Proposed Rule for Domestic Licensing of Special Nuclear Material

CRGR PRESENTATION
April 11, 2000

DIVISION OF FUEL CYCLE SAFETY AND SAFEGUARDS
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

ATTACHMENT 2

Part 70 Subpart H

Major Sections

- §70.61 performance requirements
- §70.62(a) integrated safety analysis
- §70.62(d) management measures
- §70.72 change process
- §70.76 backfit

Defining characteristics of draft revisions to 10 CFR Part 70

- Pre and post licensing changes
- Risk-informed, performance-based
- Covers major accidents only - Part 20 addresses safety for normal operating conditions/upsets
- Requires 'integrated' look at accident safety
- Consistent with OSHA MOU and compatible & consistent with OSHA and EPA process safety rules
- Explicit accident standards for worker, public, and environmental safety

§70.61 - 3 performance requirements

- Must be 'highly unlikely':
  - worker: 100 rem or more, chemical-caused fatality
  - outside 'controlled area' (public): 25 rem or more, >30 mg Uranium intake, irrev. chemical injury
- Must be 'unlikely':
  - worker: more than 25 rem but less than 100 rem, irreversible chemical injury
  - outside 'controlled area' (public): greater than 5 rem but less than 25 rem, chemically-induced transient illnesses, environmental effluent standard
- All processes must be subcritical for normal and credible abnormal conditions (ANSI/ANS 8.1)

§70.61 performance requirements

- continued -

- Chemical standards are only for
  - licensed material e.g., UO_2F_2
  - chemicals produced from licensed material (defined term) e.g., HF from UF_6
  - Defer to OSHA - general worker chemical safety issues
  - Defer to EPA - general public chemical safety issues

- Establishes meaning of 'item relied on for safety':
  - Structures, systems, equipment, components and activities of personnel that are relied on to prevent or mitigate potential accidents that could exceed the performance requirements

§70.62 safety program & ISA

ISA

- Identify radiological and chemical hazards
- Identify accident sequences
- Identify consequence and likelihood
- Identify controls and document assumptions/basis

- ISA Team qualifications
- Timing for ISA completion for existing licensees

§70.62 safety program & ISA

Management Measures

- Management measures must be established that provide continuing assurance of compliance with the performance requirements of section §70.61
- Measures may be commensurate with the reduction of the risk attributable to that item.
- Definitions
  - Management measures (e.g., maintenance, configuration management, training, audits, etc.)
  - Available and Reliable

§70.72 facility changes

General Overview

- Allows licensees to make certain changes to its facilities without NRC pre-approval
- Contains requirement for configuration management system
- Any changes which alter the list of items relied on for safety contained in the ISA summary must be submitted quarterly.
- A brief summary of all changes covered by 70.72 submitted annually.

§70.76 backfit

- Background
  - Stakeholder comments re: immediately effective backfit provision
  - December 1, 1998 SRM
  - July 8, 1999 SRM and subsequent comments
  - Consideration of backfit provision

§70.76 backfit

- Options considered
  - §50.109 or §76.76 type provision
  - Immediately effective or delayed implementation
  - Immediately effective except for Subpart H
  - Effective after guidance development

§70.76 backfit

- Included an immediately effective provision similar to §76.76 with two exceptions
  - "Substantial" test not required per SRM
  - Clarification that compliance with Part 70 does not require a backfit analysis

- Effective after guidance is published

§70.76 backfit

- Develop guidance
  - Implementation
  - Chemical consequences

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

April 3, 2000

TO: Joseph A. Murphy
Special Assistant to the Director
Office of Nuclear Regulatory Research

FROM: Michael F. Weber, Director
Division of Fuel Cycle Safety
and Safeguards, NMSS

SUBJECT CRGR MEETING TO DISCUSS PART 70 BACKFIT PROVISION

Fuel Cycle Safety and Safeguards (FCSS) staff would like to meet with the Committee to Review Generic Requirements (CRGR) on April 11, 2000, to discuss the backfit provision that is being added to 10 CFR Part 70, Subpart H, "Domestic Licensing of Special Nuclear Material," (see attachments).

A revised 10 CFR 70 has been issued for public comment as a proposed rule; the public comment period closed in October 1999 . Although the proposed rule did not include a backfit provision, the Commission did solicit comments on this matter. The public comments received on the proposed rule indicated a desire to have such a provision included in the final rule. In response to the comments, FCSS staff is currently revising 10 CFR Part 70 to include a backfit provision, similar to 10 CFR 76.76 (which is similar to 10 CFR 50.109). The final rulemaking package is due to the Commission on May 15, 2000.

The purpose of the meeting would be informational; we would not be seeking CRGR concurrence or approval. Because of the experience that the CRGR has regarding backfit, we would like to obtain any insight from the CRGR concerning the proposed backfit provision that is being added to Part 70. We would especially like to know: 1) whether the CRGR believes that adding the proposed backfit provision is a prudent course of action; 2) whether the wording of the proposed provision is adequate based on the experience gained with 10 CFR 76.76 and 10 CFR 50.109; and 3) an estimate of the annual staff time that is expended implementing 10 CFR 50.109.

Please let us know if/when the CRGR will be able to meet with us on April 11 to discuss Part 70 backfit. Should you have any questions, please call Andrew Persinko of my staff at 415-6522.

Attachments:
1. Draft Final Rule
2. Public Comments on Backfit
3. Staff White Paper

ATTACHMENT 3

PART 70--DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

1. The authority citation for part 70 continues to read as follows:

Authority: Secs. 51, 53, 161, 182, 183, 68 Stat. 929, 930, 948, 953, 954, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2282, 2297f); secs. 201, as amended, 202, 204, 206, 88 Stat. 1242, as amended, 1244, 1245, 1246 (42 U.S.C. 5841, 5842, 5845, 5846). Sec. 193, 104 Stat. 2835, as amended by Pub. L. 104-134, 110 Stat. 1321, 1321-349 (42 U.S.C. 2243).

Sections 70.1(c) and 70.20a(b) also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 70.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 70.21(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 70.31 also issued under sec. 57d, Pub. L. 93-377, 88 Stat. 475 (42 U.S.C. 2077). Sections 70.36 and 70.44 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 70.61 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237). Section 70.62 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

2. The undesignated center heading "GENERAL PROVISIONS" is redesignated as "Subpart A--General Provisions."

3. In Sec. 70.4, the definitions of Acute, Available and reliable to perform their function when needed, Configuration management, Critical mass of special nuclear material, Double contingency, Hazardous chemicals produced from licensed material, Integrated safety analysis (ISA), Integrated safety analysis summary, Items relied on for safety, Management measures, Unacceptable performance deficiencies, and Worker are added, in alphabetical order, as follows:

Sec. 70.4 Definitions.

* * * * *

Acute as used in this part means a single radiation dose or chemical exposure event or multiple radiation dose or chemical exposure events occurring within a short time (24 hours or less).

* * * * *

Available and reliable to perform their function when needed as used in subpart H of this part means that, based upon the analyzed, credible conditions in the integrated safety analysis, items relied on for safety will perform their intended safety function when needed and management measures will be implemented that ensure ~~continuous~~ compliance with the performance requirements of Sec. 70.61 of this part, considering factors such as necessary maintenance, operating limits, common cause failures, and the likelihood and consequences of failure or degradation of the items and measures.

* * * * *

Configuration management (CM) means a management measure that provides ~~ensuring, as part of the safety program,~~ oversight and control of design information, safety information, and records of modifications (both temporary and permanent) that might impact the ability of items relied on for safety to perform their function when needed.

* * * * *

Critical mass of special nuclear material (SNM), as used in Subpart H, means special

nuclear material in a quantity exceeding 700 grams of contained uranium-235; 520 grams of uranium-233; 450 grams of plutonium; 1500 grams of contained uranium-235, if no uranium enriched to more than 4 percent by weight of uranium-235 is present; 450 grams of any combination thereof; or one-half such quantities if massive moderators or reflectors made of graphite, heavy water, or beryllium may be present.

