

October 13, 1999

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Attention: Rulemakings and Adjudications Staff
Washington, D.C. 20555-0001

REFERENCE: Comments on Proposed Rule 10 CFR 70: Domestic Licensing of Special Nuclear Material ; Possession of a Critical mass of Special Nuclear Material (*Federal Register* Vol. 64, No. 146, pp. 41338-41357 dated July 30, 1999)

Dear Sir or Madam:

The Nuclear Energy Institute¹ (NEI), on behalf of the nuclear fuel cycle industry, submits the attached comments on the proposed revisions to 10 CFR 70 in response to a request for public input in the July 30, 1999 *Federal Register* notice.

NEI is generally pleased with the proposed revisions to 10 CFR 70. There remain, however, a number of provisions in the proposed rule where additional revisions are necessary to achieve the intent of promulgating an affective, safety-focused, performance-based rule. Our comments on these revisions are addressed in the attachment to this letter. NEI additionally provides comments on several issues identified in the *Federal Register* announcement for which comments were solicited by the Commission.

NEI appreciates the opportunity to work closely with the Commission, NRC Staff and other stakeholders in developing a revised 10 CFR 70. We compliment the NRC on its solicitation of stakeholder participation, the scheduling of public

¹ NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

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meetings and workshops to facilitate the exchange of ideas and the use of the NRC's Rulemaking Web Page to post comments and draft revisions. We trust that a similar process and commitment of NRC resources will continue to be made to develop a Standard Review Plan (SRP) to guide both license applicants and NRC Staff license reviewers in preparing and assessing license applications and amendments.

Yours Sincerely,

Marvin S. Fertel
Attachment

c.: The Honorable Greta Joy Dicus, Chairman, NRC
The Honorable Nils J. Diaz, Commissioner, NRC
The Honorable Edward McGaffigan, Jr., Commissioner, NRC
The Honorable Jeffrey S. Merrifield, Commissioner, NRC
Dr. William D. Travers, EDO/NRC
Dr. Carl J. Paperiello, Deputy Executive Director, Materials, Research and
State Programs, NRC
Mr. William Kane, Director, NMSS/NRC

COMMENTS ON PROPOSED REVISIONS TO 10 CFR 70

DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL; POSSESSION OF A CRITICAL MASS OF SPECIAL NUCLEAR MATERIAL (Federal Register Vol.64 No. 146 pp. 41338-41357 dated 30 July 1999)

COMMENTS SUBMITTED BY THE NUCLEAR ENERGY INSTITUTE

Introduction

Revisions to 10 CFR 70 are designed to improve confidence in the margin of safety at fuel cycle facilities through application of a safety-focused and performance-based regulatory approach. The Integrated Safety Analysis (ISA), a risk-informed forward-looking assessment of credible facility hazards and their effects on plant systems and modes of operation, will provide information vital to evaluating the safety basis of a facility. Rule revisions will focus licensee and NRC resources on those facility operations that could pose the greatest risk to human health and safety and the environment. The revisions are intended to reduce the regulatory burden on licensees and the NRC by granting the former the right to make changes to the facility or its processes without seeking a license amendment for changes that maintain or improve safety. While the existing Part 70 licensed facilities have an excellent safety record and the NRC's oversight and regulation of these facilities has been effective in protecting public health and safety, the revisions to 10 CFR 70 should enhance confidence in the margin of safety at such facilities.

The safety-focused regulatory approach incorporated in the Part 70 revisions will reduce the regulatory burden on both the NRC and licensee. For example, the proposed revisions should limit license amendment requests to those few facility changes that could have a direct impact on safety. The proposed revisions also introduce specific licensee performance requirements, streamline licensee reporting requirements and formalize incorporation of baseline design criteria for new facilities and for new processes at existing facilities.

NEI is generally pleased with the proposed rule revisions and with the manner in which they address issues raised in NEI's Petition for Rulemaking dated July 2, 1996. These revisions address NRC's current risk-informed regulatory approach, in which risk information is used in concert with operating experience and engineering judgement to ensure safe operation of fuel cycle facilities. NRC's statutory responsibilities in radiological safety and chemical safety directly related to licensed material should be better addressed with the new Part 70.

