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NUCLEAR GENERATION

July 11, 2003

Chief, Rules and Directives Branch, ADM
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

6/11/03
68 FR 35014
(1)

Dear Sir or Madam:

REFERENCE: Solicitation of Public Comments on Draft NMSS Policy and Procedures Letter 1-82 and Backfit Guidance (Fed. Reg. Vol. 68, p. 35015, dated June 11, 2003)

The Nuclear Energy Institute (NEI)¹ on behalf of its industry members has reviewed draft Policy and Procedures Letter (PPL) 1-82 for implementation of a Backfit Provision to Part 70 licensees. Issuance of this PPL is welcomed by the industry, for it assures that any new regulatory burdens imposed on licensees must first have been evaluated from a risk-significance perspective. New regulatory burdens must be supported by a cost-benefit study that demonstrates that the costs of implementation of any new NRC regulatory position are more than offset by a substantial increase provided in the overall protection of public health and safety.

PPL 1-82 provides an informative outline of internal NRC procedures for backfitting, backfit implementation and consideration of licensee appeals of NRC actions. The document lacks, however, practical guidance on how the staff should address the three critical backfit components ('substantial increase,' 'overall protection,' 'cost justification') and how a backfit analysis should be performed. For example, guidance as to how the staff should use qualitative and quantitative factors in assessing whether a regulatory action will result in the necessary 'substantial increase' in public health and safety should be added. The core elements of a backfit analysis should also be listed, perhaps with a supporting checklist of critical elements, to enable the staff and licensees to judge the adequacy and thoroughness of a backfit analysis. Citation of the NRC's experience in applying the backfit principle to power reactors and gaseous diffusion plants would improve the usefulness of the PPL. Many approaches and backfit interpretations

¹ NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

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used for Part 50 licensees, such as the 'tacit approval' concept (Paragraph IX(D)) or the 'compliance exception' (Appendix 4) should also be referenced in PPL 1-82 and used in Part 70 backfitting as well. Explanation of the applicability of 'facility-specific' and 'generic' backfits would be instructive, particularly as to how exemptions to the latter should be handled for specific licensees. Finally, NEI recommends inclusion of a new Appendix 8 ('Examples of Backfit Situations') to cite practical examples of backfitting for different licensing actions and inspection actions. As a general observation, there is considerable repetitiveness in the PPL and its appendices (particularly in stating NRC internal procedures) whose removal would enhance the overall quality of the document.

In addition to these general suggested improvements, NEI has identified several editorial corrections and enhancements for PPL 1-82:

- for clarity and accuracy excerpts from 10 CFR 70.76 should be stated verbatim and without interpretive comments (e.g. Paragraph III(C))
- excerpts from NRC documents should be properly cited to enable their applicability and relevance to be established (e.g. list of factors in Appendix 5 are, in fact, excerpted from NMSS PPL 1-53)
- references to Part 76 backfitting should be included in addition to those for Part 50 licensees. (e.g. references 28 & 29 in Paragraph X)
- a single, unified flowchart of the backfit process is preferable to the three figures included in PPL 1-82
- clarification of several issues, such as the applicability of the NRC-OSHA MOU, is required. Although no reference to the term 'Item Relied On For Safety' (IROFS) is made in §70.76(a)(1), a majority of backfits will inevitably deal with IROFS as defined in a licensee's Integrated Safety Analysis (ISA) or NRC-approved ISA Summary. For clarity, NEI recommends that the PPL include references to IROFS.
- the staff's safety analysis of a proposed backfit will parallel the licensee's ISA analysis. Guidance on how the staff should conduct a risk-significant safety analysis should be provided
- instructions should be provided to the staff on how to solicit information from a licensee in support of a proposed backfit action (see proposed text in ¶V) and the limits in doing so
- Appendix 5 has been significantly expanded to provide guidance on qualitative and quantitative regulatory analysis for a backfit
- Appendix 6 has also been expanded to provide information on the components of a backfit and checklists (in the form of questions) to enable the PPL reader to easily evaluate the adequacy of a staff backfit
- Appendix 7 has been modified to include the 'informal resolution' option for backfit appeals

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- a new Appendix 8 is added that contains seven case studies in the areas of licensing actions (SRP, regulatory guides, backfit orders) and inspection and enforcement actions (inspections, NOV's, bulletins & generic letters, staff re-analysis) to assist the staff in determining when a backfit is warranted

The 45-page attachment to this letter contains a red-lined version of draft PPL 1-82 that identifies each of NEI's recommended improvements noted editorial corrections. (As this document had to be reconstructed from the NRC's PDF file referenced in the Federal Register notice, many incidental graphics and formatting have not been included.)

