

NUCLEAR REGULATORY COMMISSION

10 CFR Part 70

[Docket No. PRM-70-7]

Nuclear Energy Institute;
Receipt of a Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; Notice of receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) has received and requests public comment on a petition for rulemaking filed by the Nuclear Energy Institute (NEI). The petition has been docketed by the Commission and assigned Docket No. PRM-70-7. The petitioner requests that the NRC amend its regulations to require uranium processing, uranium enrichment, and fuel fabrication licensees to use an integrated safety assessment (ISA), or an acceptable alternative, to confirm that adequate controls are in place to protect public health and safety. The petitioner also requests that a backfitting provision be established to ensure regulatory stability for these types of licensees.

DATE: Submit comments by (75 days after the date of publication). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except to those comments received on or before this date.

ADDRESSES: For a copy of the petition, write: Rules Review Section, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Submit comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Attention: Docketing and Service Branch.

Deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. on Federal workdays.

For information on sending comments by electronic format, see "Electronic Access," under the Supplementary Information section of this notice.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone: 301-415-7163 or Toll Free: 800-368-5642, or e-mail MTL@NRC.GOV.

SUPPLEMENTARY INFORMATION:

Petitioner

NEI represents that it is 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.

Background

The petitioner is aware that the NRC staff has considered a possible revision of 10 CFR Part 70 for several years. The petitioner believes that the NRC staff is motivated to amend 10 CFR Part 70 because of its assessment of certain conditions and events that have occurred at fuel facilities in the past, and the NRC Materials Regulatory Review Task Force report of 1992, "Proposed Method for Regulating Major Materials Licensees" (NUREG-1324).

However, the petitioner does not believe NUREG-1324 should serve as a blueprint for a major revision to 10 CFR Part 70. It further believes that possible future NRC regulation of Department of Energy facilities does not warrant a major revision to 10 CFR Part 70 and that wholesale changes to the part are not necessary. Instead, the petitioner is proposing a focused and performance-based addition to the existing regulation to address the NRC's concern about possible hazards at 10 CFR Part 70

licensed facilities.

Petitioners Request

The petitioner requests that the NRC amend 10 CFR Part 70 to require that uranium processing, uranium enrichment, and fuel fabrication licensees ensure that their safety programs are evaluated and modified, as necessary, on the basis of an ISA, or an acceptable alternative, within an appropriate time period. The petitioner also requests that 10 CFR Part 70 be modified to ensure regulatory stability for 10 CFR Part 70 licensees through the inclusion of a comprehensive backfitting requirement similar to the backfitting regulation applicable to 10 CFR Part 50 licensees.

The petitioner states that the proposed amendments would require 10 CFR Part 70 licensees to evaluate and enhance, if appropriate, their overall safety program on the basis of data generated from an ISA, or an acceptable alternative, and specifically defined performance criteria. According to the petitioner, the three principal hazards for 10 CFR Part 70 facilities are nuclear criticality, fire, and chemical accidents. The petitioner believes that its proposed changes would establish performance criteria for the evaluation of these three hazards, as well as for general radiation safety.

Discussion of Petitioner's Request

The petitioner's basis for the recommended revisions is that the fuel facilities are being operated safely under existing regulations and that the NEI's members have reviewed most of the conditions and events on which the NRC staff apparently has based its concerns. In each case reviewed, the petitioner states that:

- (1) Substantial margins of safety and conservatisms existed;
- (2) The double contingency principle and conservative assumptions built into criticality safety analyses operated effectively to prevent an accidental criticality event; and
- (3) Lessons learned from these events, as well as continuing efforts to make cost-effective improvements to operations, have provided the industry with an even larger margin of safety than existed several years ago.

The following discussion presents the principal components of the petitioner's suggested amendments and their supporting bases.

