



U.S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation

NRR OFFICE INSTRUCTION

Change Notice

Office Instruction No.: **LIC-202**

Office Instruction Title: **PROCEDURES FOR MANAGING PLANT-SPECIFIC BACKFITS AND 50.54(f) INFORMATION REQUESTS**

Effective Date: **February 10, 2004**

Primary Contacts: **Clayton Pittiglio** **George Wunder**
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Responsible Organization: **NRR/DRIP**

Summary of Changes: This is the initial issuance of LIC-202, "Procedures for Managing Plant-Specific Backfits and 50.54(f) Information Requests." This office instruction is being established to incorporate the requirements of Management Directive 8.4, "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants" (formerly Manual Chapter 0514), as was previously set forth in Office Letter (OL) 901. Therefore, this office instruction replaces OL-901. It also updates the guidance in OL-901 to make it consistent with NRR's current organization. Appendix A, "Change History," identifies the method used to announce and distribute LIC-202.

Training: **None**

ADAMS Accession No.: **ML032530229**



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Training: None

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****NOTE:** Per the attached e-mail from Brian Thomas to Larry Pittiglio dated 10/16/2003, Bob Weisman, OGC, informed NRR that OGC concurrence is not required at this time. OGC concurrence will be needed when this Office Instruction is revised to address the CRGR recommendations on backfit, which may occur in the next six months. The purpose of this revision is stated above in **Summary of Changes**.

*See Previous Concurrence

Position	RPRP:DRIP:NRR	RPRP:NRR	SC:RPRP:DRIP:NRR	BC:RPRP:DRIP:NRR	Tech. Editor	OGC		
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Date	01/13/2004	09/10/2003	09/10/2003	09/10/2003	12/02/2003			
PARALLEL NRR DIVISION DIRECTORS								
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Date	11/13/2003	11/19/2003	10/28/2003	11/20/2003	12/04/2003	02/05/2004	02/07/2004	02/10/2004

**NRR OFFICE INSTRUCTION
LIC-202
PROCEDURES FOR MANAGING PLANT-SPECIFIC BACKFITS
AND 50.54(f) REQUESTS**

1. POLICY

The Backfit Rule, 10 CFR 50.109, governs the backfitting of nuclear power plants. It requires that the NRC justify each backfit with either a regulatory analysis or a documented evaluation. Section 10 CFR 50.54(f) enables the staff to seek information necessary to determine the need to modify, suspend, or revoke a plant license. 10 CFR 50.54(f) further states "Except for information sought to verify licensee compliance with the current licensing basis for that facility, the NRC must prepare the reason or reasons for each information request 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." NRC Management Directive 8.4, "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants," establishes requirements and guidance for NRC staff implementation of 10 CFR 50.109 and 10 CFR 50.54(f).

2. OBJECTIVES

This office instruction ensures that plant-specific backfitting of nuclear power plants is properly justified and documented and establishes the responsibilities and authorities for the NRR staff in resolving backfit issues and preparing 10 CFR 50.54(f) information requests. This office instruction implements the requirements in 10 CFR 50.109, 10 CFR 50.54(f), and NRC Management Directive 8.4 (formerly NRC Manual Chapter 0514). Additional guidance is provided in NUREG-1409, "Backfitting Guidelines." This office instruction should be used in conjunction with LIC-100, "Control of Licensing Bases for Operating Reactors," which gives overall guidance for the management of design features, equipment descriptions, operating practices, site characteristics, programs and procedures, and other factors that describe a plant's design, construction, maintenance, and operation.

3. BACKGROUND

On January 11, 1990, the Director, NRR, issued Office Letter 901. The procedures in this office letter implemented the requirements of 10 CFR 50.109, 10 CFR 50.54(f), and NRC Manual Chapter 0514.

Since the issuance of Office Letter 901, NRR has adopted the office instruction system, an improved set of office-wide procedures. The procedures to implement the governing regulations and the governing management directive (Management Directive 8.4) are now contained in this office instruction (LIC-202). The guidance has been updated as necessary to adapt to organizational changes; however, the management directive has not yet been updated to reflect these organizational changes.

4. BASIC REQUIREMENTS

Appendix B applies to the information necessary to evaluate the safety significance of the proposed backfit and provides the specific responsibilities and authorities for the NRR staff during the process of managing plant-specific backfits, and for preparing 10 CFR 50.54(f) information requests. The process includes the following activities:

Identification, and procedures for handling of requests for additional safety information to enable the staff to make a decision to modify suspend, or revoke a license pursuant to 10 CFR 50.54(f).

Identification of plant-specific backfits - The NRR staff is responsible for identifying proposed plant-specific backfits. The staff must determine whether or not any proposed plant-specific position should be considered to be a backfit.
Licensee claims of plant-specific backfit - A licensee may claim that a proposed staff action constitutes a backfit even though the NRR staff did not identify it as such. The Director of NRR will forward such claims to the Director of the Division of Licensing Project Management (DLPM).

Backfit determinations - Once either the staff or a licensee has identified a proposed staff position as a potential backfit, the staff should move promptly to resolve the issue. In the case of staff-identified backfits, the person or persons identifying the potential backfit should bring it to the attention of their line management and the cognizant project manager immediately. DLPM shall ensure that the potential backfit is presented to the appropriate technical division for review. The technical division shall determine whether or not the identified position is, in fact, a backfit and whether a regulatory analysis or a documented evaluation is required. In the case of a licensee-identified backfit, DLPM is again responsible for presenting the issue to the appropriate technical division. The technical division is responsible for making the backfit determination in time to allow DLPM to inform the licensee of that backfit determination within 3 weeks of the licensee's initial written backfit claim.