NEI's major comments on the proposed rule revisions focus on the following:

- Facility Change Process (§70.72)
- ISA Summary (§70.65)
- Standards for Protection of Co-Located Workers (§70.61)
- Backfit Provision

In addition to comments on the above provisions, NEI has identified corrections or comments on the following sections:

- Correct usage of terminology (§70.4)
- Incorporation of NRC-OSHA MOU for chemical safety (§70.50)
- Failure log (§70.62)
- Safety program scope (§70.62)
- ISA (§70.62)
- Baseline design criteria and safety grading (§70.64)
- Incorporation of a rule implementation provision

Each of these comments is discussed below in the order in which they appear in 10 CFR 70.

Reasonable Assurance (§70.4)

NEI recommends that the term “*reasonable assurance*” be used in place of “*ensure*” in the definition of ‘*available and reliable to perform their function when needed*’ in §70.4. “*Ensure*” connotes a high degree of certainty – bordering on a guarantee – that a goal or objective will be met. In the Part 70 context, it may be interpreted to require certainty that an items relied on for safety will be available and reliable when required. Regardless of the thoroughness of personnel training, or the engineering excellence and quality assurance applied to the design and construction of an item relied on for safety, or the redundancy designed into a facility’s safety control systems, failures and abnormal events will inevitably occur. Thus, a licensee should be expected to provide reasonable assurance that a particular items relied on for safety will be reliable and available, when required. In the comparable regulations pertaining to items relied on for safety at nuclear power facilities (10 CFR 50, Appendix A, Criterion 1), the licensee must only “...*provide adequate assurance that these structures, systems and components will satisfactorily perform their safety functions*” [underlining added]. NEI recommends that comparable language be used in the §70.4 definition of this term.

NEI recommends that a licensee provide reasonable assurance that an item relied on for safety will be available and reliable when it is required to perform its safety function. Thus, during periods when a process is shut down, undergoing maintenance or when Special Nuclear Material is no longer present, compliance

with the safety requirements of §70.61 would no longer be required. What is important is that an item relied on for safety be available and reliable, when it is needed. NEI believes this meaning is conferred by the definition by the words “when needed” and that “*continuous*” be simply deleted. The definition should read:

§70.4 Definitions: Available and reliable to perform their function when needed: “...means that...items relied on for safety will perform their intended safety function when needed and management measures will be implemented to provide reasonable assurance of compliance with the performance requirements of §70.6...”

For consistency in the Part 70 revisions, NEI recommends that the term “adequate assurance” in §70.64(a)(1) be replaced by “reasonable assurance.”

Reporting Requirements (§70.50)

The reporting requirements of §70.50 continue to misrepresent the principles of the 1988 NRC-OSHA Memorandum of Understanding (MOU). §70.50(c)(1)(iii)(A) requires the reporting of chemical hazards and §70.50(c)(1)(iii)(B) requires the reporting of personnel exposures to chemicals. Although the MOU principles have been correctly incorporated into other proposed revisions to 10 CFR 70 (e.g. §§70.4, 70.61(b), 70.62(c), 70.64(a), 70.74 Appendix A), they are incorrectly referenced in §70.50. MOU principle (2) limits NRC jurisdiction to regulation of chemical hazards of licensed material and hazardous chemicals produced from licensed material. The two aforementioned sections of §70.50 should be corrected to properly incorporate the MOU principles.

Controlled Area and Co-Located Workers (§70.61)

§70.61(f) requires a licensee to establish a ‘controlled area’ for a facility in which it can control the activities of personnel. §70.61 states that any individual located outside of the controlled area is subject to the lower (public) radiation dose limits. NEI is concerned with the manner in which §70.61 could set radiation exposure limits for co-located workers. We are particularly concerned with the treatment of radiation exposures from an NRC-licensed facility present on a DOE site (e.g. a MOX fabrication facility on a DOE property). As currently written a worker (as defined in §70.4) who leaves the controlled area to perform a work-related function would have to be treated as a member of the public when performing the ISA and would be subject to the more stringent public radiation exposure limits. Outside of the controlled area the TEDE limit of 0.1 rem for members of the public would apply (cf. 10 CFR 20.1301(a)(1)) rather than the annual TEDE occupational dose limit of 5 rems (10 CFR 20.1201). Such a problem has arisen at the Hanford Tank Waste Remediation System-Privatization where NRC subjects ‘co-located’ workers to the appreciably lower public dose limits.

NEI recommends that the NRC apply constant radiation exposure limits to all plant workers, regardless of their presence inside or outside of the controlled area. The 10 CFR 70 regulations should be harmonized with comparable DOE radiation exposure limits.

