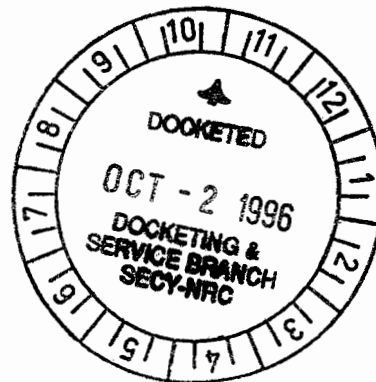




NUCLEAR ENERGY INSTITUTE

Marvin S. Fertel
VICE PRESIDENT,
NUCLEAR ECONOMICS &
FUEL SUPPLY

DOCKET NUMBER
PETITION RULE PRM 70-7
(61 FR 60057)



September 30, 1996

Mr. John C. Hoyle
Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

ATTENTION: Chief, Docketing and Service Branch

Dear Mr. Hoyle:

The Nuclear Energy Institute (NEI),* on behalf of its members who are 10 CFR Part 70 licensees, hereby submits a Petition for Rulemaking pursuant to 10 CFR 2.800 *et seq.* NEI requests that the U.S. Nuclear Regulatory Commission (NRC) amend 10 CFR Part 70 to require uranium processing, uranium enrichment, and fuel fabrication licensees to ensure their safety programs are evaluated and modified as necessary, based on the conduct of an Integrated Safety Assessment (ISA), or an acceptable alternative, within an appropriate time period. Further, the industry requests that Part 70 be modified to bolster regulatory stability for Part 70 licensees through the inclusion of a comprehensive backfitting requirement similar to that for Part 50 licensees.

As outlined in the Petition, the proposed rule would require Part 70 licensees to evaluate and enhance, if appropriate, their overall safety program based on data generated from an ISA or an acceptable alternative, and predicated on specifically-defined performance criteria. As indicated from past studies, the three principle hazards for Part 70 facilities are nuclear criticality, fire, and chemical accidents. Performance criteria are established in the proposed rule for the evaluation of these three hazards, as well as general radiation safety.

* 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.

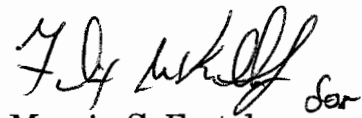


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The specification of performance criteria, the disciplined conduct of an ISA, and the use of the ISA results as a basis to adjust the licensees' safety programs, as needed, are the seminal portions of this Petition for Rulemaking. Our proposed rule has the potential to benefit both licensees and the NRC by requiring a clear, outcomes-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. Implementing the proposal would focus both licensee and NRC resources on those areas where public health and safety will benefit, and away from low risk, low consequence issues.

We would be pleased to discuss this Petition and to respond to any questions the NRC may have regarding its content or application.

Sincerely,



Marvin S. Fertel

Enclosure

**UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION**

In the Matter of a)	
Proposed Rulemaking)	
Regarding Amendments to)	Docket No.
10 CFR Part 70)	
)	

PETITION FOR RULEMAKING

This Petition for Rulemaking is submitted pursuant to 10 CFR 2.800 *et seq.* by the Nuclear Energy Institute (NEI), on behalf of certain 10 CFR Part 70 licensees and potential licensees. Petitioners request that the U.S. Nuclear Regulatory Commission (NRC), following notice and opportunity for comment, amend Part 70 by requiring uranium processing, enrichment, and fuel fabrication licensees to utilize either an Integrated Safety Assessment (ISA), or an acceptable alternative approach to confirm that adequate controls are in place to protect public health and safety. The proposed rule would also establish a backfitting provision in Part 70 for the purpose of ensuring regulatory stability.

STATEMENT OF PETITIONER'S INTEREST

NEI is the organization of the nuclear energy industry responsible for coordinating the combined efforts of materials licensees, electric utilities and other nuclear industry organizations in all matters involving generic regulatory policy issues and regulatory aspects of generic operational and technical issues affecting the nuclear industry. NEI's members include electric utilities, major architect/engineering firms, all of the major nuclear fuel supply vendors and all of the major manufacturers of radionuclides and radiopharmaceuticals. Because some of NEI's materials licensee members are subject to the requirements of Part 70, NEI is an "interested person" within the meaning of 10 CFR 2.802.

BACKGROUND

The subject of revising Part 70 has been under consideration by the NRC Staff for several years. The apparent impetus for the NRC Staff's desire to amend Part 70 has been its assessment of certain conditions and events that have occurred at fuel facilities in the past, as well as the 1992 report of the NRC's Materials Regulatory

Review Task Force entitled "Proposed Method for Regulating Major Materials Licensees" (NUREG-1324). A brief summary of the history of the NRC's deliberations on amending Part 70 follows.

