

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

March 2004, Revision 0

I. PURPOSE

The purpose of this policy and procedures letter (PPL) is to provide guidance for implementing the backfit provisions in 10 CFR 70.76 (§70.76). As stated in the regulation, §70.76 becomes effective upon issuance of “staff guidance¹” for all Part 70 requirements regardless of the status of approval of a licensee’s ISA Summary, except for Subpart H. In order for the requirements of §70.76 to become effective for Subpart H requirements, the Nuclear Regulatory Commission (NRC) also has to have approved a licensee’s process-specific or site-wide ISA Summary (referred to later in this document simply as “ISA Summary”).

II. POLICY

The policy of Nuclear Material Safety and Safeguards (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 §70.76.

The regulations in §70.76 govern the backfitting of new or modified requirements on Part 70 licensees. The regulation 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,” and NMSS PPL 1-53, “Gaseous Diffusion Plant Specific and Generic Backfit Management,” establishes guidance for NRC staff implementation of 10 CFR 50.109 (§50.109) and §76.76, respectively. The documents were used to develop this PPL because of similarities between the backfit requirements.

III. DEFINITIONS

- A. Licensee: The term “licensee” is used in this PPL 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 committed² to by a licensee at the time of the identification of a backfit, and are of several different types and

¹This NMSS policy and procedures letter was written to be that “staff guidance.”

²A 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.

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 “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 facility³, any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rule that is either new or different from a previous staff position.

A 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 or approved in the facility license,
AND
2. **Time:** A staff position is a proposed backfit if it is first identified to the licensee after NRC approves a licensee’s process-specific or site-wide Integrated Safety Analyses (ISA) Summary (for Subpart H requirements). For requirements other than Subpart H, for current licensees, backfit protection begins following issuance of staff guidance (this PPL is intended to satisfy that condition). 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.” Under such a standard, NRC would not expect that it would require safety improvements that resulted in an insignificant or small benefit to the public health and safety (regardless of costs). However, the standard not intended to be interpreted in such way that would result in disapprovals of worthwhile safety or security improvements having costs that are justified in view of the increased protection that would be provided.⁴

³This list includes, as a subset thereof, items relied on for safety, or IROFS, as defined in §70.4 and identified in a licensee’s Integrated Safety Assessment Summary.

⁴S. J. Chilk, Secretary, “SECY-93-086 - Backfit Considerations,” memorandum to J. M. Taylor, Executive Director for Operations, June 30, 1993.

IV. IDENTIFYING POTENTIAL BACKFITS

Staff at all levels should decide whether any proposed requirement or staff position should be considered as a backfit. Appendix 1 gives mechanisms used to establish and communicate regulatory positions that may be backfitted as defined in §70.76(a)(1). Use the form in Appendix 2 to track, organize and document this process. The suggested procedure in Appendix 5 may also be useful to organize and plan for this process.

The staff should apply the following sections as appropriate:

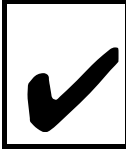
A. Staff Identification of Backfit

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. The NRC staff shall be responsible for identifying proposed backfits. The staff at all levels will evaluate any proposed staff position to determine whether the new staff position qualifies as a proposed backfit. Appendices 1 and 2 to this document provide information to help in the identification of backfits arising from selected staff activities. When a staff position is identified as a backfit, the staff should determine expeditiously whether the backfit is needed to ensure adequate protection of the public health and safety or to comply with Commission rules or Orders, the license, or written commitments. 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 final issuance of this PPL.

No new requirement or staff position should be communicated to the licensee unless an NRC official, in concert with NRC's Office of General Council, has ascertained whether or not it satisfies the backfit provisions in §70.76.

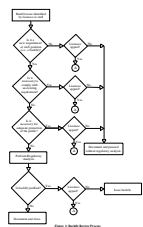
B. Licensee Claims of Backfit

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 and any other relevant NRC office.



PROCESS QUESTIONS?

See Figures 1 through 3, starting on pg. 10 for the NMSS Backfit Process & Appeals Flow-



V. DETERMINING BACKFITS

The backfit potential determination is made, that is, the staff's evaluation of the applicability of the allowed exception under §70.76(a)(4), before the backfit analysis or documented evaluation⁵ is started.

If the proposed requirement/staff position is excepted under §70.76(a)(4), the appropriate staff should proceed promptly with preparation of the documented evaluation as discussed in Section VI. 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.

If the backfit is not excepted under §70.76(a)(4), the appropriate staff should proceed promptly with the preparation of a backfit analysis as discussed in Section VII.