NEI recommends that the phrase “...*any individual*...” in sections b(2) and c(2) be clarified to exclude facility workers who may have occasion to work outside of the controlled area. This phrase should be amended to read “...*any individual (other than a worker)*...”

Safety Program Definition (§70.62)

There is inconsistent use of the term “safety program” throughout the proposed revisions. For example, sometimes the rule implies that the ISA Summary is part of the safety program (it is not), and thereby part of the license. The explanatory notes in the Federal Register also erroneously describe the safety program; for example, on page 41346, it (correctly) states that the ISA comprises one component of the safety program, but then (erroneously) states that the results of the ISA must be submitted for NRC approval. This is inconsistent with our understanding developed during the NRC workshops and clearly not consistent with the direction given by the Commission in the Staff Requirements memorandum dated December 1, 1998. §70.62(a)(1) defines the licensee’s safety program to consist of three components (process safety information, ISA, management measures). This definition is too narrow. The safety program includes these important components, but also includes the commitments and programs addressed in the eleven chapters of the Standard Review Plan (e.g. radiation protection, compliance with 10 CFR 20 occupational radiation exposure limits, etc.). In this regard, NEI recommends that the last sentence in §70.62(a)(1) be deleted. The content of §70.22 adequately defines the requirements for a licensee safety program.

Log of Failures (§70.62)

The regulatory reporting requirements of §70.62(a)(2) and §70.74(a)(1) direct a licensee to report to NRC Headquarters within one to twenty-four hours instances in which an item relied on for safety or management measure has failed or been discovered to be non-operational. The NRC will, therefore, already possess all of the information sought in the “log” of §70.62(a)(3). Tabulating data that the NRC already possesses and has presumably internally analyzed, seems to be a wasteful and inefficient use of licensee and NRC resources that should be focused exclusively on safety-significant issues. This is an unnecessarily prescriptive requirement.

NEI, therefore, recommends that §70.62(a)(3) be deleted from the rule.

Integrated Safety Analysis (§70.62)

NEI has two comments with the timing requirements specified in §70.62(c)(3) for completion of an ISA by existing licensees:

- (i) for consistency the phrase “... *[the date of publication of the final rule]*” in the first sentence should be replaced by “... *the effective date of the rule...*” as has been done in subsections (i), (ii) and (iii), and
- (ii) the 4-year period for conducting the ISA and for modifying the plan to address any identified unacceptable performance deficiencies may be too short. Also, we recommend that the period should start on the date on which the NRC approves the plan required in subsection 3(i). If the clock starts on the effective date of the rule and the NRC takes one year to approve the ISA plan, the licensee will be unduly hampered. There should be some incentive for the NRC to complete its approval process in a timely manner. NEI is also concerned over the limited time available for a licensee to not only conduct the ISA, but also to implement any modifications to the facility as is required by §70.62(c)(3)(iii). Based on the fact that licensees who have already committed to perform ISAs were generally given five years to complete them, NEI recommends that an existing licensee be granted 5 years to complete the ISA. We also recommend that appropriate and sufficient time be allowed for the licensee to present to the NRC and to implement a plan to correct any identified unacceptable performance deficiencies. Finally, we recommend of imposition of a 90-day time frame on the NRC to issue a decision on the acceptability of a licensee’s ISA approach. NEI recommends that subsection (ii) be re-written to read: “... (ii) *Within 5 years of the date of NRC approval of the licensee’s plan, complete an ...*”

For consistency with the language in §70.62(a) (...“*the safety program may be graded such that management measures applied are commensurate with the reduction of risk attributable to that item...*”), NEI recommends that the second sentence in §70.62(d) be revised to include the term “graded.” This sentence would then read: “...*The measures applied to a particular engineered or administrative control or control system may be graded commensurate with the reduction of the risk attributable to that control or control system...*”

Baseline Design Criteria (§70.64)

10 CFR70.22(i)(1)(ii) and 70.22(i)(3) require a license applicant to design an emergency plan to respond to the radiological hazards of an accidental release of special nuclear material. This plan must address how on-site workers will be protected (§70.22(i)(3)(v)). The ‘Emergency Capability’ design criterion presented in §70.64(a)(6) requires a license applicant to plan for the ‘...*evacuation of personnel...*’