1. Integrated Safety Assessment.

The petitioner states that an ISA is a process conducted to identify hazards and the potential for initiating event sequences and to assess the potential event sequences and their consequences relative to the performance objectives for the facilities, the plant structures, systems and components (SSCs), and programs relied on to prevent or mitigate these consequences. The petitioner states that subsequent to the integrated assessment, safety-related SSCs and programs would be ranked on the basis of their importance to safety and a balanced safety program. The petitioner believes that this ranking of SSCs and programs would optimize safety program implementation because the establishment of importance-to-safety rankings and interrelationships would focus facility resources effectively.

2. Performance Criteria.

The petitioner believes that the establishment of performance criteria that comprise the safety template against which licensees will be required to judge the effectiveness of their safety programs must be part of the proposed regulations. The performance criteria would be based on the criticality, radiation protection, chemical safety, and fire protection aspects of the SSCs and programs deemed important to safety. The petitioner recommends performance criteria that would:

(1) Satisfy the requirements of 10 CFR Part 20;

(2) Avoid accidental criticalities; and

(3) Make it unlikely that any member of the public off the site would receive a radiation dose of 25 rem total effective dose equivalent, an intake of 30 milligrams of uranium in a 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 under accident conditions.

3. Reference to Industry Practices.

The petitioner states that while the petitioner's suggested rule does not specifically reference the American Institute of Chemical Engineer (AIChE), "Guidelines for Hazard Evaluation Procedures, Second Edition With Worked Examples," 1992, this publication is frequently referenced by the NRC staff as an acceptable guide for performing the hazard-evaluation portion of an ISA. The petitioner believes that the AIChE document provides reasonable approaches and that other formal methods may

also be acceptable.

The petitioner states that some licensees are currently performing hazard analyses under other applicable requirements, such as the Occupational Safety and Health Administration's (OSHA) Process Safety Management regulations and the Environmental Protection Agency's (EPA) Risk Management Program regulations. The petitioner believes that analyses performed under these other regulations should be considered an acceptable means of meeting the ISA requirement for evaluating hazards within the NRC's jurisdiction.

4. Graded Approach.

The petitioner states that once any credible event is identified by an ISA, licensees will confirm that there is reasonable assurance that the performance criteria will not be exceeded and that adequate controls are in place at their facilities to prevent or mitigate any such postulated event. If credible-event or accident sequences are examined and, on the basis of a realistic evaluation, determined not to be reasonably capable of producing effects in excess of the performance criteria, no further action would be required by a licensee.

The petitioner believes that events or accidents of lesser significance would continue to be prevented and mitigated through existing licensee safety programs. The petitioner states that where an accident or event could credibly produce consequences exceeding those specified in the suggested regulations, the licensee would evaluate the controls relied upon to prevent or mitigate the incident and take additional

measures as necessary. The anticipated likelihood of an event or accident and its potential effects would be evaluated by a licensee in the process of grading the safety programs. Using these criteria, the petitioner suggests one approach to grading would be to classify SSCs and programs on the basis of their safety significance and to apply controls equal to that classification. Other approaches also may be appropriate.

5. Changes in Facility Operations.

The petitioner states that, upon completion of the ISA, each licensee would determine what, if any, changes in existing controls are needed to provide reasonable assurance that the threshold performance criteria are not exceeded. The licensee would then implement these changes in a timely manner. The petitioner 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.

6. Alternative Approaches.

The petitioner states that efforts underway at a number of fuel cycle facilities to reevaluate and/or redocument the safety basis for their operations may fulfill the requirement for the conduct of an ISA. In other cases, a licensee may have an alternative approach or program for which it believes may assure and demonstrate the safety of its operations. The petitioner believes that the proposed regulations would provide flexibility for licensees to offer alternative approaches for the NRC's

consideration. The petitioner states that these 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 petitioner believes that the proposed regulations should allow for these alternative approaches, and require the licensee to obtain NRC approval of, and complete its efforts, as the suggested rule would require for formal ISAs.

7. License Format.

The petitioner states that under its suggested regulations, ISA results would be available for review at each licensee's site but would not become part of the license. These results would include a discussion of the controls relied on to ensure that the performance criteria are not exceeded and the bases for concluding these controls are adequate. The petitioner states that a formal submittal to the NRC of an ISA report would not be required and, most importantly, the ISA would not become part of the license, which may only be changed through a codified change process. In accordance with licensees' configuration control programs, when significant plant changes are considered, licensees would be required to review and update the ISA and to implement any new controls that may be necessary as a result of that review and updating.