NEI commends the NRC for issuance of draft PPL 1-82. We believe the usefulness of this important guidance document could be enhanced through incorporation of the improvements suggested in this letter. NEI looks forward to working with the NRC to finalize this PPL and should be pleased to address any questions that you may have.

Sincerely,

A handwritten signature in cursive script, appearing to read "Felix M. Killar, Jr.", written in dark ink.

Felix M. Killar, Jr.

Attachment

**HIGHLIGHTED COMMENTS OF THE NUCLEAR ENERGY INSTITUTE
ON DRAFT PPL 1-82
(July 2003)**

**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. [Clarification: this last sentence should be clarified to address submission of partial ISA Summaries as permitted in §70.4. The Backfit Provision would apply to those portions of an existing facility whose process ISA Summaries had been approved by the NRC, even if approval of the facility's entire ISA Summary had not yet been granted.]

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). [Comment: suggest insertion of the following introductory statement: *"Backfitting provides a mechanism to evaluate whether a proposed regulatory action will substantially increase the overall protection of public health and safety and whether the costs of implementation can be justified in view of this substantial increase in protection. The backfit process focuses NRC resources on risk-significant facility and/or procedure changes that could yield further safety enhancements."*] The regulations in §70.76 govern the backfitting of new or modified requirements on Part 70 licensees. They require 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. [Comment: this PPL should also reference the backfitting guidance (and experience) for gaseous diffusion plants (10 CFR 76) and add two pertinent references in Section X.]

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" is defined in §70.76(a)(1) as "the modification of, or addition to systems, structures, components, or design of a facility, or the procedures or organization required to operate a facility, any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position". [Comments: (1) the last sentence of this paragraph fails to distinguish between the two types of backfit which are discussed in the balance of this PPL. Suggest replacement of this sentence with the following: "*Backfits may be applied to individual Part 70 licensed facilities ('facility-specific backfits') or to more than one such facility ('generic backfits')*". (2) to clarify an oversight in the drafting of Subpart H in which the very important term "Items Relied on For Safety (IROFS) was inadvertently omitted from §70.76(a)(1), the PPL should make a statement that the Backfit Provision applies to IROFS, as well as to other safety systems including systems, structures and components

The Backfit Provision applies equally to NRC consideration of all types of regulatory mechanisms including, for example, a proposed rule, a proposed generic communication, branch technical position, or any other regulatory mechanism sought to be used by the NRC staff to impose new requirements or to articulate a new NRC staff interpretation or position. Whether the potential regulatory action under consideration is recommended by the NRC, an NRC licensee, or a member of the public is immaterial. The discipline of the Backfit Provision applies, regardless of the initiating source. Changes to, or new staff positions relating to, other NRC regulations (e.g. Part 20) that affect Part 70 licensees are also covered by the Backfit Provision.

A proposed change may result from imposition of an applicable staff interpretation of NRC rules that is either new or different from a previously applicable staff position. For example, a change in staff position after an acceptance of a particular interpretation in a Safety Evaluation Report (SER) is a backfit.

An "applicable staff position" is one that has already been specifically imposed upon, or committed to by, a licensee at the time of identification of the backfit. "Applicable staff positions" include, for example:

- legal requirements (e.g. rules, regulations, orders issued in accordance with the Atomic Energy Act and the Administrative Procedure Act, plant licenses (amendments and conditions))
- written commitments (e.g. those reflected in the final SER for the ISA Summary, license commitments, docketed correspondence, responses to

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

generic letters, confirmatory action letters, responses to inspection reports, responses to Notices of Violation)

- NRC staff positions that are "documented, approved, explicit interpretations of the more general regulations" (e.g. Standard Review Plans (SRP), Branch Technical Positions, regulatory guides, generic letters, bulletins) "and to which a licensee or an applicant has previously committed or relied upon"

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 or approved in the 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 ISA Summary (for Subpart H requirements). [Comment: there may be many ISA Summaries submitted to the NRC for one licensed facility (see earlier comment in §1); recommend modifying language in this sentence for consistency and clarity.] 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 costs².

Policy and Procedures Letter 1-53 provides one other approach for justifying that a proposed backfit meets the "substantial increase" standard:

"[T]he 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 10 CFR 76.76..."³

[Comment: there are three criteria in §70.76(a)(3) that a backfit must meet: (1) 'substantial increase', (2) 'overall' protection of the public health and safety, and (3) 'justified costs'. For completeness we recommend including a comment on the meaning

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

³ NMSS Policy and Procedures Letter 1-53, Appendix 3, ¶3

of the term 'overall' and a much-expanded discussion of the cost calculations (see below).]

