



June 19, 1985

**RULEMAKING ISSUE**  
**(Affirmation)**

SECY-85-222

For: The Commissioners  
From: James R. Tourtellotte  
Chairman, Regulatory Reform Task Force  
Subject: FINAL BACKFIT RULE

Discussion: The Commission published a advance notice of proposed rulemaking and policy statement on backfitting at 48 Fed. Reg. 44217 (September 28, 1983) and more recently, a notice of proposed rulemaking at 49 Fed. Reg. 47034 (November 30, 1984). The comment period on the latter notice closed January 29, 1985.

Fifty-seven comments were filed as follows: utilities, 30; vendors, 3; architect engineers and service companies, 5; industry groups and trade associations, 3; consulting engineering firms, 3; various individuals and groups, 10; federal agency, 1 (DOE); states, 1 (Illinois); and the Advisory Committee on Reactor Safeguards.

The comments were reviewed and a summary of those comments along with a proposed final rule was prepared by the Chairman of the Regulatory Reform Task Force. The proposal was forwarded to the Executive Director of Operations and members of the RRTF on April 8, 1985.

Using the proposal as a base document, the EDO submitted a preliminary revised version to the RRTF on May 14 and a final revised version dated May 24 which reached the RRTF on May 28. The RRTF met frequently after May 28 and provided a proposed final copy of the rule to the EDO on June 13, 1985. The extent to which the EDO agrees with the final version presented here has not been determined as of the date of this paper.

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The RRTF recommends that the Commission adopt one of two options. First, the Commission could adopt no rule but use the attached proposal as the basis for a staff requirements memo. This would preserve a degree of flexibility, eliminate the litigative risk generally attending rulemakings and provide management with the latitude to solve the backfit problem on its own.

Second, the Commission could adopt the attached proposed rule. This approach would give firm guidance as well as greater certainty and stability in the process. Moreover, the rule gives management the latitude necessary to solve the backfit problem. The RRTF recommends this option.

The issue of whether the backfit rule and the requirement of a cost-benefit analysis should be applied to rulemaking was considered by all members of the Task Force to be a close question, with credible arguments on both sides. A majority of the Task Force decided to recommend in favor of applying the backfit rule to rulemaking. The Task Force viewed the major pros and cons of the issue to be the following:

Pro

-- Logically, the requirement for analysis should be the same regardless of whether a backfit is imposed as a result of generic action or single-plant action.

-- It would be unreasonable and inconsistent for the Commission's rules to require more stringent examination of single-plant backfits than of changes which may affect many plants.

-- Since under this rule a backfit analysis is required only for incremental improvements in power plants that are already adequately safe, rules which result in generic backfits should be able to a higher standard than the bare legal minimum required by the Administrative Procedure Act.

Con

-- Adding procedural requirements to Commission rulemaking increases the chance of court reversal, both for rules which tighten regulatory requirements and for those which reduce them.

-- Existing legal requirements guarantee that regulations which are not supported by a sound factual basis can be struck down.

-- In rulemaking, the fact that the Commission makes its own independent judgment on what the NRC staff proposes provides an internal protection against arbitrary or unwarranted agency action.

Cost is another important issue which deserves special attention of the Commission. Considerable public comment was received on this subject. The RRTF position on those comments is set out at pp. 23-25 of the attached proposed final rule. The RRTF proposed rule, under which a backfit analysis is required only for proposed backfits which would increase safety at plants which are adequately safe, provides for the weighing of the costs of such backfits. All members of the RRTF believe that the weighing of such costs is legal and appropriate.

Finally, it may be noted that all members of the RRTF regard management as the key to ultimately resolving the backfit problem. Even if the proposed rule is adopted, it will have little effect unless there is strong management support. Licensee participation is also important in making the process work. This does not mean that the rule contemplates contentiousness or a highly adversarial system. Reasonable men may differ, sometimes strongly, over important matters. If executed in an atmosphere of professionalism and good scientific method, the backfit rule should serve licensees, regulators and public interests alike.

Recommendation: Approve the proposed rule.



James R. Tourtellotte  
Chairman  
Regulatory Reform Task Force

Enclosures:

1. Final Rule
2. Final Rule Mark-up
3. Federal Register Notice Mark-up

This paper is tentatively scheduled for discussion at an Open Meeting during the Week of June 24, 1985. Please refer to the appropriate Weekly Commission Schedule, when published, for a specific date and time.

If the Commission does not vote on this paper, Commissioners' comments should be provided directly to the Office of the Secretary by c.o.b. Monday, July 8, 1985.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT Wednesday, June 26, 1985, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional time for analytical review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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FINAL BACKFIT RULE

NUCLEAR REGULATORY COMMISSION

10 CFR PARTS 2 AND 50

Revision of Backfitting Process for Power Reactors

AGENCY: Nuclear Regulatory Commission

Action: Final Rule

Summary: The Nuclear Regulatory Commission is issuing a revision to its rules in 10 CFR Sections 50.54, 50.109, 2.204, and 10 CFR Part 50, Appendix O, establishing standards and an agency discipline for future management of backfitting for power reactors. Backfitting is a process which can include both plant specific changes and generic changes as applied to one or more classes of power reactors. As described in the rule, backfitting is defined as the modification of or addition to: systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a new or different regulatory staff position interpreting the Commission rules after (i) the date of issuance of the construction permit for the facility for facilities having construction permits issued after [insert effective date of this amendment]; or(ii) six months before the date of docketing of the OL application for the facility for

facilities having construction permits issued before [insert effective date of amendment]; or (iii) the date of issuance of the operating license for the facility for facilities having operating licenses; or (iv) the date of issuance of the design approval under Appendix M, N or O of this Part.

EFFECTIVE DATE: June 1985

FOR FURTHER INFORMATION CONTACT: James R. Tourtellotte, Chairman, Regulatory Reform Task Force, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555. Phone: (202) 634-3300.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Commission initiated this rulemaking proceeding for the purpose of establishing requirements for the future management of backfitting for power reactors. Backfitting can include both plant-specific changes and generic changes applicable to one or more classes of power reactors.

Section 50.109 of the Commission's current power reactor regulations provides the following standard for backfitting decisions: backfitting may be required where the Commission finds "that such action will provide substantial, additional protection which is required for the public health and safety or

the common defense and security." On its face, this appears to be a relatively high standard. In practice, however, Section 50.109 has rarely been formally invoked, and it is therefore difficult to tell the extent to which this standard has actually been applied to previous backfitting decisions. The Commission has decided that a new, more specific standard and related procedures should be applied by rule to backfitting decisions.

The Commission published an advance notice of proposed rulemaking and policy statement on this subject at 48 Fed. Reg. 44217 (September 28, 1983) and more recently, a notice of proposed rulemaking at 49 Fed. Reg. 47034 (November 30, 1984). The complete record of this proceeding is available for review in the Commission's Public Document Room.

#### Public Comments

The comment period officially closed January 29, 1985. A number of comments were received after that time, the last of which was filed on March 12, 1985 by the Advisory Committee on Reactor Safeguards. All comments were considered in formulation of the final rule.

Fifty-seven comments were filed as follows: utilities, 30; vendors, 3; architect engineers and service companies, 5; industry groups and trade associations, 3; consulting engineering firms, 3; various individuals and groups, 10; federal agency, 1 (DOE); states, 1 (Illinois); Advisory Committee on Reactor Safeguards, 1.

As a result of the responses to the advance notice of proposed rulemaking, the Commission posed six numbered questions and other unnumbered questions in the notice of proposed rulemaking. The responses to these questions have assisted the Commission in reaching its determination on the content of the final rule.

#### Question 1

"Should Section 50.109 also apply to backfitting imposed through rulemaking? When a modification is imposed by rule or regulation, should the affected licensee be afforded an appeal to the EDO? What is the basis for this position?"

