of an integrated safety assessment (ISA), or its equivalent; (2) a backfitting provision; (3) limits on the applicability of a revised Part 70; (4) event reporting; and (5) supporting guidance documents.

Each of these topics is discussed below. For each topic, a summary of the discussion in SECY-96-079 is provided, followed by a summary of the petition proposal. (An analysis of the proposed revisions in the PRM, summary of public comments received, and a proposed resolution to the PRM will be provided in a separate Commission Paper.)

1. **ISA**

With regard to the ISA, the following subtopics are listed and separately discussed below:

a. Hazards Identification and Analyses
b. Consequence Limits(1)
c. Graded Level of Protection
d. Alternative Approaches to ISAs
e. License Format and ISA Documentation
f. Timeframe for Completing ISAs

a. Hazards Identification and Analyses

SECY-96-079 Summary: The performance of an ISA for a licensee subject to Part 70 would involve the following:

1) Identification of all hazards (radiological, chemical, and fire) at the facility;

2) Integrated analysis of all hazards to determine potential accidents or events that could exceed certain consequence limits; and

3) Identification of items (e.g., structures, systems, equipment, components, and activities of personnel) that are relied on for safety (i.e., to prevent the occurrence or mitigate the consequences of potential accidents or events).

Based on the ISA results, a licensee would provide in its application a summary of the hazards; an identification of those structures, systems, equipment, components, and activities of personnel relied on for safety to protect against the hazard; and a commitment to implement measures to ensure the continued availability and reliability of those items relied on for safety. The results of the ISA would be submitted to the U.S. Nuclear Regulatory Commission and would become part of the license. A time limit would be specified for a licensee to complete its ISA, identify the items relied on for safety, and implement measures necessary to ensure the continued availability and reliability of these items.

PRM-70-7 Summary: The performance of an ISA for a licensee subject to Part 70 would involve the following:

1) Identify and evaluate those hazards that "...could result in not meeting..." any of the performance criteria.

2) Determine whether adequate controls and protective measures are in place to provide reasonable assurance that the performance criteria will not be exceeded.

Based on the ISA results, licensees would implement changes to their structures, systems, and components (SSCs) or associated licensee programs that would provide reasonable assurance that the performance criteria are not exceeded, but would not identify to NRC those items relied on for safety or commit to their continued availability and reliability in their license applications. Licensees would implement facility changes in a timely manner. If the ISA results indicated that relaxation of some controls or reallocation of resources were justified, licensees would be able to do so, in accordance with applicable license amendment or commitment change procedures. The NEI petition states that "A formal submittal to the NRC of an ISA report will not be required." Instead, ISA results would be available for review at all licensees' sites, but would not become part of the licenses.

b. **Consequence Limits**

SECY-96-079 Summary: Consequence limits would be established to identify the adverse consequences that licensees must protect against. In establishing these limits, staff would consider the requirements imposed by the Occupational Safety and Health Administration (OSHA) and the U.S. Environmental Protection Agency (EPA EXIT). The specific limits were not discussed in SECY-96-079.

PRM-70-7 Summary: "Measurable performance criteria" would be established for judging the effectiveness of licensees' safety programs to protect against certain adverse consequences (i.e., potential accidents or events). The proposed performance criteria call for the following:

(1) The requirements of Part 20 to be satisfied,

(2) The avoidance of accidental criticality events, and

(3) For accident conditions, the avoidance of a dose to a member of the public of 25 rem, an intake of 30 mg uranium in soluble form, or an exposure to hydrogen fluoride in air equivalent to immersion for 30 minutes in a concentration of 25 mg/m.

c. **Graded Level of Protection**

SECY-96-079 Summary: The consequence limits would allow for a graded level of protection against potential accidents or events identified in ISAs. For example, a higher level of protection would be needed to prevent or mitigate the consequences of severe accidents (e.g., criticality events, exposures to high levels of radiation and chemicals) than would be needed for less severe accidents with lesser consequences. In addition, appropriate measures would be established, commensurate with the risks, to ensure the availability and reliability of items relied on for safety (e.g., training, maintenance).

PRM-70-7 Summary: "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." In this graded approach, the PRM stated that "Events or accidents of lesser significance would continue to be prevented and mitigated through existing licensee safety programs."

d. **Alternative Approaches to ISAs**

SECY-96-079 Summary: Alternative approaches to ISAs were not discussed in SECY-96-079. However, a variety of hazard evaluation techniques is 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. In performing ISAs, licensees and license applicants could select from among these various techniques that are recognized by the American Institute of Chemical Engineers (AIChE), to analyze process systems and to identify potential accidents. Also, licensees could select other methods, which would be subject to NRC approval.

PRM-70-7 Summary: Licensees would have the flexibility to offer alternative approaches for NRC's consideration in performing ISAs. The PRM stated that "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." Any alternative approach would be subject to NRC approval.