Resolution of plant-specific backfits - Once a position has been determined to be a backfit, the staff should move quickly to a resolution. The staff may use either a regulatory analysis or a documented evaluation to resolve a plant-specific backfit.

Resolution of plant-specific backfits with a documented evaluation - If the technical staff determines that a position proposed by the staff is a backfit that is necessary to bring a facility into compliance with a license or rules or orders of the Commission ensure, or if it is necessary to ensure that a facility provides adequate protection to the public health and safety, or defining or redefining what level of protection to the public health and safety, the technical staff should, within 2 weeks of determination that the position is a backfit, provide DLPM with a documented evaluation as described in Appendix B. DLPM should send a

letter to the licensee detailing the staff's position as described in the evaluation within 2 weeks of receiving the documented evaluation. The licensee will be given 60 days from the date of this letter to appeal the staff's position.

Resolution of plant-specific backfits with a regulatory analysis - If the technical staff determines that a proposed action constitutes a backfit but that the action is necessary neither to ensure that the plant presents no undue risk to public health and safety nor to bring the plant into compliance with rules, orders, or written commitments, the staff shall prepare a regulatory analysis in accordance with Appendix B. The staff shall normally complete this regulatory analysis and provide it to DLPM within 90 days of the backfit determination. DLPM should forward a letter detailing the staff's regulatory analysis to the licensee within 2 weeks of receiving the regulatory analysis from the technical staff. The licensee shall normally have 60 days from the date of this letter to appeal the staff's backfit determination.

The technical staff should prepare regulatory analyses for backfits other than backfits needed to ensure adequate protection or compliance. These regulatory analyses should ascertain whether or not (1) a substantial increase in the overall protection of the public health and safety or the common defense and security is to be derived from implementing the proposed backfit and (2) the direct and indirect costs of implementing the backfit are justified in view of the increased protection.

Appeal Process - A licensee may appeal any proposed backfit or denied backfit claim to NRR as discussed in Appendix B, Section IV, "Appeal Process," to modify or withdraw a backfit that has been identified and for which the staff has prepared a regulatory analysis or to appeal to reverse a denial of a previous licensee claim that a staff position is a backfit. NRR will make every effort to resolve backfit appeals within 3 weeks. If the Director of NRR determines that an appealed backfit is still warranted or that a licensee's appealed backfit claim lacks merit, the licensee can appeal this decision to the Executive Director for Operations (EDO).

Implementation of backfits - In some cases the Director of NRR may determine that it is necessary to implement a backfit immediately. In such cases, the imposition is usually done by order. If it is not necessary to implement a backfit immediately, implementation will normally be on a schedule negotiated between the licensee and DLPM.

Record keeping and reporting - The PM shall track the backfit in accordance with Section VI, "Recordkeeping and Reporting," of Appendix B to this office instruction.

Communication of information - Appendix C, "Mechanisms Used by the Staff to Establish or Communicate Requirements or Staff Positions," identifies mechanisms used by the staff to establish or communicate requirements or staff positions.

5. RESPONSIBILITIES AND AUTHORITIES

Office of the Director, NRR

The Director of NRR is responsible to the EDO for office compliance with the requirements in 10 CFR 50.109, 10 CFR 50.54(f), and NRC Management Directive 8.4. Specifically, the Director of NRR is responsible for the following:

The Director of NRR is responsible for ensuring that the NRR staff properly makes backfit determinations and that it manages plant-specific backfit actions in accordance with this office instruction and other relevant staff requirements documents.

The Director of NRR shall concur in the regulatory analysis or documented evaluation and the backfit decision before the backfit and the analysis or evaluation are forwarded to a licensee. The letter forwarding the backfit and the regulatory analysis or documented evaluation to the licensee may be signed by the Division Director, DLPM.

The Director of NRR shall appoint the members of the panel that evaluates a licensee's appeal of a staff's backfit determination or its appeal to reverse a denial of a previous licensee claim that a staff position is a backfit. After receiving the recommendation of the panel, the Director of NRR shall sign the letter to the licensee forwarding his or her decision.

The Director or Deputy Director of NRR shall concur in all information requests made pursuant to 10 CFR 50.54(f).

The Director of NRR shall consult and coordinate with the regional administrators or the Director, Office of Nuclear Material Safety and Safeguards, or the Director, Office of Nuclear Security and Incident Response, to resolve proposed plant-specific backfits in program areas for which NRR has responsibility.

NRR Division Director

The appropriate technical or projects division director shall make a backfit determination and shall ensure that a comprehensive analysis or documented evaluation is developed to support the determination.

NRR Project Manager

The assigned project manager shall evaluate all the information that supported the backfit determination to ensure that the proposed backfit is properly evaluated for backfit implications, shall coordinate all activities related to any plant-specific backfit, shall

ensure that all correspondence related to plant-specific backfits is prepared in accordance with this office instruction and associated reference documents, and shall ensure that proper determinations and regulatory analyses or documented evaluations are forwarded for management review. Appendix B gives the specific responsibilities for identifying, determining, evaluating, and implementing backfits.