The Union of Concerned Scientists (UCS) stated that Section 50.109 should not apply to rulemaking. They assert that the Atomic Energy Act and prevailing case law do not permit the consideration of cost in determining minimum safety standards. (See UCS 1983 comments, pages 4-7.) An appeal to the EDO from a requirement imposed by rule cannot be legally permitted, according to UCS, and the Commission may not circumvent the legal requirements of the Administrative Procedure Act, 5 USC Section 553, by permitting appeals outside of the public forum to the Executive Director for Operations.

The Ohio Citizens For Responsible Energy (OCRE) also oppose application of Section 50.109 to rulemaking because they say "licensees are afforded enough opportunities in the rulemaking and administrative process to contest the rules." They suggest that a petition for waiver of a rule under 10 CFR

Section 2.758 or an exemption under 10 CFR Section 50.12 provides sufficient remedies for licensees.

The Nuclear Utility Backfitting and Reform Group (NUBARG) believes that backfitting controls should apply to facility modifications imposed by rulemaking. They state four reasons for their position. First, in terms of public health and safety, they state the practical impacts of backfitting by rulemaking or backfitting on a plant specific basis are the same. Therefore, NRC regulations should require a documented analysis of a backfit regardless of the source of the requirement. Second, there is no apparent justification for excluding backfit modifications imposed by rulemaking. They suggest that the NRC should satisfy itself of the need for and efficacy of any backfit required. Third, if the backfitting rule did not apply to rulemaking, there may be a natural temptation by the staff to avoid the effects of the backfitting rule by imposing requirements through rulemaking. Fourth, there would be no additional burden because much of what the rule would require already takes place during the CRGR review of proposed rules. NUBARG states that it does not advocate the preparation of a plant specific backfitting analysis for backfits proposed in the context of a rulemaking.

NUBARG also believes that an opportunity for an appeal to the Executive Director for Operations should exist. The licensee, they say, should be given the opportunity to demonstrate that the modification established by rule or regulation should not be required for its facility because that facility is substantially different from the type, design, or vintage of facilities evaluated in the modification analysis and as a result, findings made pursuant

to Section 50.109 are not applicable. They go on to cite the need for flexibility in the rulemaking process as a basis for their position. The Atomic Industrial Forum (AIF) and other industry commenters appear to be in general agreement with the positions taken by NUBARG.

DOE also states that Section 50.109 should apply to rulemaking since rulemaking and orders are "the only two avenues through which a backfit should be imposed by the Commission." They oppose appeal to the EDO, however, and suggest use of a waiver request under 10 CFR § 2.758.

#### Question 2

"Should Section 50.109 limit backfitting to backfits imposed by rule, regulation or order? If the imposition of backfits is not limited to rules, regulations or orders, what other mechanisms should be employed?"

UCS opposes such a limitation, stating that the effect would "undoubtedly be to eliminate the condition which the Supreme Court found legally necessary to justify two-stage licensing," citing Power Reactor Development Company v. Union, 367 U. S. 396, 414 (1961).

OCRE takes a somewhat different position. They state that the Atomic Energy Act "clearly states that the Commission's safety standards are to be imposed by rule or order . . . . However, the NRC is in the habit of imposing regulatory requirements through non-enforceable means (e.g., Reg. Guides, SRP)." OCRE states that because legally binding requirements are those



reached through rulemaking or adjudication and because these processes inherently involve weighing pros and cons of adverse parties, they are reasoned, open deliberated processes subject to judicial review and therefore need no further analytical requirements. OCRE continues, "While it would be preferable if all regulatory requirements resulted from rules or orders, it is a fact of life that the staff imposes regulatory requirements on its own." OCRE appears to not take a position either way on the question but is willing to accept current staff practice as a "fact of life."

NUBARG takes a strong position that Section 50.109 should limit backfitting to those modifications imposed by rules, regulations or order. They state that current and past staff practice of requiring licensees to backfit facilities on the basis of non-binding guidance requirements is illegal. Regarding the second part of the question, NUBARG states that there are no means other than rules, regulations or orders by which the Commission may lawfully require a licensee to modify its facility. In short, it is NUBARG's position that Section 50.109 would violate the statute if it permitted imposition of backfits by any means other than rules, regulations or order. The AIF and other industry commenters appear to be in general agreement with NUBARG's position.

DOE states that backfitting should only be imposed by rule, regulation or order and that all analyses, reviews and decisions required by the proposed rule should apply to all methods of backfitting.

Question 3

"Should a documented analysis of a proposed backfit come before the backfit is issued or only after an affected licensee lodges an appeal?"

UCS urges that there be no requirement for a detailed analysis unless the licensee appeals because such analyses in absence of an appeal would, in their words, "be an utter waste of time and resources."

OCRE suggests that to require analysis of every proposed backfit would create too great a burden on the staff. OCRE appears to reserve the term "backfit" for "non-enforceable regulatory requirements" and therefore, "licensees should feel free to contest a proposed backfit."

NUBARG takes the position that there should be a documented analysis by the NRC whenever it proposes to require licensees to modify their facilities. They state, "a plant modification has the same impact regardless of who initiates it. Therefore, just as the licensee must always develop a sound technical basis in support of a proposed facility modification, so should the staff." Such an analysis is necessary, they argue, so that the NRC can be assured that the backfit it wishes to impose is truly needed to enhance safe reactor operations and that it will have the intended effects.

AIF suggests that such evaluations are needed to determine whether the proposed backfit does increase safety, to what extent, and at what costs. Further, it is needed "to impose discipline into the backfit process." AIF

also suggests that licensees should not be placed in a position of having to invoke procedure in order to initiate backfit analysis. To do so, they say, places the licensee in a position of having to jeopardize its relationship with the staff by opposing a change that the staff is requiring.

AIF also suggests that, in addition to the seven factors proposed in the Federal Register Notice, the following factors should be considered in making an analysis of a proposed backfit.

1. A precise statement of the specific objectives that the proposed modification is designed to achieve.
2. A general description of the activity that would be required by the licensees or applicants in order to complete the modification.
3. Alternatives to the proposed backfit and how these alternatives (including the recommended alternative) will affect other proposed or imposed facility backfits; and
4. A priority ranking by safety significance of each proposed backfit relative to other proposed or imposed backfits.
5. Whether, after balancing of all appropriate factors (including those in this paragraph) the demonstrations required in Section 50.109(a) have been made.

DOE states that the burden of proof for demonstrating that an increase in safety is needed should rest with the staff rather than requiring the licensee to prove that such an increase is unnecessary. Their reasoning is that, "requiring a written basis and analysis of a proposed backfit before it is imposed will increase the likelihood of improved safety and increase confidence that its effects are understood."

Question 4

"Should backfitting be defined as 'the imposition of new regulatory requirements or the modification of previous requirements' (the cause) or defined as a 'modification or addition required by the Commission to the facility or to the structure, systems or components of such facility, the design thereof, or the procedures or organization required to construct or operate such facility' (the effect)? What is the basis for this position?"

UCS believes that neither definition is appropriate, citing its 1983 comments, pages 10-30, in support of its position. UCS further suggests that exclusion of rules, regulations and orders from the definition of regulatory requirements raises questions about what is meant.

OCRE states that backfitting should be defined as "the imposition of new requirements; i.e., the cause, not the effect." Its reasoning is that "Since we interpret backfit to apply only to the non-enforceable requirements, licensees are free to use alternative methods to comply. This, again, is a difficult point which should be resolved by bringing the NRC's practices into line with the AEA; i.e., all requirements imposed by rule or order."

AIF suggests that the definition should be stated in terms of the effect which they suggest should read:

As used in this section, "backfitting" of a production or utilization facility means a modification; or addition required by the Commission to the design approval, manufacturing license, or facility or to the structures, systems or components of such facility, the design thereof, or the procedures or organization required to construct or operate such facility, after . . . (times specified in proposed rule).