The petitioner states that incorporation of the ISAs into the license would necessitate significant changes in the current license application format by dramatically expanding the description of the plant site, facilities, equipment, processes and controls

that form the basis of the license. The petitioner states that the certification applications submitted by the United States Enrichment Corporation (under criteria similar to those in the draft Part 70 SRP and SF&CG) included over 1,000 pages per plant dedicated to site, facility, and process descriptions and safety (accident) analyses. The petitioner believes that this could potentially represent a significant administrative burden for licensees and the NRC Staff, producing no measurable improvement in the safety of licensed 10 CFR Part 70 facilities.

The petitioner states that 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. Under these licenses, one part establishes binding license conditions and the other provides a safety demonstration in support of those license conditions. A request for a license amendment is needed to change the license conditions portion. However, the safety demonstration part may be modified without prior NRC approval, as long as the licensee continues to adhere to the binding license conditions. The petitioner states that the existing system provides adequate control over necessary license parameters while providing licensees with sufficient flexibility to accommodate changes within the safety envelope established by license conditions. The petitioner states that the industry does not believe that the administrative effort required to comply with a new license format -- which would be similar to a reactor licensee's SAR and which would presumably include a "§50.59" type change process -- is warranted or necessary.

8. Backfitting Provision.

The petitioner states that inclusion of a backfitting provision would ensure that future modifications to 10 CFR Part 70 licenses brought about by new regulatory requirements are based on public health and safety considerations and are appropriately cost-justified. The petitioner states that modifications resulting from new or different NRC requirements or NRC staff positions should be subjected to an appropriate analysis before implementation to ensure that the benefits obtained justify the burden that the proposed regulations would impose on licensees. The petitioner states that once its suggested regulations are issued, any subsequent plant or program modifications imposed as a result of the NRC's interpretation of the rule would require a cost-benefit review in accordance with the petitioner's rule. The petitioner believes that the concern is to seek, for example, protection from requirements to conduct highly complex and very costly probabilistic risk assessments for these low-risk facilities. The petitioner believes that this would be consistent with other NRC guidance.

The Petitioner's Proposed Amendment

1. The definition of a uranium processing and fuel fabrication plant is added to read as follows:

§ 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; or
- (v) Storage associated with such operations.

(2) Research and development activities involving any of the operations described in paragraph (1) of this definition except for research and development activities utilizing insubstantial amounts of uranium.

* * * * *

2. Section 70.40 is added to read as follows:

§ 70.40 Integrated Safety Assessment.

(a) 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 and programs that will be used by the licensee to protect public health and safety and, on the basis of 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. Licensees will classify SSCs on the basis of safety significance and will apply controls commensurate with that classification.

(b) 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:

(1) the requirements of 10 CFR Part 20 are satisfied;

(2) accidental criticalities are avoided; and

(3) for accident conditions, it is unlikely that any member of the public off the site will receive a radiation dose of 25 rem total effective dose equivalent, an intake of 30 milligrams 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.

(c) 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.

(d) Licensees who have notified the NRC of plans to decommission their facilities in accordance with the Timeliness Rule (§70.38) are not required to perform an ISA per this section.

(e) The results of the ISA shall be maintained at the licensee's facilities. Licensees will update the ISA for significant facility changes.

3. Section 70.76 is added to read as follows:

§ 70.76 Backfitting Provision.

(a)(1) Backfitting is defined as 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 NRC's regulations, or the imposition of a regulatory staff position interpreting the NRC's regulations that is either new or different from a previous NRC staff position.

(2) Except as provided in paragraph (a)(4) of this section, the NRC shall require a systematic and documented analysis, pursuant to paragraph (c) of this section for backfits that it seeks to impose.

(3) Except as provided in paragraph (a)(4) of this section, the NRC shall require the backfitting of a plant only when it determines, on the basis of the analysis described in paragraph (b) of this section, that there is a substantial increase in the overall protection for public health and safety or common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that plant are justified in view of this increased protection.