6. PERFORMANCE MEASURES

Section 4, "Basic Requirements" of this office instruction identifies who has the lead responsibility for managing the backfit process, including identifying, evaluating, estimating supporting resources, and implementing the backfit process, as well as identifying a milestone schedule to support the process. The purpose of establishing milestone deliverables is to ensure a timely review of the backfit process. While we recognize that the milestones are estimates, the management team has the flexibility to adjust the schedule on a case by case basis.

7. PRIMARY CONTACTS

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8. RESPONSIBLE ORGANIZATION

NRR/DRIP

9. EFFECTIVE DATE

February 10, 2004

10. REFERENCES

- Management Directive 8.4, "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants"
- 10 CFR 50.109, "Backfitting"
- NUREG-1409, "Backfitting Guidelines"

Attachments:

1. Appendix A - Change History
2. Appendix B - Procedures for Management of Plant-Specific Backfits
3. Appendix C - Mechanisms Used by the Staff to Establish or Communicate Requirements or Staff Positions

Appendix A - Change History

Office Instruction LIC-202 Procedures for Managing Plant Specific Backfits and 50.54(f) Information Requests

LIC-202 Change History - Page 1 of 1			
Date	Description of Changes	Method Used To Announce & Distribute	Training
02/10/2004	This is the initial issuance of LIC-202, "Procedures for Managing Plant-Specific Backfits and 50.54(f) Information Requests." This office instruction is being established to incorporate the requirements of Management Directive 8.4, "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants" (formerly Manual Chapter 0514), as was previously set forth in Office Letter (OL) 901. Therefore, this office instruction replaces OL-901. It also updates the guidance in OL-901 to make it consistent with NRR's current organization. Appendix A, "Change History," identifies the method used to announce and distribute LIC-202.	E-mail to NRR staff	None

APPENDIX B

OFFICE OF NUCLEAR REACTOR REGULATION PROCEDURES FOR MANAGING PLANT-SPECIFIC BACKFITS AND 10 CFR 50.54(f) INFORMATION REQUESTS

IV. DEFINITIONS

A. Licensee: The term licensee is used in these procedures to denote the entity that holds (1) a license to possess, use, or operate a nuclear power plant, (2) a construction permit to build a nuclear power plant, or (3) a preliminary design approval or final design approval for a standardized plant design.

B. Plant-Specific Backfit: The term backfit is used in these procedures to denote modification of or addition to (1) systems, structures, components, or design of a facility; (2) the design approval or manufacturing license for a facility; (3) the procedures or organization required to design, construct, or operate a facility if the modification or addition results from a new or amended provision in the Commission rules or from the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position. Furthermore, in order to be considered a backfit, these new or different positions must be taken after certain critical dates (e.g., after the date of issuance of a construction permit for a nuclear power plant). A backfit is plant-specific when it involves the imposition of a position that is unique to a particular plant. The backfitting determination does not apply to test and research reactors or to a modification or action proposed by a licensee.

To be classified as a backfit, a staff position must meet conditions involving both the substance of the elements of a proposed staff position and the time of the identification of the staff position. The conditions are:

- (1) A staff position may be a proposed backfit if it would cause a licensee to change the design, construction, or operation of a facility from that consistent with already applicable regulatory staff positions as described in Section I.C.
- (2) A staff position as described above is a proposed backfit if it is first made known to the licensee after certain important design, construction, or operation milestones involving NRC approvals of various kinds have been reached. A new or revised staff position will be considered a backfit:
 - a. After the date of issuance of the construction permit (CP) for the facility (for facilities having CPs issued after May 1, 1985); or
 - b. Within 6 months of the date of docketing of the operating license (OL) application for the facility (for facilities having CPs issued before May 1, 1985); or
 - c. after the date of issuance of the design approval under 10 CFR Part 52, Appendix M, N, or O.

C. Applicable Regulatory Staff Positions: The term "applicable regulatory staff positions" is used in these procedures to denote those requirements, commitments, or positions specifically imposed on a licensee or committed to by a licensee when the plant-specific backfit is identified. Applicable regulatory staff positions are of several different types and sources:

- (1) Legal requirements, as in explicit regulations, orders, and plant licenses (including amendments, conditions, technical specifications). Some regulations have update features built into them; for example, 10 CFR 50.55a, "Codes and Standards." Such update features are applicable as described in the regulation.
- (2) Written commitments, as contained in the final safety analysis report, licensee event reports, docketed correspondence, and confirmatory action letters, including responses to bulletins, generic letters, inspection reports, or notices of violation.
- (3) NRC staff positions that explicitly interpret the more general regulations and that are approved and stated in such documents as the standard review plans (SRPs), branch technical positions (BTPs), regulatory guides, generic letters, and bulletins, and to which a licensee has previously committed or upon which a licensee has previously relied. Positions contained in these documents are not considered applicable regulatory staff positions with respect to a particular licensee unless the staff has, in a previous licensing or enforcement action, identified to the licensee part or all of the position.

II. BASIC REQUIREMENTS

A. Information Requests Pursuant to 10 CFR 50.54(f)

(1) Paragraph 50.54(f) of 10 CFR requires that the staff justify its information requests, before issuing it to the licensee, that supports the determination that the burden imposed by the information request is justified in terms of its safety significance.