* * * * *

Double contingency means ~~a~~ that process designs ~~that~~ incorporates sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a nuclear criticality accident is possible.

* * * * *

Hazardous chemicals produced from licensed materials means substances having licensed material as precursor compound(s) or substances that physically or chemically interact with licensed materials; that are toxic, explosive, flammable, corrosive, or reactive to the extent that they can endanger life or health if not adequately controlled. These include substances commingled with licensed material, and include substances such as hydrogen fluoride that is produced by the reaction of uranium hexafluoride and water, but do not include substances prior to process addition to licensed material or after process separation from licensed material.

* * * *

Integrated safety analysis (ISA) means a systematic analysis to identify plant and external hazards and their potential for initiating accident sequences, the potential accident sequences, their likelihood and consequences, and the items relied on for safety. As used here, integrated means joint consideration of, and protection from, all relevant hazards, including radiological, nuclear criticality, fire, and chemical. However, with respect to compliance with the regulations of this part, the NRC requirement is limited to consideration of the effects of all relevant hazards on radiological safety, prevention of nuclear criticality accidents, or chemical hazards directly associated with NRC licensed radioactive material.

* * * *

Integrated safety analysis summary means the document submitted with the license application, license amendment application, or license renewal application that provides a synopsis of the results of the integrated safety analysis and contains the information specified in Sec. 70.65(b).

* * * *

Items relied on for safety means structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in Sec. 70.61 or to mitigate their potential consequences. This does not limit the licensee from identifying additional structures, systems, equipment, components, or activities of personnel (i.e., beyond those in the minimum set necessary for compliance with the performance requirements) as items relied on for safety.

* * * * *

Management measures mean the functions performed by the licensee, generally on a continuing basis, that are applied to items relied upon for safety, to ensure the items are available and reliable to perform their functions when needed. Management measures include configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance elements.

* * * * *

Unacceptable performance deficiencies mean deficiencies in the items relied on for safety or the management measures that need to be corrected to ensure an adequate level of protection as defined in 10 CFR 70.61(b), (c), or (d).

* * * * *

Worker, when used in Subpart H of this Part, means an individual ~~whose assigned duties in the course of employment involve exposure to radiation and/or radioactive material from licensed and unlicensed sources of radiation (i.e., an individual who is subject to~~ who receives an occupational dose as defined in 10 CFR 20.1003.

4. In Sec. 70.8 paragraph (b) is revised to read as follows:

Sec. 70.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in Secs. 70.9, 70.17, 70.19, 70.20a, 70.20b, 70.21, 70.22, 70.24, 70.25, 70.32, 70.33, 70.34, 70.38, 70.39, 70.42, 70.50, 70.51, 70.52, 70.53, 70.57, 70.58, 70.59, 70.61, 70.62, 70.64, 70.65, 70.72, 70.73, 70.74 and Appendix A.

* * * * *

5. The undesignated center heading "EXEMPTIONS" is redesignated as "Subpart B--Exemptions."

Secs. 70.13a and 70.14 [Redesignated]

6. Sections 70.13a and 70.14 are redesignated as Secs. 70.14 and 70.17, respectively.

7. The undesignated center heading "GENERAL LICENSES" is redesignated as "Subpart C--General Licenses."

8. The undesignated center heading "LICENSE APPLICATIONS" is redesignated as "Subpart D--License Applications."

9. The undesignated center heading "LICENSES" is redesignated as "Subpart E--Licenses."

10. The undesignated center heading "ACQUISITION, USE AND TRANSFER OF SPECIAL NUCLEAR MATERIAL, CREDITORS' RIGHTS," is redesignated as "Subpart F--Acquisition, Use, and Transfer of Special Nuclear Material, Creditors' Rights."

11. The undesignated center heading "SPECIAL NUCLEAR MATERIAL CONTROL RECORDS, REPORTS AND INSPECTIONS" is redesignated as "Subpart G--Special Nuclear Material Control Records, Reports, and Inspections."

12. In Sec. 70.50 paragraph (c) is revised and paragraph (d) is added to read as follows.

Sec. 70.50 Reporting requirements.

* * * *

(c) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees shall make reports required by paragraphs (a) and (b) of this section, and by Sec. 70.74 and appendix A of this part if applicable, by telephone to the NRC Operations Center.³ To the extent that the information is available at the time of notification, the information provided in these reports must include:

\3\ The commercial telephone number for the NRC Operations Center is (301)

816-5100.

(i) Caller's name, position title and call back telephone number;

(ii) Date, time, and exact location of the event;

(iii) Description of the event, including;

(A) Radiological or chemical hazards involved including isotopes, quantities, and chemical and physical form of any material released;

(B) Actual or potential health and safety consequences to the workers, the public, and the environment, including relevant chemical and radiation data for actual personnel exposures to radiation or radioactive materials or hazardous chemicals produced from licensed materials (e.g., level of radiation exposure, concentration of chemicals, and duration of exposure);

(C) The sequence of occurrences leading to the event, including degradation or failure of structures, systems, equipment, components, and activities of personnel relied on to prevent potential accidents or mitigate their consequences; and

(D) Whether the remaining structures, systems, equipment, components, and activities of personnel relied on to prevent potential accidents or mitigate their consequences are available and reliable to perform their function.

(iv) External conditions affecting the event;

(v) Additional actions taken by the licensee in response to the event;

(vi) Status of the event (e.g., whether the event is on-going or was terminated);

(vii) Current and planned site status, including any declared emergency class;

(viii) Notifications related to the event that were made or are planned to any local, State, or other Federal agencies;

(ix) Status of any press releases related to the event that were made or are planned.

(2) Written report. Each licensee who makes a report required by paragraph (a) or (b) of this section, or by Sec. 70.74 and appendix A of this part if applicable, shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the report contains all of the necessary information and the appropriate distribution is made. These written reports must be sent to the U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, with a copy to the appropriate NRC regional office listed in appendix D of 10 CFR part 20. The reports must include the following:

(i) Complete applicable information required by Sec. 70.50(c)(1);

(ii) The probable cause of the event, including all factors that contributed to the event and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(iii) Corrective actions taken or planned to prevent occurrence of similar or identical events in the future and the results of any evaluations or assessments; and

(iv) For licensees subject to subpart H of this part, whether the event was identified and evaluated in the Integrated Safety Analysis.

(d) The provisions of Sec. 70.50 do not apply to licensees subject to Sec. 50.72. They do apply to those part 50 licensees possessing material licensed under part 70 who are not subject to the notification requirements in Sec. 50.72.

13. The undesignated center heading "MODIFICATION AND REVOCATION OF LICENSES" is redesignated as "Subpart I--Modification and Revocation of Licenses."

Secs. 70.61 and 70.62 [Redesignated]

14. Sections 70.61 and 70.62 are redesignated as Secs. 70.81 and 70.82, respectively.

15. The undesignated center heading "ENFORCEMENT" is redesignated as "Subpart J--Enforcement."

Secs. 70.71 and 70.72 [Redesignated]

16. Sections 70.71 and 70.72 are redesignated as Secs. 70.91 and 70.92, respectively.

17. In part 70, a new subpart H (Secs. 70.60-70.74) is added to read as follows:

Subpart H--Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material

Sec.

70.60 Applicability.
70.61 Performance requirements.
70.62 Safety program and integrated safety analysis.
70.64 Requirements for new facilities or new processes at existing facilities.
70.65 Additional content of applications.
70.66 Additional requirements for approval of license application.
70.72 Facility changes and change process.
70.73 Renewal of licenses.
70.74 Additional reporting requirements.

Sec. 70.60 Applicability.