They also suggest that backfits should include requirements to perform extensive analytical efforts or tests, regardless of whether modifications or additions to the structures, systems or components of a facility or design result from such analytical efforts or tests. The basis for rejecting regulatory requirements as a part of the definition is directly related to their previous argument that backfits may only be legally imposed by rule, regulation or order. AIF's position is generally supported by other industry comments.

DOE would recommend the following in lieu of either the "cause" or "effect" definition:

1. A "modification," means a change required by the Commission to a site permit; a design approval; a production or utilization facility, or the structures, systems, or components of a facility; to the procedures pursuant to which a facility is to be constructed

or operated; or to the organization required to construct or operate such a facility.

2. A "backfit" means "a modification not imposed by the Commission for achieving compliance with a construction permit or operating license, at the time of issuance or as amended, or contained in the requirements incorporated by reference in the permit or license."

The State of Illinois rejects the use of "regulatory requirements" as too ambiguous and suggests the definition be more precise for clarity and scope.

#### Question 5

"The industry's proposed standard for justification of a backfit is 'substantial improvement in the overall safety of the plant considered over its remaining life.' Is it appropriate to include the concept of 'over its remaining life'? What other standard could be used?"

UCS suggests that it is not appropriate to consider the concept of "over its remaining life" for the following reasons:

1. Such analysis can only be based on probabilistic risk assessment and that methodology is not appropriate.
2. The concept creates an incentive for delay and obstructionism and rewards those who delay the most.

3. "Benefits" are currently expressed by NRC in terms of annual average dose "avoided" and this is inconsistent with the concept of "remaining life".
4. The concept does not account for problems caused by aging and deterioration of equipment which are likely to increase as a plant ages.
5. There is no justification in law or policy for subjecting people around older plants to a greater risk than those who live around newer plants.

OCRE also objects to the use of the standard because of what they perceive to be implication of required use of probabilistic risk assessments.

NUBARG suggests that use of the concept is appropriate as being one factor among many that should be considered when a backfit is required. Industry commenters generally support this position.

#### Question 6

"To what extent may the Commission consider cost, including the economic costs in backfitting decisions under standards and processes proposed in Section 50.109?"



UCS cites its previous 1983 comments in support of its position that costs may not be considered under the Atomic Energy Act and established case law. OCRE also opposes cost consideration as a part of the decision process.

AIF takes the position that cost may be considered and that such costs should include:

1. Costs of evaluation, engineering, construction, material procurement, AFUDC (Allowance for Funds Used During Construction) and investigations;
2. An attributable portion of replacement power costs during down time for implementation;
3. Operating costs due to changes in specifications, procedures, operator retraining and training manuals, increases in manpower requirements and net generation losses;
4. Impact on preoperational startup, operator training, procedure development and system turnover during plant construction; and
5. Any incremental increase in man rem exposure as a result of installation and subsequent operation of the modification.

As a basis for the position stated, AIF attaches to their comment a legal memorandum entitled, "Consideration of Cost and Benefits in Connection with

Backfitting." This memorandum takes the position that the Atomic Energy Act and its legislative history, court decisions, Commission regulations and documents, the Energy Reorganization Act and Executive Order 12291 and the NRC's General Counsel memorandum dated May 4, 1984, all support the conclusion that costs may be considered in connection with backfitting. Industry comment generally supported the AIF position.

DOE also conducted a legal analysis of the cost question. They stated:

The legal conclusion which emerges from the foregoing is that, except for deciding the narrow question of whether a backfit should be required for construction permittees to eliminate or reduce to a threshold level a particular risk in order to meet the "adequate protection" test, the NRC has broad discretion to consider the relationship between benefits and costs in deciding whether to impose a backfit.

The Commission also requested comments on whether reliance upon probabilistic risk assessments is prohibited by the Atomic Energy Act as suggested by UCS. OCRE agreed with the UCS position.

AIF takes the position that UCS mischaracterizes the industry position on the use and value of PRAs. They point out that probabilistic risk assessment should support, not supplant, determinative requirements. NUBARG points out that neither the industry nor the proposed backfitting rule mandates the use of PRAs. They point to the fact that the proposed industry rule would require the use of PRAs only "where appropriate and where pertinent data is

available." They also suggest that the Atomic Energy Act does not prohibit the use of PRAs.

The Commission requested comments on the correctness of the UCS position that "the Commission exercises its rulemaking authority to establish nuclear reactor safety standards, and licensees may avoid those standards only by obtaining a waiver under 10 CFR Section 2.758." NUBARG states that UCS misunderstands Section 2.758 and the operation of the backfit rule. They further suggest that neither of the proposed backfitting rules can reasonably be read as permitting licensees to avoid requirements applicable to their facilities. Those rules, they state, would simply require the staff to document the basis for its conclusion that a backfit is required.

The Commission requested comments on whether the elements of the proposed backfitting rule are too prescriptive and are truly needed to assure that the staff considers all factors that are appropriate before it imposes a backfit. NUBARG points out that virtually all of the elements of the analysis have been used by NRC before and are sufficiently broad to be applied in most, if not all, by backfitting situations. The State of Illinois remarked: "The Department [State] believes that the seven factors contained in the proposal provide an appropriate means for balancing all factors in determining whether backfitting should apply." AIF agreed with the seven factors but suggested the addition of five more.

The Commission also expressed a concern over whether preparation of a backfitting analysis should be required as a condition precedent to the

issuance of a license amendment. NUBARG stated that "unless requested by a licensee, the staff should not be requested to prepare a backfitting analysis as a condition precedent to issuance of a license amendment if the licensee requests an amendment pursuant to 10 CFR Section 50.90." NUBARG points out that application for significant amendments requires a description of the proposed modification and the preparation of a safety analysis report by the licensee. Since the licensee presumably will have subjected the amendment to an internal cost effectiveness review, a backfitting analysis by the NRC would appear to be neither necessary nor appropriate. AIF was in general agreement with this position and stated further that the option to allow a licensee to request a backfitting analysis should be retained. AIF suggested that there are instances when licensees are under informal but intense regulatory pressure to submit an amendment request. In this circumstance, backfitting analysis should precede the issuance of a license amendment according to AIF. General comments from other members of the industry tend to support the NUBARG and AIF positions.

#### Comments on the Additional Views of Commissioner Asselstine

Commissioner Asselstine's additional views were generally supported by Ecology/Alert, Federal Conservationists of Westchester County, Inc., Ohio Citizens for Responsible Energy, and UCS. Industry comment generally opposed Commissioner Asselstine's approach. Similarly, the Department of Energy did not support Commissioner Asselstine's alternative backfit rule, and the State of Illinois had a mixed response.

Although UCS endorses Commissioner Asselstine's position, it suggests two changes. First, it takes exception to Commissioner Asselstine's rule to the extent that it prohibits consideration of monetary costs at the operating license stage only for backfits related to safety matters that were left unresolved at the time of issuance of the construction permit. UCS believes that so long as construction permits are to be granted on the basis of preliminary design concepts, it is not legitimate to consider as backfits, changes required between the construction permit and operating license, or to consider costs at that stage. Second, UCS objects because Commissioner Asselstine's proposal does not provide for formal public participation in backfitting decisions. UCS believes that the decisionmaking process should be open and accessible to all persons who might be affected.

OCRE also suggested two changes to Commissioner Asselstine's proposal. First, they would remove review by CRGR because, they say, CRGR does not further the mission of the Commission but serves only to discourage new safety improvements. Second, they, like UCS, would provide an opportunity for public comment for both generic and plant specific backfits.