In response to the 1992 issuance of NUREG-1324, the Staff developed an action plan for implementing regulatory changes applicable to major materials licensees. (SECY-92-337, October 5, 1992). After being briefed on the action plan, the Commission directed the Staff to reconsider various aspects of the plan. (Staff Requirements Memorandum (SRM), January 15, 1993). Subsequently, the Staff amended its approach and explicitly recommended a "major revision" to Part 70. (SECY-93-128, May 12, 1993). The Commission endorsed the Staff's recommendations (SRM, June 7, 1993).

The Staff later concluded that it would not be practical to work within the framework of the existing Part 70 and therefore recommended that a completely new version be developed. A six month extension of the schedule for preparation of a proposed rule was also proposed. (SECY-94-057A, April 13, 1994). The Staff then proposed an additional five month extension until June, 1995. (SECY-94-288, November 29, 1994). In March 1995, the Commission directed the Staff to "reconsider the current plan to revise 10 CFR Part 70 in its entirety . . ." The Commission directed the Staff to "determine [major fuel cycle licensee] attitudes towards revising Part 70, . . [and] the cost to revise and implement a new Part 70 . . . , as well as to consider and evaluate "alternative approaches . . ." (SRM, March 28, 1995).

A draft of the Staff's proposed revisions was first made available to licensees and the public in Spring 1995. (SECY-95-151, June 12, 1995). Once the draft became available and the Staff held a public meeting to discuss licensees' views, the Staff recommended that the rulemaking be "placed on hold" to permit further dialog with interested parties. The Commission approved that recommendation. (SRM, June 29, 1995). After a November 1995 public workshop, the Staff issued SECY-96-079, setting forth six alternative approaches for regulating fuel cycle facilities. (SECY-96-079, April 16, 1996). A July 2, 1996 Commission briefing then followed.

At the July 2 Commission briefing, NEI stated that in the interest of maintaining and improving the margin of safety of fuel facilities, and achieving some resolution of this issue, it would support certain carefully designed additions to Part 70. (Previously, NEI had taken the position that no rule changes were necessary). At the July 2 briefing, the Commission noted the change in the industry's position on revising Part 70 and strongly encouraged NEI to submit a rulemaking petition. In a letter dated July 11, 1996, NEI advised the Commission of the industry's intent to submit such a petition in early Fall 1996.

GROUNDS FOR PROPOSED ACTION

There are two fundamental principles underlying NEI's recommended approach. First, as recognized by the NRC Staff, fuel facilities are being operated safely under existing regulations. Recently completed NRC Plant Performance Reviews at three major facilities confirm that conclusion.

Second, the NEI's members have reviewed most of the conditions and events upon which the Staff apparently has based its concerns.¹ In each of the cases reviewed, we found 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 such events, as well as continuing efforts to make cost-effective improvements in industry's operations, have provided the industry with an even larger margin of safety than existed several years ago. In our analysis, we also explained why NUREG-1324 should not serve as a blueprint for a major revision to Part 70,² and why possible future NRC regulation of DOE facilities does not warrant a major revision to Part 70.³

Therefore, the industry does not believe that wholesale changes to Part 70 are necessary. We are proposing a focused and performance-based addition to the existing rule to address the NRC Staff's concern about possible hazards at Part 70 licensed facilities.

¹ NEI's review is documented in "Additional Discussion of Part 70 Industry Experience," which was discussed at the July 2, 1996, Commission briefing, and made part of the record of that proceeding.

² NUREG-1324 documented the results of an effort to propose an "ideal method" for regulating major materials licensees, "unfettered by any existing regulations or regulatory guidance, concerns about backfitting, or limitations on resources . . ." The Director of NMSS at the time described the regulatory approach offered in NUREG-1324 as "admittedly highly idealistic." (Memorandum, Robert L. Bernero to NUREG-1324 recipients). Furthermore, two senior NRC managers documented their "independent analysis" of the NUREG, and found that "[i]t will require a very substantial increase in resources and take years to complete action on all of the Report's recommendations. Given the characteristics of the facilities at which the Report's regulatory improvements are directed, the reality of agency resource constraints, and the availability of required skills, it is essential to prioritize the Report's recommendations." NUREG-1324, Appendix A, p. 33.

³ The NRC Staff has expressed the desire to improve the "clarity" of Part 70 given the "possibility that NRC will be given the responsibility for regulating DOE facilities in the future . . ." SECY-96-079, at Attachment 1, p.4. NEI does 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. In fact, 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. See, for example, the Commission's recently released "Direction Setting Issue Paper" on "Oversight of the Department of Energy," released as part of the strategic assessment effort (September 16, 1996).

