

**OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
POLICY AND PROCEDURES LETTER 1-82,
10 CFR PART 70 BACKFIT GUIDANCE**

I. PURPOSE

The purpose of this Policy and Procedure Letter (PPL) is to provide guidance for implementing the backfit provisions in 10 CFR 70.76. As stated in the regulation, 10 CFR 70.76 becomes effective upon issuance of this Office of Nuclear Materials Safety and Safeguards (NMSS) PPL for all Part 70 requirements, except for Subpart H. In order for the requirements of 10 CFR 70.76 to become effective for Subpart H requirements, the U.S. Nuclear Regulatory Commission (NRC) also has to have approved a licensee's Integrated Safety Assessment (ISA) Summary.

II. POLICY

The policy of NMSS regarding backfitting is that a new requirement or regulatory position interpreting a requirement will only be imposed on a fuel cycle facility licensee if it satisfies the backfitting provision of 10 CFR 70.76 (§70.76).

The regulations in §70.76 govern the backfitting of new or modified requirements on Part 70 licensees. It requires that the NRC justify each backfit with a backfit analysis (§70.76(a)(2)) or a documented evaluation (§70.76(a)(4)) and specify its use and contents. NRC Management Directive (MD) 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. MD 8.4 was used to develop this guidance because of similarities between §70.76 and 10 CFR 50.109.

III. DEFINITIONS

- A. Licensee: The term "licensee" is used to denote a person that holds a license under 10 CFR Part 70.
- B. Applicable Regulatory Requirements: "Applicable regulatory requirements" are those already specifically imposed upon or committed¹ to by a licensee at the time of the identification of a facility-specific backfit, and are of several different types and sources: legal requirements are regulations, orders, and facility licenses. Some requirements might have update features built into them. Such update features are applicable as described in the requirements.
- C. Backfit: The term "backfit" or the related term "backfitting" means the modification of, or addition to systems, structures, components, or design of a facility, or the procedures or organization required to design, construct, or operate a facility, any of which may result

¹A fuel cycle licensee's commitment is a regulatory requirement if it appears in an enforceable document. Consult with OGC regarding whether a licensee's commitment is a regulatory requirement.

from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rule that is either new or different from a previous staff position. A backfit is facility-specific when it involves the imposition of a modification or addition for a particular facility.


A facility-specific backfit must meet conditions involving both the substance of a proposed staff position and the time of the identification of the staff position.

1. Substance: 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, AND
2. Time: A staff position is a proposed backfit if it is first identified to the licensee after NRC approves a licensee's ISA Summary (for Subpart H requirements). For requirements other than Subpart H, for current licensees, backfit protection begins following issuance of this NMSS Policy and Procedures Letter (10 CFR Part 70.76(a)). For future licensees, backfit protection begins upon issuance of their Part 70 license.

D. Substantial Increase: "Substantial increase" means "important or significant in a large amount, extent, or degree," and not resulting in insignificant or small benefit to the public health and safety, common defense and security, or the environment, regardless of costs. However, this standard is not intended to be interpreted in a way that would result in disapproval of worthwhile safety or security improvements with justifiable costs.²

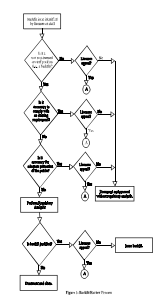
IV. IDENTIFYING POTENTIAL BACKFITS

Staff at all levels should decide whether any proposed requirement or staff position (generic or facility-specific) should be considered as a backfit. The PPL appendices are provided to give staff additional tools to assist in the §70.76 process. Appendices 1 and 2 give examples of and guidance on mechanisms used to establish and communicate regulatory positions related to backfit determinations. The form in Appendix 3 may be useful to the staff for tracking, organizing and documenting the entire backfit process. The suggested procedures in Appendix 4 may also be useful for organizing and planning for this process. The staff should apply the following sections as appropriate:



PROCESS QUESTIONS?

See Figures 1 through 3, starting on pg. 10 for the NMSS Backfit Process flow-charts



²S. J. Chilk, Secretary, "SECY-93-086 - Backfit Considerations," memorandum to J. M. Taylor, Executive Director for Operations, June 30, 1993.


A. Staff Identification of Backfit

For any proposed staff position, the staff must exercise judgement to conclude whether a staff position may cause a licensee to modify or change a system, structure, component, procedure, or organization required to operate a facility. A staff position is a proposed backfit if it is first identified to the licensee after NRC approves a licensee's ISA Summary (for Subpart H requirements) or for requirements other than Subpart H, backfit protection begins following issuance of this NMSS Policy and Procedures Letter.

No new requirement or staff position should be communicated to the licensee unless an NRC official has ascertained whether or not it satisfies the backfit provisions in §70.76.

B. Licensee Claims of Backfit

A staff position may be claimed to be a backfit position by a licensee. If a licensee claims an NRC action is a backfit, the licensee should send its written claim to the Director of NMSS with a copy to the Executive Director for Operations (EDO). The NMSS Director's Office shall refer the claim to the Fuel Cycle Safety and Safeguards (FCSS) Division Director. The FCSS Division Director shall inform the appropriate Branch Chief, Section Chief, and Project Manager (PM) of the claim. The PM should ensure that a copy of the claim has been forwarded to the EDO.



10 CFR 70.76(a)(2) states that a systematic backfit analysis is required for all backfits that the NRC seeks to impose, with the exception of backfits conforming to §70.76(a)(4).

10 CFR 70.76(a)(4) states that a supporting documented evaluation (not a backfit analysis) is required if (1) a modification is necessary to bring a facility into compliance with the regulations, license, orders, written commitments, (2) regulatory action is necessary to ensure adequate protection to the health and safety of the public or common defense and security, or (3) the regulatory action involves redefining what level of protection to the public health and safety or common defense and security is adequate.

V. DETERMINING BACKFITS

The staff must determine whether the backfit that the staff seeks to impose is excepted under §70.76(a)(4). This determination is made before the backfit analysis or documented evaluation³ is started. If excepted under §70.76(a)(4), the staff should proceed promptly with a documented evaluation as discussed in Section VI. If not excepted under §70.76(a)(4), the staff should proceed promptly with the preparation of a backfit analysis as discussed in Section VII.

NOTE: NRC has discretion whether to use this exception, i.e., for some cases where the exception could be applied, the NRC may decide to perform a backfit analysis instead.