If the issue was identified by the licensee, the Office Director (OD) will report to the EDO and inform the licensee, within 3 weeks after receipt of the written backfit claim, of the receipt of the claim and the plan, including a schedule, for resolving the claim. Following the OD'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 PPL.

Information Requests to Licensees

The NRC staff is not required to prepare a documented statement for information requests related to verifying a licensee's compliance with its current licensing basis, Orders, or commitments. However, if the staff requests information specifically related to a backfit determination, the staff must prepare, for the record, a statement of its reasons and anticipated costs. In addition, if the staff is preparing information requests to the licensee, it must take care to objectively determine into which of the backfit



10 CFR 70.76(a)(2) states that a systematic, documented backfit analysis is required for all backfits that the NRC seeks to impose, with the exception of backfits that meet the criteria under §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 Subpart H, (2) a modification is necessary to bring a facility into compliance with a license, rules, Orders, or written commitments, (3) regulatory action is necessary to ensure adequate protection to the health and safety of the public and is in accord with the common defense and security, or (4) the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security is adequate.

⁵The backfit analysis and documented evaluation are two different types of analyses. They are not equivalent. They are used in specific situations as discussed in this PPL.

categories the request falls. If a statement is required it must include at least the following elements:

1. A description of the need for the information in terms of potential safety benefit and any applicable regulatory requirements and references,
2. A description of the actions requested from the licensee and an estimate of the costs incurred by the licensee in responding to the request, and
3. A schedule stating when NRC will review and act on the information.

VI. DOCUMENTED EVALUATIONS FOR BACKFITS

A documented evaluation is required for backfits that the NRC intends to treat as exceptions per §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.



NRC generic communications (such as Bulletins & Generic Letters)

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."

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,
3. if an immediate regulatory action is required, the documented evaluation will delineate the basis for the urgency, or
4. if the compliance exception is invoked, the documented evaluation must identify the specific regulatory basis.

The documented evaluation will be forwarded as soon as practicable to the licensee for their information.

VII. BACKFIT ANALYSIS

The proposed backfit and supporting backfit analysis must be approved by the Office Director, and forwarded to the EDO, for information, before the backfit and its supporting backfit analysis are transmitted to the licensee. The EDO may review and revise any backfit decision on the EDO's own initiative. 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 (defined in Section III,

above) and cost standards is given in Appendix 3. The staff is encouraged to use the steps given in Appendix 6 for backfit analysis.

VIII. APPEAL PROCESS FOR BACKFITS

A licensee can appeal any proposed backfit or denied backfit claim to NMSS as discussed herein. The EDO may review and revise any backfit decision on its own initiative or at the request of a licensee. The appeal processes described in this section apply to two different situations:

1. Appeal to modify or withdraw an identified backfit for which has been identified and 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.

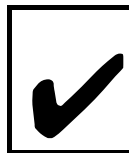
For the first situation described above, licensees should address an appeal of the proposed backfit to the OD with a copy to the EDO. The appeal should provide

arguments against the rationale for imposing the backfit as presented in the staff's backfit analysis. The OD will report to the EDO within 3 weeks of receipt concerning the plan, including a schedule, to resolve the issue. The licensee should be promptly informed in writing regarding staff plans. The decision of the OD may be appealed to the EDO. The EDO will promptly resolve the appeal and state its reasons. Summaries of all appeal meetings will be promptly prepared,

provided to the licensee, and placed in the public document room. During the appeal process, primary consideration will 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. For the second situation described above the process will be the same as for the first, however, the appeal will take into consideration the staff's analysis, the licensee's response, and any other information that is relevant and material to the determination. If in this case the staff reevaluation in response to the appeal again determines that the position is not a backfit or that they are excepted from a backfit analysis, these matters are to be handled within the normal licensing and inspection process. See Appendix 7 for suggested steps to follow when processing either of these appeals.

If, after an appeal and a subsequent final decision is made by the appropriate OD or EDO rejecting the appeal, the licensee may either implement or refuse to implement the backfit. If the licensee refuses to implement the backfit, the NRC may Order the licensee to implement the backfit. Once an Order is issued, whether or not it is immediately effective, this guidance no longer applies. Any appeals are governed by the requirements of 10 CFR Part 2, Subpart B.

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



IX. IMPLEMENTATION OF BACKFITS

A. Implementation of Backfit

Following approval of any required backfit analysis by the OD, review by the EDO (if any), issuance of the backfit to the licensee, and the resolution of any appeals (as discussed in VIII above), the licensee will implement the decision. Implementation of backfits should normally 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, or the facility construction or maintenance planned for the facility, in order to maintain high quality construction and operations. 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.

