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MEMORANDUM FOR: Willard B. Brown, Special Assistant, Regulatory and International Safeguards Branch, Division of Fuel Cycle Safety and Safeguards, NMSS

FROM: Gary L. Shear, Chief, Fuel Cycle and Decommissioning Branch, Division of Radiation Safety and Safeguards, Region III

SUBJECT: REVIEW OF PROPOSED PART 70 FOR FUEL CYCLE PLANT SAFETY

The Region III staff appreciates the opportunity to review and comment on proposed Part 70 Fuel Cycle Safety Requirements. We concur with the proposed changes to Part 70 as they are currently structured. However, the Commission's regulation that is currently enforced is titled Part 70 Domestic Licensing of Special Nuclear Material. In the subject text the revised title is referenced as Part 70 Fuel Cycle Safety Requirements. Although this may be a misunderstanding on our part, it is not clear as to which of the titles will be the official title for revised Part 70.

Thank you for allowing Region III to participate in the review of the proposed new Part 70.

/s/

Gary L. Shear, Chief
Fuel Cycle and Decommissioning Branch

cc: J. H. Joyner, RI
D. M. Collins, RII
L. J. Callan, RIV
J. Reese, RV

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MEMORANDUM FOR: James H. Joyner, Chief
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Leonard J. Callan, Director
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FROM: Willard B. Brown, Special Assistant
Regulatory and International Safeguards Branch
Division of Fuel Cycle Safety and Safeguards
Office of Nuclear Material Safety and Safeguards

SUBJECT: REVIEW OF PROPOSED FUEL FACILITY SAFETY RULE, AS REVISED

Elizabeth Ten Eyck, Deputy Director, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards, directed that we again solicit comments from you and your staff on the current version of the proposed Part 70 Rule for Fuel Cycle Plant Safety (Enclosed). A previous version of the rule has been sent (10/05/93) to the Office of Nuclear Regulatory Research (RES) for formal rulemaking action. At the moment, efforts in that Office are underway to contract for assistance in preparing an Environmental Assessment and a Regulatory Analysis for inclusion in the paper that will forward the rule to the Commission, scheduled for July, 1994. We have taken advantage of this hiatus in RES, caused by the time required to amend an existing contract to perform the desired work, to change the rule into the format that was used in preparing the Standard Review Plan (SRP) Chapters, to establish consistency between the rule and the SRP, and to make other changes in response to Divisional staff comments from ongoing reviews.

This seemed an opportune time to give you a chance to comment on the content of the rule as it is structured currently, before we send it back to RES. Since we expect the Division of Contracts to approve the contract modification momentarily, you will appreciate our need for a quick turnaround on this request. Please provide comments to me (WBB, 504-2654) by Friday, 12/17/93.

We have attempted to respond to comments received from prior reviews either by adopting suggested changes or by rewording rule paragraphs that were in contention to eliminate the expressed concern. We would be interested in your views on these efforts.

Enclosure: Part 70 Rule

ENCLOSURE

PROPOSED PART 70 FUEL CYCLE SAFETY REQUIREMENTS

§ *70.4 Definitions*

Act means ...

Accident means the ultimate result of a loss of control over a hazardous material.

Conditions adverse to safety means those unplanned and unevaluated situations that are different from the expected, normal or routine.

Control means an established mode that restricts the activity of individuals to prescribed actions or that limits the operation of a component, a process or a portion of a process, or a system to performance within defined bounds, in order to assure confinement of radiation or of radioactive material in approved locations under predetermined conditions.

Control parameter means an independent variable whose value is maintained within established limits in order to assure the safety of an operation.

Double contingency practice means the establishment of margins of criticality safety whereby sufficient controls exist so that no credible single mishap could lead to an inadvertent criticality excursion. This practice requires that sufficient controls be provided to prevent the occurrence of sequences of related mishaps which could lead to an excursion.

Engineered barrier means a component or system that has been intentionally designed and constructed to provide a substantial obstacle to the unintentional release or migration of special nuclear material from its assigned location, and may include containers, process equipment, waste pond liners, gloveboxes, rooms, buildings, etc.

Fuel cycle facility means any plant licensed under the provisions of *10 CFR Part 70* to produce special nuclear material or to process it for purposes of research and development or for the preparation of material for the production of reactor fuel.

Hazard means a source of risk.

Important to safety means any component or system which has a defined role in protecting the environment or the health and safety of workers and the public.