³The backfit analysis and documented evaluation are two different bodies of work; they are not equivalent. These bodies of work are used in specific situations as discussed in this guidance. Please see the text box on this page for further explanation.

If the issue was identified by the licensee, the Office Director will report to the EDO and inform the licensee, within 3 weeks after receipt of the written backfit claim, of the receipt of the backfit claim and the plan for resolving the claim. Following the Office Director's written determination that a claimed backfit, in the judgement of the NRC, is not a backfit, the licensee may appeal this determination as described in Section VIII of this letter.

VI. DOCUMENTED EVALUATIONS FOR BACKFITS

A documented evaluation is required for backfits that the NRC intends to treat as exceptions in §70.76(a)(4)(i) - (iv). For these cases, the regulation requires that the documented evaluation provide the basis for the determination that: (1) the modification is necessary to bring a facility into compliance with Subpart H of Part 70; (2) the modification is necessary to bring the facility into compliance with a license or rules or orders of the Commission, or into conformance with written commitments by the licensee; (3) that regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security; or (4) that the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security should be regarded as adequate.

A documented evaluation must include the following items:

1. statement of the objectives of and reasons for the modification,
2. statement of the basis for invoking the exception, and
3. if an immediate regulatory action was required, the documented evaluation will delineate the basis for the urgency,
4. if the compliance exception is invoked, the documented evaluation must identify the specific regulatory basis.



Generic communications requiring responses from Part 70

licensees will include a backfit discussion in accordance with Inspection Manual Chapter 0730, "Generic Communications Regarding Materials and Fuel Cycle Issues."

VII. BACKFIT ANALYSIS

The proposed backfit and supporting backfit analysis must be approved by the Office Director and forwarded to the EDO before the backfit and its supporting backfit analysis are transmitted to the licensee. The staff should note that the complexity and comprehensiveness of the analysis should be limited to that necessary to provide an adequate basis for decision-making. Simplicity, flexibility, and common sense should be emphasized, in terms of both the type of information supplied and the detail provided. Guidance on application of "substantial increase" and cost standards is given in Appendix 5.

The staff is encouraged to use the steps given in Appendix 6 for the backfit analysis.

VIII. APPEAL PROCESS FOR BACKFITS

The EDO may review and revise any backfit decision on the EDO's own initiative or at the request of a licensee. In addition, the licensee can appeal any proposed backfit or denied

backfit claim to NMSS as discussed herein. The appeal processes described in this section apply to two different situations:

1. appeal to modify or withdraw an identified backfit for which the staff has prepared a backfit analysis and transmitted it to the licensee; OR
2. appeal to reverse a decision denying a licensee claim concerning a backfit.

See Appendix 7 for specific description and suggested steps to follow when processing either of these appeals.

See Figures 2 & 3 on page 11 & 12 for the applicable NMSS Backfit Appeal Process Flowcharts

Figure 3 - Appeal Process

IX. IMPLEMENTATION OF BACKFITS

A. Implementation of Backfit

Following approval of any required backfit analysis by the Office Director, review (if any) by the EDO, and issuance of the backfit to the licensee, the licensee will either implement or appeal the decision (as previously discussed).

Implementation of facility-specific backfits should be accomplished on a schedule negotiated between the licensee and the NRC. Scheduling criteria should include the importance of the backfit relative to other safety related activities underway at the facility, including construction or maintenance planned for the facility, in order to maintain high levels of safety and quality operations.

If immediate imposition (see Section IX.B, below) is not necessary, staff-proposed backfits shall not be imposed, and facility construction, licensing activities, or operations, shall not be interrupted or delayed by NRC actions, during the staff's evaluation and backfit transmittal process, or a subsequent appeal process, until final action is completed under this letter.

B. Immediate Imposition of Backfit

A backfit proposed by the staff may be imposed by order prior to completing any of the procedures set forth in this letter provided the NRC official authorizing the order determines that immediate imposition is necessary to provide adequate protection to the public health and safety or the common defense and security. In such cases, the EDO shall be notified promptly of the action and a documented evaluation must be performed in accordance with this letter, in time to be issued with the order, if at all possible.⁴

⁴Once an order is issued, whether or not it is immediately effective, this letter no longer applies. Any appeals are governed by the requirements of 10 CFR Part 2, Subpart B.



DEVIATIONS BY EDO

Nothing in this Policy and Procedures Letter shall be interpreted as requiring the staff to make facility-specific backfits or assessments subject to review by the CRGR or approval by the EDO, unless the EDO determines that significant facility-specific issues were not considered during the prior reviews or the EDO authorizes a deviation by finding that the deviation is in the public interest and otherwise complies with the applicable regulations.

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X. REFERENCES

- 1) U. S. Nuclear Regulatory Commission, "Domestic Licensing of Special Nuclear Material; Possession of a Critical Mass of Special Nuclear Material," Final Rule, *Federal Register*, Vol. 65, No. 181, pp. 56211-56231.
- 2) U. S. Nuclear Regulatory Commission, "Backfitting Guidelines," NUREG-1409, June 1990.
- 3) U. S. Nuclear Regulatory Commission, "Regulatory Analysis Guidelines of the U. S. Nuclear Regulatory Commission," NUREG/BR-0058, Revision 3, July 2000.
- 4) U. S. Nuclear Regulatory Commission, "Regulatory Analysis Technical Evaluation Handbook," NUREG/BR-0184, January 1997.
- 5) U. S. Nuclear Regulatory Commission, "Policy Statement on Safety Goals for the Operation of Nuclear Power Plants," *Federal Register*, Vol. 51, p.30028, August 21, 1986.
- 6) U. S. Nuclear Regulatory Commission, "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants," Management Directive 8.4, August 26, 1998.
- 7) U. S. Nuclear Regulatory Commission, "Generic Communications Regarding Materials and Fuel Cycle Issues," Inspection Manual Chapter 0730.
- 8) U. S. Nuclear Regulatory Commission, "Benefit-Cost Analysis of Federal Programs; Guidelines and Discounts," Circular No. A-94, *Federal Register*, Vol. 57, November 10, 1992, pp. 53519-53528.
- 9) U. S. Nuclear Regulatory Commission, "Collections of Information and Reports Management," Management Directive 3.54, July 1989.
- 10) U. S. Nuclear Regulatory Commission, "NRC Regulations Handbook," NUREG/BR-0053, Rev. 2, December 1989.
- 11) U. S. Nuclear Regulatory Commission, "NMSS Procedures for Management of Plant-Specific Safeguards Backfitting of Nuclear Power Plants," NMSS Policy and Procedures Letter 1-34, October 10, 1986.
- 12) U. S. Nuclear Regulatory Commission, "Plant-Specific Backfit Audit Report," J. V. Kauffman, Office of Nuclear Regulatory Research, April 2002.
- 13) U. S. Nuclear Regulatory Commission, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," Regulatory Guide 1.174, Revision 1, November 2002.
- 14) U. S. Nuclear Regulatory Commission, "Revision of Backfitting Process for Power Reactors," *Federal Register*, Vol. 50, September 20, 1985, pp. 38097-38113.
- 15) U. S. Nuclear Regulatory Commission, "Revision of Backfitting Process for Power Reactors - Final Rule," *Federal Register*, Vol. 53, June 6, 1988, pp. 20603-20611.