This criterion should be made specific to on-site personnel to be consistent with the requirements of 10 CFR 70.22. A licensee should not be required to demonstrate that the design provides for evacuation of off-site personnel, for this implies the involvement of FEMA and constitutes emergency preparedness measures that have never before been placed on fuel cycle facility licensees. NEI recommends that §70.64(a)(6)(ii) be written as: “...*Evacuation of on-site personnel; and...*”

The proposed definition of ‘*items relied on for safety*’ (§70.4) encompasses both physical devices and activities of personnel. §70.64(a)(8) requires that the design of items relied on for safety provides for inspection, testing and maintenance of items relied on for safety. However, such activities (testing and maintenance) can not be applied to activities of personnel. The breadth of the term items relied on for safety requires addition of language that is appropriate to administrative controls and to personnel activities. Either the definition of ‘*items relied on for safety*’ should be rewritten to separate engineered and administrative safety controls (e.g. ‘*items relied on for safety*’ versus ‘[personnel] *activities relied on for safety*’), or additional qualifying text should be inserted. NEI recommends that baseline design criterion (8) be rewritten as follows:

“...the design of items relied on for safety must provide for adequate inspection, testing, and maintenance, or adequate training, testing and qualification for personnel whose activities relied on for safety, to ensure their availability and reliability to perform their function when needed...”

§70.64(b) directs a license applicant to apply ‘defense-in-depth practices’ to the facility design and then indicates that engineered controls should be used in preference to administrative safety controls. Consistent with the ability granted a licensee to grade all aspects of its safety program (cf. §70.62(a)), grading of the defense-in-depth safety concepts in the design of the facility should also be permitted. Safety design criterion (b)(1) appears unnecessarily prescriptive by discouraging a licensee from using anything but an engineered safety control. So long as the licensee can satisfactorily demonstrate that an administrative safety control or a system of administrative and engineered controls will enable the performance criteria to be satisfied, the choice of items relied on for safety and the nature of ‘defense-in-depth’ practices that is applied should be flexible.

Technical Edits:

- (i) §70.64(a): the last sentence refers to a paragraph (c). There is no paragraph (c) in §70.64. This sentence should be deleted.
- (ii) §70.64(a)(5): the words “*produced from*” in the first sentence should be deleted. The sentence should read: “...*The design must provide for adequate protection against chemical risks of licensed material, plant...*”

- (iii) §70.64(a)(9): for consistency with correct terminology, NEI recommends that the word 'nuclear' be added before 'criticality.'

ISA Summary (§70.65)

NEI's comments on §70.65(b), which outlines the content of an ISA Summary, relate to the level of detail that will be expected in this document. The rule should not prescribing an acceptable level of detail, but should defer this issue to be developed in the SRP. Use of terms such as "...*types of accident sequences...*" rather than detailed description of each accident sequence in §70.65(b)(3) is commended. However, in §70.65(b)(6) the required level of descriptive detail for items relied on for safety ("...*sufficient detail...*") remains vague. NEI recommends that information at the 'systems level' should be required, rather than at the 'component' or 'sub-component' level.

The ISA will examine the proposed locations, quantities and risks of chemicals at the facility and determine whether any could serve as an initiating event for a credible accident sequence or potentially affect the safety of licensed materials. For any chemicals falling into either category and posing a high or intermediate risk, their locations and characteristics would need to be specified in the ISA Summary. A licensee should not be required to keep the NRC appraised of the contents of bulk storage tanks kept in the "back 40" if the ISA has shown that they pose no credible risk to the facility, its operations, the public and the environment. Thus, NEI believes the §70.65(b)(7) requirement for information on the locations of on-site chemicals is unnecessary.

§70.65(b)(3) seeks information on each process analyzed in the ISA including the hazards identified for each. This information should not extend to include process safety information that is specifically excluded from the requirements of §70.65. As the ISA Summary only requires specification of the items relied on for safety for high- and intermediate-consequence events (cf. §70.65(b)(6)), there should be no need for an applicant to include in the ISA Summary information on processes and hazards for accident sequences and processes that are determined in the ISA not to produce consequences that exceed the performance criteria of §70.61. Such information will, however, be maintained at the facility site for review by NRC staff. The ISA Summary should, consequently, only address those processes for which accident sequences have been identified that would produce consequences that exceed the performance criteria of §70.61.