If a licensee does not elect to implement the backfit, it may be imposed by Order of the NMSS Director. Once an Order is issued, whether or not it is immediately effective, this guidance no longer applies and appeals are governed by the procedures in 10 CFR Part 2, Subpart B.

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 guidance 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 PPL in time to be issued with the Order, if at all possible.

If a licensee does not elect to implement the backfit, it may be imposed by Order of the NMSS Director. Once an Order is issued, whether or not it is immediately effective, this guidance no longer applies and appeals are governed by the procedures in 10 CFR Part 2, Subpart B.

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, September 18, 2000.
- 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, "Office of Nuclear Materials Safety and Safeguards Policy and Procedures Letter 1-53 Gaseous Diffusion Plant Specific and Generic Backfit Management," NMSS Policy and Procedures Letter 1-53, September 1999.
- 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," NUREG-1718, August 2000.
- 18) U.S. Nuclear Regulatory Commission, "Memorandum of Understanding Between the Nuclear Regulatory Commission and the Occupational Safety and Health

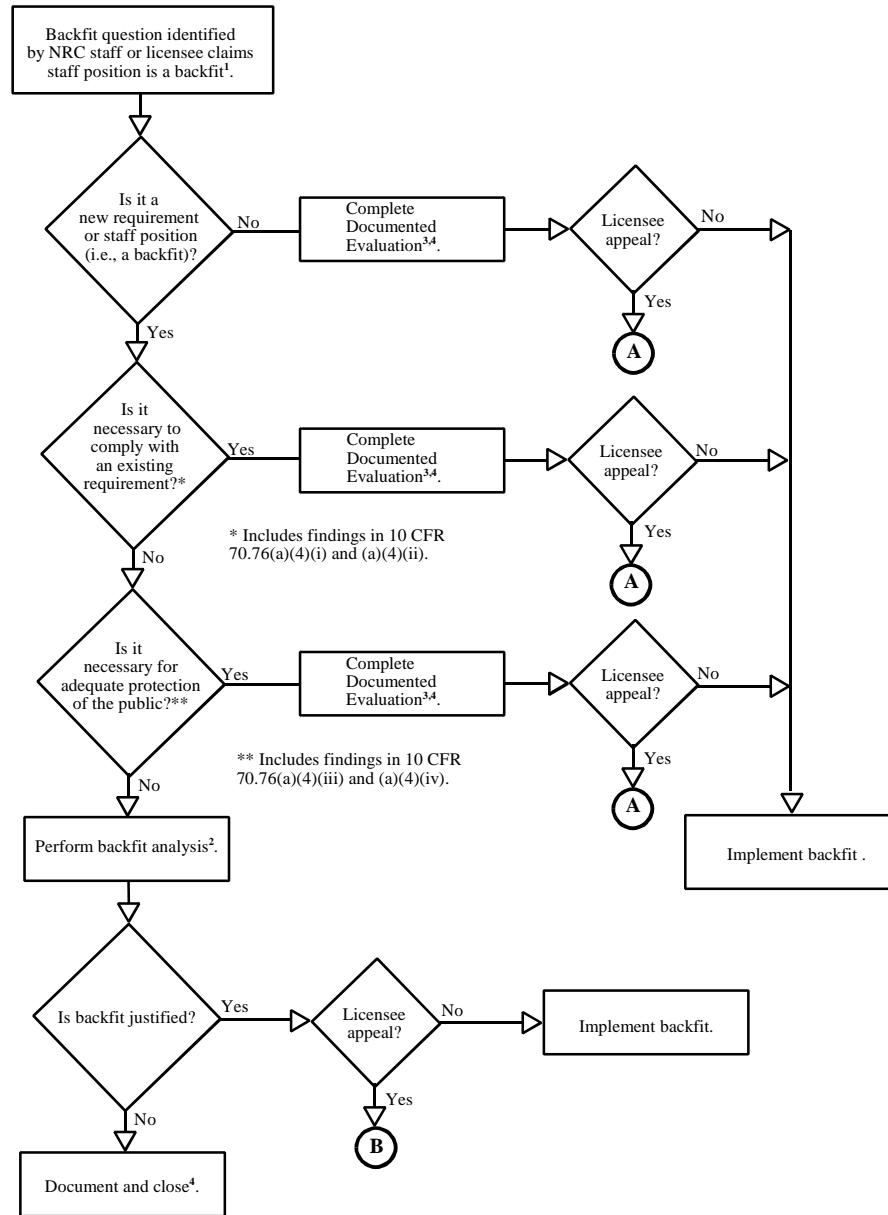
Administration: Worker Protection at NRC-Licensed Facilities," *Federal Register*, Vol. 53, No. 210, October 31, 1998, pp 43950-43951.