(4) The provisions of paragraphs (a)(2) and (a)(3) of this section are inapplicable and, therefore, backfit analysis is not required and the standards in paragraph (a)(3) of this section do not apply where the Commission or NRC staff, as appropriate, finds and declares, with appropriately documented evaluation for its finding, any of the following:

(i) That a modification is necessary to bring a plant into compliance with the rules or orders of the Commission or into conformance with written commitments by the licensee;

(ii) That regulatory action is necessary to ensure that the plant provides adequate protection to public health and safety and is in accord with the common defense and security; or

(iii) That the regulatory action involves defining or redefining what level of protection to public health and safety or common defense and security should be regarded as adequate.

(5) The Commission shall always require backfitting of a plant if it determines that the regulatory action is necessary to ensure that the plant provides adequate protection to public health and safety and is in accord with common defense and security.

(6) The documented evaluation, required by paragraph (a)(4) of this section, must conclude a statement of the objectives of and reasons for the modification and the basis for invoking the exception. If immediately effective regulatory action is required, then the documented evaluation may follow, rather than precede the regulatory action.

(7) If there are two or more ways to achieve compliance with the rules or orders of the Commission, or with written licensee commitments, or there are two or more ways to reach a level of protection that is adequate, then ordinarily the licensee is free to choose the way that best suits its purposes. However, should it be necessary or appropriate for the Commission to prescribe a specific way to comply with its requirements or to achieve adequate protection, then cost may be a factor in selecting the way, provided that the objective of compliance or adequate protection is met.

(b) In reaching the determination required by paragraph (a)(3) of this section, the Commisison will consider how the backfit should be scheduled, in light of other ongoing regulatory activities at the plant and, in addition, will consider information available concerning any of the following factors, as may be appropriate, and any other information relevant and material to the proposed backfit:

(1) Statement of the specific objectives that the proposed backfit is designed to achieve;

(2) General description of the activity that would be required by the licensee in order to complete the backfit;

(3) Potential change in the risk to public health and safety from the accidental release of radioactive material or chemical hazards per §70.40(b)(iii);

(4) Potential impact on radiological exposure of facility employees;

(5) Installation and continuing costs associated with the backfit, including the direct and indirect costs of plant downtime;

(6) The potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements;

(7) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;

(8) The potential impact of differences in plant type, design, or age on the relevancy and practicality of the proposed backfit; and

(9) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

(c) No license will be withheld during the pendency of backfit analyses required by the Commission's regulations.

(d) The Executive Director for Operations shall be responsible for implementation of this section, and all analyses required by this section shall be approved by the Executive Director for Operations or his or her designee.

Summary

The petitioner believes that this proposed amendment has the potential to benefit both licensees and the NRC by requiring a clear, outcome-based understanding of the risks, their consequences, and established levels of safety, and by focusing regulatory and licensee attention on those areas that have the greatest risks. The petitioner believes that issuing the proposed regulations would focus both licensee and NRC resources on those areas in which public health and safety will benefit, and away from low risk, low consequence issues.

Electronic Access

Comments may be submitted electronically, in either ASCII text or WordPerfect format (version 5.1 or later), by calling the NRC Electronic Bulletin Board (BBS) on FedWorld. The bulletin board may be accessed using a personal computer, a modem, and one of the commonly available communications software packages, or directly via Internet. Background documents on the petition for rulemaking also are available, as practical, for downloading and viewing on the bulletin board.

If using a personal computer and modem, the NRC rulemaking subsystem on

FedWorld can be accessed directly by dialing the toll free number 800-303-9672.

Communication software parameters should be set as follows: parity to none, data bits to 8, and stop bits to 1 (N,8,1). Using ANSI or VT-100 terminal emulation, the NRC rulemaking subsystem then can be accessed by selecting the "Rules Menu" option from the "NRC Main Menu." Users will find the "FedWorld Online User's Guides" particularly helpful. Many NRC subsystems and data bases also have a "Help/Information Center" option that is tailored to the particular subsystem.