- 16) U. S. Nuclear Regulatory Commission, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," NUREG-1520, March 2002.
- 17) U. S. Nuclear Regulatory Commission, "Standard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility," August 2000.
- 18) U. S. Nuclear Regulatory Commission, "Memorandum of Understanding Between the Nuclear Regulatory Commission and the Occupational Safety and Health Administration: Worker Protection at NRC-Licensed Facilities," *Federal Register*, Vol. 53, No. 210, October 31, 1998, pp 43950-43951.
- 19) Administrative Conference of the United States, "Agency Procedures for Performing Regulatory Analysis of Rules," (Recommendation No. 85-2, 1 CFR 305.85-2) and "Valuation of Human Life in Regulatory Decision making," (Recommendation No. 88-7, 1 CFR 305.88-7).
- 20) Executive Office of the President, "Regulatory Planning and Review," Executive Order 12866, *Federal Register*, Vol. 58, No. 190, October 4, 1993, pp. 51735-51744.
- 21) Executive Office of the President, "Federal Regulation," Executive Order 12291, *Federal Register*, Vol. 46, No. 32, February 19, 1981, pp. 13193-13198.
- 22) Office of Management and Budget, "Regulatory Impact Analysis Guidance," Appendix V in the Regulatory Program of the United States Government: April 1, 1992 - March 31, 1993.
- 23) A. Vietti-Cook, Secretary, U. S. Nuclear Regulatory Commission, memorandum to W. D. Travers, Staff Requirements Memorandum - Affirmation Session, July 25, 2000.
- 24) W. D. Travers, Executive Director for Operations, U. S. Nuclear Regulatory Commission, memorandum to Office Directors, "Notification of the Revised Charter of the Committee to Review Generic Requirements (CRGR)," November 8, 1999.
- 25) S. J. Chilk, Secretary, U. S. Nuclear Regulatory Commission, memorandum to J. M. Taylor and W. C. Parler, "SECY-93-086 - Backfit Considerations," June 30, 1993.
- 26) O. H. Paananen and P. L. Hendrickson, "Selection of Discount Rate for Use in Regulatory Analyses Prepared by the U. S. Nuclear Regulatory Commission and Application of Discount Rates to Future Averted Health Affects," PNL-8970, Pacific Northwest Laboratory, Richland, Washington, January 1993.
- 27) P. Shewmon, Advisory Committee on Reactor Safeguards, letter to J. M. Taylor, U. S. Nuclear Regulatory Commission, Subject: Revised Regulatory Analysis Guidelines, November 12, 1992.

Copies of these references are available for inspection and copying for a fee from the NRC Public Document Room (PDR) at the U. S. NRC's Headquarters Building located at 11555 Rockville Pike, Rockville, MD, 20852. The PDR's mailing address is U. S. Nuclear Regulatory Commission, Washington, DC, 20555-0001. Phone: 301-415-7000, 7 am to 4:15 pm (ET), Monday through Friday TDD: 301-415-5575.