Integrated safety analysis means the documented facility description, process description, hazards identification, and accident analysis performed by either qualitative or quantitative methods to produce a basis for safety limits and controls for the conduct of plant operations without adverse affect on the environment or on the health and safety of the public.

New manufacturing process means a fundamentally different method or operation for the enrichment of uranium or for the processing, fabrication or scrap recovery of special nuclear material.

Potential accident pathway means the sequence of happenstances and/or actions that could lead from the loss of control of a hazard to an unanticipated occurrence having adverse consequences.

Safety Audit means the documented in-depth evaluation of the effectiveness of the management systems established to assure the safety of the environment and the public.

Safety Inspection means the day-to-day examination of systems and operations to detect conditions adverse to safety.

....

§ *70.22 Contents of Applications*

(a) <u>Unless required in more detail under paragraph (o) of this section,</u>

~~[E]~~each application...
(f) delete
(g)...(n)...
(o) Fuel cycle facility applicants shall demonstrate that their proposed activities will not adversely affect the environment or public health and safety. The demonstration shall include consideration of normal and potential abnormal operations and shall provide means to assure an adequate level of protection of the health and safety of the public and the environment under both conditions. Means to assure an adequate level of safety shall include natural or inherent plant operating characteristics, inclusion of safety provisions in operating procedures, siting considerations, and engineered safety features of the plant. The means relied on by applicants to provide an adequate level of safety shall result in a continuing capability to provide controlled operations under all known credible events or conditions. Consideration shall be given to minimizing the likelihood of or to preventing adverse events; to stopping event progression; and to mitigating event consequences. To meet these considerations, each application for a license to possess and use special nuclear material in a fuel cycle facility must address the provisions of *10 CFR 70.22 (a)* through *(o)*, as applicable, and must include:

(1) The Safety Plan.
The Safety Plan shall define and limit the types and quantities of special nuclear material to be possessed under license, the forms of the material to be processed, and the intended uses for the material. In addition, the Plan shall describe the practices and the commitments necessary to manage operations to ensure safe possession and use of the material in compliance with the requirements of *§ 70.80*. The contents of the Safety Plan, when approved, will be binding and must be followed in their entirety unless changed in accordance with the provisions of *§ 70.32 (1) or § 70.34* of this part. The submittal must contain sufficient detail to enable the Commission to evaluate the applicant's proposed processes and operations and to understand the associated hazards and controls, in conjunction with the Safety Analysis Report, in order to assess the adequacy of the applicant's planned safety programs and commitments, as described in the Safety Plan, to control those hazards and to safely operate the plant; and

(2) The Safety Analysis Report.
The Safety Analysis Report will not be incorporated into the license, but must provide the details and analyses needed to support related information and to provide the basis for the safety commitments contained in the Safety Plan and, in addition, must provide the information and analyses required by *§ 70.90*. The Safety Analysis Report shall include sufficient information to demonstrate that adherence to the commitments and control measures in the Safety Plan will provide an adequate level of protection for public health and safety and for the environment.

....

§ 70.24 (a)(2) and *§ 70.24 (d)*--delete; also, move the remainder of *§ 70.24* to *§ 70.84 (b)*, and renumber appropriately.

....

§ 70.32 Conditions of licenses

(a)...(k)...

(l) (1) The holder of a license to possess and use special nuclear material pursuant to the requirements of *§ 70.80* of this part, may make changes to the facility, including the plant operations and equipment, without prior Commission approval, provided that:

(i) There is no change to approved integrated safety analysis methodology:

(ii) The licensee evaluates the changes on the basis of integrated safety analyses that demonstrate the changes would not create a safety issue or the potential for any accident of a type different from those previously evaluated and described in the Safety Analysis Report;

(iii) There is no projected increase in annual individual occupational radiation exposures or in the types of and the amounts of effluents released to the environment;

(iv) The changes do not involve the installation of a new manufacturing process or a significant increase in the amount of special nuclear material to be processed in a unit time period;

(v) The changes do not reduce minimum safety margins for any safe operating parameter specified in the Safety Plan;

(vi) The changes do not modify: the separation between operations management and safety management: the qualifications established for key positions important to safety: or the established maximum time intervals between training periods, safety audits and inspections;

(vii) Except for criticality safety limits and controls, no change is made to the approved criticality safety practices established under *§ 70.84 (a)* or *§ 70.84 (c)*.