Attachment A to this Petition presents NEI's proposed rule in response to the Commissioners' guidance at the July 2, 1996, briefing. NEI recommends the addition of three new provisions to the existing Part 70. First, a new Section 70.40 would be added to require the use of an ISA or an approved, alternative integrated approach to safety, hereafter referred to as ISA, for convenience to the reader. Second, a "backfit" provision would be added. Third, a definition would be added to clarify the scope of applicability of the proposed rule.

The ISAs would identify and evaluate those hazards that could imperil certain specified performance criteria, using methods similar to those described in the American Institute of Chemical Engineers' (AIChE) 1992 Guidelines for Hazard Evaluation Procedures or other acceptable methods. After the conduct of the assessment, the plant Structures, Systems and Components (SSCs) and programs relied on for safety would be ranked, based on their importance to safety. This ranking process would yield the foundation for a graded approach to safety, an approach that would focus resources on those SSCs and program areas that have the greatest risks (consequence and frequency).

Upon completion of the ISAs, licensees would modify their facility or health and safety programs, if necessary, to provide reasonable assurance that the specified performance criteria would not be exceeded. In doing so, licensees would use a graded approach to safety to ensure that the focus of attention remained on those matters with the most significant potential to adversely affect public and worker health and safety. Licensees and license applicants would be required to maintain the results of the ISA, and make those results available at their respective sites for NRC review.

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

The principle components of the industry's proposed rule and their supporting bases are discussed below.

1. Integrated Safety Assessment

An ISA is a process conducted to identify hazards and their potential for initiating event sequences, assess the potential event sequences and their consequences relative to the performance objectives for the facilities, the SSCs and programs relied on to prevent or mitigate such consequences.

Subsequent to the integrated assessment, safety-related SSCs and programs will be ranked based on their importance to safety and a balanced safety program. 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

A cornerstone of this regulatory process is the establishment of performance criteria that comprise the safety template against which licensees will be required to judge the effectiveness of their safety programs. The establishment of performance criteria must therefore be part of the new rule. The performance criteria will be based on the criticality, radiation protection, chemical safety and fire protection aspects of the SSCs and programs deemed important to safety. We recommend the following performance criteria.

- The requirements of Part 20 are satisfied;
- Avoidance of accidental criticalities; and
- 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 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.

Draft NUREG-1513 stated that “[a]ppropriate controls must be in place to provide reasonable assurance that any accidents identified in the ISA having these consequences will not occur.” We fully agree, and we feel it is essential that the rule itself contain measurable performance criteria to that end.

3. Reference to Industry Practices

While the rule does not specifically reference the American Institute of Chemical Engineers (AIChE) “Guidelines for Hazard Evaluation Procedures, Second Edition with Worked Examples,” 1992, it is frequently referenced by the NRC Staff as an acceptable guide for performing the hazard-evaluation portion of an ISA. NEI believes the AIChE document provides reasonable approaches, and that other formal methods may also be acceptable.

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 regulation. These analyses performed under these regulations should be considered acceptable means of meeting the ISA

requirement for evaluating hazards within the NRC's jurisdiction -- namely hazards associated with radioactive materials, nuclear criticality, and those fire and chemical hazards that could affect nuclear safety.⁴ The NRC's draft NUREG-1513 states that the "ISA guidance . . . is intended to be consistent with the requirements of OSHA and EPA . . ." so long as the ISA addresses "radiological, nuclear criticality, and certain chemical hazards (*i.e.*, UF6 release) not covered under other regulations."

4. Graded Approach

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 such postulated events. If credible event or accident sequences are examined and, based on a realistic evaluation, determined not to be reasonably capable of producing impacts in excess of the performance criteria, no further action by a licensee would be required. Events or accidents of lesser significance would continue to be prevented and mitigated through existing licensee safety programs. Where an accident or event could credibly produce consequences exceeding those specified in the rule, however, 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, 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.

5. Changes in Facility Operations

Upon completion of the ISA, each licensee will determine what, if any, changes in existing controls are needed to provide reasonable assurance that the threshold performance criteria are not exceeded, and will implement such changes in a timely manner. 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.

⁴ In accordance with the existing NRC/OSHA Memorandum of Understanding, the NRC would not regulate purely chemical hazards. "Memorandum of Understanding Between the Nuclear Regulatory Commission and the Occupational Safety and Health Administration; Worker Protection at NRC-Licensed Facilities," 53 Fed. Reg. 43590 (October 31, 1988).

6. Alternative Approaches

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 feel that it has an alternative approach or program for assuring itself of, and demonstrating to the NRC, the safety of its operations. The rule should provide flexibility for licensees to offer alternative approaches 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.