The regulations in Sec. 70.61 through Sec. 70.74 apply, in addition to other applicable Commission regulations, to each applicant or licensee that is or plans to be: authorized to possess greater than a critical mass of special nuclear material, and engaged in enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, fabrication of mixed-oxide fuel or fuel assemblies, scrap recovery of special nuclear material, or any other activity that the Commission determines could significantly affect public health and safety. The regulations in Sec. 70.61 through Sec. 70.74 do not apply to decommissioning activities performed pursuant to other applicable Commission regulations including Sec. 70.25 and Sec. 70.38 of this Part. Also, the regulations in Sec. 70.61 through Sec. 70.74 do not apply to activities that are certified by the Commission pursuant to Part 76 of this chapter or licensed by the Commission pursuant to other parts of this chapter. Unless specifically addressed in this section, implementation of the Subpart H requirements shall be completed no later than the time of the ISA summary submittal required in §70.62(c)(3)(ii). Section 70.76, backfit, will be effective at the time NRC staff publishes guidance which implements §70.76. Appendix A reporting requirements (a)(1), (a)(2), (b)(4) are effective on the effective date of the final rule."

Sec. 70.61 Performance requirements.

(a) Each applicant or licensee shall evaluate, in the integrated safety analysis performed in accordance with Sec. 70.62, its compliance with the performance requirements in paragraphs (b), (c), and (d) of this section.

(b) The risk of each credible high-consequence event must be limited, unless the event is highly unlikely, through the application of engineered controls, administrative controls, or both, that reduce the likelihood of occurrence of the event or its consequence. Application of additional controls is not required for those high-consequence events demonstrated to be highly unlikely. High-consequence events are those internally or externally initiated events that result in:

(1) An acute worker dose of 1 Sv (100 rem) or greater total effective dose equivalent;

(2) An acute dose of 0.25 Sv (25 rem) or greater total effective dose equivalent to any individual located outside the controlled area identified pursuant to paragraph (f) of this section;

(3) An intake of 30 mg or greater of uranium in soluble form by any individual located outside the controlled area identified pursuant to paragraph (f) of this section; or

(4) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that:

(i) Could endanger the life of a worker, or

(ii) Could lead to irreversible or other serious, long-lasting health effects to any individual located outside the controlled area identified pursuant to paragraph (f) of this section. If an applicant possesses or plans to possess quantities of material capable of such chemical exposures, then the applicant shall propose appropriate quantitative standards for these health effects, as part of the information submitted pursuant to Sec. 70.65 of this part.

(c) The risk of each credible intermediate-consequence event must be limited, unless the event is unlikely, through the application of engineered controls, administrative controls, or both, that reduce the likelihood of occurrence of the event or its consequence. Application of additional controls is not required for those intermediate-consequence events demonstrated to be unlikely. Intermediate-consequence events are those internally or externally initiated events, that are not high-consequence events, that result in:

(1) An acute worker dose of 0.25 Sv (25 rem) or greater total effective dose equivalent;

(2) An acute dose of 0.05 Sv (5 rem) or greater total effective dose equivalent to any individual located outside the controlled area identified pursuant to paragraph (f) of this section;

(3) A 24-hour averaged release of radioactive material outside the restricted area in concentrations exceeding 5000 times the values in table 2 of appendix B to 10 CFR part 20; or

(4) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that:

(i) Could lead to irreversible or other serious, long-lasting health effects to a worker, or

(ii) Could cause mild transient health effects to any individual located outside the controlled area as specified in paragraph (f) of this section. If an applicant possesses or plans to possess quantities of material capable of such chemical exposures, then the applicant shall propose appropriate quantitative standards for these health effects, as part of the information submitted pursuant to Sec. 70.65 of this part.

(d) In addition to complying with paragraphs (b) and (c) of this section, the risk of nuclear criticality accidents must be limited by assuring that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety. Preventive controls and measures must be the primary means of protection against nuclear criticality accidents.

(e) Each engineered or administrative control or control system necessary to comply with paragraphs (b), (c), or (d) of this section shall be designated as an item relied on for safety. The safety program, established and maintained pursuant to Sec. 70.62 of this part, shall ensure that each item relied on for safety will be available and reliable to perform its intended function when needed and in the context of the performance requirements of this section.

(f) Each licensee must establish a controlled area, as defined in Sec. 20.1003, and in which the licensee retains the authority to ~~determine all activities, including exclusion~~ exclude or

~~removal of~~ remove personnel and property from the area. For the purpose of complying with the performance requirements of this section, individuals who are not workers, as defined in Sec. 70.4, may be permitted to perform ongoing activities (e.g., at a facility not related to the licensed activities) in the controlled area, if the licensee:

(1) Demonstrates and documents, in the integrated safety analysis, that the risk for those individuals at the location of their activities does not exceed the performance requirements of paragraphs (b)(2), (b)(3), (b)(4)(ii), (c)(2), and (c)(4)(ii) of this section; or

(2) Provides training ~~in accordance with~~ that satisfies 10 CFR 19.12(a)(1)-(5) to these individuals ~~to~~ and ensures that they are aware of the risks associated with accidents involving the licensed activities as determined by the integrated safety analysis, and conspicuously posts and maintains notices stating where the information in 10 CFR 19.11(a) may be examined by these individuals. Under these conditions, the performance requirements for workers specified in paragraphs (b) and (c) of this section may be applied to these individuals.

Sec. 70.62 Safety program and integrated safety analysis.

(a) Safety program. (1) Each licensee shall establish and maintain a safety program that demonstrates compliance with the performance requirements of Sec. 70.61. The safety program may be graded such that management measures applied are graded commensurate with the reduction of the risk attributable to that item. ~~The~~ Three elements of ~~the~~ this safety program; namely, process safety information, integrated safety analysis, and management measures, are described in paragraphs (b) through (d) of this section.

(2) Each licensee shall establish and maintain records that demonstrate compliance with the requirements of paragraphs (b) through (d) of this section.

(3) Each licensee shall ~~establish and~~ maintain ~~a log,~~ records of failures readily retrievable and available for NRC inspection, documenting each discovery that an item relied on for safety or management measure has failed to perform its function either in the context of the performance requirements of Sec. 70.61 or upon demand. ~~This log~~ These records must identify the item relied on for safety or management measure that has failed and the safety function affected, the date of discovery, date (or estimated date) of the failure, duration (or estimated duration) of the time that the item was unable to perform its function, any other affected items relied on for safety or management measures and their safety function, affected processes, cause of the failure, whether the failure was in the context of the performance requirements or upon demand or both, and any corrective or compensatory action that was taken. ~~The log must be initiated~~ A failure must be recorded at the time of discovery and the record of that failure updated promptly upon the conclusion of each failure investigation ~~of a failure~~ of an item relied on for safety or management measure.

(b) Process safety information. Each licensee or applicant shall maintain process safety information to enable the performance of an integrated safety analysis. This process safety information must include information pertaining to the hazards of the materials used or produced in the process, information pertaining to the technology of the process, and information pertaining to the equipment in the process.

(c) Integrated safety analysis. (1) Each licensee or applicant shall conduct an integrated safety analysis, that is of appropriate detail for the complexity of the process, that identifies:

(i) Radiological hazards related to possessing or processing licensed material at its facility;

(ii) Chemical hazards of licensed material and hazardous chemicals produced from licensed material;

(iii) Facility hazards which could affect the safety of licensed materials and thus present

an increased radiological risk;

(iv) Potential accident sequences caused by process deviations or other events internal to the plant and credible external events, including natural phenomena;

(v) The consequence and the likelihood of occurrence of each potential accident sequence identified pursuant to paragraph (c)(1)(iv) of this section, and the methods used to determine the consequences and likelihoods; and

(vi) Each item relied on for safety identified pursuant to Sec. 70.61(e) of this part, the characteristics of its preventive, mitigative, or other safety function, and the assumptions and conditions under which the item is relied upon to support compliance with the performance requirements of Sec. 70.61.