(viii) Major changes are reviewed by the licensee's safety committee and all changes are approved and authorized by appropriate safety management and operational management;

(ix) The licensee submits, as specified in *§ 70.5* of this part, within 30 days of adoption, revised pages to the Safety Plan and the Safety Analysis Report, which are marked and dated to indicate each change; and

(x) The licensee maintains records of facility changes and the associated integrated safety analyses for the life of the processes analyzed, and records of changes in procedures for a period of 2 years.

(2) Changes made without NRC's approval are subject to its subsequent review and evaluation, and could result in direction to take corrective action on changes that the NRC determines to degrade safety.

(3) The licensee may make administrative-type changes that have no effect on plant safety or for which application of an integrated safety analysis would be inappropriate, but must submit revised pages to the Safety Plan and the Safety Analysis Report, notifying NRC of the changes within 60 days of their implementation.

(4) Changes not covered under *§ 70.32 (l)* will require an amendment of license as specified in *§ 70.34* of this part.

....

§ 70.33 Renewal of licenses.

(a) ...

(b) In any case...by the Commission~~[.]~~, unless the licensee is subject to the provisions of *§ 70.80* of this Part, in which case the licensee will

have 180 days following the end of the day, in the month and year stated in the license for its termination, to resolve staff-identified issues. If all issues are not resolved during this time period, the licensee's authority to continue to conduct operations involving special nuclear material shall be suspended pending renewal of the license, except as provided in *§ 70.38 (e)*.

....

§ 70.34 Amendments of licenses.
Applications for amendment of a license shall be filed in accordance with *§ 70.21(a)*, shall specify the respects in which the licensee desires ~~[this]~~ its license to be amended and the grounds for such amendment, including a safety evaluation of the change and an assessment of its environmental impact, except that applications for amendment of a license issued submitted pursuant to § 70.22 (o), of this part shall include an integrated safety analysis of the change and submission of proposed page revisions to the Safety Plan, and the Safety Analysis Report.

....

§ 70.50 Reporting requirements

(a) Immediate report. Each licensee shall notify the NRC as soon as possible but not later than 4 hours after the discovery of~~[a]~~:

(1) An event that prevents immediate protective ... toxic gas releases, etc.)~~[.]~~ ;

(2) The loss of a criticality safety control if:

(i) The control is not reestablished within 4 hours of the initial observation of the loss;or

(ii) Corrective actions to reestablish the control are not readily identifiable.

(3) The loss of control of a measure important to safety, as identified by the licensee's integrated safety analysis, if:

(i) The measure is not reestablished or brought under control within 4 hours of the initial observation of the loss;

(ii) Corrective actions to reestablish controls are not readily identifiable; or

(iii) An integrated safety analysis deficiency, resulting in an inadequately controlled hazard, is found to exist.

(b) ...

(1) ...

(2) An event in which equipment is disabled or fails to function as designed when:

(i) ...

(ii) The equipment is required to be available and operable [~~when it is disabled or fails to function~~]; and

(iii) ...

(4)...

(5) Criticality safety events that did not meet the criteria for 4 hour

reporting but that did result in a violation of the double contingency practice.
(6) The loss of control of a measure important to safety, as identified by the licensee's integrated safety analysis, or discovery of a deficiency in the integrated safety analysis, that do not meet the criteria for 4 hour reporting.
(7) A criticality safety analysis deficiency, resulting in ineffective or inadequately controlled parameters, is found to exist.

....

§ 70.80 Safety Plan for the Possession and Use of Special Nuclear Material
Each licensee who is authorized to possess and use special nuclear material in the operation of a fuel cycle facility shall, in addition to other applicable requirements of this Chapter:

(a) Specify the quantity and form (including the elemental and the isotopic content and the chemical and physical form) of special nuclear material to be located, used, processed or produced at the plant, as applicable; and
(b) Establish, maintain and follow a documented safety program designed to comply with the requirements specified in *§§ 70.81* through *70.89* of this part, as appropriate, and such other controls as the Commission determines to be essential for the safety of the public or the environment.