In its discussion rejecting the proposed use of "regulatory requirements" in the definition of backfitting, the State of Illinois endorses "the more precise definitions of backfitting proposed by Commissioner Asselstine and the industry" and to that extent, could be considered as endorsing Commissioner Asselstine's approach. However, the State of Illinois also stated that they did not agree with Commissioner Asselstine's proposals to specify in the regulations a presumption in favor of the backfit. They

believe that seven factors contained in the proposal provide an appropriate means for balancing all factors in determining whether backfitting should apply.

The thrust of the industry position appears to be that many of the terms used by Commissioner Asselstine in his proposed rule are ambiguous and undefined and in other instances, where the standard is well understood, it is simply misconceived. For example, NUBARG points to Commissioner Asselstine's proposal to define backfits in terms of changes to facility design, construction or operation "imposed by the staff to . . . satisfy a regulatory staff position" developed after a specified period. NUBARG complains that "regulatory staff position" is not defined. AIF states that the word "satisfy" in this context cannot be anchored to any applicable statutory standard, nor to any prevailing doctrine of administrative jurisprudence. NUBARG questions the ultimate effectiveness of such an alternative rule because, they argue, backfits may not be legally imposed on the basis of such documents.

Industry takes a different tack with regard to the position espoused by Commissioner Asselstine that the basic premise of nuclear regulation should be to "reduce the risk to the public caused by these facilities to a level that is as low as reasonably achievable." NUBARG suggests that this approach reverses the presumption of regularity associated with past NRC licensing decisions. Those who have already been granted licenses and thus have been deemed "safe enough" by the NRC could, according to NUBARG, find themselves having to justify routinely why their licenses should not be modified. This,

NUBARG states, raises serious legal questions of fundamental fairness and due process, and appears to be at odds with the Administrative Procedure Act. NUBARG also complains that the standard suggested by Commissioner Asselstine is potentially open-ended.

AIF further suggests that the Atomic Energy Act requires "reasonable assurance of the public health and safety" and reasonable assurance is not equated with "as low as reasonably achievable." AIF further states that this standard is at odds with Section 103 (b) of the Atomic Energy Act, which provides, in part, that "The Commission shall issue such licenses . . . to persons applying therefor . . . (to) who are equipped to observe and who agree to observe such safety standards to protect health and to minimize danger to life or property as the Commission may, by rule, establish: . . ." AIF suggests that this language has been interpreted by the Commission in its regulations to require "reasonable assurance" that licensed activities of the Commission can be conducted without endangering the health and safety of the public, citing, for example, 10 CFR Section 50.57 (a) (3). They also cite Citizens for Safe Power, Inc. v. Nuclear Regulatory Commission, 524 Fed. Second 1291, 1297 (D.C. Circuit 1975) for the proposition that "absolute or perfect assurances are not required by AEA and neither present technology or public policy admit of such a standard."

The Department of Energy also does not support Commissioner Asselstine's alternative proposed backfit rule. This proposed rule, DOE states, "detracts from the basic purpose for instituting a new backfit rule and, if adopted, would perpetuate the significant deficiencies of backfitting practices of the



past." DOE further suggests that Commissioner Asselstine's definition of backfitting is too narrow; that the "as low as is reasonably achievable" standard is inappropriate, and would probably be inconsistent with safety goals should those be established; that the limitations on the use of quantitative cost benefit balancing would be "overly restrictive" and would be "a regressive step for modern analysis techniques"; that the decision criteria are not identified in Commissioner Asselstine's rule; and that the implementation procedures have several major deficiencies.

#### Commission Position

The Commission is appreciative of the time and effort expended by those who submitted comments. Backfitting is a matter of considerable importance and the views expressed in the comments have been very helpful to the Commission in its deliberation. To some extent, the final rule will be modified from the proposed rule to reflect the views expressed.

Since there is no practical difference between a backfit that is imposed pursuant to a rule or a staff position interpreting a rule, the Commission will alter the final rule to require a documented analysis of required backfits regardless of the source. A plant-specific backfit analysis will not be required in rulemaking and the factors specified in the rule will be reviewed only on a generic basis for rulemaking purposes. Because there must be safety reasons for the agency to impose any changes to a regulatory requirement or a staff position, applicable to the licensee, because the safety consequences are unknown until analyzed, and because the Commission should fully understand

the effects of a proposed backfit before its imposition, it is of little consequence how a backfit is imposed. Safety and sound management require that analysis precede imposition of a new or modified regulatory requirement or staff position. It follows that those backfits imposed by rulemaking should undergo the same scrutiny as proposed by other means. It also follows that changes in regulatory requirements or staff positions for procedures and organization should also be analyzed before implementation to determine, inter alia, the safety significance of any such proposed change. The final rule reflects this position.

Many of the most important changes in plant design, construction, operation, organization, and training have been put in place at a level of detail that is expressed in staff guidance documents which interpret the intent of broad, generally worked regulations. The NRC has determined that the correct focus for backfit regulation is the establishment of effective management controls on existing staff processes for the interpretation of regulations that are known to result in valuable upgrades in industry safety performance. Thus, the Commission opts to adopt a management process not only for the promulgation of regulations as backfit instruments, but also for the lower tier staff review and inspection processes known to result in reactor plant changes.

The Commission agrees with those who suggest that the Staff should not be required to prepare a backfitting analysis as a condition precedent to issuance of a license amendment if the licensee requested the amendment pursuant to 10 CFR § 50.90. If a licensee believes that the amendment process

is being used by the staff to impose a backfit, the licensee may invoke the rule under § 50.109. It is unnecessary to amend the rule in this regard since mention of the point here provides adequate direction to the Staff and licensees.

Considerable attention was given to the question of whether backfitting should be defined in terms of its cause or its effects. After due consideration, the Commission believes that the definition for backfitting should take into account both the cause and the effects. Therefore, the definition is modified accordingly.

Question 5 concerned the industry's proposed standard for justification of a backfit and the suggestion that the "substantial improvement in overall safety of the plant considered over its remaining life" should be incorporated into the rule. In our view, the concept of "over its remaining life" is already incorporated in the rule under factor 8 of Section 50.109 (d). There is no need to place that concept in the rule at another place.

The additional factors suggested by the industry for inclusion under § 50.109(c) generally appear to be reasonable and not unduly burdensome. Therefore, the thrust of the additional factors will be included as appropriate in the final rule.

As the accountable manager for backfitting, the Commission has directed the EDO to establish backfit procedures and to assure appropriate rights of

appeal. The Commission believes it is unnecessary to include in the rule a section establishing appeal rights to the Executive Director for Operations.

#### Consideration of Costs in Backfit Decisions

In the current rulemaking, comments were filed by UCS and AIF stating strongly contrasting legal views concerning the Commission's authority to consider the costs of new safety requirements which the Commission would impose if costs were not a factor in the decision. (See Question 6, supra.) In view of the importance of the cost issue and the strongly divergent views stated in the comments, it is important to set forth the Commission's legal and policy views on this matter.

The costs associated with proposed new safety requirements may be considered by the Commission provided that the Atomic Energy Act finding "no undue risk" to the public health and safety can be made. There may be any number of ways by which the Commission can arrive at such a conclusion. Each approach could have different costs associated with it and it cannot be seriously argued that in such circumstances the Commission is statutorily prevented from choosing the most cost effective means of protecting public health and safety.

Similarly, it may be presumed that the current body of NRC safety regulations provides adequate protection. Where new information indicates that improvements are needed to assure there is "no undue risk" on either a plant-specific or generic basis which the Commission believes to be the minimum necessary, such requirements must be imposed. However, where there are alternatives for

achieving the improvements which have different associated costs, such costs may be considered.