(2) Integrated safety analysis team qualifications. In order to assure the adequacy of the integrated safety analysis, the analysis must be performed by a team with expertise in engineering and process operations. The team shall include at least one person who has experience and knowledge specific to each process being evaluated, and persons who have experience in nuclear criticality safety, radiation safety, fire safety, and chemical process safety. One member of the team must be knowledgeable in the specific integrated safety analysis methodology being used.

(3) Requirements for existing licensees. ~~Notwithstanding other provisions regarding the effective date for part 70, subpart H, requirements, licensees shall comply with the provisions in paragraphs (c)(3)(i), (ii), and (iii) of this section beginning on [the date of publication of the final rule].~~ Individuals holding an NRC license on [the date of publication of the final rule] shall, with regard to existing licensed activities:

(i) ~~Within 6 months of~~ By <the effective date of ~~publication of~~ the final rule plus 6 months>, submit for NRC approval, a plan that describes the integrated safety analysis approach that will be used, the processes that will be analyzed, and the schedule for completing the analysis of each process.

(ii) ~~Within 4 years of~~ By <the effective date of ~~publication of~~ the final rule plus 4 years>, or in accordance with the approved plan submitted under Sec. 70.62(c)(3)(i), complete an integrated safety analysis, correct all unacceptable performance deficiencies, and submit, for NRC approval, an integrated safety analysis summary, including a description of the management measures, in accordance with Sec. 70.65 ~~or the approved plan submitted under paragraph (c)(3)(i) of this section.~~ The Commission may approve a request for an alternative schedule for completing the correction of unacceptable performance deficiencies if the Commission determines that the alternative is warranted by consideration of the following:

(A) Whether it is technically feasible to complete the correction of the unacceptable performance deficiency within the allotted 4 year period;

(B) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis.

(iii) Pending the correction of unacceptable performance deficiencies identified during the conduct of the integrated safety analysis, the licensee shall implement appropriate compensatory measures to ensure adequate protection.

(d) Management measures. Each applicant or licensee shall establish management measures to provide continuing assurance of compliance with the performance requirements of Sec. 70.61. The measures applied to a particular engineered or administrative control or control system may be commensurate with the reduction of the risk attributable to that control or control system. The management measures shall ensure that engineered and administrative controls and control systems that are identified as items relied on for safety pursuant to Sec. 70.61(e) of this part are designed, implemented, and maintained, as necessary, to ensure they are available and reliable to perform their function when needed, in the context of compliance with the performance requirements of Sec. 70.61 of this part.

Sec. 70.64 Requirements for new facilities or new processes at existing facilities.

(a) Baseline design criteria. Each prospective applicant or licensee shall address the following baseline design criteria in the design of new facilities. Each existing licensee shall address the following baseline design criteria in the design of new processes at existing facilities that require a license amendment under Sec. 70.72. The baseline design criteria must be applied to the design of new facilities and new processes, but do not require retrofits to existing facilities or existing processes (e.g., those housing or adjacent to the new process); however, all facilities and processes must comply with the performance requirements in Sec. 70.61). Licensees shall maintain the application of these criteria unless the evaluation performed pursuant to ~~paragraph~~ Sec. 70.62(c) ~~of this section~~ demonstrates that a given item is not relied on for safety or does not require adherence to the specified criteria.

(1) Quality standards and records. The design must be developed and implemented in accordance with management measures, to provide adequate assurance that items relied on for safety will be available and reliable to perform their function when needed. Appropriate records of these items must be maintained by or under the control of the licensee throughout the life of the facility.

(2) Natural phenomena hazards. The design must provide for adequate protection against natural phenomena with consideration of the most severe documented historical events for the site.

(3) Fire protection. The design must provide for adequate protection against fires and explosions.

(4) Environmental and dynamic effects. The design must provide for adequate protection from environmental conditions and dynamic effects associated with normal operations, maintenance, testing, and postulated accidents that could lead to loss of safety functions.

(5) Chemical protection. The design must provide for adequate protection against chemical risks produced from licensed material, plant conditions which affect the safety of licensed material, and hazardous chemicals produced from licensed material.

(6) Emergency capability. The design must provide for emergency capability to maintain control of:

(i) Licensed material;

(ii) Evacuation of on-site personnel; and

(iii) Onsite emergency facilities and services that facilitate the use of available offsite services.

(7) Utility services. The design must provide for continued operation of essential utility services.

(8) Inspection, testing, and maintenance. The design of items relied on for safety must provide for adequate inspection, testing, and maintenance, to ensure their availability and reliability to perform their function when needed.

(9) Criticality control. The design must provide for criticality control including adherence to the double contingency principle.

(10) Instrumentation and controls. The design must provide for inclusion of instrumentation and control systems to monitor and control the behavior of items relied on for safety.

(b) Facility and system design and plant layout must be based on defense-in-depth practices[4].; ~~The design process must incorporate, to the extent practicable:~~

\4\ As used in Sec. 70.64, defense-in-depth practices means a design philosophy, applied from the outset and through completion of the design, that is based on providing successive levels of protection such that health and safety will not be wholly dependent upon any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating defense-in-depth practices is a conservatively designed facility and system that will exhibit greater tolerance to failures and external challenges. The risk insights obtained through performance of the integrated safety analysis can be then used to supplement the final design by focusing attention on the prevention and mitigation of the higher-risk potential accidents.

~~(1) Preference for the selection of engineered controls over administrative controls to increase overall system reliability; and~~

~~(2) Features that enhance safety by reducing challenges to items relied on for safety.~~

Sec. 70.65 Additional content of applications.

(a) In addition to the contents required by Sec. 70.22, each application must include a description of the applicant's safety program established under Sec. 70.62. ~~,including the integrated safety analysis summary and a description of the management measures.~~

(b) The integrated safety analysis summary must be submitted with the license or renewal application (and amendment application as necessary), but shall not be incorporated in the license. However, changes to the integrated safety analysis summary shall meet the conditions of Sec. 70.72. The integrated safety analysis summary must contain:

(1) A general description of the site with emphasis on those factors that could affect safety (i.e., meteorology, seismology);

(2) A general description of the facility with emphasis on those areas that could affect safety, including an identification of the controlled area boundaries;

(3) A description of each process (defined as a single reasonably simple integrated unit operation within an overall production line) analyzed in the integrated safety analysis in sufficient detail to understand the theory of operation; and, for each process, the hazards that were identified in the integrated safety analysis pursuant to Sec. 70.62(c)(1)(i)-(iii) and a general description of the types of accident sequences;

(4) Information that demonstrates the licensee's compliance with the performance requirements of Sec. 70.61, including a description of the management measures; the requirements for criticality monitoring and alarms in Sec. 70.24; and, if applicable, the requirements of Sec. 70.64;

(5) A description of the team, qualifications, and the methods used to perform the integrated safety analysis;

(6) A list briefly describing ~~all~~ each items relied on for safety which is ~~are~~ identified pursuant to Sec. 70.61(e) in sufficient detail to understand their functions in relation to the performance requirements of Sec. 70.61;

(7) A description of the proposed quantitative standards used to assess the consequences from acute chemical exposure to licensed material or chemicals produced from licensed materials which are on-site, or expected to be on-site as described in Sec. 70.61(b)(4) and (c)(4);

(8) A descriptive list that identifies all items relied on for safety that are the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of Sec. 70.61; and

(9) A description of the definitions of ~~likely;~~ unlikely, highly unlikely, and credible as used in the evaluations in the integrated safety analysis.

Sec. 70.66 Additional requirements for approval of license application.

(a) An application for a license from an applicant subject to subpart H will be approved if the Commission determines that the applicant has complied with the requirements of Sec. 70.21, Sec. 70.22, Sec. 70.23 and Sec. 70.60 through Sec. 70.65.