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XI. FIGURES

Figure 1. NMSS Backfit Process Flow-chart

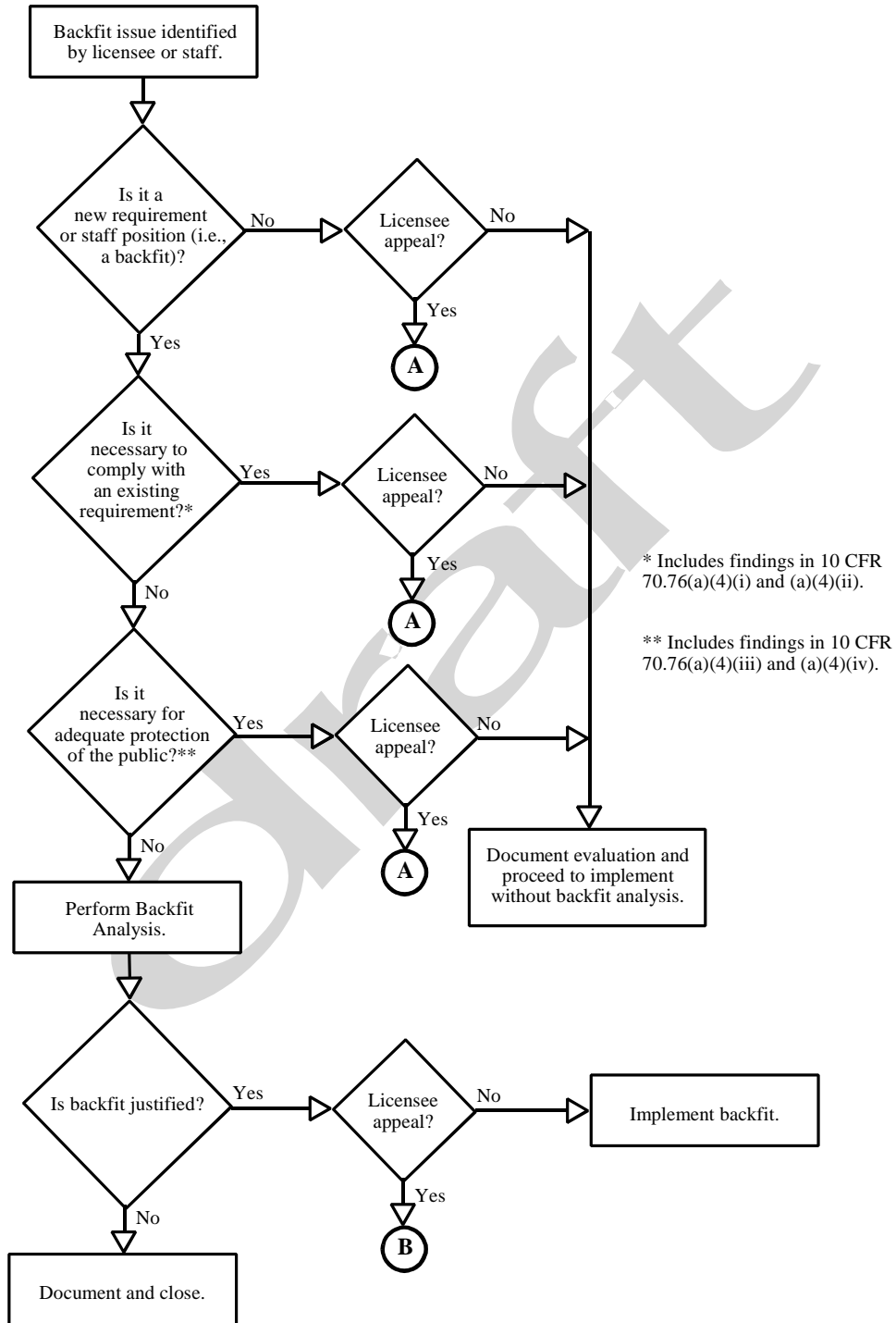


Figure 2. NMSS Backfit Appeals Process Flow-Chart (for Exceptions)

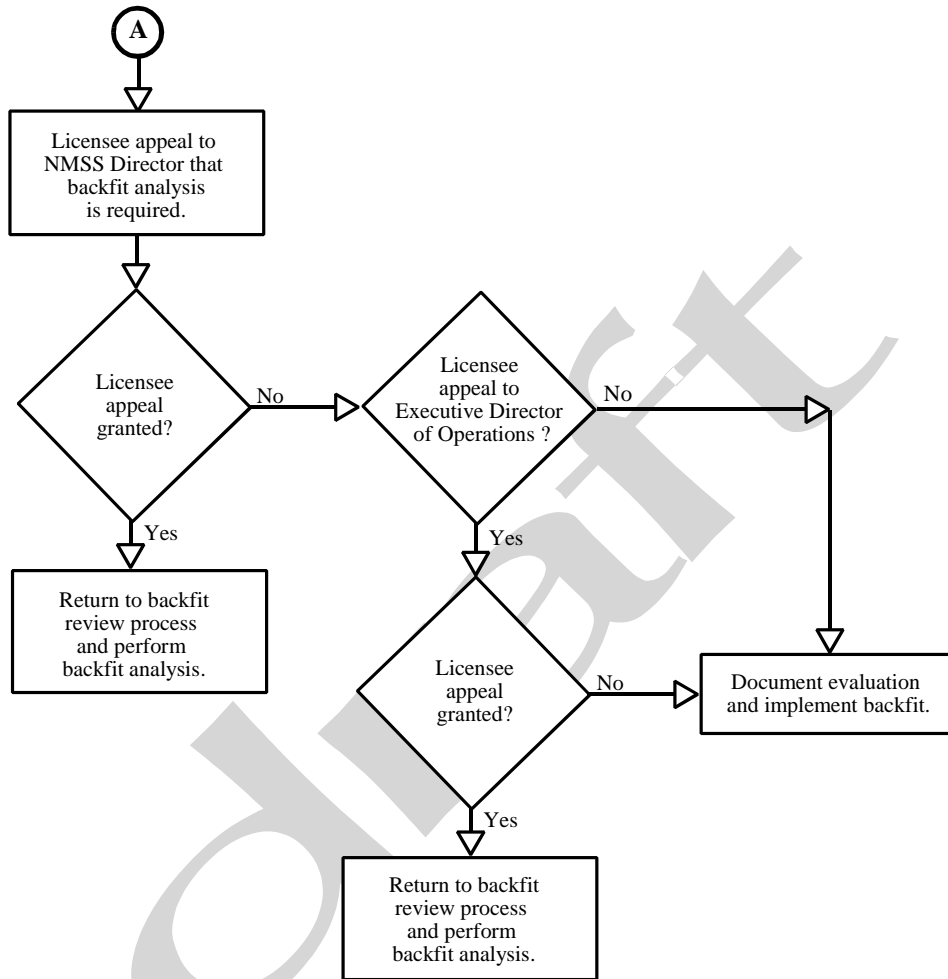
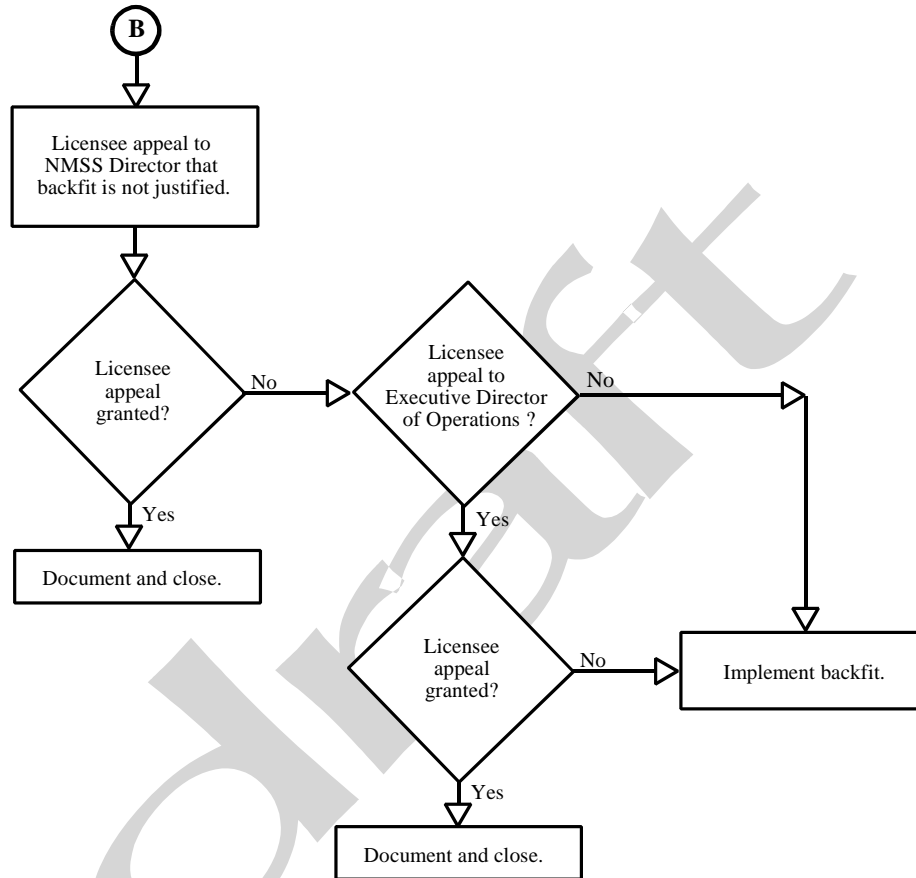