7. License Format

Under the industry's proposed rule, 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 upon to ensure that the performance criteria are not exceeded and the bases for concluding such controls are adequate. A formal submittal to the NRC of an ISA report will not be required. Most importantly, the ISA will 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 necessitated as a result of that review and updating.

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. We note, for example, 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. This could potentially represent a significant administrative burden for licensees and the NRC Staff, producing no measurable improvement in the safety of licensed Part 70 facilities.

Furthermore, 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 existing system provides adequate control over necessary license parameters while providing licensees with sufficient flexibility to accommodate

changes within the safety envelope established by the license conditions. 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

To assure that future modifications to Part 70 licenses brought about by new regulatory requirements are based on public health and safety considerations, and are appropriately cost-justified, NEI requests inclusion of a backfitting provision in the revised Part 70. Modifications resulting from new or different NRC requirements or Staff positions should be subjected to an appropriate analysis before implementation to ensure that the benefits obtained justify the burden that the proposed change would impose upon licensees. It is imperative that once the rule is promulgated, any subsequent plant or program modifications imposed as a result of the Staff's interpretation of the rule would require a cost-benefit review in accordance with the rule. Here 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. This would be consistent with other NRC guidance.

STATEMENT IN SUPPORT OF PROPOSED ACTION

For the reasons stated herein, consistent with the guidance given to the industry by the Commission during the July 2, 1996, public briefing (to consider submitting a Petition for Rulemaking to address the NRC's concerns in a manner that the industry thought would be most productive), this Petition to amend 10 CFR Part 70 was prepared. The proposed rule will provide for licensees' safety programs to be grounded in the results of an integrated assessment of all aspects of safety. The rule would establish well-defined performance criteria and would require licensees to take steps to provide reasonable assurance that the performance criteria are not exceeded. In addition, a backfitting provision should be added. These additions to Part 70 will provide a more focused and performance-based rule without the imposition of costly new generic programmatic requirements that would not substantially contribute to increased safety margins.

ATTACHMENT A

DISCUSSION OF PROPOSED RULE BY SECTION

I. Introduction and Scope

Section 70.4 provides a definition of uranium processing and fuel fabrication facilities, and the proposed Section 70.40 provides the basis to assure the plant is being operated with an adequate safety margin. Section 70.76 establishes enhanced regulatory stability, as it establishes specific requirements that proposed regulatory changes must be evaluated against in order to assure that the benefit of the change is justified by its economic impact.

II. General Requirements

The regulation of Part 70 facilities has evolved significantly since Part 70 was first promulgated; however, Part 70 has not been comprehensively modified or updated to reflect the changes in regulatory philosophy that have occurred since that time. Concerns related to chemical and fire safety have been raised by the NRC Staff, along with a continuing concern related to a potential criticality incident. The industry has concluded that the conduct of Integrated Safety Assessments (ISA's) would be beneficial. As a result, the industry has proposed the incorporation of an ISA requirement in Part 70, which will ensure that licensees grade their facilities' Structures, Systems and Components (SSCs) and programs important to safety, and evaluate their respective facilities against established safety performance criteria in a disciplined manner. The criteria target fire, nuclear and radiation safety so that, as an example, an offsite release under off-normal conditions, will not exceed 25 rem, total effective dose equivalent, and normal operations would not produce doses in excess of the limits established in Part 20. For radiation and chemical safety, performance criteria are, as an example, under accident conditions, a member of the public will receive less than 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.

If the ISA indicates that the performance criteria could be exceeded under reasonably anticipated conditions, the licensee would be required to take necessary steps to ensure that modifications are made to the facility's SSCs and programs important to safety, to meet those performance criteria.

The inclusion of a backfitting provision is intended to assure that regulatory changes that are demonstrated to be cost effective are incorporated by the licensee in a timely manner, and that any changes that do not provide benefits commensurate with the burden they would impose, are not implemented.

TEXT OF PROPOSED RULE

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.

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, 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. Licensees will classify SSCs based on 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: (i) the requirements of 10 CFR 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 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.

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 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.

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

(3) Except as provided in paragraph (a)(4) of this section, the Commission shall require the backfitting of a plant only when it determines, based on the analysis described in paragraph (b) of this section, that there is a substantial increase in the overall protection of the public health and safety or the 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 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; or

(ii) That regulatory action is necessary to ensure that the plant provides adequate protection to the health and safety of the public 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 the public health and safety or common defense and security should be regarded as adequate.

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

(6) The documented evaluation, required by paragraph (a)(4) of this section, must include 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 which is adequate, then ordinarily the licensee is free to choose the way which 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 Commission 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 the public 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 rules.

(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.