(2) When the staff requests information pursuant to 10 CFR 50.54(f), the statement of its reasons for requesting the information must contain the following elements:

- a problem statement that describes the need for the information in terms of potential safety benefit,
- the licensee actions required and the cost to develop a response to the information request, and
- an anticipated schedule for the NRC use of the information.

(3) When a statement of reasons is required, the EDO or his or his or her designee must approve the information request and the statement. The request for information should be sent to the licensee over the signature of the Director of the Division of Licensing Project Management (DLPM).

B. Identifying Plant-Specific Backfits

The NRR staff is responsible for identifying proposed plant-specific backfits. Staff at all levels should decide whether or not any proposed plant-specific position should be considered a backfit. The staff shall follow the procedures given below.

(1) Staff Identification

(a) When conducting a licensing review for a construction permit, operating license, or operating reactor, the staff should identify the regulatory positions applicable to the specific plant. For any proposed plant-specific position, the staff must exercise judgment to conclude whether or not that position would cause a licensee to change the design, construction, or operations of a plant.

(b) To identify the regulatory positions applicable to the specific plant, the staff should refer to the following:

- All commitments written by the licensee, including responses to bulletins, generic letters, inspection reports, or notices of violation
- Any supporting licensing basis documents such as commitments contained in the final safety analysis report, as well as confirmatory action letters, bulletins, generic letters, inspection reports, or notices of violation
- Dates of CP issuance, OL issuance, and OL docketing

(c) To identify the appropriate acceptance criteria, the staff should consult technical guidance documents such as regulatory guides and NUREG reports.

- Although these documents offer acceptable methods of meeting the requirements in the rules, *they do not contain requirements*. Methods and solutions different from those set forth in these documents may be acceptable if they provide a basis that demonstrates compliance with the regulatory requirements by offering an equivalent level of protection.
- For the original acceptance criteria in the review for an operating reactor, the staff should consult the safety evaluation reports and the final environmental impact statement issued in support of the operating license.
- For future reference, the staff should ensure that acceptance criteria used during licensing reviews are documented in each safety evaluation in accordance with NRR Office Instruction LIC-101, "License Amendment Review Procedures." The FSAR, once updated, also provides or references acceptance criteria for each plant.

(d) Following initial licensing, staff-imposed revisions to existing technical specifications or deviations from standard technical specifications (STS) may have to be treated as backfit items. When reviewing technical specifications proposed for the near-term operating license or revisions to technical specifications for operating reactors, the staff should consult NRR Office Instruction LIC-101, "License Amendment Review Procedures."

- For operating reactors, unless specific deficiencies are identified, existing technical specifications are considered to be adequate and need not be upgraded to the latest version of the STS or SRP solely for consistency with these documents.

(2) Licensee Claims

A licensee may claim that a proposed staff position is a backfit even if the staff does not identify it as such. The licensee should send its written claim that an item is a backfit to the Director of NRR. The NRR Director's office will refer the claim to the Director of DLPM. The project manager (PM) should ensure that a copy of the claim has been forwarded to the Executive Director for Operations (EDO).

C. Backfit Determination

Once either the licensee or the staff has identified a proposed staff position as a potential backfit, the staff should promptly determine whether or not the proposed staff position in fact constitutes a backfit. Sections (1) and (2) below provide guidance on making a backfit determination. The backfit determination is usually made before the regulatory analysis or documented evaluation is started.

(1) Backfits Identified by the Staff

When an issue is identified as a potential backfit, the staff should use the following procedure to determine if it is or is not a backfit. *The position that constitutes the potential backfit should not be communicated to the licensee until the issue has been resolved and the regulatory analysis or documented evaluation has been approved by the Director of NRR.*

(a) The staff member that has identified a potential backfit should immediately notify line management and the appropriate project manager (PM).

(b) The PM is responsible for coordinating staff action concerning the potential backfit.

- The PM should open a technical assignment control (TAC) number on the issue.
- The PM should ensure that the potential backfit is submitted to the appropriate technical staff management for action.
- The PM should complete the form in Appendix C.

(c) The technical staff should evaluate the potential backfit to determine whether or not the proposed staff position in fact constitutes a backfit.

- The technical branch's section chief shall assign the responsibility to the appropriate staff to evaluate the potential backfit. The technical staff section chief should establish a review schedule for the potential backfit. Normally the backfit determination should be completed within 2 weeks.
- The technical staff performing the review should reference NRC rules, licensee commitments, licensing basis for the plant, and other appropriate guidance documents to provide the basis for the backfit determination. The staff should not address the technical ramifications of the issue in the determination.
- The technical management may assign the responsibility to evaluate the potential backfit to other senior members of the Division staff.
- If necessary, the technical staff management should consult with the Director of NRR on how to interpret the backfit rule.

(d) Backfit justification is normally accomplished through regulatory analysis; however, a proposed staff position or modification does not require a regulatory analysis if the position or modification is needed to bring the facility (a) into compliance with a license or with the rules or orders of the Commission or (b) into conformance with written commitments made by the licensee. In this case, in place of a regulatory analysis, the staff should prepare a documented evaluation as described in Section II.D.(1).

(e) If the technical staff determines that the proposed staff position is a backfit that is required for adequate protection (to ensure that the plant presents no undue risk to the public health and safety), no regulatory analysis is required. A documented evaluation is required as described in Section II.D.(1).