- E. Overall: Although a proposed backfit may increase the reliability of a specific IROFS or safety system, it may represent a minor increase in the overall protection of the public. The staff regulatory analysis requires evaluation of the proposed change as it affects the total facility – that is, the overall additional protection provided.
- F. Justified Cost: [Comment: inclusion in this set of backfit principles should be some references to the requirement of §70.76(a)(3) of justified costs.]

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.

PROCESS QUESTIONS?

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

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:

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, Item Relied on For Safety (IROFS), procedure, or organization required to operate a facility. [Comment: the following sentence appears redundant and could be deleted. This is the third time that the timing of a backfit is addressed.] 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.

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 evaluation⁴ 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.

[Comment: Some guidance should be provided to the staff on how information may be sought from a licensee in support of a backfit determination. NEI recommends addition of the following paragraph.]

The NRC may request from the licensee information to verify compliance with the current licensing basis for a Part 70 facility (e.g. license review, inspections, approval of license amendment, accident and incident investigation, review of a facility modification). There is no provision equivalent to 10 CFR 50.54(f) in 10 CFR 70 that requires the staff to explain its reasons and justifications for any other information requests and to obtain EDO approval prior to its issuance.

NMSS staff may submit requests to the licensee for information that is not part of routine license review, but only with the concurrence of the Fuel Cycle Safety and Safeguards (FCSS) Division Director and only with an accompanying explanation of what information is needed, how it will be used, an estimate of the costs for the licensee to develop responses and a schedule for NRC use of the information. Requiring NMSS staff to obtain FCSS approval for information requests related to a backfit consideration will ensure that the burden to be imposed upon the licensee is justified in view of the potential safety significance of the issue to be addressed in the requested information.

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 of 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.

⁴ The 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.

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 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 judgment 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

The Backfit Provision provides two exceptions where the regulatory action is necessary to provide the minimum level of "adequate protection" required by the Atomic Energy Act, or where it is necessary to bring a licensee's facility into compliance with its license, written commitments or the Commission's regulations (the so-called "compliance exception") [§70.76(a)(4)].

The NRC has established acceptable levels of radiological risk from plant operations and has developed regulatory practices to provide reasonable assurance that licensed facilities comply with the basic statutory standard of "adequate protection". "Adequate protection" simply means the plant operations should pose no undue risks to public health and safety and that the plant should operate in full compliance with the regulations.

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

[Comment: guidance should be provided for handling generic backfits. Suggest adding the following sentence: *"When a generic backfit is applicable to a facility of a given type, a licensee can request an exemption from the regulation due to facility-specific design considerations."*]

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

IX. IMPLEMENTATION OF BACKFITS

A. Normal Backfit Implementation

[Comment: correct the following sentence to present the three options available to the licensee.] 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 implement the decision, file a backfitting claim or appeal the decision (as previously discussed). If the licensee files a claim or appeal, it need not implement the staff position until completion of the staff's consideration and resolution of any subsequent appeals. If the licensee appeals and a final determination is made rejecting the appeal, the licensee may elect to implement the change or await an order from the NRC to do so. Further appeal from this point must conform to the appeal process described in 10 CFR Part 2.

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 [Clarification: recommend use of "PPL" rather than "letter" in this sentence, as the term "letter" is unreferenced and potentially confusing.] PPL, in time to be issued with the order, if at all possible⁵.

[Comment: recommend inclusion of two additional paragraphs in this Section IX. The first [¶C] provides guidance on interpretation of §70.76(c), and the second [¶ D] addresses the concept of 'tacit approval' which has been used in reactor licensing and backfitting.]

C. Impact of Backfitting on Licensing Action

The provisions of 10 CFR 70.76(c) deserve special mention. This section states: "No license will be withheld during the pendency of backfit analyses required by the Commission's rules." The intent of this provision is to prohibit the staff from delaying a licensing action and approval (issuance of initial license or license amendment, authorization to restart, etc.) when a backfitting claim or appeal is filed. Otherwise there would be a great disincentive for licensees to exercise their rights under the Backfit Provision. For this reason the NRC has emphasized that this provision is to be interpreted for Part 50 licensees in a broad context and should be applicable at each stage of the licensing process (construction, initial licensing, license amendments). The protections afforded by the Backfit Provision are stressed further by the NRC:

"If immediate imposition is not necessary, staff-proposed backfits shall not be imposed and plant construction, licensing action or operation 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 chapter."⁶

⁵ Once 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.

⁶ NRC Manual Chapter 0514, "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants."

In practice, questions involving 10 CFR 70.76(c) typically will arise in two situations. The first is where the NRC withholds action on a pending license amendment request in order to pursue another issue which the licensee believes is technically unrelated to the proposed amendment and may involve a backfit. In this situation 10 CFR 70.76(c) requires the staff to act on the pending license amendment if the amendment is separable from the potential backfitting issue. The second situation involving 10 CFR 70.76(c) is where the plant is shut down and the NRC raises a restart issue that the licensee believes is a backfit. Again, one can argue that 10 CFR 70.76(c) precludes the NRC from delaying restart in order to pursue a backfitting issue (unless immediate imposition is necessary for the minimum "adequate protection").