The NRC subsystem on FedWorld also can be accessed by a direct dial telephone number for the main FedWorld BBS, 703- 321-3339, or by using Telnet via Internet: fedworld.gov. If using 703- 321-3339 to contact FedWorld, the NRC subsystem will be accessed from the main FedWorld menu by selecting the "Regulatory, Government Administration and State Systems," then selecting "Regulatory Information Mail." At that point, a menu will be displayed that has an option "U.S. Nuclear Regulatory Commission" that will take the user to the NRC online main menu. The NRC online area also can be accessed directly by typing "/go NRC" at a FedWorld command line. If the user accesses NRC from FedWorld's main menu, he or she may return to FedWorld by selecting the "Return to FedWorld" option from the NRC online main menu. However, if the user accesses NRC at FedWorld by using NRC's toll-free number, he or she will have full access to all NRC systems but will not have access to the main FedWorld system.

If the user contacts FedWorld using Telnet, he or she will see the NRC area and menus, including the Rules Menu. Although the user will be able to download

documents and leave messages, he or she will not be able to write comments or upload files (comments). If the user contacts FedWorld using FTP, all files can be accessed and downloaded but uploads are not allowed; all the user will see is a list of files without descriptions (normal Gopher look). An index file is available listing and describing all files within a subdirectory. There is a 15-minute time limit for FTP access.

Although FedWorld also can be accessed through the World Wide Web, like FTP that mode only provides access for downloading files and does not display the NRC Rules Menu.

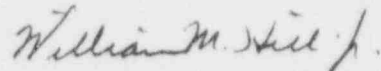
For more information on NRC bulletin boards, call Mr. Arthur Davis, Systems Integration and Development Branch, NRC, Washington, DC 20555-0001, telephone 301-415-5780; e-mail AXD3@nrc.gov.

Single copies of this petition for rulemaking may be obtained by written request or telefax ((301) 415-5144) from: Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, Mail Stop T6-D59, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001. Certain documents related to this petition for rulemaking, including comments received, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level),

Washington, DC. These same documents may also be viewed and downloaded electronically via the Electronic Bulletin Board established by NRC for this petition for rulemaking as indicated above.

Dated at Rockville, Maryland, this ^{20th} day of November 1996.

For the Nuclear Regulatory Commission.

A handwritten signature in cursive script, appearing to read "William M. Hill, Jr.", written in dark ink.

William M. Hill, Jr., Acting
Secretary of the Commission.

CONGRESSIONAL CORRESPONDENCE SYSTEM
DOCUMENT PREPARATION CHECKLIST

This check list is to be submitted with each document (or group of Qs/As) sent for processing into the CCS.

1. BRIEF DESCRIPTION OF DOCUMENT(S) Hr. Sen Fairclough
2. TYPE OF DOCUMENT ☒ CORRESPONDENCE ☐ HEARINGS (Qs/As)
3. DOCUMENT CONTROL ☐ SENSITIVE (NRC ONLY) ☒ NON-SENSITIVE
4. CONGRESSIONAL COMMITTEE AND SUBCOMMITTEE (if applicable)

Congressional Committee

Subcommittee
5. SUBJECT CODES
(A) _____
(B) _____
(C) _____
6. SOURCE OF DOCUMENTS
(A) _____ 5520 (DOCUMENT NAME _____)
(B) _____ SCAN (C) _____ ATTACHMENTS
(D) _____ OTHER _____
7. SYSTEM LOG DATES
(A) 12/17/96 DATA OCA SENT DOCUMENT TO CCS
(B) _____ DATE CCS RECEIVED DOCUMENT
(C) _____ DATE RETURNED TO OCA FOR ADDITIONAL INFORMATION
(D) _____ DATE RESUBMITTED BY OCA TO CCS
(E) _____ DATE ENTERED INTO CCS BY _____
(F) _____ DATE OCA NOTIFIED THAT DOCUMENT IS IN CCS

COMMENTS:

180041

RELEASE TO PDR