- 19) U.S. Nuclear Regulatory Commission, "Criteria for Staff Implementation of 'Backfitting' Requirements for Gaseous Diffusion Plants, 62 FR 14456, March 26, 1997.
- 20) 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).
- 21) Executive Office of the President, "Regulatory Planning and Review," Executive Order 12866, *Federal Register*, Vol. 58, No. 190, October 4, 1993, pp. 51735-51744.
- 22) Executive Office of the President, "Federal Regulation," Executive Order 12291, *Federal Register*, Vol. 46, No. 32, February 19, 1981, pp. 13193-13198.
- 23) 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.
- 24) A. Vietti-Cook, Secretary, U.S. Nuclear Regulatory Commission, memorandum to W. D. Travers, Staff Requirements Memorandum - Affirmation Session, July 25, 2000.
- 25) 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.
- 26) 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.

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.

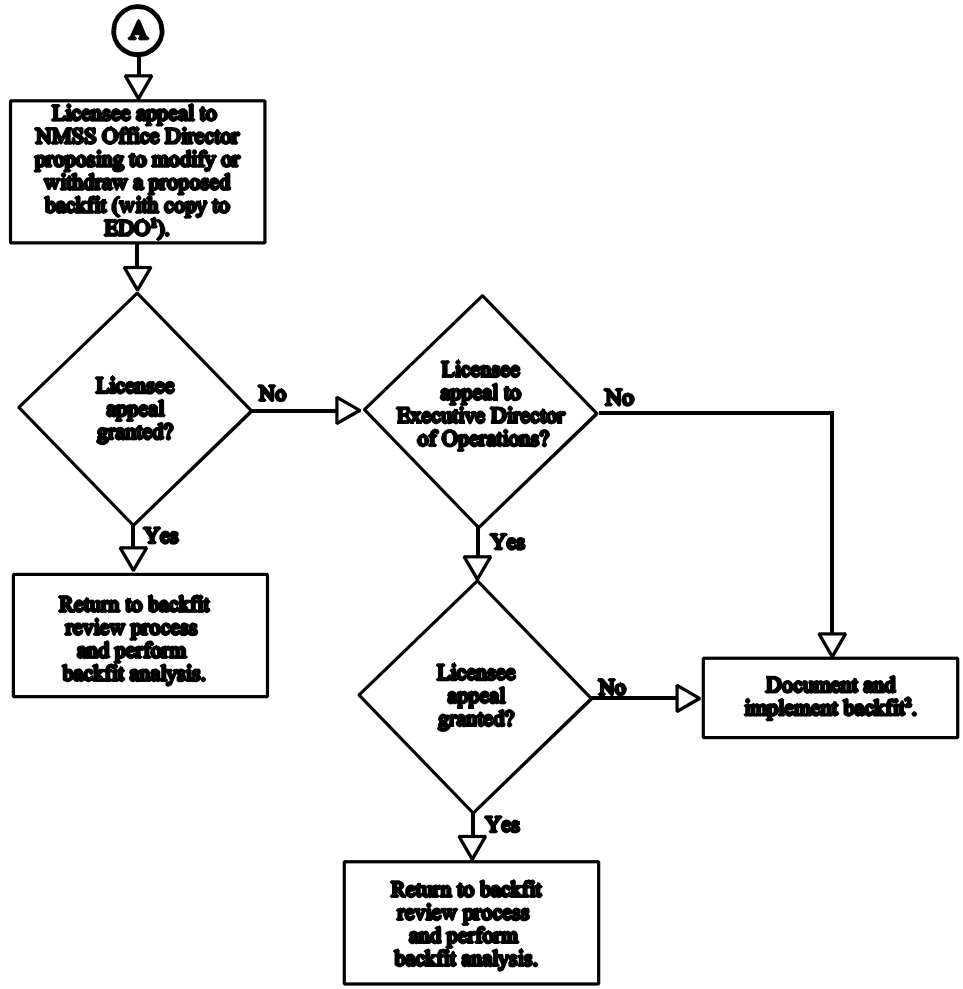
XI. FIGURES

Figure 1. NMSS Backfit Process Flow-chart



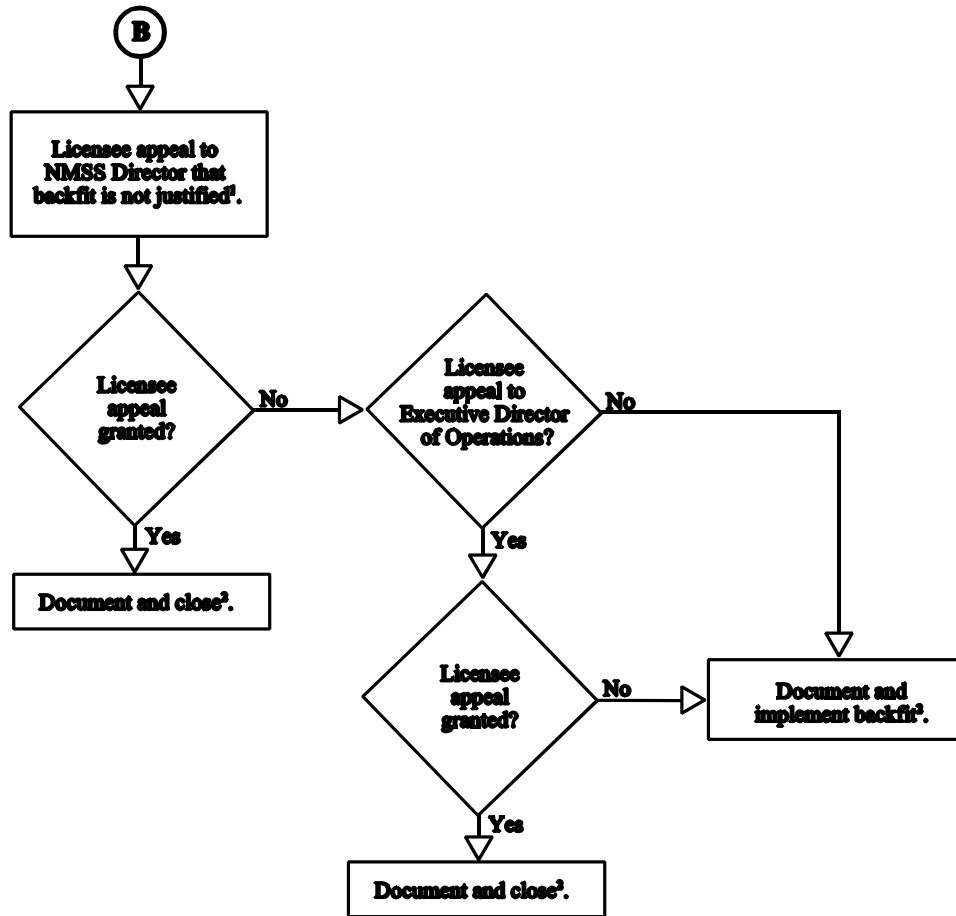
1. If the issue was identified by the licensee, the NMSS OD will report to the EDO and inform the licensee, within 3 weeks of receipt, of the backfit question and the plan, including a schedule, for resolving the issue.