D. Tacit Approval and the Backfit Provision

The NRC generally recognizes the concept of "tacit approval" in situations where a licensee has proposed a program or course of action to satisfy an NRC requirement and the staff has not responded on a timely basis. Under the tacit approval concept, a backfit arises if the staff later objects to part of the licensee's program or other course of action. There is a need for stability in the regulatory process where a licensee's proposal has not received timely review, as well as the unfairness that would result were the staff to question a licensee's program after it had moved forward with implementation in reliance on the staff's inaction. How much time must elapse before the staff is deemed to have "tacitly approved" a licensee's action will depend upon the circumstances (e.g. the complexity of the program area). For Part 50 licensees, as a general rule or thumb, NRC staff representatives have suggested that two years are sufficient for the staff to review a licensee's proposal and to identify any objections. A lesser amount of time should suffice where the matter is comparatively simple – for example, a licensee's proposed schedule for implementing an action.

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.

X. REFERENCES

[Comment: (1) as noted earlier, recommend inclusion of two references pertaining to implementation of the Backfit provision for Gaseous Diffusion Plants. These are added as references 28 & 29, although they should be integrated into the other NRC references, and (2) for uniformity in the table of references (such as with references 5, 8, 14 & 15), add the date of publication of reference (1).]

- 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, 2001.
- 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 Effects," 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.
 - 28) U.S. Nuclear Regulatory Commission, "Policy and Procedures Letter 1-53, Gaseous Diffusion Plant Specific and Generic Backfit Management, etc.
 - 29) U.S. Nuclear Regulatory Commission, "Criteria for Staff Implementation of 'Backfitting' Requirements for Gaseous Diffusion Plants, 62 Fed. Reg. 14456 (March 26, 1997

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. April 2003 9 PPL 1-82

XI. FIGURES

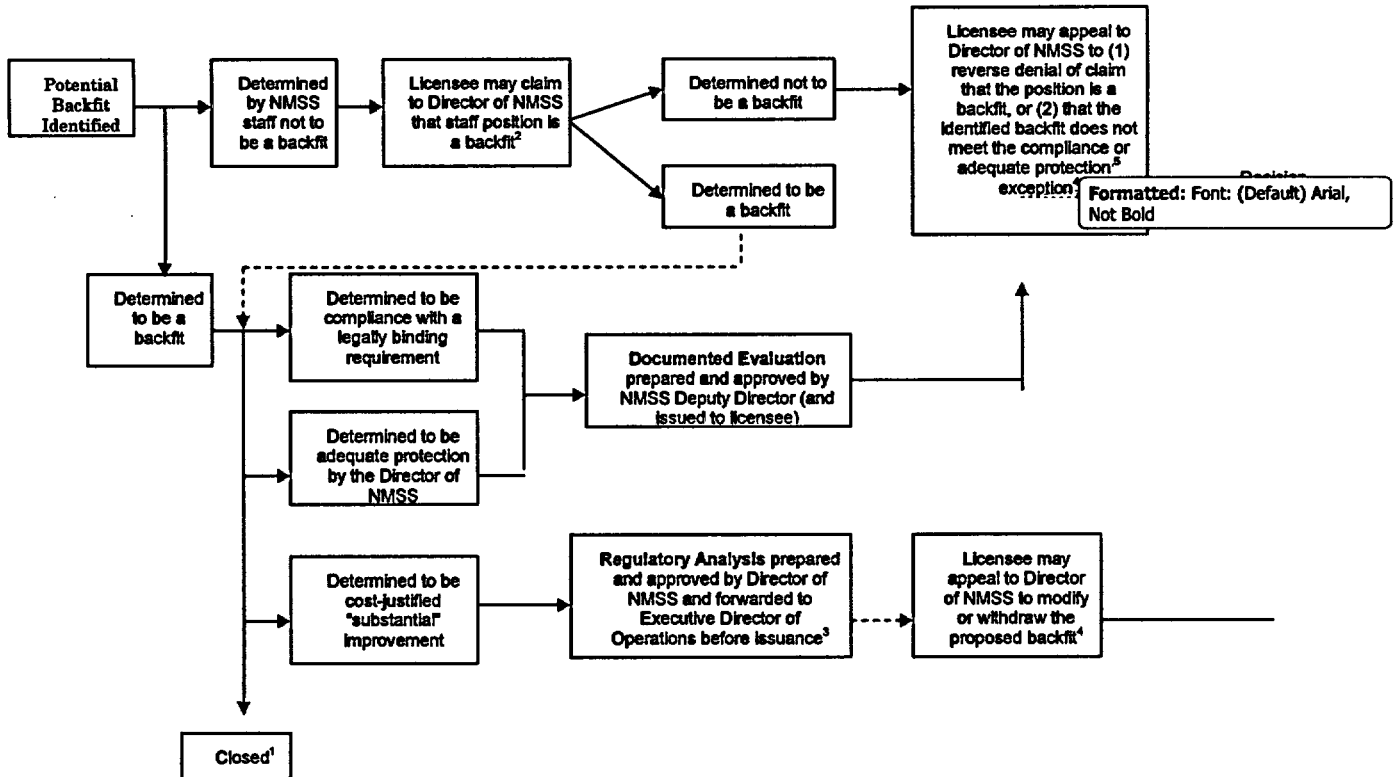
[Comment: use of three flowsheets seems somewhat unnecessary. Recommend use of a single flowchart as noted on the next page.]