Cost considerations have been a part of the Commission's regulatory approach in many other instances. For example, the ALARA principle requires Commission licensees to meet an absolute set of radiation exposure standards but also requires further reductions in exposure where the cost of the exposure avoided outweighs the cost of implementing controls to avoid the exposure. Commenters who addressed the proposed backfit rule and opposed the use of costs did not address this point. It would appear that the only situation where the consideration of costs may be seriously challenged is where a new requirement is necessary to provide an absolutely minimum level of protection to the public health and safety and no alternative means of achieving such protection are apparent.

In general, the consideration of costs associated with incremental safety improvements is within the NRC's statutory mandate. However, the cost of new safety requirements will not be considered where such requirements are necessary to assure there is no undue risk to the public health and safety and no alternatives are available.

After reviewing all of the comments and positions stated, the Commission believes that there is sufficient authority in the statutes, case law, and Commission practice to justify making cost considerations in backfitting decisions. Since consideration of costs was a part of the proposed rule, the rule will remain unchanged in this regard. The Commission also rejects as

without merit the suggestion that probabilistic risk assessments are precluded by law.

#### Description of Final Rule

The proposed amendment of Section 50.54(f) assures that each information request related to a backfit for which analysis is required under section 50.109 is to be evaluated prior to its issuance to determine whether the request is for information already in the possession of the applicant or licensee or instead will require the institution of studies, procedures, or other extensive effort to generate the necessary data to respond. If extensive effort is reasonably anticipated, the request will be evaluated to determine whether the burden imposed by the information request is justified in view of the potential safety significance of the issue to be addressed.

It should be noted that § 50.54(f) does not by its terms apply to the review of applications for licenses or amendments. Consequently, if the staff seeks information of a type routinely sought as a part of the standard procedures applicable to the review of applications, no analysis will be necessary. If the request is not part of routine licensing review and falls within the purview of section 50.109, however, a full analysis is most likely indicated. Requests for information to determine compliance with existing facility requirements or for fact-finding reviews, inspections and investigations of accidents or incidents, however, usually are not made pursuant to §50.54(f) nor are such requests normally considered within the scope of the backfit rule. Amendment of this section also provides for management control and

accountability for backfits by requiring that staff evaluations be reviewed by the Executive Director for Operations or his designees prior to the issuance of the request.

The amendment of § 50.54(f) should be read as indicating a strong concern on the part of the Commission that extensive information requests be carefully scrutinized by staff management prior to initiating such requests. The Commission recognizes that there may be instances where it is not clear whether a backfit will follow an information request. Those cases should be resolved in favor of analysis. In short, staff management should develop an internal review process to assure that there is a rational basis for all information requests, even where it is not clear that a backfit will result.

Section 50.109(a) sets out the definition of backfitting, the analysis requirement, the standard to be used in determining whether a backfit should be imposed and the exceptions to the rule. The definition focuses on modifications to systems, structures, components, designs, procedures or organization which may be caused by new or modified Commission rules or orders or staff interpretations of Commission rules or orders. <sup>1/</sup> Thus, this definition includes both cause and effect of backfitting. It may also be noted that "cause" includes not only Commission rules and orders, but staff interpretations of those rules and orders. This is not to say that staff interpretations of rules are viewed by the Commission as being legal require-

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<sup>1/</sup> The term "regulations" is not in the text because that term is synonymous with "rule."



ments. Clearly, they are not. Nevertheless, staff interpretations of broadly stated rules are often necessary to give a rule effect and in some instances may be a causal factor in initiating a backfit.

Section 50.109(a)(2) requires a systematic and documented analysis as a condition precedent to the imposition of a backfit. This will assure that the safety significance of any modification and its relation to other relevant factors is well understood before changes are required.

The standard against which proposed backfits would be measured is stated in section 50.109(a)(3) as "substantial increase in the overall protection of the public health and safety or the common defense and security." Substantial means "important or significant in a large amount, extent, or degree." Under such a standard, the Commission would not ordinarily expect that safety improvements would be required as backfits which result in an insignificant or small benefit to public health and safety or the common defense and security, regardless of the implementation costs. On the other hand, the standard is not intended to be interpreted in a manner that would result in disapprovals of worthwhile safety or security improvements having costs that are justified in view of the increased protection that would be provided.

The phrase "overall protection of the public health and safety or the common defense and security" in the proposed backfit standard also deserves some discussion. The principal purpose of requiring consideration of the overall protection that would be provided by a proposed backfit is to assure that both its negative and positive effects are taken into account in deciding whether

the backfit is justified. A backfit for a part of a plant should be evaluated in light of the net increase in overall protection that the entire plant would provide as a result of the backfit, taking into account the effects it would have on other aspects of the plant. Thus, the net benefit of a backfit to the protection provided by the plant as a whole is the overriding consideration, not just the benefit to the part of the plant being backfitted.

However, the Commission does not intend use of the phrase "overall protection" in the backfit standard to signal a departure from its traditional reliance on defense in depth for protection of public health and safety. Therefore, safety improvements in one line of defense against undue risk should not be disapproved or approved based solely on the presence or absence of another line of defense to cope with the failure of the first. For example, safety improvements in the integrity of the the reactor coolant system should not be dismissed merely because an emergency core cooling system has been provided to protect public health and safety with high confidence in the event that the integrity of the reactor coolant system is lost. On the other hand, such a suggested improvement may be precluded because it does not meet the substantial test, or does not increase overall protection provided by the plant due to, for example, the negative impacts on other aspects of the plant. The proposed requirement that the costs of backfits be considered and justified in view of the increased protection to public health and safety or security is based on the Commission's view that it should, in these circumstances, consider the direct and indirect costs of implementation in making safety decisions under the Atomic Energy Act.

The consideration and weighing of costs contemplated by the rule applies to backfits that are intended to result in incremental safety improvements for a plant that already provides an acceptable level of protection. In this area the Commission believes that direct and indirect implementation costs are especially relevant. Without cost as a competing consideration in these circumstances, the regulatory process takes on the characteristics of a quest for a risk-free plant an unattainable objective as recognized by Congress in establishing the standard of no undue risk in the Atomic Energy Act.

Section 50.109(a)(4) creates exceptions for modifications necessary to bring a facility into compliance or to assure that a licensee meets a standard of no undue risk to public health and safety. In those cases, backfit analysis is not required and the standard does not apply. The compliance exception is intended to address situations in which the licensee has failed to meet known and established standards of the Commission because of omission or mistake of fact. It should be noted that new or modified interpretations of what constitutes compliance would not fall within the exception and would require a backfit analysis and application of the standard.

There are two reasons for excepting modifications necessary to assure that a licensee meets the standard of no undue risk to the public health and safety. First, this will assure that operation of the backfit rule will not preclude the Commission from assuring that minimum standards are met to protect the public health and safety. Second, the exception permits the Commission to act in emergency situations. The exception anticipates the existence of significant new information or the occurrence of an event which clearly

demonstrates that the standard of no undue risk to the public health and safety cannot be maintained without the designated modification. Moreover, the presumption of safety which ordinarily accompanies the issuance of any license must be overcome in order for the exception to be used. As with the compliance exception, there is no intent on the part of the Commission to include within the scope of the exception new or modified interpretations of what constitutes no undue risk to the public health and safety. In such a case, the rule applies.

To assure that the discipline is maintained in the process and that the exceptions do not become the rule, the Commission directs the staff to document each exception. Documentation shall include a precise statement of the specific objectives of and reasons for the modification and the basis for the exception. It may also serve useful regulatory purposes to include such matters as a general description of the activity that would be required by the licensees or applicants in order to complete the modification and the identification by type, design and vintage of the design approvals, manufacturing licenses for production or utilization facilities to which the modification would apply.

Section 50.109(b) "grandfathers" backfits imposed prior to the effective date of this rule.

Section 50.109(c) sets out nine factors to be used by the staff in its backfit analysis. Finally, § 50.109(d) explicitly recognizes the responsibility of the Executive Director for Operations to manage the Commission's backfitting

program in general and requires approval of backfit analyses by the Executive Director for Operations or his designees.