2. NMSS staff may decide the backfit is not likely to be justified and close the action with appropriate documentation.
3. As noted in this PPL, the NRC has discretion to whether to use the exceptions, and may optionally choose to perform a backfit analysis in cases where they are not required by regulation.
4. A copy must be sent to ADAMS.

Figure 2. NMSS Backfit Appeals Process Flow-Chart (for §70.76(a)(4) Exceptions)



1. A copy must be sent the EDO and to ADAMS
2. A copy must be sent to ADAMS.

Figure 3. NMSS Backfit Appeals Process Flow-Chart (for Agency Actions with Backfit Analyses)



1. A copy must be sent the EDO and to ADAMS
2. A copy must be sent to ADAMS.

XII. APPENDICES

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

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

- Formal Requirements
 - Rules/Regulations
 - License Conditions
 - Orders, including show cause Orders and confirmatory Orders
 - Facility Licenses

- Staff Positions⁶
 - Regulatory Issue Summaries
 - Bulletins
 - Generic Letters
 - Regulatory Guides
 - Standard Review Plans (including Branch Technical Positions)
 - Evaluations and resolutions of unresolved safety/safeguards or security Issues (USI NUREGs)

Inspection Manual (including Temporary Instructions)

⁶Documents 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. However, these documents, by themselves, are not requirements and do not constitute “backfitting.”