(f) The technical staff should document how it determined that the potential backfit is or is not an actual backfit and should document this determination in a memorandum to the Director of DPLM from the cognizant technical branch chief with concurrence from the technical division director. The memorandum should document the joint effort in making the backfit determination, and include concurrence from the PM and the project director.

(g) Based on input from the staff, the Director of DLPM and the cognizant NRR technical division director should make the final determination of whether or not the proposed position is in fact a backfit. Once the determination is made that a staff position or proposed modification constitutes a backfit, it should be resolved in accordance with Section II. The PM should also inform the Director of NRR of the backfit, in accordance with Section VI.

(2) Licensee Backfit Claims

If a licensee writes to the Director of NRR to claim that a proposed staff position constitutes a backfit, the staff should promptly evaluate the claim using the following procedure:

- The PM is responsible for coordinating staff action and preparing correspondence concerning the potential backfit issue.
- The PM should open a TAC number for review of the issue.
- The PM should prepare a work request in accordance with LIC-101 and ensure that the claimed backfit is submitted to the appropriate technical staff management for action.
- The PM should fill out form in Appendix C.
- The PM should inform the Director of NRR of the backfit claim in accordance with Section VI. Note that the Director of NRR should be informed of the backfit claim before the backfit determination is made.
- The technical staff section chief should assign a reviewer to evaluate the potential backfit and the technical staff section chief should establish a review schedule for the potential backfit. Normally the backfit determination should be completed within 2 weeks.
- The technical staff should evaluate the backfit claim to determine whether or not the proposed staff position constitutes a backfit. It should follow the steps in Section II.C. above as appropriate.
- Within 3 weeks of receiving the written backfit claim, the PM should send a letter signed by the Director of DLPM to the licensee. This letter should detail the staff's backfit determination. A copy of this letter should be sent to the EDO.
 - If the staff determines that the proposed staff position is not a backfit, the staff should advise the licensee in the letter that the licensee can appeal the decision as discussed in Section IV, "Appeal Process," of this appendix or can provide a technical discussion of proposed alternative actions to meet the relevant regulatory requirements outside the provision of this procedure. If the licensee's backfit claim is denied, the staff should state that if the licensee decides to appeal the staff's backfit determination, it should do so within 60 calendar days of the date of the letter. Section IV provides guidance for submitting appeals; this guidance should be referenced in the letter.
 - If the staff determines that the proposed position is a backfit, the letter should document the staff's agreement with the licensee's claim and establish a proposed plan and schedule for resolution. The backfit should be resolved in accordance with Section II.
- Once the backfit determination is made, the PM should provide an update to the Director of NRR in accordance with Section VI, "Recordkeeping and Reporting," of this appendix.

D. Resolution of Backfits

Once a proposed staff position or modification has been determined to be a backfit, the staff should act to resolve the issue promptly, after deciding whether the backfit should be imposed immediately. Section V, "Implementation of Backfits" provides additional guidance.

(1) Backfits Identified by the Staff

(a) When a Documented Evaluation Is Used:

(1) If the staff determines that the proposed modification is necessary to bring the plant into compliance with the license or in to compliance with Commission Rules or Orders or is necessary to bring the plant into conformance with written commitments made by the licensee, the documented evaluation provided in place of the regulatory analysis should provide the following:

- the objectives of, and reasons for, the modification; and
- the basis for determining that the modification is required to ensure compliance or conformance.

The technical staff should normally complete this documented evaluation within 2 weeks of determining the issue to be a backfit and should forward the evaluation to the PM. The PM should prepare a letter to the licensee containing the staff's resolution and the documented evaluation. In the letter, the staff should state that if the licensee decides to appeal the staff's resolution, it should do so within 60 calendar days of the date of the letter. Section IV provides guidance for submitting appeals; this guidance should be included in the letter as appropriate. The letter should be signed by the Director of DLPM, with the concurrence of the Director of NRR. This letter should normally be issued within 2 weeks of completing the associated documented evaluation. A copy of the letter should be sent to the EDO.

(2) If the technical staff determines that a position proposed by the staff is a backfit that is necessary to ensure adequate safety, the documented evaluation, in place of the regulatory analysis, should include:

- a description of the objectives of, and reasons for, the modification;
- the basis for invoking the exception to the requirement to perform a regulatory analysis; and
- an evaluation of the safety significance and appropriateness of the action; and
- if the staff prescribes how adequate protection will be achieved from various alternatives, a description of how the cost factored into the decision.

The technical staff should normally complete this documented evaluation within 2 weeks of determining the issue to be a backfit and should forward it to the PM. The PM should prepare a letter to the licensee containing the staff's resolution and the documented

evaluation. In the letter, the staff should state that if the licensee decides to appeal the staff's resolution, it should do so within 60 calendar days of the date of the letter. The letter should be signed by the director of DLPM, with the concurrence of the Director of NRR. This letter should normally be issued within 2 weeks of completing the associated documented evaluation. A copy of the letter should be sent to the EDO.