(b) Submittals by existing licensees according to Sec. 70.62(c)(3)(i) will be approved if the Commission determines that:

(1) the integrated safety analysis approach is in accordance with the requirements of Sec. 70.61, Sec. 70.62(c)(1) and Sec. 70.62(c)(2);and

(2) the schedule is in compliance with Sec. 70.62(c)(3)(ii).

(c) Submittals by existing licensees according to Sec.62(c)(3)(ii) will be approved if the Commission determines that:

(1) the requirements of Sec. 70.65(b) are satisfied; and

(2) the performance requirements in Sec. 70.61 (b), (c) and (d) are satisfied, based on the information in the ISA summary, together with other information submitted to NRC or available to NRC at the licensee's site.

Sec. 70.72 Facility changes and change process.

(a) The licensee shall establish a configuration management system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel. This system must be documented in written procedures and must assure that the following are addressed prior to implementing any change:

(1) The technical basis for the change;

(2) Impact of the change on safety and health or control of licensed material;

(3) Modifications to existing operating procedures including any necessary training or retraining before operation;

(4) Authorization requirements for the change;

(5) For temporary changes, the approved duration (e.g., expiration date) of the change; and

(6) The impacts or modifications to the integrated safety analysis, integrated safety analysis summary, or other safety program information, developed in accordance with Sec. 70.62.

(b) Any change to site, structures, processes, systems, equipment, components, computer programs, and activities of personnel must be evaluated by the licensee as specified in paragraph (a) of this section, before the change is implemented. The evaluation of the change must determine, before the change is implemented, if an amendment to the license is required to be submitted in accordance with Sec. 70.34.

(c) The licensee may make changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, without prior Commission approval, if the change:

(1) Does not:

(i) Create new types ~~\5\~~ of accident sequences that, unless mitigated or prevented, would exceed the performance requirements of Sec. 70.61 and that have not previously been described in the integrated safety analysis summary; or

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~~\5\ Any change in the defining characteristics of the elements of an accident sequence may change the "type" of the accident sequence for a given process. For example, a new type of accident could involve a different initiator, significant changes in the consequence, or a change in the safety function of a control (e.g., temperature limiting device versus a flow limiting device).~~

(ii) Use new processes, technologies, or control systems for which the licensee has no prior experience;

(2) Does not remove, without at least an equivalent replacement of the safety function, an item relied on for safety that is listed in the integrated safety analysis summary;

(3) Does not alter any item relied on for safety, listed in the integrated safety analysis summary, that is the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of Sec. 70.61; and

(4) Is not otherwise prohibited by this section, license condition, or order.

(d)(1) For any changes that affect the list of items relied on for safety contained in the integrated safety analysis summary, as submitted in accordance with Sec. 70.65, but do not require NRC pre-approval, the licensee shall submit revised pages ~~to~~ of the integrated safety analysis summary to NRC ~~within 90 days of the change~~ quarterly, within 30 days after the end of the calendar year quarter .

(2) For changes that require pre-approval under Sec. 70.72, the licensee shall submit an amendment request to the NRC in accordance with Sec. 70.34 and Sec. 70.65.

(3) A brief summary of all changes to the records required by Sec. 70.62(a)(2) of this part, that are made without prior Commission approval and revised pages to the integrated safety analysis summary, must be submitted to NRC ~~every 12 months~~ annually, within 30 days after the end of the calendar year.

(e) If a change covered by Sec. 70.72 is made, the affected on-site documentation must be updated promptly.

(f) The licensee shall maintain records of changes to its facility carried out under this section. These records must include a written evaluation that provides the bases for the determination that the changes do not require prior Commission approval under paragraph (c) or (d) of this section. These records must be maintained until termination of the license.

Sec. 70.73 Renewal of licenses.

Applications for renewal of a license must be filed in accordance with Secs. 2.109, 70.21, 70.22, 70.33, 70.38, and 70.65. Information contained in previous applications, statements, or reports filed with the Commission under the license may be incorporated by reference, provided that these references are clear and specific.

Sec. 70.74 Additional reporting requirements.

(a) Reports to NRC Operations Center. (1) Each licensee shall report to the NRC

Operations Center the events described in appendix A to part 70.

(2) Reports must be made by a knowledgeable licensee representative and by any method that will ensure compliance with the required time period for reporting.

(3) The information provided must include a description of the event and other related information as described in Sec. 70.50(c)(1).

(4) Follow-up information to the reports must be provided until all information required to be reported in Sec. 70.50(c)(1) of this part is complete.

(5) Each licensee shall provide reasonable assurance that reliable communication with the NRC Operations Center is available during each event.

(b) Written reports. Each licensee who makes a report required by paragraph (a)(1) of this section shall submit a written follow-up report within 30 days of the initial report. The written report must contain the information as described in Sec. 70.50(c)(2).

18. Appendix A to part 70 is added to read as follows:

Sec. 70.76 Backfitting

(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 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 (b) 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 an 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 facility into compliance with Subpart H of this part; or

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

(iii) 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

(iv) 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 immediate 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 a certificate or the rules or orders of the Commission, or with written Corporation commitments, or there are two or more ways to reach a level of protection which is adequate, then ordinarily the Corporation 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 Corporation in order to complete the backfit;

(3) Potential change in the risk to the public from the accidental release of radioactive material;

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

(5) Installation and continuing costs associated with the backfit, including the cost 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 certificate 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.

Appendix A to Part 70--Reportable Safety Events

As required by 10 CFR 70.74, licensees subject to the requirements in subpart H of part 70, shall report:

(a) One hour reports. Events to be reported to the NRC Operations Center within 1 hour of discovery, supplemented with the information in 10 CFR 70.50(c)(1) as it becomes available, followed by a written report within 30 days:

(1) An inadvertent nuclear criticality.

(2) An acute intake by an individual of 30 mg or greater of uranium in a soluble form.

(3) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that exceeds the quantitative standards established to satisfy the requirements in Sec. 70.61(b)(4).

(4) An event or condition such that no items relied on for safety, as documented in the Integrated Safety Analysis summary, remain available and reliable, in an accident sequence evaluated in the Integrated Safety Analysis, to perform their function:

(i) In the context of the performance requirements in Sec. 70.61(b) and Sec. 70.61(c), or

(ii) Prevent a nuclear criticality accident (i.e., loss of all controls in a particular sequence).

(5) Loss of controls such that only one item relied on for safety, as documented in the Integrated Safety Analysis summary, remains available and reliable to prevent a nuclear criticality accident, and has been in this state for greater than eight hours.

(b) Twenty-four hour reports. Events to be reported to the NRC Operations Center within 24 hours of discovery, supplemented with the information in 10 CFR 70.50(c)(1) as it becomes available, followed by a written report within 30 days:

(1) Any event or condition that results in the facility being in a state that was not analyzed, was improperly analyzed, or is different from that analyzed in the Integrated Safety Analysis, and which results in failure to meet the performance requirements of Sec. 70.61.

(2) Loss or degradation of items relied on for safety that results in failure to meet the performance requirement of Sec. 70.61.

(3) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed materials that exceeds the quantitative standards that satisfy the requirements of Sec. 70.61(c)(4).

(4) Any natural phenomenon or other external event, including fires internal and external to the facility, that has affected or may have affected the intended safety function or availability or reliability of one or more items relied on for safety.

(5) An occurrence of an event or process deviation that was considered in the Integrated Safety Analysis and:

(i) Was dismissed due to its likelihood; or

(ii) Was categorized as unlikely and whose associated unmitigated consequences would have exceeded those in Sec. 70.61(b) had the item(s) relied on for safety not performed their safety function(s).