APPENDIX 2 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 3 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 the interim, the staff will use the "net benefits" approach, discussed in NUREG/BR-0058, when addressing cost justification under §70.76. In making this determination, the staff will use a qualitative, non-monetary methodology to derive the value of the safety/safeguards or security improvement, taking into consideration the specific facility hazards. The use of qualitative arguments for benefits where quantification has not been available is established in other areas regulated by the Commission (see Committee to Review Generic Requirements Charter). As an example, the incorporation of industry standards (including revisions to existing codes and standards) into NRC rules or staff positions, as a prudent means of assuring continued performance with currently voluntary standards and practices that provide substantial safety benefit, can provide the basis for a finding that a proposed backfit meets the "substantial increase" standard of §70.76.

Additional factors may be used to assess the "substantial increase" in safety/safeguards or security 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.
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.

APPENDIX 4 GUIDANCE FOR BACKFIT DETERMINATIONS WITH EXAMPLES

General

In this section 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 discussion in this appendix is intended to aid the staff in identifying backfits in accordance with the requirements of the regulation. 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 its procedures or organization. In making this determination, the fundamental question is whether the staff's action is directing, telling, or coercing, or is merely suggesting or asking the licensee to consider a staff proposed action.

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 issued to confirm commitments to take specific actions, even if the specific actions are in excess of the current license requirements, is not a backfit, provided the commitment was not the only acceptable alternative given by the staff. An Order requiring prompt imposition of a backfit may be issued prior to completing any of the procedures set forth in this guidance provided that the Director, NMSS, determines that prompt imposition is necessary to ensure "adequate protection."

Standard Review Plans (SRPs)

SRPs delineate the scope and depth of staff review of licensee submittals associated with various review activities. 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 concerning the license/regulations to clarify staff understanding of proposed actions in order to determine whether the actions will meet the intent of regulatory requirements is not considered a backfit. Requiring the licensee to meet the letter of the SRP may be a backfit. SRPs provide guidance to the NRC staff by giving the scope and depth of the staff review of licensing submittals.

On the other hand, 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 compliance with 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, that exceed the requirements of applicable regulations, Orders, and exemptions granted, are voluntary and not subject to the Backfit Rule.

The staff should be aware of the licensing requirements for a facility and ensure that during licensing action reviews the same regulatory requirements and acceptance criteria are applied to a facility as they were when the facility license was issued. The staff should also be aware of licensee commitments that update or exceed those original acceptance criteria. Staff questions, intended to clarify understanding of a proposed action or to establish specific requirements and licensee commitments are not backfits.

Three scenarios exist that should be discussed in order to clarify the applicability of a specific revision of the SRP. First, if a licensee makes a change in its facility that meets the conditions of §70.72(c), those changes do not need prior regulatory approval. Second, if a facility desires changes in its current facility or process(es) that do not meet the exceptions given in §70.72(c) then the licensee must submit a license amendment application in accordance with §70.34. Since the changes, in this second scenario, related to currently installed process equipment or facility, no integrated safety assessment is required by 10 CFR Part 70. In this case, the regulatory requirements and acceptance criteria (e.g., the SRP criteria) are likely to be the same as were applied during the issuance of the original license. If, in this case, a newer version of the SRP was applied to the license application review, the staff may be in danger of backfitting new requirements on the licensee. In the third case, the licensee desires to license a new process or facility. In this case, the regulations require that the staff apply new criteria (i.e., NUREG-1520, Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility). In the third case, this is not a backfit.

SRP COMPLIANCE EXAMPLE

Question: NUREG-1520, SRP, directs that a certain type of analysis be performed in a particular fashion. However, due to changes in technology and the state-of-the-art, the licensee chose to perform a different type of analysis that the licensee believes is an acceptable alternative to the type discussed in the SRP. Upon receipt of the analysis, the staff discovers that they have no procedures or tools to evaluate the analysis, and the staff takes the position that the analysis is not acceptable because it is not consistent with the SRP. Therefore, the staff requests that the licensee perform an analysis using the SRP. Is this a backfit?

Answer: NUREG-1520 specifically states that it is guidance and that compliance is not required. The backfit exists not in the staff requesting an analysis, but in that the staff must have the same type of analysis discussed in the SRP. If the staff insists that the SRP must be strictly adhered to by the licensee, the licensee may be justified in submitting a backfit appeal to the NMSS Office Director.

Alternative: For complex future licensing actions, the staff should be aware of, and ask licensees to identify, specific deviations from the SRP guidance so that the implications and impact on the license amendment review schedule can be assessed. In this case, if the staff understood the analysis that the licensee intended to submit in its license application, the staff could then inform the licensee that the alternative review may result in delays and increased review costs related to the license amendment request. The licensee could then use this information to decide whether their proposed alternative was worth the increased risk and cost.