Figure 3. NMSS Backfit Appeals Process Flow-Chart (for Backfit Justifications)



XII. APPENDICES

1. Mechanisms Used by NRC Staff to Establish or Communicate Generic Requirements or Staff Positions
2. Guidance for Backfit Determinations
3. Backfit Identification Form
4. Identification of Backfit - Suggested Procedures
5. Guidance on Application of the Substantial Increase and Justified Cost Standards
6. Backfit Analysis - Suggested Procedures
7. Appeal Process - Suggested Procedures

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APPENDIX 1 MECHANISMS USED BY THE NRC STAFF TO ESTABLISH OR COMMUNICATE REGULATORY POSITIONS THAT COULD CONSTITUTE BACKFITS

- Formal Requirements
 - Multi-plant orders, including show cause orders and confirmatory orders
 - Technical Safety Requirements
- Staff Positions⁵
 - Regulatory Issue Summaries
 - Bulletins
 - Generic Letters
 - Regulatory Guides
 - Standard Review Plans (including Branch Technical Positions)
 - Evaluations and resolutions of Unresolved Safety/Safeguards Issues (USI NUREGs)
 - Information Notices
 - Inspection Manual (Including Temporary Instructions)

⁵Documents that reflect staff positions which, unless complied with or a satisfactory alternative offered, the staff would impose or seek to have imposed by formal requirement.

APPENDIX 2 GUIDANCE FOR BACKFIT DETERMINATIONS

General

In this appendix, selected regulatory activities or documents are discussed in order to enable NRC staff to better understand the conditions under which a backfit may be recognized. It is important to understand that the necessity for making backfit determinations should not inhibit the normal informal dialogue between the NRC staff and the licensee. The intent of this process is to manage backfit imposition, not to quell it. The discussion in this Appendix is intended to aid in identifying backfits in accordance with the principles that should be implemented by all staff members. This Appendix is not intended to be an exhaustive, comprehensive workbook providing an example for each situation that may arise. There will be some judgment necessary to determine whether a staff position would cause a licensee to change the operation, repair, or modification of a facility or procedures or organization. In making this determination, the fundamental question is whether the staff's action is directing, telling, coercing, merely suggesting, or asking the licensee to consider a staff proposed action.

Standard Review Plans (SRPs)

SRPs delineate the scope and depth of staff review of licensee submittals. They are definitive NRC staff explanations of measures which, if taken, will satisfy the requirements of the more generally stated, legally binding body of regulations, primarily found in Title 10 of the Code of Federal Regulations (CFR). Asking a licensee operational questions to clarify staff understanding of licensee proposed actions in order to determine whether those actions will meet the intent of SRPs is not considered a backfit.

However, using acceptance criteria more stringent than those contained explicitly in SRPs or proposing licensee actions more stringent than or in addition to those specified explicitly in SRPs may be considered backfits if (1) the facility has a current license and (2) NRC approval of the license means that the facility met the acceptance criteria in the SRP. Application of SRPs to an operating facility after the license is granted generally is considered a backfit unless the SRPs were approved specifically for operating facility implementation and are applicable to such operating facility or facilities.

Note that licensee-proposed modifications to its current license basis is voluntary and not subject to the Backfit Rule.

Regulatory Guides

There are regulatory guides written specifically for fuel fabrication facilities and there are regulatory guides that address generic issues, such as As Low As Reasonably Achievable (ALARA)⁶. Such implementation has been addressed by the licensee in its application. Future regulatory guides which address areas where there may be no prior NRC position should be discussed with management; they may not be backfits. These regulatory guides go through the NRC's public review and comment process before staff implementation of these guides.

⁶For more information on this term, please see the definition given in 10 CFR 20.1003.

With respect to facility-specific backfit, any staff-proposed implementation of a generic regulatory guide not previously applied to the facility may be a facility-specific backfit. In addition, a staff action taken after a facility has a current license that expands on, adds to, or modifies a generic regulatory guide, such that the position taken is more demanding than that in the original generic regulatory guide (referenced as part of the facility licensing basis), is likely a facility-specific backfit.

Orders

An Order issued to cause a licensee to take actions which are not otherwise existing requirements is considered to be a backfit. An Order effecting prompt imposition of a backfit may be issued prior to completing any of the procedures set forth in this letter provided that the Director, NMSS, determines that prompt imposition is necessary to ensure "adequate protection" (§70.76(a)(5)&(a)(6)).

Inspections

NRC inspection procedures govern the scope and depth of staff inspections associated with licensee activities such as operation, repair, or modification. As such, they define those items the staff is to consider in its determination of whether the licensee is conducting its activities in a safe manner.

When communicating to the licensee, the inspector should always categorize their comments as either compliance matters or matters to be discussed with NRC management. In the normal course of inspecting to determine whether the licensee's activities are being conducted safely, inspectors may examine and make findings in specific technical areas wherein prior NRC positions and licensee commitments do not exist. Examination of such areas and the subsequent findings may not be considered a backfit. Likewise, discussion of findings with the licensee is not considered a backfit. If during such discussions, the licensee agrees that it is appropriate to take action in response to the inspector's findings, such action is not a backfit provided the inspector does not indicate that the specific actions are the only way to satisfy the staff, and the licensee freely volunteers to take such action. The inspector should, in such discussions, communicate to the licensee whether the comments are compliance matters.