(c) Concurrent Reports. Any event or situation, related to the health and safety of the

public or onsite personnel, or protection of the environment, for which a news release is planned or notification to other government agencies has been or will be made, shall be reported to the NRC Operations Center concurrent to the news release or other notification.

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland, this 23rd day of July, 1999.
Annette Vietti-Cook,
Secretary of the Commission.

9. Section 70.65 (9). A description of the definitions of likely, unlikely, highly unlikely, and credible as used in the evaluations in the integrated safety analysis.

   The NRC should define the terms likely, unlikely, highly unlikely, and credible in the rule so that there will be one set of definitions applied to all nuclear fuel facilities. This will minimize the interpretation and application of these terms in the integrated safety analysis.

10. Section 70.73 states that a description of changes made to structures, systems, components, etc., should be sent periodically by the licensee to the NRC. The term "periodically" should be defined.

11. On the ISA update summary, the 90 day period appears to be too cumbersome. An annual update (similar to the annual FSAR updates for reactors per 10CFR50.71 (e)) should suffice. If the spirit of the regulation is not being met based on experience, the licensee should face enforcement action.

12. A backfit process similar to that in 10 CFR 50.109 or 10 CFR 76.76 should be incorporated into the revisions to Part 70 and should apply to the current proposed changes to the extent they apply to existing facilities.

13. Because DOE facilities do not have the uncertainty of continued corporate sponsorship inherent in commercial facilities, the timeliness and schedule requirements in the decommissioning requirements of § 70.38 should be revised to include separate requirements for DOE facilities.

14. The criticality requirements of § 70.24 should be revised to permit alternate criticality control provisions to be accepted for DOE facilities without requiring an exemption.

15. As additional DOE facilities are licensed by the NRC under the provisions of Part 70, NRC should ensure that the requirements address the full range of fissionable and fissile materials at these facilities.

Comments on NUREG 1513, Integrated Safety Analysis Guidance Document

Guidance on the quality assurance of the ISA process itself should be supplied.

Comments on NUREG 1520, Standard Review Plan (SRP)

This review focuses on the Integrated Safety Analysis (ISA) Chapter 3 of the SRP, since most of remaining SRP Chapters are dependent on the ISA results. The comments only address Chapter 3, ISA, and Appendix A.

Quantitative and non-quantitative determination of likelihood of accidents:

Section	Comment
70.65(a)	The concept of establishing a safety program under 70.62 is confusing. As stated in the previous comment on 70.62(a), the requirements for including the additional information as part of a license application can be included without creating a narrowly focused definition of the safety program.
70.72(c)(1)(i)	This section seems clear until the reader tries to understand the footnote, which attempts to explain new types of accident sequences. Taken literally, which we must be able to do with regulations, this footnote will require nearly all process changes to require a license amendment. This outcome is in direct conflict with commission directives issued during the development of the rule. BWXT recommends the footnote be deleted. The language in 70.72(c)(1)(i) is completely adequate in the absence of the footnote.
70.72(d)(1)	BWXT believes the 90-day update requirement is unnecessary and is inconsistent with the requirements in 10CFR50.71 for reactor licensees whose potential consequences are significantly greater than those at fuel facilities. BWXT supports an annual update of the ISA Summary.
70.72(d)(3)	This section requires annual submittal summarizing <u>all</u> changes to <u>records</u> required by 70.62(a)(2). The requirements for records in 70.62(a)(2) apply to all records described in 70.62(b) through (d). These records include Process Safety Information (70.62(b)) which enables the performance of the Integrated Safety Analysis. This would include procedures, drawings, detailed equipment lists, etc. BWXT does not believe NRC requires a summary of changes to this type information.
70.73	NRC should consider including a maximum timeframe for license renewal that is substantially longer than the current practice of 10 years. If a "living license" is truly the outcome, as described in the Supplementary Information, it seems renewal periods as long as 20 years would be appropriate.
Appendix A (b)	The terminology in (b)(1) clearly ties the failure to the performance requirements. The phrase, "and which results in failure to meet the performance requirements of Sec. 70.61", is very clear. This phrase should be consistently included in (b)(2)-(5) using the exact same wording.

Specific comments were also solicited in the following topics:

1. Backfit Provision

   BWXT believes the Backfit Provision should be immediately effective. This view has been clearly articulated in past meetings and in the NEI comments on this rule.

If the backfit provision is not immediately effective, an alternative would be to make it effective for facilities or systems for which the ISA has been completed and take ISA Summary submitted to NRC.

In either case, backfit language should be included in the rule now with dates or circumstances under which it is effective.

2. NRC-OSHA Preemption

   BWXT has no comment

3. ISA Methodology

   BWXT believes the proposed rule offers sufficient flexibility.

4. ISA Summary Update Frequency

   As stated in comments to 72.72, BWXT believes an annual update to the ISA Summary is adequate and consistent with 10CFR50.

6) Backfit: The Statements of Consideration request specific comments on the Commission's intent to defer consideration of a qualitative backfit provision. It further solicits suggestions for backfit provisions specifically applicable to fuel cycle backfit needs; requests identification of information available to conduct the analysis associated with backfits; and asks what period of time is reasonable before a backfit provision should be implemented.

USEC firmly believes that deferring consideration of a backfit provision would be evading an extremely important issue. The revisions to 10 CFR 70 will result in a dramatic change in the regulations applicable to fuel cycle facilities. Regardless of intentions to make the new regulations clear and explicit, there are many opportunities for interpretations of the new regulations. Differing interpretations of the language in the rule are predictable. A key difference in interpretations could result in the need to modify or add to plant systems, structures, components, procedures, or organization. It is certain that some key differences in understanding, interpretation or position will lead to justifiable differences of opinion between members of the staff and the licensee.

USEC's view of backfitting aligns almost exactly with NRC's "Backfitting Guidelines" (NUREG-1409) dated July 1990. The following two paragraphs describe this view.

Backfits are expected to occur as part of the regulatory process to ensure safety. It is important for sound and effective regulation, however, that backfitting be conducted by a controlled and defined process. The backfitting process is intended to provide for a formal, systematic, and disciplined review of new or changed positions before imposing them.

The backfit process enhances regulatory stability by ensuring that changes in regulatory staff positions are justified and suitably defined. For example, even if not needed to meet the standard for adequate protection or to ensure compliance, backfitting is proper if a substantial safety benefit is realized and the costs are justified by the safety benefit.

The proposed 10 CFR 70 changes many things. It adds substantive new performance requirements, new design basis criteria, new reporting requirements, new safety analysis requirements, new requirements for management measures and a new change control process. All of these new provisions can add uncertainty to the regulation of fuel cycle facilities. It is vital that a formal, systematic, and disciplined review of new, changed or differing positions that could backfit existing facilities be applied to increase regulatory certainty. The backfit provision provides for this systematic review.

10 CFR 76, Certification of Gaseous Diffusion Plants contains a backfit provision (§76.76). §76.76 is very similar to 10 CFR 50.109 and should serve as a model for a provision to be included in 10 CFR 70. Many of the same arguments that have been raised in opposition to the inclusion of a backfit provision in 10 CFR 70 were raised in opposition to §76.76.

Former Commissioner Remick, commenting on SECY 93-285, addressed similar concerns registered by the staff regarding the incorporation of a backfit provision in 10 CFR 76. He wrote:

> "I believe that the proposed regulations should contain a backfit provision which is as much like §50.109 as possible. I would think, for instance, that all of §50.109(a)(2)-(7) and (c) could apply in the new context. We should make use of the experience embodied in the backfit rule. Doing so will add some consistency to our regulatory practices. The only flexibility it will deprive us of is the flexibility to impose ill-considered backfits."