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)

BACKFITTING FLOW DIAGRAM



- Notes:**
- 1: NMSS staff may decide the backfit is not likely to be justified and close the action
 - 2: Report to the Executive Director for Operations (EDO) and inform the licensee within 3 weeks. Also, place in the Public Document Room or ADAMS.
 - 3: Approval by the EDO before issuance is not required
 - 4: Copy to be sent to the EDO and placed in the PDR or ADAMS
 - 5: Report to EDO within 3 weeks of decision and inform licensee promptly. Also place in PDR and/or ADAMS.

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**
- 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**
- 8. Examples of Backfit Situations**

**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 Positions⁷**
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)

⁷ Documents 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. 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. [Comment: what is the meaning of the phrase "...to quell the backfit process..."? Surely the purpose is to foster reasoned assessment of backfit claims.] 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 [Comment: Clarification may be warranted to state that "meeting the intent of an SRP is not required by Part 70 regulations. An SRP simply provides one avenue to meet staff expectations.] 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 are 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)⁸. 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

⁸ For more information on this term, please see the definition given in 10 CFR 20.1003.

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 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 meet the regulatory requirements, 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.

[Comment: the cited example has been relocated to Appendix 8 with all other practical backfit examples.]

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:

Closing Action

Date Reg Analysis Sent:

Closing Action Date:

Closing Organization:

Closing Official:

Closing Action Description (Describe how technical aspects of issue were resolved):

APPENDIX 4: IDENTIFICATION OF BACKFIT - SUGGESTED NRC 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 Document 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 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. The NMSS Director should be consulted, in such cases, for resolution. [Comment: greater discussion of the referenced criteria would be appropriate here.]

BACKFIT VERSUS COMPLIANCE EXCEPTION

The licensee must ensure that the "compliance exception" [§70.76(a)(4)(i) & (ii)] is not inappropriately cited as the justification for imposition of a new regulatory requirement. The experience of Part 50 licensees has been that the compliance exception is frequently cited because neither of the other two criteria of the backfit rule – adequate protection or cost-justified substantial safety enhancement – can be satisfied for a new requirement or position that the NRC staff wants to adopt. In its justification to rely on the compliance exception, the NRC staff has pointed to a very broad statement in regulation, and has then argued that the proposed new agency position is meant to accomplish what the regulation has always intended.

Misuse of the compliance exception defeats the fundamental backfit policy which is to promote greater regulatory stability so as not to require licensees to continually update their facilities with any and all new developments or new ideas for improving the operation of their plants. The Part 70 Backfit Provision is structured to allow imposition of only those new requirements of NRC staff positions that offer substantial safety benefits for the costs involved in implementing the changes at existing facilities, unless required for adequate protection or compliance with existing regulatory requirements, the facility's license or written licensee commitments. If new positions are routinely imposed under exceptions to the Backfit Provision without the requisite cost-benefit analysis, the instability that led to the need for the Backfit Provision will be created again. As the Commission recognized when it promulgated the current backfitting rule for nuclear power plants in 1985, a proper cost-benefit analysis of proposed new initiatives will promote regulatory stability and overall safety by ensuring that only cost-justified, substantial safety enhancements are mandated and that they are assigned a proper priority and scheduled for action in view of existing licensee activities.

The Commission's discussion of the compliance exception to the backfit rule provides clear guidance relevant to the intent of the Backfit provision:

The compliance exception is intended to address a situation in which the licensee has failed to meet known and established standards of the Commission because of omission or mistake of fact. It should be noted that new or modified interpretations of what constitutes compliance would not

fall within the exception and would require backfit analysis and application of the standard.⁹

The compliance exception is intended to address situations in which a licensee has not met explicit requirements. It is not intended, for example, to allow the NRC staff to require that licensees use new technology as it becomes available to demonstrate compliance with an existing NRC regulation. In a similar vein, the NRC can not invoke the compliance provision to implement new regulatory methodologies that the NRC subsequently deems necessary to satisfy a broad standard. It cannot be appropriately cited to compel a licensee to comply with a new regulatory position or a new interpretation of what a previously adopted regulation requires or intended.