As an example of an inspection finding, the licensee committed to an American National Standards Institute (ANSI) standard in its license and the inspector finds the licensee's implementing procedures do not contain all the elements required by the ANSI standard. If the inspector asks why the licensee has not taken action to include all the elements in its implementing procedures this is not a backfit issue. Likewise, if the inspector finds the licensee has included all the required elements of the ANSI standard, but has not included certain of the optional elements in its implementing procedures, an inspector discussion with the licensee regarding the merits of including the optional elements is not a backfit issue. Rather, the issue is a written commitment issue and should be handled as defined in the inspection and enforcement process. However, if the inspector tells the licensee that the implementing procedures must include any or all of the optional elements in order to satisfy the staff, inclusion of such elements may be a backfit, whether or not agreed to by the licensee.

Bulletins and Generic Letters

NRC Bulletins and Generic Letters are part of generic communications regarding materials and fuel cycle issues (See NRC Manual Chapter 0730). In general, it is not necessary to apply the facility-specific backfit process to the actions requested in a Bulletin or Generic Letter.

However, if the staff expands the actions requested by a Bulletin or Generic Letter during its application to a specific facility, such an expansion is considered a backfit, and would have to be justified in accordance with applicable facility-specific backfit procedures. An exception would be if, during the staff review of the actions requested in a Bulletin or Generic letter, the staff was to request additional information to verify compliance with existing requirements.

Re-analysis of Issues

Throughout facility lifetime, many inspectors have an opportunity to review the licensing requirements. Inevitably, there will be occasions when an inspector concludes that a licensee's current design or licensing basis in a specific area does not satisfy a regulation, license condition, or compliance plan. In the case where the NRC staff previously accepted the licensee's program as adequate, any staff specified change in the program may raise backfitting concerns.

APPENDIX 3 BACKFIT IDENTIFICATION FORM

Facility Name: _____

Project Manager: _____

Branch: _____

Office Responsible for Providing Backfit Determination: _____

Identifier of Backfit or Potential Backfit
(Licensee, NMSS, or Region): _____

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 Date (forwarded to licensee): _____

Backfit Determination Organization: _____

Backfit Determination Official (last name, initial): _____

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

Predicted Appeal Date: _____

Predicted Closing Action Date: _____

Appeal by Licensee

Appeal Date: _____

Predicted Closing Action Date: _____

Appeal Description: _____

APPENDIX 4 IDENTIFICATION OF BACKFIT - SUGGESTED PROCEDURES

I. BACKFITS IDENTIFIED BY THE STAFF

When a proposed requirement/staff position or modification is identified as a potential backfit, the staff should use the following procedure to determine if it is a backfit:

- A. The staff that has identified a potential backfit should immediately notify line management and the facility PM.
- B. The PM is responsible for coordinating staff action concerning the potential backfit.
 1. The PM should open a technical assignment control (TAC) number on the issue.
 2. The PM should ensure that the appropriate technical staff evaluates the potential backfit. Objectivity in the review should be maintained by the PM. If possible, technical staff not previously involved in the issue should evaluate it.
- C. The technical staff should evaluate the proposed requirement/staff position or modification to determine whether it constitutes a backfit.
 1. The technical staff performing the review should consult with FCSS Division management to ensure there is a common understanding of the interpretation of the backfit rule for the issue under review.
 2. The technical staff should identify all existing requirements and commitments applicable to the evaluation. This will establish the basis for the evaluation (see PPL 1-82, Section IV.A for guidance).
 3. Pursuant to 10 CFR 70.76(a)(4)(i), a detailed backfit analysis is not required if the modification is needed to bring the facility into compliance with Subpart H. This conclusion must be found in a documented evaluation. (see PPL 1-82, Section VI).
 4. Pursuant to 10 CFR 70.76(a)(4)(ii), a detailed backfit analysis is not required if the modification is needed to bring the facility into compliance with a license or the rules or Orders of the Commission, or into conformance with written commitments by the licensee. This conclusion must be found in a documented evaluation. (see PPL 1-82, Section VI).
 5. Pursuant to 10 CFR 70.76(a)(4)(iii), a detailed backfit analysis is not required if the regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security. This conclusion must be found in a documented evaluation. (see PPL 1-82, Section VI).
 6. Pursuant to 10 CFR 70.76(a)(4)(iv), a detailed backfit analysis is not required if the proposed requirement/staff position or modification involves defining or redefining what level of protection to the public health and safety or common defense and

security should be regarded as adequate. This conclusion must be found in a documented evaluation. (see PPL 1-82, Section VI).

7. If the technical staff determines that a backfit analysis is required, it should be performed as described in PPL 1-82, Section VII.
 8. The initial recommendation on whether the proposed requirement/staff position or modification is a backfit should be provided to the FCSS Division Director in a memorandum from the originating branch chief. The memorandum should include concurrence from the PM. If the FCSS Division Director determines that implementation of a backfit originally identified by the staff is not justified, closure of the issue should be documented, and the staff need take no further action.
- D. The staff should forward the determination to the NMSS Director, immediately.
 - E. If the NMSS Director agrees that a proposed requirement/staff position or modification is a backfit, it should be resolved as described in PPL 1-82, Section IX.

II. LICENSEE BACKFIT CLAIMS

If a licensee provides a written claim that a proposed requirement/staff position or modification constitutes a backfit, the staff should promptly evaluate the claim using the following procedure:

- A. The PM is responsible for coordinating staff action concerning the potential backfit.
 1. The PM should immediately notify line management.
 2. The PM should open a technical assignment control (TAC) number on the issue.
 3. The PM should contact the appropriate technical staff to review the issue. Objectivity in the review should be maintained by the PM. If possible, technical staff not previously involved in the issue should evaluate it.
 4. The PM is responsible for coordinating staff action and preparing correspondence concerning the potential backfit issue.
- B. The technical staff should evaluate the proposed requirement/staff position or modification to determine whether it constitutes a backfit.
- C. The FCSS Division Director should inform the NMSS Deputy Director of the backfit claim. Note that the NMSS Deputy Director should be informed of the backfit claim before the backfit determination is made.
- D. The technical staff should evaluate the backfit claim and recommend to the FCSS Division Director whether or not the proposed requirement/staff position or modification constitutes a backfit. It should follow the steps noted in PPL 1-82, Section IV.