Regulatory Guides

There are regulatory guides written specifically for fuel fabrication facilities and there are regulatory guides that address generic issues, such as ALARA. 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.

With respect to a backfit, any staff-proposed plant-specific implementation of a regulatory guide provision, whether orally or in writing, for a plant not encompassed by the generic implementation determination is considered a plant-specific backfit. In addition, a staff action taken after a facility has a current license that expands on, adds to, or modifies a generically approved regulatory guide, such that the position taken is more demanding than intended in the original regulatory guide (referenced as part of the facility licensing basis), is a backfit.

Inspections

NRC inspection procedures are to 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. The conduct of an inspection establishes no new requirements and is not a backfit. However, during the course of an inspection, a new or different staff interpretation of the requirements that must be met by the licensee may be a backfit.

When communicating to the licensee, the inspector should always categorize his or her 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. Likewise, discussion of findings with the licensee is not considered a backfit. If, during the course of 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 his or her comments are compliance matters.

INSPECTION EXAMPLE

A licensee committed to the American National Standards Institute (ANSI) ANSI/ANS-8.1, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors," standard in its license and the inspector finds the licensee's implementing procedures do not contain all the elements required by ANSI/ANS-8.1. The staff's position that all the elements of the ANSI/ANS-8.1 standard must be included in the implementing procedures is not a backfit. If the inspector finds the licensee has included all the required elements of ANSI/ANS-8.1, but has not included certain of the optional elements in its implementing procedures and the inspector states that they also must be included in the implementing procedures, this is a backfit. If the inspector finds the licensee has included all the required elements of ANSI/ANS-8.1, but has not included certain of the optional elements in its implementing procedures and the inspector discusses with the licensee the merits of including the optional elements is not a backfit issue. Any action that the licensee took as a result of this discussion would be at their own discretion and is not a backfit.

Enforcement

A Notice of Violation (NOV) may constitute a backfit if it reflects the imposition of a new or modified staff position. However, the licensee's recourse is to challenge the perceived backfit through the normal enforcement process (and not through the backfit claim or appeal process).

NOTICE OF VIOLATION EXAMPLE

Issue: A licensee receives an NOV based on a finding that a change made to an IROFS under §70.72 did not address equivalent replacement of its safety function. The licensee removed an engineered control and replaced it with an administrative control (not listed in the ISA Summary) from a process. The licensee believed that they maintained the safety function by keeping the same number of safety controls. Is this a backfit?

Answer: No. In this case, the licensee did not correctly evaluate the impact of the change under 70.72. The change reduced the reliability of the system from that originally approved by the NRC. Although the staff, in its safety evaluation, did not specifically review or approve the use of the administrative control, this does not prohibit the staff from holding the position that the substituted control does not maintain the same level of safety as was originally approved. The original approval was based on the staff finding, among other things, that the licensee's proposed controls met the performance requirements of §70.61.

Bulletins and Generic Letters

NRC Bulletins and Generic Letters are not requirements and are simply generic communications regarding materials and fuel cycle issues (See NRC Manual Chapter 0730).

However, it is generally useful to provide to the staff justification for cases in which a staff-recommended action or schedule will not be followed. In addition, it is not a backfit if, during the staff review of actions requested, the staff requests additional information to verify compliance with existing requirements. If the bulletin or generic letter requests a response and the staff is not satisfied with that response, then the staff may be required to follow the backfitting process to direct (i.e., by Order) further actions by the licensee. If a facility falls outside of the generic backfitting analysis performed for the bulletin or generic letter, the licensee may point this out as a justification for why it is not following the recommendations for its facility.

Re-analysis of Issues

Throughout the lifetime of a Part 70 facility many inspectors will have had an opportunity to review the licensing requirements. Inevitably, there will be occasions when an inspector concludes that a previously approved program does not satisfy the licensee's current design or licensing basis, 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 be a backfit.

APPENDIX 5 IDENTIFICATION OF BACKFIT - SUGGESTED PROCEDURES

I. BACKFITS IDENTIFIED BY THE STAFF

When a proposed requirement/staff position 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 to determine whether it constitutes a backfit as defined in §70.76(a)(1). The bases for this determination should be documented.
 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 Section IV.A for guidance).
 3. Pursuant to 10 CFR 70.76(a)(4)(i), a detailed backfit analysis is not required if the proposed requirement/staff position is needed to bring the facility into compliance with a license or with the rules or Orders of the Commission. This conclusion must be documented (see Section VI).
 4. Pursuant to 10 CFR 70.76(a)(4)(ii), a detailed backfit analysis is not required if the proposed requirement/staff position is needed to bring a facility into compliance with a license or the rules or Orders of the Commission, or into conformance with written commitments by the licensee. This conclusion must be documented (see 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 documented (see 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 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 documented (see Section VI).
 7. If the technical staff determines that a backfit analysis is required, it should be performed as described in Section VII.
 8. The initial recommendation on whether the proposed requirement/staff position 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.
- D. The NMSS Director should determine whether the proposed requirement/staff position is a backfit.
 - E. If the NMSS Director determines that a proposed requirement/staff position is a backfit, it should be resolved in accordance with Section IV.
 - F. 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.