⁹ 50 Fed. Reg. at 38103 (emphasis added)

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

[Comment: This Appendix 5 needs to provide more guidance on the appropriateness of different approaches to performing the cost-benefit analysis. NEI recommends inclusion of separate sections that address the merits of use of 'qualitative,' 'quantitative' and 'mixed' approaches. Commission guidance and NRC experience with GDP backfitting should also be referenced. Rule and document citations should (again) be made with greater accuracy.]

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 the public health and safety or the common defense and security to be derived from the backfit, and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection" (10 CFR 70.76(a)(3)).

Quantitative versus Qualitative Approaches

The NRC staff must establish what type of regulatory analysis – quantitative, qualitative or a combination of both – is adequate to demonstrate that a generic safety problem actually exists and that the proposed backfit will both address the problem effectively and provide a "substantial" safety improvement in a cost-beneficial manner. The costs and benefits of a proposed regulatory action must be expressed on a common basis to enable their comparison. Such comparisons of, for example, the expected risk reductions resulting from the proposed backfit or changes in the anticipated regulatory burden to the licensee are the key to successful backfit analysis.

NRC experience with backfitting has been primarily acquired for Part 50 licensees. For such Part 50 licensees a quantitative approach is used for the regulatory analysis. Nuclear reactors benefit from the use of Probabilistic Risk Analysis (PRA) which can be used to quantify the risk reduction and corresponding quantitative benefits and costs of a proposed new requirement. But even for facilities with comprehensive PRAs, certain parameters cannot be unequivocally forecast without controversy (e.g. off-site and on-site "averted costs" – that is, the costs that could conceivably be avoided by implementing the change and avoiding possible accidents).

Part 70 facilities, in contrast, are generally not amenable to quantitative risk assessment. Risk assessments, such as used in conducting the ISA, are primarily based on engineering or regulatory judgement or qualitative analysis. Estimation of risk reduction and its costs and benefits must, therefore, rely more on qualitative analysis. Such qualitative analyses will be inherently subjective, will rely on simple models to provide some quantitative perspective or insight on the nature or magnitude of the risk, and typically will have broad, but hopefully meaningful, uncertainty limits. Costs for certain backfit changes can be easily established (e.g. the cost for additional plant insurance, added labor cost to implement a process fire watch, increased Part 171 costs for NRC monitoring of change implementation). Other costs and benefits can not be quantified with any level of confidence (e.g. the benefit of increased protection by using a passive-engineered IROFS rather than an administrative IROFS, benefits from an improved emergency preparedness program, benefits from reducing an occupational radiation exposure limit in a process area). For these reasons, a Part 70 backfit regulatory analysis will primarily be qualitative in nature.

Quantitative Approach

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 exposures¹⁰, 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.

Use of a purely a qualitative standard is not consistent with NUREG/BR-0058, nor does it place a sufficiently high burden on the staff to justify a finding that a proposed backfit will meet the "substantial increase" requirement. Throughout NUREG/BR-0058 the Staff asserts that quantitative analyses are much preferred over qualitative ones, even if values and impacts can not be expressed in "monetary" terms (i.e. \$2,000 per person-rem value for change impacts). In particular, NUREG/BR-0058 (Rev. 2) (pp. 20-21) states:

- "estimated values and impacts should be expressed in monetary terms whenever possible"
- "consequences that cannot be expressed in monetary terms should be...quantified in appropriate units to the extent possible"
- "[for materials licensees] the staff needs to make every reasonable effort to apply alternative tools that can provide a quantitative perspective ...concerning the value of the proposed action"
- "even inexact quantification with large uncertainties is preferable to no quantification"
- "[where PRAs or other statistics-based analyses are not available] the generally recommended approach is to utilize whatever data may be available within a simplified model to provide some quantitative perspective"
- "[where quantification is not possible] reliance on the qualitative approach should be a last resort, to be used only after efforts to develop pertinent data or factual information have proved unsuccessful", and
- "certain issues, such as those involving emergency preparedness, security, and personnel requirements, tend to fall into [the] category [of issues requiring qualitative analyses]"

Compliance with provisions of the 10 CFR 70.76 Backfit Provision requires use of quantitative data. In four instances cost data are required (emphasis added):

- "...direct and indirect costs of implementation [must be justified]..." [§70.76(a)(3)]

¹⁰ The 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, 1988, pp 43950-43951.