No change to the backfit language in 10 CFR 50.109 is needed to allow for qualitative analysis. There has been considerable discussion of a qualitative versus a quantitative backfit provision. NEI proposed and USEC endorses the use of the tried and true backfit language used successfully in 10 CFR 50.109. This is neither a quantitative nor a qualitative backfit provision. The standard incorporated in the rule is that backfitting will be required if 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 facility are justified in view of this increased protection." NRC's own guidance in NUREG/BR-0058, Rev 2, "Regulatory Analysis Guidance of the U.S. Nuclear Regulatory Commission" states the Commission's preference that quantitative analyses are much preferred over qualitative ones.

The staff contends that a quantitative determination of incremental risk would require a Probabilistic Risk Assessment. This is clearly not the case. While the existence of Probabilistic Risk Assessments may aid the staff in quantifying the increase in the overall protection of the public, it is by no means essential that Probabilistic Risk Assessments exist as a basis for backfit analyses.

The Commission revised the reactor backfit rule (10 CFR 50.109) in 1985 "to establish standards and an agency discipline for future management of backfitting for power reactors." This was well before Probabilistic Risk Assessments were available for many reactors. Indeed, it wasn't until late 1991, as required by Generic Letter 88-20, "Individual Plant Examination for Severe Accident Vulnerabilities – 10 CFR §50.54(f)," that risk analysis information became widely available for reactors. This was years after the revision of 10 CFR 50.109.

NRC guidance recognizes the need for flexibility in quantification and offers substantial information available for fuel cycle risk quantification. "Backfitting Guidelines" (NUREG-1409) gives examples of situations in which the backfit rule does not require a strict quantitative showing that benefits exceed costs, but rather "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.

"Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" (NUREG/BR-0058, Rev.2) anticipates the need for flexibility in quantification. It states:

> "Estimated values and impacts should be expressed in monetary terms whenever possible; many regulatory actions, such as those affecting...materials licensees, may not be supported by available PRA analysis...the staff needs to make every reasonable effort to apply alternative tools that can provide a quantitative perspective...concerning the value of the proposed action;
> [Where PRAs or other statistics-based analyses are not available] the generally recommended approach is to utilize whatever data may be available within a simplified model to provide some quantitative perspective;
> [Where quantification is not possible] reliance on the qualitative approach should be a last resort, to be used only after efforts to develop pertinent data or factual information have proved unsuccessful;

"The Regulatory Analysis Technical Evaluation Handbook" (NUREG/BR-0184) provides guidance to the analyst on how to prepare regulatory analysis and implements the policy in NUREG/BR-0058. Appendix C of NUREG/BR-0184 provides information for performing regulatory analysis for non-reactor facilities. Appendix C discusses the need for quantification as follows:

> "...the analyst should strive to use quantitative attributes when performing a regulatory analysis for non-reactor licensees. The Commission has determined, for example, that PRA should be used for analyses involving materials licensees when the potential safety consequences warrant its use, sufficient data are

available, and the licensees can reasonably b e expected to be capable of performing such analyses (NRC 1996c). However, it should be recognized that there are many benefits of improved regulation of non-reactor facilities that do not lend themselves to quantification. For example, increased confidence in the margin of safety may be a non-quantifiable benefit of a particular proposed regulatory requirement. As noted in Section 4.5, non-quantifiable benefits and costs can be significant elements of a regulatory analysis and need to be considered by the analyst and decision maker as appropriate."

NUREG/BR-0184, Appendix C contains estimated accident frequencies and other information and references to assist the analyst in quantifying regulatory analyses for fuel cycle facilities.

PRA was not a prerequisite to §50.109, nor to 10 CFR 76.76, nor is it required to prepare a quantitative determination of incremental risk for fuel cycle facilities. NRC guidance recognizes the need for qualitative as well as quantitative arguments. Just as a regulatory analysis was prepared for proposed 10 CFR 70, responsible regulatory analyses can be performed on potential backfits of fuel cycle facilities.

This new regulation will be applied to facilities that have been operating for over 30 years. Changes will likely be required at the facilities, most of which will be voluntarily undertaken by the licensee. There will also likely be differences between the licensee and some members of the NRC staff regarding what, and the extent of, changes that should be made. Adoption of a backfit provision allows these differences to be examined on a cost/benefit basis through a disciplined process.

The Statements of Consideration state "Without a baseline determination of risk, as provided by the initial ISA process, it is not clear how a determination of incremental risk, as needed for a backfit analysis, would be accomplished." USEC does not believe that a comprehensive risk baseline is necessary before reasoned judgements can be made on the benefits and risks of a proposed backfit. USEC agrees with the staff that conducting an ISA is beneficial and will enhance our mutual ability to understand the integrated risk of operation of these facilities. However, fuel cycle facilites, like our gaseous diffusion plants, have operated for many years. The risks associated with the facilities are largely known from years of operational experience and from numerous analyses that have been performed. NUREG/BR-0184 Appendix C provides a comprehensive summary of the information that is available. There is plenty of basis on which to evaluate the relevant benefits and costs of potential backfits and this will be added to with the performance of ISAs.

Fuel cycle backfit needs are not dissimilar to production and utilization backfit needs. §50.109 was the product of a concerted effort by the industry to stem the flow of new staff requirements and positions that started shortly after the Three Mile Island incident in March 1979. This incident prompted the issuance of numerous bulletins, orders and other NRC direction that resulted in modifications or additions to plant systems, structures, components, procedures and organization. The Commission saw

the need to formalize and achieve a disciplined process for review of new or changed NRC staff positions before imposing them. The Sequoyah Fuels incident in 1986 and the General Electric incident in 1991 were the Three Mile Islands of the fuel cycle industry. It is appropriate and needed to enhance regulatory certainty in the fuel cycle industry by ensuring that changes in regulatory staff positions are justified and suitably defined by inclusion of an immediately effective backfit provision in 10 CFR 70.

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:

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 July 30, 1999)

Comments Submitted by GE Nuclear Energy

NRC Solicited Comments

1. ***Backfit Provisions*** (FR p 41340) – GE believes that the backfit provisions should be immediately effective for the new rule. The Commission has granted this to virtually all facilities – with the exception of the fuel fabricators.

   The NRC has indicated that the basis of safety is not currently clear enough to make a backfit determination; however, that position must be questioned as all the facilities have been licensed, approved for operation and routinely inspected over roughly a 30 year period. Backfit has been granted to Part 76 facilities without anywhere near the formal interrelationship.

2. ***Preemption of OSHA*** (FR p 41342, 70.61) - As GE understands the proposed rule, it describes a situation wherein the current terms of the MOU between NRC and OSHA are incorporated into the regulations to avoid misunderstanding. This should result in more effective implementation for all concerned parties.

   GE supports the proposed rule in this respect.

3. ***ISA Methodology*** (FR p 41346, 72.62(c)) - GE believes that the current proposed rule offers sufficient flexibility in selecting ISA methodology so that a broad spectrum of facilities can be addressed and such that licensees have flexibility to interface with their site processes, procedures and resources.

4. ***ISA Summary Update Frequency*** (FR p 41348, 72.72(c)) - GE believes that the 90 day reporting of changes is entirely too frequent.

White Paper
on the Inclusion of a Backfit Provision
in the Final Part 70 Rulemaking

During the Part 70 rulemaking process the industry strongly suggested that NRC include an immediately effective rulemaking provision in the revised rule. The staff position was to defer making a decision about whether or not there is a need for a backfit provision until NRC had more experience with the new regulation. The Commission stated in the SRM dated July 8, 1999:

"The Commission has approved the current staff position to defer a backfit provision until the safety basis has been established and incorporated in the license, and after licensees and staff have gained experience with implementation of the integrated safety analysis (ISA) requirements of the rule. The Federal Register Notice should solicit comments on what would constitute a reasonable period of time, including supporting rationale, before a backfit should be implemented..."

Therefore, in relation to the ISA requirements, the issue is how long after publication of the rule should backfit become effective. A companion issue is whether the backfit provisions should apply to other aspects of Part 70 not affected by the current rulemaking.