- E. The PM should arrange a meeting between the licensee and the NMSS technical staff in order to resolve the issue. This meeting may be chaired by the FCSS Director and the PM should consider whether the meeting should be open to the public.
- F. The PM should provide a written summary of the discussions in the meeting for input into PPL 1-82, Section V.
- G. The PM should prepare a letter, from the NMSS Office Director to the licensee, incorporating the report on the staff backfit determination, with a copy to the EDO. This letter should normally be sent within four weeks of receiving the written backfit claim.
 - 1. If the NMSS Office Director determines that the proposed requirement/staff position or modification is not a backfit, the licensee should be advised in the letter that it can appeal the decision as discussed in proposed requirement/staff position PPL 1-82, Section VIII or can provide a technical discussion of proposed alternative actions to meet the relevant regulatory requirements outside the provision of this letter. If the licensee's backfit claim is denied, the licensee should be advised 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. (PPL 1-82, Section VIII provides guidance for submitting appeals; this guidance should be included in the letter as appropriate.)
 - 2. If the NMSS Office Director agrees that the proposed requirement/staff position or modification is a backfit, the letter should document agreement with the licensee's claim and establish a proposed plan and schedule for resolution. The backfit should be resolved in accordance with PPL 1-82, Section XI.

III. RESOLUTION OF BACKFITS

Once a proposed requirement/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. (See PPL 1-82, Section IX)

A. When a Documented Evaluation Is Used:

If it is determined that the proposed requirement/staff position or modification is necessary to bring the facility into compliance with the license, Commission rules, or orders, or is necessary to ensure adequate protection the documented evaluation provided in lieu of the backfit analysis should include the following:

- 1. a description of the objectives of, and reasons for, the change;
- 2. a basis for determining that the change is required to ensure compliance or conformance;
- 3. an analysis to document the safety/safeguards significance and appropriateness of the action;

4. a description of how any consideration of costs was limited to selecting the solution among various acceptable alternatives;
5. a citation of appropriate portions of the license(s) or Commission rules.

The technical staff should normally complete the documented evaluation within 3 weeks of the determination that the issue is 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. The letter should state that if the licensee decides to appeal the staff resolution, it should do so within 60 calendar days from the date of the letter. (PPL 1-82, Section VIII provides guidance for submitting appeals; this guidance should be included in the letter as appropriate). Within two weeks of completing the documented evaluation, the NMSS Office Director should send the letter to the licensee. The Director, NMSS shall make the determination and the action should be imposed with an order. The NMSS Deputy Director's concurrence is needed on the evaluation and the Deputy and the EDO provided copies of the letter and the evaluation.

B. When a Backfit Analysis Is Used:

If it is determined that a proposed requirement constitutes a backfit and is not within the scope of PPL 1-82, Section VI.

1. The technical staff should prepare, usually within six weeks of the time the backfit determination is made, a backfit analysis in accordance with PPL 1-82, Section VII.
2. If, at any time, the backfit analysis shows that a backfit identified by the staff is not justified because of the lack of "substantial increase" in additional overall protection, or excessive direct and indirect costs of implementation, the issue may be closed. In this case, the technical staff should notify the facility PM of the findings. The FCSS Division Director should then inform the NMSS Deputy Director of the backfit disposition. The PM should complete the Backfit Identification Form (see PPL 1-82, Appendix 3) to document the backfit disposition.
3. The technical staff should forward the backfit analysis to the PM.
4. If the staff decides to modify its position so that no licensee action is required, the PM should prepare a letter for the signature of the NMSS Office Director, advising the licensee that it need not take the proposed action, with a copy to the EDO and the NMSS Deputy Director.
5. The PM should prepare a letter, from the NMSS Office Director, to the licensee, containing the staff's resolution and the backfit analysis, with a copy to the EDO. Usually, the letter to the licensee should be issued within two weeks of completing the backfit analysis. The letter should state that if the licensee decides to appeal the staff's backfit determination, it should do so within 60 calendar days from the date of the letter. (PPL 1-82, Section VIII provides guidance for submitting appeals; this guidance should be included in the letter as appropriate.)

6. There may be proposed actions which do not meet the “substantial increase” standard but, in the staffs judgment, should be promulgated nonetheless. The Commission has indicated a willingness to consider such exceptions to the Backfit Rule on a case-by-case basis. The NMSS Director should be consulted, in such cases, for resolution.

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APPENDIX 5 GUIDANCE ON APPLICATION OF THE SUBSTANTIAL INCREASE AND JUSTIFIED COST STANDARDS

The Backfit Rule states that, aside from exceptions for cases of compliance, adequate protection, or a redefinition of what constitutes adequate protection, the Commission shall require the backfitting of a facility only when it determines, based on a backfit analysis, "that there is a "substantial increase" in the overall protection of 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" (10 CFR 70.76(a)(3)).

Although NUREG/BR-0058, "Regulatory Analysis Guidelines of the U. S. Nuclear Regulatory Commission," contains specific guidance for nuclear power reactors, this NUREG can be a source of guidance on application of the "substantial increase" and cost justification standards for non-reactor facilities. The \$2,000 per person-rem conversion factor, is still a correct figure for avoiding the risk of latent cancer from radiological exposure. For chemical exposures⁷, research has shown that the avoidance of the chemical toxicity from soluble uranium intakes exceeding 230 mg should be given a value of \$3,000,000. The bases for this conclusion are that: a 230-mg uranium intake may cause a fatality, and the avoidance of a fatality has a value of \$3,000,000. This is conservative since medical treatment could prevent fatalities from this intake or even somewhat larger intakes. The avoidance of the chemical toxicity from uranium intakes of less than 230 mg is given no value. This is based, in part, on the conclusion that there are no demonstrated long term health effects from soluble uranium intakes of less than 230 mg.

The staff may also use the "net benefits" approach, discussed in NUREG/BR-0058, when addressing cost justification under 10 CFR 70.76. In making this determination, the staff may use a qualitative, non-monetary methodology to derive the value of the safety/safeguards improvement, taking into consideration the specific facility hazards. The NRC has used qualitative arguments for benefits where quantification has not been available in other areas regulated by the Commission (see Attachment 3 of CRGR Chapter, Rev. 6, April 1996). As an example, the incorporation of industry standards (including revisions to existing codes and standards) into NRC rules or staff positions may meet the "substantial increase" standard of 10 CFR 70.76 because they can provide a significant safety benefit.