- in the event of multiple ways to achieve compliance, "...cost may be a factor in selecting the way..." [§70.76(a)(7)]
- "...installation and continuing costs associated with the backfit [is information relevant to the proposed backfit]..." [§70.76(b)(5)]
- "...cost of facility downtime [is information relevant to the proposed backfit]..." [§70.76(b)(5)]

Consequently, a Part 70 backfit regulatory analysis can not totally avoid consideration of quantitative data (e.g. monetary costs).

Qualitative Approach

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.

NRC staff has proposed use of a qualitative backfit provision on several occasions. For example, referring to a Part 70 backfit provision SECY-97-137 states: *"Staff proposes that a qualitative 'backfit' mechanism...be considered..."*¹¹

NRC staff also proposed adopting a "qualitative" backfit standard in connection with the certification of GDPs. The staff proposed to use a *"qualitative non-monetary methodology to derive the safety/safeguards benefit..."*¹² under the 10 CFR 76.76 backfit provision.

The NRC staff continues to favor the "qualitative" backfit approach for Part 70 facilities and recommends adoption of a "net benefits" approach that involves *"...the use of a qualitative non-monetary methodology to derive the value of the safety/safeguards improvement, taking into consideration the specific facility hazards"*¹³.

Finally, the Commissioners provided some guidance to the staff in developing implementing guidance for the Part 70 Backfit Provision by stating that *"...staff should develop guidance to make clear that an adequate demonstration can be based on quantitative or qualitative evaluations of the nature of the increase in the overall health and safety protection of the public..."*¹⁴.

Compromise Approach – Maximize Use of Quantitative Data

The staff should use quantitative analyses to the maximum extent possible, consistent with existing guidelines in NUREG/BR-0058. Estimation of the costs and benefits of the change and the choice of a preferred alternative can only be facilitated through maximum use of available

¹¹ SECY-97-137, Attachment 1, Page 11

¹² 62 Fed. Reg. 14456, Appendix 3 (March 26, 1997)

¹³ SECY-00-0111, Appendix 8, Item 2, p. 2 (May 19, 1997)

¹⁴ SRM 000725 (July 25, 2000)

quantitative (e.g. monetary) data derived from available models, reasonable assumptions and passed practices.

A purely qualitative approach, while inherently appealing in view of the difficulty in applying quantitative risk analysis to Part 70 facilities, introduces considerable subjectivity into the backfit regulatory analysis. Disagreements between the NRC and licensee will be inevitable as honest differences arise both in the professional opinions of safety specialists evaluating the risk reduction of a proposed change and preparing a cost-benefit analysis of the change. For a licensee to contest a purely qualitative staff backfit regulatory analysis, "quantification" of the regulatory analysis may be the only alternative available to the licensee. For example, the licensee may be obliged to estimate – even on an order-of-magnitude basis – the benefits and costs of the backfit to defend against the conclusions of a purely subjective staff assessment. While some impacts can only be qualitatively presented, the licensee may have to develop reasonable, monetary data to demonstrate, for example, that the implementation costs for the proposed backfit are exorbitant and unjustifiable in view of the safety benefits that could be realized.

NRC should not rely on purely qualitative backfit regulatory analyses for controversial changes that could otherwise not be defended by means of a rigorous quantitative analysis, especially if quantitative, monetary data could be reasonably developed. Obliging a licensee by default to prepare a quantitative analysis to refute the claims and assertions of a staff qualitative backfit regulatory analysis runs counter to the basic premise of the Backfit Provision – that the onus lies on the staff to identify the need for a change and to develop convincing arguments for its implementation in a cost effective manner.

Qualitative backfit mechanisms must not be used as a crutch to avoid the more arduous task of developing a sound, defensible, quantifiable, cost-benefit analysis for a proposed backfit.

Additional factors may be used to assess the "substantial increase" in safety/safeguards of a proposed modification or backfit from NMSS Policy and Procedures Letter 1-53. 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.

Policy and Procedures Letter 1-53 provides one other approach for justifying that a proposed backfit meets the "substantial increase" standard:

" [T]he 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 10 CFR 76.76..."¹⁵

¹⁵ NMSS Policy and Procedures Letter 1-53, Appendix 3, ¶3

APPENDIX 6: BACKFIT ANALYSIS AND DOCUMENTED EVALUATION - SUGGESTED PROCEDURE

[Comment: This Appendix lays out internal NRC procedures for handling a backfitting action. For balance, it should definitely include procedures (and checklists) for conducting a documented evaluation. Appendix 6 could be improved by offering specific guidance on how the staff should actually perform the supporting analyses for the backfitting action. NEI recommends addition of an introductory section on the mechanics of backfit analysis. The NRC internal procedures could either be left as a separate, second part of this Appendix. Reformatting the Appendix into 3 sections ('Backfit Analysis', 'Documented Evaluation', 'NRC Internal Procedures' is recommended.]