As a matter of information, it may be noted that the nine factors in 50.109(c) have precedent in existing NRC practices as seen in the Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, NUREG-BR-0058, the approved CRGR Charter and the Commission's approved plan for the management of plant specific backfitting, SECY-83-321. <sup>2/</sup>

The nine factors to be used by the Staff for a systematic and documented analysis are listed under 50.109(c) and read as follows: "(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 or applicant in order to complete the backfit; (3) potential change in risk to the public from the accidental offsite release of radioactive materials; (4) potential impact on radiological exposure of facility employees; (5) installation and continuing costs associated with backfit, including the cost of facility down time for the cost of construction delay; (6) the potential safety impact of changes in plant or operational complexity in-

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<sup>2/</sup> The Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, NUREG-BR-0058, may be purchased for \$3.75 by calling (301) 492-9530 or by writing to the Public Services Section, Document Management Branch, Division of Technical Information and Document Control, U. S. Nuclear Regulatory Commission, Washington, DC 20555; or may be purchased from the National Technical Information Services, Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161. Copies of the CRGR Charter and SECY-83-321 may be inspected or copied for a fee from the NRC Public Document Room, 1717 H Street, NW, Washington, DC 20555.

cluding the effect on other 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 facility type, design or age on the relevancy and practicality of the proposed backfit; (9) whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis. These nine factors are to be used as balancing mechanisms in the decisionmaking process for backfitting.

During internal review of the rule, a question was raised as to whether licensing action should be withheld during backfit review. The answer is that the rule never contemplated such a withholding. To the contrary, until a backfit analysis is complete, licensing action should continue along a course consistent with normal practice. For clarification of the point, subsection (d) was added to the final rule.

Section 50.109(e) emphasizes and codifies the Commission's intent that backfit management is of paramount importance to responsible regulatory practice. Accordingly, the Executive Director for Operations is responsible for implementation of the backfit rule.

It may be noted that the resolution of any backfit case can be by Commission rule or order, or by written commitment of a licensee. Recognition of this point completes the design of the backfit management process and establishes that licensee compliance with approved backfits may be accomplished by

voluntary commitment, but that the legal instrument of a rule or order can and will be used if necessary.

The proposal to amend 10 CFR Part 50, Appendix O is necessary to conform Appendix O to the final rule. The amendment provides that information requests to the approval holder regarding an approved design shall be evaluated prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such evaluation performed by the NRC staff shall be in accordance with 10 CFR § 50.54(f) and shall be approved by the Executive Director for Operations or his designees prior to issuance of the request.

Section 2.204 is amended to assure that any order for modification of a license involving a backfit is subject to the provisions of the new section 50.109.

#### ENVIRONMENTAL IMPACT: CATEGORICAL EXCLUSION

The promulgation of this rule would not result in any activity affecting the environment. The rule relates only to internal Commission procedures. Accordingly, the categorical exclusion in 10 CFR 51.22(c)(3) applies and no environmental impact statement or environmental assessment need be prepared.



#### PAPERWORK REDUCTION ACT STATEMENT

This proposed rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, Approval Number 3150-0011.

#### REGULATORY FLEXIBILITY ACT CERTIFICATION

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. The affected facilities are licensed under the provisions of 10 CFR 50.21(b) and 10 CFR 50.22. The companies that own these facilities do not fall within the scope of "small entities" as set forth in the Regulatory Flexibility Act or the small business size standards set forth in regulations issued by the Small Business Administration in 13 CFR Part 121.

#### LIST OF SUBJECTS IN 10 CFR PART 50

Antitrust, Classified information, Fire prevention, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Penalty, Radiation protection, Reactor siting criteria, Reporting requirements.



For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, notice is hereby given that adoption of the following amendments to 10 CFR Part 2 and 50 are contemplated.

#### PART 50-DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for Part 50 continues to read as follows:

AUTHORITY: Secs. 103, 104, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2133, 2134, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846), unless otherwise noted.

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Sections 50.57(d), 40.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2071, 2073 (42 U.S.C. 2133, 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80-50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Sections 50.100-50.102 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273), §§ 50.10(a), (b), and (c), 50.44, 50.46, 50.48, 50.54, and 50.80(a) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); §§ 50.10(b) and (c) and 50.54 are issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 50.55(e), 50.59(b), 50.70, 50.71, 50.72, 50.73, and 50.78 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. In § 50.54, paragraph (f) is revised to read as follows:

#### 50.54 CONDITIONS OF LICENSES

- (f) The licensee shall at any time before expiration of the license, upon request of the Commission submit written statements, signed

under oath or affirmation, to enable the Commission to determine whether or not the license should be modified, suspended or revoked. Each information request which relates to a backfit for which analysis is required under 10 CFR § 50.109(a) must be evaluated prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such evaluation performed by the NRC staff must be approved by the Executive Director for Operations or his designees prior to issuance of the request.

3. § 50.109, paragraph (a) is revised, paragraph (b) is deleted, paragraph (c) is revised and relettered and new paragraphs (c), (d) and (e) are added to read as follows:

#### 50.109 BACKFITTING

- (a) (1) Backfitting is defined as the modification of or addition to: systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; 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 previously applicable staff position after:

- (i) the date of issuance of the construction permit for the facility for facilities having construction permits issued after [insert effective date of this amendment]; or
  - (ii) six months before the date of docketing of the OL application for the facility for facilities having construction permits issued before [insert effective date of amendment]; or
  - (iii) the date of issuance of the operating license for the facility for facilities having operating licenses.
  - (iv) the date of issuance of the design approval under Appendix M, N or O of this Part.
- (2) The Commission shall require a systematic and documented analysis pursuant to paragraph (c) of this section for backfits which it seeks to impose.
- (3) The Commission shall require the backfitting of a facility only when it determines, based on the analysis described in paragraph (c) of this section, that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.

(4) The provisions of subparagraphs (2) and (3) of this paragraph are inapplicable and, therefore, backfit analysis is not required and the standard does not apply where the staff finds and declares, with appropriate documentation for its finding, either:

- a. that a backfit is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee; or
- b. that modification is necessary to assure that the facility poses no undue risk to the public health and safety.

Such documentation shall include a statement of the objectives of and reasons for the modification and the basis for invoking the exception.

(b) Paragraph (a) of this section shall not apply to backfits imposed prior to (insert the effective date of this amendment).

(c) In reaching the determination required by paragraph (a) of this section, the Commission will consider how the backfit should be prioritized and scheduled in light of other regulatory activities ongoing at the facility and in addition will consider information available concerning such 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 or applicant in order to complete the backfit;
  - (3) Potential change in the risk to the public from the accidental off-site 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 facility downtime or the cost of construction delay;
  - (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 facility type, design or age on the relevancy and practicality of the proposed backfit;
  - (9) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.
- (d) No licensing action will be withheld during the pendency of backfit analyses required by the Commission's rules.
- (e) 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 designees.

4. In Appendix O to 10 CFR Part 50, a new section (8) is added to read as follows:

APPENDIX O - STANDARDIZATION OF DESIGN; STAFF REVIEW OF STANDARD DESIGNS.

\* \* \* \* \*

- (8) Information requests to the approval holder regarding an approved design shall be evaluated prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such evaluation performed by the NRC staff shall be in accordance with 10 CFR § 50.54(f) and shall be approved by the Executive Director for Operations or his designees prior to issuance of the request.

5. The authority citation for Part 2 continues to read as follows:

Authority: Secs. 161, 181, 68 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 84-615, 76 Stat. 408 (42 U.S.C. 2341); sec. 201, 88 Stat. 1342, as amended (42 U.S.C. 5841; 5 U.S.C. 552.