Additional factors may be used to assess the "substantial increase" in safety/safeguards of a proposed modification or backfit. These include:

1. Incorporation of advances in science and technology.
2. Greater uniformity of practice.
3. Greater flexibility in practice/less prescriptive requirements.

⁷The NRC is able to evaluate this hazard due to an agreement between the U.S. NRC and OSHA. This agreement delineates the regulatory authority of each body and states that NRC jurisdiction applies to chemical risks produced from licensed material, facility conditions that affect the safety of licensed material, and hazardous chemicals produced from licensed material. For more information, see U.S. Nuclear Regulatory Commission, "Memorandum of Understanding Between the Nuclear Regulatory Commission and the Occupational Safety and Health Administration: Worker Protection at NRC-Licensed Facilities," *Federal Register*, Vol. 53, No. 210, October 31, 1998, pp 43950-43951.

4. Greater specificity in existing generally-stated requirements.
5. Correction of significant flaws in current requirements.
6. Greater confidence in the reliability and timeliness of information or programs.
7. Fewer exemption requests and interpretative debates.
8. Better focusing of corrective actions towards the sources of problems.
9. Benefits that may accrue in the longer term, beyond the immediately apparent effect of the backfit.

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APPENDIX 6 BACKFIT ANALYSIS - SUGGESTED PROCEDURE

- I. State the specific objective that the proposed backfit is designed to achieve. This statement should include a succinct description of the proposed backfit, and how it may impact overall protection.
- II. Generally describe the activity that would be required by the licensee in order to complete the backfit.
- III. Determine the potential safety/safeguards impact of changes in facility design or operational complexity. Include the relationship of these changes to proposed and existing regulatory requirements.
- IV. State whether the proposed backfit is interim or final and, if interim, justify imposing the proposed backfit on an interim basis.
- V. Prepare a statement describing the benefit and the cost of implementing the backfit. Qualitative assessment of benefits may be made in lieu of the quantitative analysis where it would provide more meaningful insights or is the only analysis available. This statement should include consideration of at least the following factors:
 - A. The potential change in risk to the public from the accidental offsite release of radioactive material.
 - B. The potential impact on radiological and/or chemical exposure of facility employees which is a regulatory responsibility of the NRC defined in the Memorandum of Understanding with OSHA dated October 21, 1988. Also, consider the effects on other onsite workers due to procedural or hardware changes. Consider the effects of the changes for the remaining lifetime of the facility.
 - C. The installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay.
 - D. The estimated resource burden on the NRC associated with the proposed backfit and the availability of these resources.
- VI. Consider important qualitative factors bearing on the need for the backfit at the particular facility, such as, but not limited to, operational trends, significant facility events, management effectiveness, or the results of performance reports such as inspection reports.
- VII. Prepare a statement affirming interoffice (e.g. regions if needed) coordination related to the proposed backfit and the plan for its implementation.
- VIII. 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 facility personnel.

- IX. Establish a schedule for staff actions involved in the implementation and verifying the implementation of the backfit, as appropriate.
- X. Determine the importance of the proposed backfit activities considered in light of other safety/safeguards-related activities underway at the affected facility.
- XI. Consider whether the proposed facility-specific backfit is, or could be, a potential generic backfit.

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APPENDIX 7 APPEAL PROCESS - SUGGESTED PROCEDURES

I. APPEAL TO MODIFY OR WITHDRAW A BACKFIT

Issues that NMSS has determined are backfits and for which the staff has prepared a backfit analysis, may be appealed as follows:

A. Licensees should address an appeal of the proposed backfit to the Office Director with a copy to the EDO. The appeal should provide arguments against the rationale for imposing the backfit as presented in the staff's backfit analysis.

B. Within 3 weeks after the staff receives the appeal request, the Office Director should report to the EDO concerning the plan for resolving the issue.

The PM is responsible for developing and managing the staff's plans regarding the appeal process. The facility PM should ensure that all relevant information is available for supporting the staff's position.

C. The licensee should be promptly and periodically informed in writing regarding the staff's plans.

D. The PM should arrange a meeting at which the licensee can present its appeal to the Director. This meeting should take place as soon as practical.

E. No later than two weeks after the appeal meeting, the PM should issue a meeting summary. The PM should include on the distribution list: the licensee, the EDO, the NMSS Director and Deputy Director, the Division of Fuel Cycle Safety and Safeguards Division Director, the lead NMSS branches, and the public document room.

F. The NMSS Director, with input from the NMSS Deputy Director as appropriate, will decide whether or not the backfit appeal will be granted or denied and whether the backfit is to be imposed on the licensee. The NMSS Director's decision should be forwarded to the licensee within about four weeks of the appeal meeting. The PM should also prepare a letter to the licensee for the signature of the NMSS Director, with a copy to the EDO. During the appeal process, primary consideration shall be given to how and why the proposed backfit provides a "substantial increase" in overall protection and whether the associated costs of implementation are justified in view of the increased protection. This consideration should be made in the context of the backfit analysis as well as any other information that is relevant and material to the proposed backfit.

G. If, as a result of the meeting, the NMSS Director decides that the backfit is still warranted and the licensee agrees to implement it, the backfit should be implemented in accordance with PPL 1-82, Section IX.

H. All correspondence related to the appeal shall be made available to the public by docketing the correspondence, unless otherwise protected against disclosure under applicable law and regulations.

NOTE: If the NMSS Director decides that the backfit appeal is denied and the licensee does not agree, the licensee may appeal the decision to the EDO. The EDO shall promptly resolve the appeal in accordance with applicable management directives.

II. APPEAL TO REVERSE DIRECTOR'S DECISION DENYING A LICENSEE APPEAL TO WITHDRAW A BACKFIT

When a licensee has claimed that a staff position is a backfit or when the staff has determined that a backfit meets the compliance or adequate-protection exception and the licensee claims that it does not meet the exception, and the NRC continues to disagree, the licensee may appeal the decision regarding the backfit claim to the NRC EDO. The EDO may review and modify a decision either at the request of the licensee or on its own initiative. The EDO will promptly resolve the appeal in accordance with applicable procedures. Backfit claims and resultant staff determinations that are reevaluated in response to an appeal, and that are again determined by the NRC not to be backfits, or are excepted from the requirement for a backfit analysis, are not to be treated further.

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