§70.65(b)(6) requires the applicant to list all items relied on for safety for high- and intermediate-consequence events and any other accident sequences for which the licensee has defined items relied on for safety. This is far too broad a requirement. The items should only need to be described at the systems level, rather than at the component or sub-component level. While this list will include "...*activities of*

personnel relied on for safety...” it should not include procedures that the personnel must follow. As procedures are constantly being adjusted, revised and improved, their inclusion in the list of items relied on for safety would necessitate frequent revisions to the ISA Summary that may have little if any safety significance.

The ISA Summary should, therefore, provide a concise summary of pertinent information on technology, equipment and hazardous materials used in each process, but not include detailed process safety information that is maintained at the facility as ‘ISA documentation.’ As stated before, the on-site ISA documentation is available for review by the NRC Staff if such detailed information need be examined.

Facility Change Mechanism (§70.72)

The intent of the new Facility Change Mechanism is to permit, based on specific criteria, the licensee to make certain changes to the facility and its operations that maintain or improve safety without seeking NRC pre-approval. The merits of this new mechanism are threefold: (i) the NRC need only assess safety-significant changes, (ii) the licensees’ regulatory burden (and commitment of resources) to filing license amendment requests for even the most safety benign changes is reduced, and (iii) protection of public health and safety and the environment will be enhanced by directing regulatory attention to potentially higher-risk conditions. However, as currently worded, §70.72 will not achieve the intended goals.

§70.72(a) requires that *any change* to the facility be formally evaluated by means of the configuration management (CM) system to evaluate, among other things, its potential impact on safety and the need to modify the ISA and ISA Summary. This requirement is too broad and all-encompassing and would require CM evaluation of changes having no or absolutely minimal effect on health and safety (e.g. office remodeling, planting of shrubbery, changing paint colors). Rather than to first evaluate every change by means of CM, the licensee should first rely on internal procedures to initially screen any proposed changes for their potential adverse safety impacts. If this preliminary screening indicates that implementing the change could place the licensee at risk of not meeting the performance requirements of 10 CFR 70.61, then the change would be evaluated by the ISA methodology and the CM system. What appears to be outlined in §70.72(a) are steps in the ISA methodology that will be used in evaluating a proposed change. The CM system function will be applied in evaluating the change and in recording it in the facility on-site documentation so as to ensure consistency among design requirements, physical configuration and facility documentation. §70.72(b), like §70.72(a), contains unsatisfactory language by requiring that *any change* to the facility be first evaluated by CM to establish if there is need for a license amendment.

§70.72(c) prescribes what facility changes can be made without NRC pre-approval. This section is patterned after a similar provision for nuclear power reactors described in 10 CFR 50.59(a) and (b). In contrast to 10 CFR 50.59, which addresses changes to the facility's safety analysis report (the equivalent document for Part 70 licensees being the ISA Summary), §70.72(c) would again apply to any change to the facility, its operating procedures or items relied on for safety. The NRC pre-approval exclusion provision should be patterned after 10 CFR 50.59, whereby only changes to contents of the ISA Summary would be required to be reviewed under §70.72(c). Incorporating corrections to terminology (discussed below) this section should be revised to read: “(c) *the licensee may make changes to the site, processes or items relied on for safety as described in the ISA Summary, without prior...*”

§70.72(c)(1)(i) parallels the language of 10 CFR 50.59(a)(2) whereby NRC pre-approval would be required for “...*an accident...of a different type than any evaluated previously in the safety analysis report...*” NEI concurs with this criterion. However, the footnote appended to “*new types of accidents*” is contrary to the stated goal of limiting requests for license amendments to those that are safety significant. The footnote's reference to accident initiators, changes in consequences and changes in the safety function of a control could be literally interpreted to require essentially any change to the facility to require NRC pre-approval and a license amendment. NEI strongly recommends that the footnote be deleted for consistency with the intent of 10 CFR 70.72.

§70.72(d) requires notification to the NRC within 90 days of any change that does not require NRC pre-approval, but for which changes to the ISA Summary were necessary. The corresponding reporting period for nuclear power licensees for such changes can be as long as 24 months (cf. 10 CFR 50.71(e)(3)(i)). Information pertaining to the change (e.g. ISA analysis and supporting documentation, CM information) will be available at any time at the facility for NRC inspection and review. For consistency with the Facility Change Mechanism reporting requirements (§70.72 (d)(3)), NEI recommends that all changes be reported annually to NRC headquarters consistent with the recommendations of the Commissioners.