§ 70.81 Organization
The licensee shall delineate the plant and, as appropriate, the corporate organizational functional structure, separating to the extent practical the top management function associated with plant safety from those management functions involving plant operations. The responsibility, authority and independence needed for safely carrying out each function shall be delegated in writing. The overall planning, coordination and administration of the plant safety program for activities involving special nuclear material shall be vested in individuals at an organizational level sufficient to assure independence of action and decision-making. Key employees in the organizational structure shall be qualified by experience and education to engage in the licensed activities. The organizational structure shall include: a plant safety committee, duties and responsibilities of which shall be described in writing, especially its role in establishing the plant nuclear safety policy, in advising the plant manager on matters involving nuclear safety, and in evaluating proposed activities and trends in plant safety; and a Quality Assurance capability to be applied to all aspects of the plant systems and activities that are important to safety, including: the integrated safety analysis process and its applications; controls established over pathways to accidents; procedure approval, dissemination, control and use; equipment maintenance and periodic testing; processes used to obtain representative samples and to make measurements; and, for new construction, facility and equipment design, construction, start-up testing and operation.

§ 70.82 Conduct of Operations
The licensee shall establish and maintain a management control system for the conduct of operations. The conduct of operations shall include:

(a) Configuration Control System
The configuration control system shall provide for:

(1) Integrated Safety Analyses
An integrated safety analysis process which is established and utilized on an ongoing basis to assure that potential pathways to accidents with unacceptable consequences are identified and effectively controlled or

mitigated such that the facility, including equipment and processes, can be routinely operated without adversely affecting the environment or the health and safety of the public. The integrated safety analysis program shall include:

(i) The facility description, including: the plant environs, structures and estimated work force; the plant processes, process chemistry and mechanical operations; the process equipment; and the associated safety features;

(ii) A comprehensive and systematic process for identifying hazards and credible accidents;

(iii) A process to identify, establish and maintain controls over hazards that could result in a loss of control of nuclear materials;

(iv) A system of approvals and authorizations of safety controls by appropriate, designated plant management;

(v) A change-control process for facility equipment, process, and procedure changes which utilizes integrated safety analysis results to provide a safety basis for their authorization; and

(vi) A system to assure that current documentation is maintained for all integrated safety analyses, including the facility, the process, and the hazards identified, and is updated as changes are made in plant operations or design. In addition, the system shall be designed to document current copies of operating procedures; as-built or modified facility and equipment drawings; control logic and sequence programs or codes; computer programs for operation of equipment and activities that are important to safety; maintenance records for the facility, process equipment and operations; and safety evaluations.

(2) Written Procedures

Written procedures, containing the limits and controls derived from integrated safety analyses to safely operate and maintain the facility, processes and equipment, shall be prepared according to written plant policies and programs, and shall be approved and authorized in a manner established by management.

(3) Maintenance

A corrective and preventive maintenance program shall be established and maintained for equipment important to safety or to the response capability for an event or an emergency. The maintenance program shall cover, as a minimum, that equipment determined by integrated safety analyses to be important to safety. The program shall utilize written procedures for: the maintenance or repair of equipment needed to maintain personnel, chemical, mechanical, radiological, and nuclear-criticality safety; post-maintenance testing and inspection of equipment important to safety; calibration and testing of equipment and instrumentation important to safety; and preventive maintenance of equipment and instrumentation important to safety.

(4) Employee Training on the Conduct of Operations

Training on the conduct of operations shall be provided on a periodic basis to employees who are involved with special nuclear material related operations.

(b) Safety Inspections, Audits and Investigations

Safety Inspections shall be routinely performed by trained individuals to determine that routine activities are conducted according to written procedures and to determine if safety practices should be improved. Independent safety audits are periodically performed to determine if effective management control structures and systems are in place. Safety reports shall be issued to involved managers on the findings and results of inspections and audits and on the status of remedial actions. Safety investigations shall be performed to identify conditions adverse to safety and to identify similar situations where those conditions may exist, and to determine underlying causes. Conditions adverse to safety shall be corrected under a corrective action system designed to ensure implementation of effective remedial action and routine notification of appropriate management of the status of planned corrective actions associated with plant safety.

(c) Safety Training

Plant employees performing operations involving special nuclear material or equipment important to safety shall receive performance-based training before performing operations that could affect plant or radiological safety, and shall be retrained periodically. Training topics shall include work procedures, radiation safety, maintenance, criticality safety, fire safety, and emergency response.

(d) Material Storage

Potentially hazardous materials, including wastes, shall be stored in locations or under conditions where their presence does not create an accident pathway for the release of radioactive material.

§ 70.83 Radiation Safety

(a) Radiation Protection Program

The licensee shall establish a radiation protection program designed to meet those provisions in *10 CFR Part 20* that are applicable to facility operations.

(b) Engineered-Barriers

To limit risk to the public and to the environment from potential releases of radioactive material from special nuclear material processes, the licensee shall ensure that special nuclear material in process in a form which is not readily dispersed is confined within at least one engineered barrier and that special nuclear material in process in readily dispersable form is confined within at least two engineered barriers.