(b) When a Regulatory Analysis Is Used:

- If the technical staff determines that a proposed action constitutes a backfit and is not within the scope of Section II.C.(1):
 - The technical staff should prepare, within 90 days of the time the backfit determination is made, a regulatory analysis in accordance with Section III.
 - If, at any time, the regulatory analysis shows that a backfit identified by the staff is not justified because of the lack of substantial additional overall protection or justification of the direct and indirect costs of implementation, the issue may be closed. In this case, the technical staff should notify the PM of the findings. The PM should then inform the Director of NRR of the backfit disposition in accordance with Section VI. The PM should complete the Backfit Identification and Tracking Form in Appendix C to allow the staff to document the backfit disposition in the tracking system.
 - The technical staff should forward the regulatory analysis to the PM.
 - The PM should prepare a letter to the licensee, containing the staff's resolution and the regulatory analysis. The letter should be signed by the Director of DLPM for the specific plant, with the concurrence of the Director of NRR. A copy should be sent to the EDO. Usually, the letter to the licensee should be issued within 2 weeks of completing the regulatory analysis. The PM should state in the letter that if the licensee decides to appeal the staff's backfit determination, it should do so within 60 calendar days of the date of the letter.
- The PM should provide updated information on the backfit to the Director of NRR in accordance with Section VI.

(2) Backfits Identified by the Licensee

(a) When a Documented Evaluation Is Used:

- If the backfit is needed to bring the plant (a) into compliance with a license or with the rules or orders of the Commission or (b) into conformance with written commitments made by the licensee, the staff should prepare a documented evaluation supporting the backfit. This evaluation should be prepared and sent as instructed in Section II.(D).(1).
- If the backfit is needed for adequate protection (to ensure that the plant presents no undue risk to public health and safety), the staff should prepare a documented evaluation supporting the backfit. This evaluation should be prepared and sent as instructed in Section II.D.(1).

(b) When a Regulatory Analysis Is Used:

- The PM should provide updated information on the backfit to the Director of NRR in accordance with Section VI.

III. REGULATORY ANALYSIS

Once the staff has determined that a position is in fact a backfit and that the backfit is not needed either to ensure adequate protection or to ensure compliance, the staff should prepare a regulatory analysis. The purpose of a regulatory analysis is to determine formally (1) if a substantial increase in the overall protection of the public health and safety or the common defense and security is to be derived from implementing the backfit and (2) if the direct and indirect costs of implementing the backfit for that facility are justified in view of the increased protection.

A. The division with the lead responsibility for reviewing the plant-specific backfit should perform a regulatory analysis, in accordance with these procedures.

B. The regulatory analysis generally should conform to the directives and guidance of NUREG/BR-0058 ("Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Rev. 1, May 1984) and NUREG/CR-3568 ("A Handbook for Value-Impact Assessment," December 1983), which are the NRC's governing documents concerning the need for and preparation of a regulatory analysis. The analysis should be only as comprehensive as necessary to choose among alternatives. Simplicity, flexibility, and common sense should be emphasized, in terms of both the type of information supplied and the level of detail provided. The staff should do the following:

- Determine the specific objective that the proposed backfit is designed to achieve.
- Describe the proposed backfit, and state how it substantially increases overall protection.
- Describe the activity that the licensee would engage in to complete the backfit.
- Determine the potential impact on safety of changes in plant or operational complexity. Include the relationship of these changes to proposed and existing regulatory requirements.
- State whether or not the proposed backfit is interim or final and, if interim, justify imposing the proposed backfit on an interim basis.
- Prepare a statement describing the benefits and the cost of implementing the backfit. This statement should include consideration of at least the following factors identified below. :

- The potential change in risk to the public from accidental release of radioactive material. Once NRC has developed the supporting guidance on how to quantitatively evaluate the potential risk from the accidental release of radioactive material to the public, both MD 8.4 and this document will be revised to reference the guidance. Currently, a qualitative evaluation of the change in risk to the public should be included.
- The potential impact on plant employees and other onsite workers of procedural or hardware changes for the remaining lifetime of the plant.
- The installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay.
- The estimated resource burden on the NRC associated with the proposed backfit and the availability of these resources.
- Use information to the extent that it is reasonably available. Make a qualitative assessment of benefits in lieu of a quantitative analysis if it will provide more meaningful insights or will be the only analysis practicable.
- Prepare a statement affirming interoffice (the regions, the Office of Nuclear Material Safety and Safeguards, or the Office of Nuclear Security and Incident Response, as appropriate) coordination related to the proposed backfit and the plan for its implementation.
- State the basis for requiring or permitting implementation on a particular schedule, including sufficient information to demonstrate that the schedules are realistic, and provide adequate time for in-depth engineering, evaluation, design, procurement, installation, testing, development of operating procedures, and training of operators and other plant personnel.
- Establish a schedule for staff actions involved in implementing and verifying the implementation of the backfit.
- Determine the importance of the proposed backfit activities in light of other safety-related activities in progress at the specific plant.

C. The staff should normally complete its regulatory analysis within 90 days. The regulatory analysis should be sent by memorandum from the technical branch chief or designee to the appropriate DLPM section chief. The PM should include the regulatory analysis in a letter to the licensee about the resolution of the potential backfit.

D. Refer to NUREG/CR-4568, "A Handbook for Quick Cost Estimates," April 1986.

IV. APPEAL PROCESS

Licensees may appeal any proposed backfit or denied backfit claim to NRR; specifically licensees can either appeal to have the staff modify or withdraw a backfit that has been identified and for which the staff has prepared a regulatory analysis and transmitted it to the licensee, or appeal to reverse a denial of a previous licensee claim that a staff

position, not identified by the NRC as a backfit requiring a regulatory analysis, is such a backfit. Licensees can also appeal staff determinations that a backfit meets the compliance or adequate-protection exception.