NEI understands the intent of §70.72(d)(3) to be a requirement for licensees to submit annually a brief summary of facility changes that are implemented without NRC pre-approval, whether or not they affect the ISA Summary. However, the wording of this section (“...*records required by §70.62(a)(2) of this part...*”) will inadvertently and significantly expand the information that would have to be reported. §70.62(a)(2) requires records not only pertaining to the ISA (and ISA Summary), but also pertaining to process safety information and management measures. §70.72(d)(3) will, therefore, require the licensee to submit voluminous information that could include updates of process safety information including drawings, process flow diagrams, piping and instrument diagrams, information on process chemicals, technology, equipment and process conditions (temperatures,

intermediates, pressures, etc.), updates of material safety data sheets (MSDS), etc. The licensee has made a binding license commitment to maintain this detailed information at the facility as one of the components of the facility safety program (cf. 10 CFR 70.62(a)). Information that would be reported annually under §70.72(d)(3) pertains to changes having a low risk or safety significance. Annual submission to NRC Headquarters of such detailed information of low safety significance seems unnecessary and as such, this section should be reworded to read:

“...a brief summary of all changes to the integrated safety analysis and ISA Summary, that are made without prior Commission approval, must be submitted to the NRC every 12 months...”

To summarize, the Facility Change Mechanism (§70.72) should be revised to:

- (i) incorporate consideration of risk in deciding which changes should be controlled by the CM system and clearly distinguish between ISA functions and CM
- (ii) demonstrate consistency in the use of terminology (e.g. ‘*items relied on for safety*’ rather than the formerly used ‘*structures, systems and components*’)
- (iii) delete the footnote for §70.62(c)(1)(i)
- (iv) permit a licensee to improve or enhance an item relied on for safety without seeking NRC pre-approval
- (v) lengthen the reporting time frame of §70.72(d)(1) to one year in accordance with the Commissioners’ in the July 1999 SRM
- (vi) clarify the annual reporting requirements of §70.72(d)(3) to encompass descriptions of changes made to the facility without NRC pre-approval and to exclude submission of up-dated data that should remain at the facility (referred to as ISA documentation).

Backfit Provision:

NEI has documented in letters to former Chairman Jackson (May 26, 1999) and to Dr. Carl Paperiello (February 12, 1999) and in its September 1996 Petition for Rulemaking (PRM-70-7) why an immediately effective backfit provision should be included in 10 CFR 70. We continue to believe that application of the backfit provision upon the effective date of the revised rule is justified and appropriate. Our concern with the timing of the backfit provision is accentuated by the refusal of the Staff to implement an immediately-effective backfit provision in 10 CFR 76 that the Commission had approved and directed.

NEI clearly believes that the safety bases of Part 70 facilities are sufficiently well understood to permit a backfit provision now. The fuel cycle facilities’ exemplary operating history must provides demonstrable evidence that there is current

understanding of “safety bases” (even in the absence of an ISA). The ISA’s primary advantage is that it will better and more efficiently direct the NRC and licensees’ attention to what has been existing practice of licensees – focusing attention and resources on safety significant issues. By conducting systematic safety analyses of Part 70 facilities, a licensee will be able to qualitatively assess the improvement in public health and safety that a change can afford. NEI has consistently advocated implementation of a *qualitative* methodology to derive the safety benefit of a backfit modification. This approach obviates the need to establish the incremental risk of a proposed facility modification and acknowledges the inappropriateness of applying quantitative methodologies to Part 70 facilities.

We are particularly concerned with the open-ended time frame to implement the backfit provision. The NRC has approved license renewals for fuel fabricators that incorporated an ISA into their license renewal application. For those licensees that have prepared an ISA and had their license renewed, NEI believes that an immediately effective backfit provision should be implemented.

In summary, NEI recommends that:

- (i) backfit language be included as part of the proposed 10 CFR 70 revisions, and
- (ii) the backfit provision be immediately effective to those processes or parts of an existing facility for which the ISA has been completed.

NEI provided the NRC with streamlined language for an immediately effective backfit provision in its letter to former Commissioner Shirley Jackson on May 26, 1999. NEI recommends that this language be incorporated into the Part 70 revisions.