(c) Contamination Control

The licensee shall incorporate features into the plant to limit and control the spread of radioactive contamination and to facilitate the timely return of any contaminated areas beyond the engineered barrier(s) to conditions acceptable for normal operations, unless the barrier provides an interface with the environment, in which case the contaminated areas beyond the barrier shall be returned to conditions acceptable for unrestricted release of the facility.

§ 70.84 Nuclear Criticality Safety

(a) Double Contingency Practice

The licensee shall establish criticality controls in accord with the double contingency practice to protect against accidental critical excursions.

(b) Criticality Accident Requirements

[Delete *§ 70.24 (a)(2)* and references thereto, delete *§ 70.24 (d)*, renumber *§ 70.24* as *§70.84 (b)*, and copy the section here.]

(c) Criticality Safety Analyses

Criticality safety limits and controls shall be obtained from criticality safety analyses performed using either appropriate critical mass data or by analytical methods which have been validated using appropriate critical mass data. Each criticality safety analysis shall show that all limits and controls incorporate safety factors which have been identified in the Safety Plan, and shall be performed and documented by a person trained in criticality physics and in implementation of criticality safety practices for conditions similar to those that pertain at the licensee's plant. Each analysis shall be independently reviewed and documented by an analyst who has demonstrated experience in using validated analytical methods and in applying criticality safety practices for conditions similar to those that pertain at the licensee's plant.

§ 70.85 Fire Safety

A fire safety program, designed to prevent, detect, contain, and suppress fires that have the potential for causing loss of confinement of special nuclear material, shall be established.

§ 70.86 Environmental Monitoring

An environmental monitoring program shall be established to assess the impact of the facility on the environment, including monitoring of the quantity of radioactive materials released from the plant, sampling of the plant environs to detect any leakages of radioactive materials beyond the plant's engineered barrier systems for material confinement, and sampling of the environmental media (soil, air, water, vegetation, etc.) to verify control over the potential spread of contamination to the environment. The program shall contain action levels, based on applicable limits in *10 CFR Part 20,* on the radioactive material content of effluent streams, including sewage and sludge from sewage treatment, and on the radioactive material content of environmental samples, and shall have a corrective action plan to be implemented if the levels are exceeded.

§ 70.87 Emergency Planning

The licensee shall establish and implement an Emergency Plan in compliance with the provisions of *§ 70.22 (i)* of this part.

§ 70.88 Decommissioning Plan

A preliminary decommissioning plan shall be developed to assure that the site will be in a condition suitable for unrestricted release to the public when the license is terminated, including, if required by *§ 70.25* of this part, a corresponding decommissioning funding plan. The decommissioning plan shall include: a system to record information about unplanned releases of radioactive material that have spread beyond the engineered barrier(s) for material confinement required by *§ 70.83 (b)*, as appropriate; to record estimates and locations of residual contamination beyond the barrier(s) after decontamination, including radioactive materials in surface water, in ground water, or otherwise below the site surface; to document the basis for the estimates; and to comply with the provisions of *§ 70.25 (g)* of this part. The decommissioning plan shall be updated by the annual submittal of revised pages, to reflect changed radiological conditions at the site and to incorporate improved techniques for site decommissioning, and shall include an updated decommissioning funding plan estimate, if appropriate.

§ 70.89 Records

The licensee shall establish and maintain a system of records designed to document the information required by this Chapter, including records pertaining to: reportable abnormal occurences; criticality and radiological safety analyses that are part of integrated safety analyses; radiation work permits; inspections, audits and investigations; instrument calibrations; employee training and retraining; radiation and contamination surveys; and environmental surveys. The records shall be retained for a period of two years or for the life of the activity, whichever is longer, unless, for retention of specific records, a longer period is prescribed in this Chapter.

§ 70.90 Safety Analysis Report.