II. LICENSEE BACKFIT CLAIMS

If a licensee provides a written claim that a proposed requirement/staff position 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. The objectivity of the technical staff assigned to 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 to determine whether it constitutes a backfit as defined in §70.76 (a)(1). The basis for this determination should be documented.

- 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 constitutes a backfit. It should follow the steps noted in 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 Section IV.
- G. The PM should prepare a letter, from the NMSS Office Director to the licensee, incorporating the report on the 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 is not a backfit, the licensee should be advised in the letter that it can appeal the decision as discussed in 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. (Section VIII provides guidance for submitting appeals; this guidance should be included in the letter as appropriate.)
 - 2. If the NMSS Office Director determines that the proposed requirement/staff position 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 Section IV.

III. RESOLUTION OF BACKFITS

Once a proposed requirement/staff position 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 Section IX)

A. When a Documented Evaluation Is Used:

If it is determined that the proposed requirement/staff position is necessary to bring the facility into compliance with the regulations, license, Commission rules, commitments, or Orders, or is necessary to ensure adequate protection the documented evaluation, or is a result of a definition or re-definition of what constitutes adequate protection, a

documented evaluation is required in lieu of the backfit analysis and 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 or security 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 the specific provisions of the license(s), Order, or Commission rules for which compliance is to be required by the backfit.

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. (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 approve 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/staff position requires a backfit, as defined in §70.76(a)(1), and does not fall within the exceptions given in §70.76(a)(4)(i)-(iv), then a backfit analysis is required.

1. The technical staff should prepare, usually within six weeks of the time the backfit determination is made, a backfit analysis in accordance with 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 additional overall protection (of the public health and safety or common defense and security) or lack of justification for the direct and indirect costs of implementation, the issue may be closed⁷. In this case, the technical staff should notify the PM of the findings. The FCSS Division Director should then inform the NMSS Deputy Director of the backfit disposition.

⁷Alternatively, the staff may seek an "exception" to §70.76 from the Commission (see B.6 below).

The PM should complete the Backfit Identification Form (see Appendix 2) to document the backfit disposition.

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.

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. (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 staff’s 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. See [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]. The NMSS Director should be consulted, in such cases, for guidance.

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 substantially increases 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 or security 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 (from licensed material or hazardous chemicals produced from licensed material) 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 or security-related activities underway at the affected facility.

APPENDIX 7 APPEAL PROCESS - SUGGESTED PROCEDURES

I. APPEAL TO NMSS OD TO MODIFY OR WITHDRAW A BACKFIT

Issues that NMSS has determined are backfits should be appealed as follows:

- A. Licensees should address an appeal of the proposed backfit to the OD with a copy to the EDO. The appeal should provide arguments against the rationale for imposing the backfit.
- B. Within 3 weeks after the staff receives the appeal request, the OD should report to the EDO concerning the plan, including a schedule, for resolving the issue.

The PM is responsible for developing and managing the staff's plans regarding the appeal process. The 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 for resolving the appeal.
- D. The PM will arrange a meeting, if desired by the licensee, 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 the following addressees on the distribution list: the licensee, the EDO, the NMSS Director and Deputy Director, the Division of Fuel Cycle Safety and Safeguards (FCSS) 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 direct and indirect 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 Section IX of this PPL.
- 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 THE NRC EDO TO REVERSE A DENIAL OF A LICENSEE CLAIM

Issues that NMSS has determined are backfits and for which the staff has prepared an evaluation or analysis, issued it to the licensee, where the licensee claimed the backfit was not justified, should be appealed to the EDO. The appeal should take into account the staff's evaluation, the licensee's response, and any other information that is relevant and material to the backfit determination. The EDO will promptly resolve the appeal in accordance with applicable procedures. The EDO may review and modify a decision either at the request of the licensee or on its own initiative. 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 that are correctly excepted from the requirement for a backfit analysis, are not to be treated further under this guidance.