It was stated that "...the AIChE document provides reasonable approaches, and that other formal methods may also be acceptable." It is requested that hazard analyses being performed under OSHA and the EPA Risk Management Program regulations be considered an acceptable means of meeting the ISA requirements for evaluating hazards within NRC's jurisdiction.

e. **License Format and ISA Documentation**

SECY-96-079 Summary: The license applications would include licensees' commitments to identify and implement the items relied on for safety and the measures needed to ensure their continued availability and reliability. These would be determined on the basis of the performance of ISAs. To reflect changes made to facility processes that affect the safety bases,[(2)] licensees would provide NRC with revisions to their ISA documentation and their licenses. Licenses would become "living licenses" in that they would reflect the current configurations of the nuclear process, and major renewals would not be necessary.

PRM-70-7 Summary: The results of an ISA, which 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," would be available for review at each licensee's site. This information would not become part of the license. Also, an ISA report would not be submitted to NRC, and a commitment would not be made to ensure the continued availability and reliability of items relied on for safety.

When "significant" plant changes are under consideration, licensees would review and update their ISAs and implement any new controls that might be necessitated from these reviews and updates, without NRC review and approval. The updated information would also remain at licensees' sites.

f. **Timeframe for Completing ISAs**

SECY-96-079 Summary: For newly constructed facilities or for new construction at existing facilities, "preliminary" ISAs would be performed and the results submitted to NRC for approval before construction. The ISA results would serve as the design bases for the facilities (i.e., the safety features incorporated into the designs that provide protection against credible internal and external 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 for approval as part of the license applications.

For existing licensees, ISAs would be completed within a specified time period. This time period would allow for completion of quality ISAs, correction of vulnerabilities identified in the ISAs, and submissions of the ISA information to NRC. The specific time period was not discussed in SECY-96-079.

PRM-70-7 Summary: For new facilities, ISAs would be completed before NRC issued the initial licenses to operate. For existing licensees, ISAs would be completed within five years after promulgation of the amended rule and implementation of the associated guidance. The ISA results would not be submitted to NRC for approval, as previously discussed.

2. **Backfitting**

SECY-96-079 Summary: A backfitting provision was not discussed in SECY-96-079.

PRM-70-7 Summary: A backfitting provision would be included in the amended rule. The recommended provision is similar to the regulation in 10 CFR 50.109, "Backfitting," which applies to power reactors. (Plant changes resulting from "licensee-performed analyses" [e.g., ISAs] would also be subject to a backfit analysis.)

3. **Applicability of Part 70**

SECY-96-079 Summary: The licensing of new facilities (e.g., U.S. Department of Energy [DOE] facilities or new processes) was considered in identifying possible regulatory changes. One of the objectives is to develop a rule that is risk-based and that could be used to effectively license or certify new licensees as well as existing licensees.

Besides the proposed changes discussed in Sections 1.a - 1.f above, other rule changes that would assist new license applicants include creating a new *U.S. Code of Federal Regulations Part* (CFR). This new Part would avoid adding additional patches (multiple amendments) to the current Part 70 and would distinguish the requirements for licensees that are authorized to possess critical quantities of special nuclear material (SNM) from those for licensees authorized to possess subcritical quantities of SNM. The requirements transferred to the new CFR Part would be rewritten to: (1) present the requirements in more performance-oriented language wherever possible; (2) eliminate redundant requirements; (3) address and correct inconsistent requirements that are now difficult to administer and are presented in a disjointed format; and (4) identify and delete any unnecessary requirements. These changes would be made in the interests of minimizing the misinterpretation of the rule and expediting the learning process regarding NRC regulations since the rule would be organized and structured in a more systematic and logical manner and would be more "user-friendly."

PRM-70-7 Summary: 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." (These "significant new programmatic changes" were not specifically identified in the PRM.) It was 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." Thus, it is requested that the amended rule apply to uranium processing and fuel fabrication facilities that conduct specified operations or activities.

4. **Event Reporting**

SECY-96-079 Summary: The voluntary reporting function established by Bulletin 91-01, which addresses licensee reporting to NRC of the loss of criticality safety controls, would be codified and broadened.

PRM-70-7 Summary: Reporting requirements subject to Part 70 were not discussed.

5. **Supporting Guidance Documents**

SECY-96-079 Summary: A new Standard Review Plan and a revised Standard Format and Content Guide would be developed as guidance to support Part 70. Also, a guidance document would be published that provides guidance on how to perform an ISA and document the results. (A draft NRC ISA guidance document was distributed and discussed with industry at the August 1993 and September 1994 NRC-sponsored public workshops.)

PRM-70-7 Summary: Supporting guidance documents for Part 70 are mentioned 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).

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1. The term "consequence limits," which is used in SECY-96-079, or "performance criteria," which is used in PRM-70-7, refers to the adverse consequences of potential accidents or events that licensees must protect against.

2. The safety basis is comprised of the potential accidents or events that exceed the consequence limits; items that are relied on (e.g., site, structures, systems, equipment, components, and activities of personnel) to prevent or mitigate the consequences of accidents or events; and measures

implemented to ensure the continued availability and reliability of these items.