In the Statements Of Considerations which was published with the Proposed Rule the NRC specifically requested comments on both the appropriate timing for implementation of the backfit provision and any fuel cycle specific language which should be incorporated. Most industry responses continued to state that a backfit provision should be effective immediately, and thus were not responsive to the spirit of the Commission request. In a letter dated October 13, 1999 NEI stated:

"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."

It should be noted that the current ISAs developed by industry are not geared toward the performance requirements in the revised rule. With one exception, the comments do not clearly state why it is important for the provision to be effective as soon as the rule is published. However, a letter to the Commission dated October 12, 1999 from USEC does try to explain the industry position. USEC states:

> "Differing interpretations of the language in the (new part 70) rule are predictable. It is certain that some key differences in understanding, interpretation or position will lead to justifiable differences of opinion between members of the staff and industry."
>
> "This new regulation will be applied to facilities that have been operating for over

30 years. Changes will likely be required at the facilities, most of which will be voluntarily undertaken by the license. There will also likely be differences between the licensee and the some members of the NRC staff regarding what, and the extent of, changes that should be made. Adoption of a backfit provision allows these differences to be examined on a cost/benefit basis through a disciplined process."

In these statements USEC is speaking about differences of opinion on how the facility would meet the new regulation. The backfit provision as written in 50.109 states that a backfit analysis is not required if the modification is necessary to bring the plant into compliance with the rules of the Commission. Accordingly, this argument does not support the need for an immediately effective backfit provision. In addition, this misunderstanding by the industry could result in substantial effort put forth by staff in arguing with the industry over compliance versus backfit in areas which are clearly outside of the backfit provision. However, the industry still may argue the need to have a formal process in which to resolve the conflict between the staff and industry on what constitutes compliance with the rule. As stated in SECY-99-147, the proposed rulemaking package, if differences of opinion between the staff and the industry cannot be resolved at staff level, as in the past, it will be elevated to higher levels of NRC and licensee management for resolution.

Staff is also concerned with the imposition of an immediately effective backfit provision because of the need to develop FCSS specific guidance documents and procedures for this process which would be based on guidance developed by NRR, but would need to address FCSS specific issues as well.

An additional consideration is the scope of the rule and the backfit provision. The current rulemaking only applies to those licensees required to submit an ISA. OGC has stated that the inclusion of a backfit provision would therefore only apply to those Part 70 licensees required to follow Subpart H. If it is determined that the backfit provision should apply to all Part 70 licensees, a separate rulemaking covering the backfit provision may have to be pursued.

For Subpart H licensees the backfit provision would encompass all actions at the site, even those areas which are not impacted by Subpart H. For example, normal operational radiation safety covered under Part 20 should not be affected by Subpart H and therefore, there is not expected to be significant changes in staff position in these areas so a backfit provision is appropriate. An option is for the backfit provision to be immediately effective (or slightly deferred) for these areas outside of Subpart H (e.g., operational safety) and be deferred for those areas included in Subpart H (e.g., ISA).

In addition to the timing for the implementation of a backfit provision, the exact wording of the provision needs to be determined. There are several backfit provisions in the regulations. The original provision is included in 10 CFR 50.109 and is the most extensive provision applying to both existing facilities and to the construction of new facilities. There is also a provision in 10 CFR 76.76 which is almost identical to 10 CFR

50.109 except it does not apply to the construction of new facilities. Either of these provisions could apply to fuel cycle facilities, however, if 76.76 type language is adopted it may have some shortcomings in relation to the construction of the MOX facility (needs to be reviewed). If 50.109 or 76.76 language is adopted, a change to the language could be suggested to require the licensees to provide cost estimates for the changes and NRC staff would then review these estimates. Also, it is anticipated that the backfit language would be modified to reflect Commissioner McGaffigan's suggested changes, as stated in the December 1, 1998 SRM.

> "The Commission supports a requirement that any new backfit pass a cost-benefit test, without the "substantial" increase in safety test. The Commission believes that modest increases in safety at minimal or inconsequential cost could be justified on a cost benefit basis"

Based on the statements in the SRM, and by the industry, and staff needs and concerns, the following are several options to approach this issue:

A. An immediately effective 50.109 or 76.76 type provision in the final rule
B. Include a 50.109 or 76.76 type provision effective for Subpart H licensees after a licensee wide baseline has been established.
C. Option B except include an immediately effective backfit provision for all areas of Part 70 not affected by the Subpart H rulemaking.
D. Option B except include backfit provision effective after one year for all areas of Part 70 not affected by the Subpart H rulemaking.

Pros and Cons

A. An immediately effective 50.109 or 76.76 type provision in the final rule

This option would take effect as soon as the rule is published.

Pro 1. It is responsive to the industry's comments

Con 1. Any changes in staff positions (i.e., facility upgrades needed based on ISA results) after the rule is published would be subject to backfit - may be difficult since staff has not fully developed its positions on issues which can arise when first implementing this rule.
2. Could result in time delays and increased costs if conflicts develop between the staff and industry on the proper implementation of the backfit provision (industry arguing that it is a backfit situation and staff is arguing that it is needed to be in compliance with the rule).
3. Absence of FCSS specific guidance or procedures for implementing the provision.
4. Does not meet the direction in SRM to defer backfit implementation.

B. Include a 50.109 or 76.76 type provision effective for Subpart H licensees after a licensee wide baseline has been established.

The backfit provision would be included in this rulemaking and would apply to all licensees for which subpart H applies but only once all ISAs, and ISA summaries have been reviewed and it has been determined which deficiencies are going to be corrected to meet the new rule.

Pros 1. Meets the direction in the SRM to defer backfit
2. Would allow the staff to establish a consistent baseline for all licensees
3. Would allow the staff time to develop FCSS specific guidance.

Cons 1. Is not responsive to industry comments
2. Would defer applying backfit to those areas outside of the Subpart H rulemaking activity (i.e., operational safety requirements under Part 20).

C. Option B except include an immediately effective backfit provision for all areas of Part 70 not affected by the Subpart H rulemaking.

A 50.109 or 76.76 type backfit provision would be included in this rulemaking and would apply to all licensees for which Subpart H applies. It would be immediately effective for those provisions of Part 70 outside of Subpart H. The same backfit provision would apply to Subpart H activities once all ISAs, and ISA summaries have been reviewed and it has been determined which deficiencies are going to be corrected to meet the new rule.

Pros
1. Meets the direction in the SRM to defer backfit
2. Would allow the staff to establish a consistent baseline for all licensees
3. Would allow the staff time to develop FCSS specific guidance (applicable to ISA results only).
4. Would not defer applying backfit to those areas outside of the Subpart H rulemaking activity.
5. Would partially address industry's comments (immediately effective for some parts of the safety program).

Con
1. Is not totally responsive to industry comments.
2. Absence of FCSS specific guidance or procedures for implementing the provision for areas outside of Subpart H (i.e., Part 20).

D. Option B except include backfit provision effective after one year for all areas of Part 70 not affected by the Subpart H rulemaking.

A 50.109 or 76.76 type backfit provision would be included in this rulemaking and would apply to all licensees for which Subpart H applies. It would be effective after one year for those provisions of Part 70 outside of Subpart H. The same backfit provision would apply to Subpart H activities once all ISAs, and ISA summaries have been reviewed and it has been determined which deficiencies are going to be corrected to meet the new rule.

Pros
1. Meets the direction in the SRM to defer backfit
2. Would allow the staff to establish a consistent baseline for all licensees
3. Would allow the staff time to develop FCSS specific guidance (applicable to all areas for which backfit would apply).
4. Would not defer applying backfit to those areas outside of the Subpart H rulemaking activity.
5. Would partially address industry's comments (effective sooner for some parts of the safety program).

Con
1. Is not totally responsive to industry comments.