The Safety Analysis Report shall: provide the detailed information that establishes the bases for the program descriptions and commitments made in the Safety Plan; describe the facility and the details of its operations; identify the hazards associated with plant operations; assess the likelihood and the consequences associated with loss of control of an identified hazard, considering both normal and abnormal conditions; assess the risks posed by the operations to the environment and to the health and safety of the public; provide the analyses and results necessary to demonstrate that the commitments made in the Safety Plan will be effective to prevent the hazards identified through application of the integrated safety analysis process from contributing to accidents associated with special nuclear material at the plant; present a safety analysis of the plant structures, systems, components and processes and of the facility as a whole; and shall include the following:

(a) The site description and characteristics, including location, regional geology, climatology and local meteorology; surface and subsurface hydrology to the extent it may be affected by plant conditions or may affect plant safety; geology and seismology as they may affect plant stability; uses of nearby lands and water; potential affects on or potential effects by nearby industrial and transportation activities; the geography and demography of the area out to a distance of 5 miles from the plant boundary in all directions; and a projected population trend for the local area for the expected life of the plant;

(b) The estimated potential exposure of plant employees and the public, projected in *§ 70.90(a)*, to any radioactive materials or radiation resulting from routine operations at the plant, from postulated plant accidents caused by credible events both internal and external to the plant, including the range of the natural phenomena that have been reported during the last 500 years for the site and surrounding area, and from postulated loss of control of hazards identified by application of the integrated safety analysis process;

(c) The site suitability analysis, based on the results of the information developed in *§ 70.90(a) and (b)*.

(d) The identification of the building codes and standards to be followed in the design and construction or renovation of the facility and the process equipment, including any equipment important to safety to be included in the facility and the basis for selection of that equipment;

(e) To the extent enhanced plant and equipment design is required to mitigate adverse findings in *§ 70.90 (a) and (b)*, the analysis and

evaluation of the design and performance of structures, systems and components of the facility, with the objective of protecting the public health and safety and the environment from hazards associated with operation of the facility during routine operations, under conditions of postulated accidents, and under adverse conditions due to natural phenomena;

(f) A discussion of each principal protection system used at the plant, including systems for protection against fire initiation and fire suppression; criticality safety; chemical safety; radiological protection, including engineered confinement barriers; materials handling and storage systems; environmental protection systems; and engineered features to assist in decontamination of the plant; and

(g) The detailed description of the methodology to be used to perform integrated safety analyses of the plant's processes. The analyses shall include both equipment and operations involved with processing special nuclear material or with enriching uranium. The methodology shall address all provisions of *§ 70.82 (a)(1)(i)* through *§ 70.82 (a)(1)(iii)* of this part.

....

§ 70.91 Safety Plan and Safety Analysis Report Submittals

Twelve months after publication of the final requirements contained in *§§ 70.80* through *70.91*, in the *Federal Register*, each licensee subject to these requirements shall submit a full description of the safety program for use of special nuclear material possessed under license, in the form of: a *Safety Plan*, to show how compliance with these requirements will be accomplished; and a *Safety Analysis Report* prepared in conformance with *§ 70.90* of this part to conform with the *Safety Plan* and with the *Safety Analysis Report*. The *Safety Plan* shall be followed by the licensee after the submittal is approved by the NRC.

....

§ 70.92 Backfitting

(a) (1) Backfitting is defined either as modification of special nuclear material processing systems or components that are important to safety, or as change of the organization or the procedures required to operate a plant, both of which could result from a new or amended Commission requirement or from the imposition of a regulatory staff position that is at variance with the staff position extant at the time of issuance of a license or a renewal of a license under this part.

(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 backfitting 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 environment, the public health and safety or the common defense and security to be derived from the backfit and that each licensee's direct and indirect cost of implementation is justified in view of this increased protection.

(4) The provisions of paragraphs (a)(2) and (a)(3) of this section are inapplicable, backfit analysis is not required and the provisions of paragraph (a)(3) of this section do not apply where the Commission or staff, as appropriate, finds and declares, based on an appropriately documented evaluation, any of the following:

(i) That a modification is necessary to bring an operation into compliance with the rules or orders of the Commission, or into conformance with written commitments by a licensee;
(ii) That regulatory action is necessary to ensure that the licensee provides adequate protection to the health and safety of the public or the environment 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 environment, the public health and safety or common defense and security should be regarded as adequate.

(5) The Commission shall always require backfitting if it determines that such regulatory action is necessary to ensure that a licensee 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 shall include a statement of the objectives of and reasons for the change or modification and the basis for invoking the exception. If immediately effective regulatory action is required, 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 if there are two or more ways to reach a level of protection which is adequate, then ordinarily a licensee may select the option 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 considered in that selection, provided that the achievement of compliance or of 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 by the licensee 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) Any potential change in the risk to the public or to the environment from an 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 lost production;
(6) The potential safety impact of any changes;
(7) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;
(8) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

(c) No licensing action will be postponed 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 designee.