Section 2.101 as issued under secs. 53.62, 63.81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 102, Pub. L. 91-190, 63 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Section 2.105 as issued under

Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 2.200-2.206 also issued under secs. 186, 234, 68 Stat. 955, 83 Stat. 444, as amended (42 U.S.C. 2236, 2282); sec. 206, 88 Stat. 1246 (42 U.S.C. 5846). Section 2.300-2.309 also issued under Pub. L. 97-415, 96 Stat. 2071 (42 U.S.C. 2133). Sections 2.600-2.606 also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 as amended (42 U.S.C. 4332). Sections 2.700a, 2.719 also issued under 5 U.S.C. 554. Sections 2.754, 2.760, 2.770 also issued under 5 U.S.C. 557. Section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133) and 5 U.S.C. 552. Sections 2.800 and 2.808 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553 and sec. 29, Pub. L. 85-256, 71 Stat. 579, as amended (42 U.S.C. 2039). Appendix A also issued under sec. 6, Pub. L. 91-580, 84 Stat. 1473 (42 U.S.C. 2135).

6. Section 2.204 is revised to read as follows:

#### 2.204 ORDER FOR MODIFICATION OF LICENSE

The Commission may modify a license by issuing an amendment on notice to the licensee that the licensee may demand a hearing with respect to all or any part of the amendment within twenty (20) days from the date of the notice or such longer period as the notice may provide. The amendment will become effective on the expiration of the 20-day period during which the licensee may demand a hearing. In the event that the licensee requests a hearing, the amendment will become effective on the date specified in an order made following the hearing. When the Commission finds that the public health, safety, or interest so requires, the order may be made immediately effective. If the amendment involves a backfit, the provisions of section 50.109 of this chapter shall be followed.

FINAL RULE MARK-UP



FINAL  
RULE  
MARK-UP

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, notice is hereby given that adoption of the following amendments to 10 CFR Part 2 and 50 are contemplated.

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AUTHORITY: Secs. 103, 104, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2133, 2134, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846), unless otherwise noted.

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Sections 50.57(d), 40.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2071, 2073 (42 U.S.C. 2133, 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80-50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Sections 50.100-50.102 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273), §§ 50.10(a), (b), and (c), 50.44, 50.46, 50.48, 50.54, and 50.80(a) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); §§ 50.10(b) and (c) and 50.54 are issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 50.55(e), 50.59(b), 50.70, 50.71, 50.72, 50.73, and 50.78 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. In § 50.54, paragraph (f) is revised to read as follows:

#### 50.54 CONDITIONS OF LICENSES

FINAL  
RULE

MARK-UP

- (f) The licensee shall at any time before expiration of the license, upon request of the Commission submit written statements, signed

under oath or affirmation, to enable the Commission to determine whether or not the license should be modified, suspended or revoked. Each information request which relates to a backfit for which analysis is required under 10 CFR § 50.109(a) must be evaluated prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such evaluation performed by the NRC staff must be approved by the Executive Director for Operations or his designees prior to issuance of the request.

ADDED

3. § 50.109, paragraph (a) is revised, paragraph (b) is deleted, paragraph (c) is revised and relettered and new paragraphs (c), (d) and (e) are added to read as follows:

#### 50.109 BACKFITTING

- (a) (1) Backfitting is defined as the modification of or addition to: systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; 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 previously applicable staff position after:

Revised  
definition  
AS PER  
COMMENTS

- (i) the date of issuance of the construction permit for the facility for facilities having construction permits issued after [insert effective date of this amendment]; or
- (ii) six months before the date of docketing of the OL application for the facility for facilities having construction permits issued before [insert effective date of amendment]; or
- (iii) the date of issuance of the operating license for the facility for facilities having operating licenses.

(iv) the date of issuance of the design approval under Appendix M, N or O of this Part.

ADDED

- (2) The Commission shall require a systematic and documented analysis pursuant to paragraph (c) of this section for backfits which it seeks to impose.

IDEA  
BREAKOUT  
FROM  
ORIGINAL  
50.109(a)(1)

- (3) The Commission shall require the backfitting of a facility only when it determines, based on the analysis described in paragraph (c) of this section, that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.

VERBATIM  
BREAKOUT  
FROM  
ORIGINAL  
50.109(a)(1)

(4) The provisions of subparagraphs (2) and (3) of this paragraph are inapplicable and, therefore, backfit analysis is not required and the standard does not apply where the staff finds and declares, with appropriate documentation for its finding, either:

- a. that a backfit is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee; or
- b. that modification is necessary to assure that the facility poses no undue risk to the public health and safety.

Such documentation shall include a statement of the objectives of and reasons for the modification and the basis for invoking the exception.

SECOND  
SENTENCE  
IN ORIGINAL  
50.109(a)(1)

REVISED

EXISTING  
50.109(b)

REVISED

&  
REORDERED

(b) Paragraph (a) of this section shall not apply to <sup>[REGULATORY REQUIREMENTS]</sup> backfits imposed prior to (insert the effective date of this amendment).

50.109(c)  
REVISED

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

ADDED  
PER  
COMMENT

- (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 or applicant in order to complete the backfit;
- (3) Potential change in the risk to the public from the accidental off-site 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 facility downtime or the cost of construction delay;
- (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 facility type, design or age on the relevancy and practicality of the proposed backfit;
- (9) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

ADDED  
PER  
COMMENTS

- (d) No licensing action will be withheld during the pendency of backfit analyses required by the Commission's rules.

ADDED  
FOR  
CLARITY

- (e) The Executive Director for Operations shall be responsible for implementation of this section and all analyses required by this section

[SUBMITTED TO]  
shall be approved by the Executive Director for Operations or his  
designees.

4. In Appendix O to 10 CFR Part 50, a new section (8) is added to read as follows:

APPENDIX O - STANDARDIZATION OF DESIGN; STAFF REVIEW OF STANDARD DESIGNS.

\* \* \* \* \*

(8) Information requests to the approval holder regarding an approved design shall be evaluated prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such evaluation performed by the NRC staff shall be in accordance with 10 CFR § 50.54(f) and shall be approved by the Executive Director for Operations or his designees prior to issuance of the request.

5. The authority citation for Part 2 continues to read as follows:

Authority: Secs. 161, 181, 68 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 84-615, 76 Stat. 408 (42 U.S.C. 2341); sec. 201, 88 Stat. 1342, as amended (42 U.S.C. 5841; 5 U.S.C. 552.

Section 2.101 as issued under secs. 53.62, 63.81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 102, Pub. L. 91-190, 63 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Section 2.105 as issued under



Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 2.200-2.206 also issued under secs. 186, 234, 68 Stat. 955, 83 Stat. 444, as amended (42 U.S.C. 2236, 2282); sec. 206, 88 Stat. 1246 (42 U.S.C. 5846). Section 2.300-2.309 also issued under Pub. L. 97-415, 96 Stat. 2071 (42 U.S.C. 2133). Sections 2.600-2.606 also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 as amended (42 U.S.C. 4332). Sections 2.700a, 2.719 also issued under 5 U.S.C. 554. Sections 2.754, 2.760, 2.770 also issued under 5 U.S.C. 557. Section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133) and 5 U.S.C. 552. Sections 2.800 and 2.808 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553 and sec. 29, Pub. L. 85-256, 71 Stat. 579, as amended (42 U.S.C. 2039). Appendix A also issued under sec. 6, Pub. L. 91-580, 84 Stat. 1473 (42 U.S.C. 2135).

6. Section 2.204 is revised to read as follows:

#### 2.204 ORDER FOR MODIFICATION OF LICENSE

The Commission may modify a license by issuing an amendment on notice to the licensee that the licensee may demand a hearing with respect to all or any part of the amendment within twenty (20) days from the date of the notice or such longer period as the notice may provide. The amendment will become effective on the expiration of the 20-day period during which the licensee may demand a hearing. In the event that the licensee requests a hearing, the amendment will become effective on the date specified in an order made following the hearing. When the Commission finds that the public health, safety, or interest so requires, the order may be made immediately effective. If the amendment involves a backfit, the provisions of section 50.109 of this chapter shall be followed.