A. Appeal To Modify or Withdraw a Backfit

Issues that NRR has determined are backfits and for which the staff has prepared a regulatory analysis should be appealed as follows:

- After the backfit decision has been made and the regulatory analysis has been forwarded to the licensee, the PM should ask the licensee if there will be an appeal. If there will be an appeal, the PM should inform the licensee that such appeal should be based on the fact that the backfit would not provide a substantial increase in overall protection or that its direct and indirect costs are not justified in comparison to the degree of increased protection or that it may be implemented by an alternative approach. The licensee's appeal may be based on the existing or additional information.
- The licensee should address its appeal to the Director of NRR. The PM should ensure that a copy of the appeal is forwarded to the EDO.
- Within 3 weeks after the staff receives the appeal request, the director of DLPM should respond to the licensee informing them of the staff plans for review of the appeal. The Director of DLPM should also send a copy of the correspondence to the EDO.
- The PM is responsible for tracking the appeal through the process. The PM should ensure that all relevant information is available for supporting the staff's position.
- The Director of NRR will appoint three division directors as members of a backfit review panel to evaluate the licensee's appeal. The Director will appoint one of the members to be chairman of the panel. The panel will report its recommendation to the Director of NRR. The Director of DLPM, as well as any other division director responsible for the original evaluation of the backfit or backfit claim may brief the panel, but may not be a panel member.
- The PM should arrange a public meeting at which the licensee can present its appeal to the panel and to the Directors of the lead technical division and DLPM. This meeting should take place within 4 weeks of the staff's receipt of the backfit appeal.
- The panel will recommend to the Director, NRR, whether or not the backfit is to be imposed on the licensee. The Director's decision should be forwarded to the licensee within 4 weeks of the appeal meeting. The PM should prepare a letter to the licensee for the signature of the Director of NRR, with a copy to the EDO.
- If, as a result of the meeting, the Director of NRR decides that the backfit is still warranted and the licensee agrees to implement it, the backfit should be implemented in accordance with Section V.

- If the Director of NRR decides that the backfit is still warranted and the licensee continues to refuse to implement it, the licensee may appeal the decision to the EDO. If the appeal to the EDO is not made, the backfit may be imposed by order of the Director of NRR.

B. Appeal To Reverse Denial of a Previous Licensee Backfit Claim or Claim That a Backfit Does Not Meet the Compliance or Adequate-Protection Exception

When a licensee has claimed that a staff position is a backfit and the NRC subsequently has determined that it is not, the licensee may appeal the NRC decision regarding the backfit claim. Also, when the staff has determined that a backfit is a compliance or adequate-protection exception and the licensee claims that it does not meet the exception, the licensee may appeal the NRC decision. The licensee may also appeal to the Director of NRR even if the backfit was denied or decided by a region. The decision should be appealed as instructed in Section IV.A.

V. IMPLEMENTATION OF BACKFITS

A. Immediate

A backfit proposed by the staff may be imposed on the licensee before any of these procedures have been completed when the Director of NRR decides that the backfit must be imposed promptly to ensure that the plant poses no undue risk to the public health and safety.

- The staff member identifying the requirement with the potential for prompt imposition should elevate it expeditiously through management levels to the Director of NRR. The staff should notify the PM promptly of any plant-specific backfits identified for his or her plant.
- The division responsible for identifying the requirement should prepare a written description of the issue along with the basis for the prompt imposition that could be used as technical substance for an order.
- Prompt imposition will usually be done by issuing an order. The PM is responsible for preparing the order, assisted by the identifying division's technical staff.
- The PM should prepare a memorandum, from the Director of NRR to the EDO, notifying the EDO of the prompt imposition. The memorandum should include a description of the requirement and the basis for the prompt imposition. The documented evaluation should be included with the backfit, if possible. Otherwise, it may be prepared later.

B. Other

If immediate imposition is not necessary, a backfit proposed by the staff should not be imposed and plant operation should not be interrupted until final action is completed either by the licensee or by the Director of NRR or the EDO (if appealed to the EDO).

The licensee may elect to implement the backfit requirement after receiving the backfit determination and the approved documented evaluation or regulatory analysis or after any level of appeal.

The backfit requirement may be imposed by order from the Director of NRR if the final appeal decision requires the licensee to implement it and the licensee chooses not to implement it.

C. Schedule

Plant-specific backfits not requiring immediate implementation will usually be implemented on a schedule negotiated between the licensee and the PM. To maintain high-quality construction and operations, the staff, when scheduling, should consider the priority of the requirement relative to other safety-related activities in progress or other plant construction or maintenance.

VI. RECORDKEEPING AND REPORTING

A. Recordkeeping

The tracking system is used for keeping records of plant-specific backfits that result from licensing activities. The tracking system is the responsibility of the PM. Currently, it is an informal process with the PM having the responsibility for entering the appropriate records into ADAMS. Currently, DRIP has the responsibility for follow up and to determine if need for additional action is required.

CRGR has recommended taking ownership, centralizing and formalizing this process, and this office instruction will be revised to reference the new tracking system if it is implemented. The record keeping system will be maintained as a permanent and current record. The PM will be responsible for keeping the plant-specific records updated.