Implementation Provision:

The proposed revisions to 10 CFR 70 should have an implementation provision similar to that presented in 10 CFR 20.1008. NEI believes that such an implementation provision should be included in the Part 70 revisions to address potential conflicts between existing license conditions and the new Part 70 requirements. We believe this additional provision is necessary, especially in light of license conditions modeled after proposed Part 70 revisions that have added to licenses recently renewed by the NRC.

Topics for Which Comment Are Solicited:

The Federal Register notice solicited public and stakeholder comments on the following four topics:

- (1) **Backfit Provision** [Fed. Reg. P.41340]: NEI has commented above that the backfit provision should be immediately effective upon approval of a licensee's license renewal, and in any case, upon submittal of an ISA Summary to the NRC (See comments and rationale above)

- (2) **NRC-OSHA Preemption** [Fed. Reg. P.41342 re §70.61]: The NRC/OSHA MOU is, in NEI's view, consistent with the statutory allocation of jurisdiction between the NRC and OSHA, and serves as a useful frame of reference for discussing these issues. The proposed treatment of chemical hazards in Part 70 revisions will not encroach in any way on OSHA's traditional authority over non-radiological chemical hazards at NRC licensed facilities. Had the NRC retained authority over purely non-radiological hazardous chemicals that could have no impact on radiological safety, OSHA would have had a legitimate concern that the rule would unintentionally "preempt" OSHA regulations. However, the draft rule makes clear that the rule encompasses: (1) the hazards of NRC-licensed materials; and (2) non-radiological hazards that may affect the safety of NRC-licensed materials; but not (3) purely chemical hazards or other potentially hazardous working conditions that are within OSHA's province. By clarifying these parameters of the rule, the NRC has appropriately limited its role so as not to intrude on OSHA's traditional authority. This would include OSHA's Process Safety Management rules, its Permissible Exposure Limits (PELs), and other OSHA requirements.

The §70.62 requirement to perform an ISA will not preempt OSHA requirements. While licensees will need to determine whether any non-radiological chemicals present at their sites could affect the safety of NRC-licensed materials, the NRC would not impose any restrictions on the use or handling of such chemicals unless, through the ISA, it was determined that they could have such an effect. (In doing so, the NRC would actually be regulating the safety of the licensed material itself, rather than regulating the "direct" hazards of the non-radiological chemicals). Finally, NEI does not believe that OSHA would be precluded from addressing workplace hazards arising out of the decommissioning process -- so long as it does not attempt to regulate the hazards of licensed material subject to NRC jurisdiction.

- (3) **ISA Methodology**. [Fed. Reg. P.41346 re §72.62(c)] NEI believes the rule offers a license applicant or licensee sufficient flexibility in selecting an appropriate ISA methodology. We have no comments to add.

- (4) **ISA Summary Update Frequency** [Fed. Reg. P.41348 re §72.72(c)]: NEI wholeheartedly supports the Commissioners' recommendation that the timeframe for reporting changes to the ISA Summary to the NRC be

lengthened from 90 days to 12 months. As discussed above, we believe the reporting period should be consistent with that imposed on reactor licensees (12 to 24 months). The analyses of any changes made to the ISA (and which may have to be included in the ISA Summary) will be available at the facility for review and inspection. We do not foresee an adverse safety impact by retaining the updated information at the facility and submitting it to the NRC on an annual basis.

Miscellaneous Comments: NEI urges the NRC to correct inaccuracies that are present in Part II '*Description of Proposed Action*' of the Federal Register notice. We are concerned that such inaccuracies could contribute to public misunderstanding of the intent of the rule's provisions. Examples of such inaccuracies include the following:

- (1) ***Terminology:*** several terms that we understood were included in earlier drafts, but since were deleted from the rule remain. For example: '*facility vulnerability*' (instead of '*unacceptable performance deficiency*'), '*structures, systems and components*' (instead of '*items relied on for safety*')
- (2) ***SRM (December 1998):*** statements of approach are included with no comment that they were subsequently deleted, and therefore give the reader an incorrect impression of what is contained in the revisions. For example, on p. 41339 it is stated that the ISA results are part of the application and license and that a preliminary ISA and decommissioning ISA are needed.
- (3) ***Safety Grading:*** the text continues to erroneously indicate that safety grading is required (p. 41341) even though the rule language was changed.
- (4) ***ISA:*** the text (p. 41347) states that the ISA can be used to supplement the final design of the facility. This suggests that a second ISA (or at least an update of the initial ISA) may be required, even if no changes are made to the facility design during construction