REWORD

THE EXCEPTION  
IS IN 50.109.  
NO NEED  
TO REPEAT  
IT HERE

FEDERAL REGISTER NOTICE MARK-UP



FEDERAL  
REGISTER  
NOTICE

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, notice is hereby given that adoption of the following amendments to 10 CFR Part 2 and 50 are contemplated.

MARK  
UP

#### PART 50-DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for Part 50 continues to read as follows:  
AUTHORITY: Secs. 103, 104, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2133, 2134, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846), unless otherwise noted.

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Sections 50.57(d), 40.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2071, 2073 (42 U.S.C. 2133, 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80-50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Sections 50.100-50.102 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273), §§ 50.10(a), (b), and (c), 50.44, 50.46, 50.48, 50.54, and 50.80(a) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); §§ 50.10(b) and (c) and 50.54 are issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 50.55(e), 50.59(b), 50.70, 50.71, 50.72, 50.73, and 50.78 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. In § 50.54, paragraph (f) is revised to read as follows:

50.54 CONDITIONS OF LICENSES.

FEDERAL  
REGISTER  
NOTICE

\* \* \* \* \*

(f) The licensee shall at any time before expiration of the license, upon request of the Commission submit written statements, signed under oath or

affirmation, to enable the Commission to determine whether or not the license should be modified, suspended or revoked. Each information request<sup>addition</sup> must be evaluated prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such evaluation performed by the NRC staff must be reviewed by the Executive Director for Operations or his designee prior to issuance of the request.

3. §50.109, paragraphs (a) and (c) are revised and new paragraphs (d) and (e) are added to read as follows:

50.109 BACKFITTING.

- (a) (1) The Commission shall require the backfitting of a facility only when it determines, based on a systematic and documented analysis of the relevant and material factors listed in paragraph (d) of this section that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect cost of implementation for that facility are justified in view of this increased protection. This analysis need not be performed, however, if the Commission determines that immediate imposition of the backfit is required to protect the public health and safety or the common defense and security. Imposition of the backfit <sup>n</sup> ~~ix~~ this circumstance shall not relieve the Commission of documenting the analysis after the fact.
- TO  
50.109  
(a)(3)
- TO  
50.109  
(a)(4)b.
- DROPPED

(2) As used in section, "backfitting" of a production or utilization facility means the imposition of new regulatory requirements, or the modification of previous regulatory requirements applicable to a facility, by means other than rulemaking after:

CHANGE

- (i) the date of issuance of the construction permit for the facility for facilities having construction permits issued after [insert effective date of this amendment]; or
- (ii) six months before the date of docketing of the OL application for the facility for facilities having construction permits issued before [insert effective date of amendment]; or
- (iii) The date of issuance of the operating license for the facility for facilities having operating licenses.

ADDED  
(iv)

(3) For standard design approvals issued pursuant to Appendices M, N, and O to this part, "backfitting" means the imposition of new regulatory requirements upon the design after the approval has been issued or the modification of existing regulatory requirements by means other than rulemaking.

INCLUDED  
IN  
FINAL  
RULE  
DEFINITION

(b) Remains unchanged. \* \* \* \* \*

NEW  
50.109  
(a)(4)b

<sup>b</sup>  
(c) Paragraph (a) of this section shall not apply to <sup>backfits</sup> ~~regulatory requirements~~ imposed prior to (insert the effective date of this amendment).

<sup>c</sup>  
(d) In reaching the determination required by paragraph (a) of this section, the Commission will consider <sup>1</sup> information available concerning the following factors considered to be relevant and material, and any other information relevant and material to the proposed backfit:

WORDS  
ADDED

2  
FACTORS  
ADDED

- (1) Potential reduction in the risk to the public from the accidental off-site release of radioactive material;
- (2) Potential impact on radiological exposure of facility employees;
- (3) Installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay;
- (4) The potential safety impact of changes in plant or operational complexity including the effect on other proposed and existing <sup>REGULATORY</sup> requirements;
- (5) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;
- (6) The potential impact of differences in facility type, design or age on the relevancy and practicality of the proposed backfit; and
- (7) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

ADDED  
SUB #

(e) The Executive Director for Operations shall be responsible for implementation of this section and all analyses required by this section shall be <sup>APPROVED BY</sup> ~~submitted to~~ the Executive Director for Operations or his designee.

4. In Appendix O to 10 CFR Part 50, a new section (8) is added to read as follows:

APPENDIX O - STANDARDIZATION OF DESIGN; STAFF REVIEW OF STANDARD DESIGNS.

\* \* \* \* \*

(8) Information requests to the approval holder regarding an approved design shall be evaluated prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such evaluation performed by the NRC staff shall be reviewed by the Executive Director for Operations or his designee prior to issuance of the request.

ADDED  
WORDS

5. The authority citation for Part 2 continues to read as follows:  
Authority: Secs. 161, 181, 68 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 84-615, 76 Stat. 408 (42 U.S.C. 2341); sec. 201, 88 Stat. 1342, as amended (42 U.S.C. 5841; 5 U.S.C. 552).

Section 2.101 as issued under secs. 53.62, 63.81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 102, Pub. L. 91-190, 63 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Section 2.105 as issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 2.200-2.206 also issued under secs. 186, 234, 68 Stat. 955, 83 Stat. 444, as amended (42 U.S.C. 2236, 2282); sec. 206, 88 Stat. 1246 (42 U.S.C. 5846). Section 2.300-2.309 also issued under Pub. L. 97-415, 96 Stat. 2071 (42 U.S.C. 2133). Sections 2.600-2.606 also issued under sec. 102, Pub. L. 91-190, 63 Stat. 853 as amended (42 U.S.C. 4332). Sections 2.700a, 2.719 also issued under 5 U.S.C. 554. Sections 2.754, 2.760, 2.770 also issued under 5 U.S.C. 557. Section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133) and 5 U.S.C. 552. Sections 2.800 and 2.808 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553 and sec. 29, Pub. L. 85-256, 71 Stat. 579, as amended (42 U.S.C. 2039). Appendix A also issued under sec. 6, Pub. L. 91-580, 84 Stat. 1473 (42 U.S.C. 2135).

6. Section 2.204 is revised to read as follows:

#### 2.204 ORDER FOR MODIFICATION OF LICENSE

The Commission may modify a license by issuing an amendment on notice to the licensee that the licensee may demand a hearing with respect to all or any part of the amendment within twenty (20) days from the date of the notice or such longer period as the notice may provide. If the amendment involves a backfit, ~~the provisions of section 50.109(a) of this chapter, the determination required by that paragraph shall be made using the relevant and material factors set forth in paragraph 50.109(d) of this chapter prior to issuance of the amendment unless the immediate action on items required by the amendment is needed to protect the public health and safety.~~ <sup>SHALL APPLY.</sup> The amendment will become effective on the expiration of the 20-day period during which the licensee may demand a hearing. In the event that the licensee requests a hearing, the amendment will become effective on the date specified in an order made following the hearing. When the Commission finds that the public health, safety, or interest so requires, the order may be made immediately effective.

#### ADDITIONAL VIEWS OF COMMISSIONER ASSELSTINE

Backfitting is one of the most difficult and complex issues facing the Commission. The industry argues that the present process for considering and imposing changes to operating reactors and reactors under construction is informal and undisciplined, and results in the imposition of costly new requirements that are of only marginal safety benefit, or at their worst can



12/82

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Meeting Date: 6/26/85 Open ☒ Closed ☐

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