B. Reporting

In addition to the following specific directions, the PM should ensure that the Director of NRR receives copies of all correspondence associated with backfits and potential backfit claims.

(1) Backfits Identified by the Staff

- When the staff determines that a potential backfit is in fact a backfit and a regulatory analysis or a documented evaluation is to be performed, the PM should inform the Director of NRR and his Technical Assistant (TA) by e-mail. The PM should provide all the information on page 4 of Appendix C when initially reporting the backfit. DLPM management should be on cc. PM should coordinate with ET a date for a joint briefing on the backfit issue, or at a minimum, provide ET the option to have a briefing on the subject matter.
- The PM should provide updated information as events occur in the backfit sequence. Significant events in the backfit sequence include the following:
 - completion of the backfit determination;
 - completion of the regulatory analysis or documented evaluation;
 - appeal by licensee;
 - completion of appeal process; and
 - implementation of backfit, or other action that completes the backfit process.

The PM should send the updated information to the Director of NRR, and his TA. DLPM and technical staff management should be on cc.

- With regard to closure for a backfit being imposed on a licensee, the closure information should include a reference to a written licensee commitment to implement the backfit (or an order to implement the backfit). The closure information for this situation should also reference a docketed statement from the licensee that the backfit has been implemented or any NRC verification of implementation deemed to be appropriate. The closure information should document any additional required inspections or performance measures, if necessary, to support the backfit.

(2) Backfit Claims Made by Licensees

- When the staff receives a written backfit claim, the PM should inform the Director of NRR of the backfit claim, as instructed in Section VI.A.(1).
- The PM should provide updated information, as discussed in Section VI.A.(1).

APPENDIX C

MECHANISMS USED BY THE NRC STAFF TO ESTABLISH OR COMMUNICATE REQUIREMENTS OR STAFF POSITIONS

Rulemaking¹

- Advance notices
- Proposed rules
- Final rules
- Policy statements

Other Formal Requirements²

- Multi plant orders, including show cause orders and confirmatory orders
- License conditions

Staff Positions³

- Bulletins, generic letters, and regulatory issue summaries
- Multi-plant letters (including 10 CFR 50.54(f) and TMI Action Plan letters)
- Regulatory guides
- Standard review plans
- Branch technical positions
- Standard technical specifications
- Evaluations and resolutions of unresolved safety issues

¹Although rulemaking is an action of the Commission rather than of the staff, most rules are proposed or prepared by the staff.

²These documents impose legal requirements.

³These documents reflect staff positions that, unless complied with or unless a satisfactory alternative is offered, the staff would impose or seek to have imposed by formal requirement.

MECHANISMS OFTEN USED TO INTERPRET
REQUIREMENTS OR STAFF POSITIONS

- Action on petitions for rulemaking
- Action on 10 CFR 2.206 requests
- Approval of topical reports
- Facility licenses and amendments
- NRC Inspection Manual
- Safety evaluation reports
- Preliminary and final design approvals
- NUREG reports
- Operator licenses and amendments
- Single-plant orders
- Staff technical positions on code committees
- Unresolved issues resulting from inspections

ADDITIONAL MECHANISMS SOMETIMES USED TO COMMUNICATE
REQUIREMENTS OR STAFF POSITIONS

- Draft and final environmental statements
- Entry, exit, and management meetings
- Information notices
- Licensee event reports and construction deficiency reports (sent to other licensees)
- NRC operator licensing staff contact with licensees
- Telephone calls or site visits by NRC staff or Commissioners to obtain information (e.g., inspection corrective actions, establish schedules, conduct surveys)
- Pleading
- Preliminary notifications
- Press releases
- Proposed findings
- Public meetings, workshops, and technical discussions
- Resident inspector day-to-day contact
- SECY papers
- Special reports
- Speeches to local groups or industry associations
- Technical specifications
- Telephone calls and meetings with licensees, vendors, industry representatives, and owners groups
- Testimony

BACKFIT IDENTIFICATION AND TRACKING FORM

Plant Name:_____ Unit(s) Affected:
Project Manager:_____ Division:____
Office Responsible for Providing Backfit Determination: _____
Identifier of Backfit or Potential Backfit
(Licensee, NRR, NMSS, NSIR, RI, RII, RIII, RIV, or RV):_____

Identification of Backfit

Document Listing (List documents pertaining to the backfit or backfit claim. Description should only identify relationship to backfit.)

Date:_____ Description:_____

Date:_____ Description:_____

Date:_____ Description:_____

Backfit Issue Substance (Describe the technical substance of the issue, including licensee and staff positions.):

Predicted Backfit Determination Date:_____

Backfit Determination

Backfit Determination Date (forwarded to licensee):_____

Backfit Determination Organization (e.g., NRR/DRIP):_____

Backfit Determination Official (last name, initial):_____

Backfit Determination Substance (Describe why issue was, or was not, determined to be a backfit.):

Predicted Appeal Date:_____ Predicted Closing Action Date:_____

Appeal by Licensee

Appeal Date:_____ Appeal Organization:_____

Appeal Official (last name, initial):_____

Appeal Description:_____

Closing Action

Date Reg Analysis Sent:_____ Closing Action Date:_____

Closing Organization:_____ Closing Official:_____

Closing Action Description (Describe how technical aspects of issue were resolved. See Section VI.B.1.):