A. Backfit Analysis

Components of a Backfit Analysis

This section outlines the core elements of a backfit analysis and a list of questions that may be useful in evaluating the adequacy and thoroughness of a backfit analysis performed by the NRC staff. A backfit analysis addresses three issues:

- the backfit results in a "substantial" safety improvement
- the backfit can be implemented in a cost-beneficial manner (i.e. safety benefits clearly justify costs)
- the backfit provides an increase in the overall protection of health and safety

The backfit analysis should include the following six elements:

- (1) **Problem Identification**: statement of the problem within the current regulatory framework that needs correction. How did the problem develop and why is corrective action needed? Is this a risk-significant issue?

Note: If the requested modification is being initiated for adequate protection or compliance and not as a safety enhancement, a documented evaluation" rather than a backfit analysis is needed.

- (2) **Problem Resolution Alternatives**: identification of reasonable alternatives that could be used to resolve the problem.

Note: Alternatives should be performance-based and in agreement with the Part 70 regulatory revisions. Alternatives that are technologically impractical, exorbitantly expensive or difficult to implement can be eliminated at this stage of the backfit analysis.

- (3) **Cost and Benefit Analysis**: the costs and benefits of each feasible alternative should be evaluated in as quantitative manner as possible.

Benefits may include: (i) enhancements to health and safety, (ii) protection of the environment (iii) reductions in public and occupational radiation exposure, (iv) savings to licensee and/or NRC, (v) reductions in safeguards risks, (vi) averted onsite impacts.

Costs may include: (i) costs to the licensee to implement, operate and comply with the change, (ii) costs to the NRC and Agreement states to administer the change, (iii) adverse effects on health and safety, and (iv) increases in Part 171 fees.

Estimates of benefits and costs for each alternative should be at an appropriate level of detail commensurate with the uncertainties in the approach and methods of analysis. They must justify the anticipated regulatory burden. Based on the availability of data, the analysis may be primarily qualitative (with greater subjectivity, imprecision and uncertainty) or more quantitative. As recommended in NUREG/BR-0058, quantitative cost and benefit data should be expressed on a common basis using conversion factors that reflect the monetary worth of a unit of radiation exposure (e.g. the \$2,000 per person-rem is recommended in NUREG/BR-0058) and on a present-worth basis.

- (4) **Conclusions Based on Evaluation of Costs and Benefits:** cost-effectiveness analysis and ranking of alternatives.
- (5) **Selection of Proposed Regulatory Action:** why the proposed action is recommended over other alternatives. Identification of decision criteria (e.g. net value, relative importance of attributes of non-quantifiable attributes, impacts on existing NRC programs) and demonstration that the "substantial" criterion is met.
- (6) **Implementation:** schedule for implementing the proposed action (in order of safety significance) and identification of the proposed NRC instrument for implementation (e.g. rule, regulatory guide, BTP).

Satisfaction of the three backfitting principles can be demonstrated by addressing the following issues:

(1) Meeting the "Substantial Increase" Standard

- Has the staff demonstrated that the proposed backfit will result in a "substantial increase" in the overall protection of the public health and safety or the common defense and security?
- Is the increase in protection large, important or significant?

(2) Meeting the "Overall Protection" Standard

- Does the increased protection flow from overall plant operation or from the improved functioning of an individual IROFS, systems, structure, component, procedure or organization?

Note: An improvement in one system may not represent a substantial increase in overall plant safety, particularly if there are adverse effects for plant design or operation.

(3) Meeting the "Justified Cost" Standard

- Are the direct and indirect costs of implementing the backfit justified in view of the increased protection?

Note: While the backfitting rule does not require the preparation of a strict cost-benefit analysis for either generic or plant-specific issues, it does require a disciplined analysis of the expected costs and benefits. The ultimate decision regarding imposition of a backfit need not be based solely on a cost-benefit analysis. Rather, it may rest on best engineering judgement given all of the available information. In all cases the NRC is required to document its basis for imposing the backfit.

Some measures against which the overall adequacy of a backfit analysis can be judged follow:

1. Has the staff considered accurately and adequately the applicable factors identified in the rule?
2. Will the backfit achieve its stated objectives?
3. Did the staff identify all major licensee activities triggered by the backfit?
4. Are all employee radiation exposure impacts identified correctly?
5. Are all of the direct and indirect costs of implementation identified correctly? For example, has the NRC considered the long-term continuing costs of the backfit (e.g. additional engineering support)?
6. Has the increase in plant complexity as a result of the backfit been adequately addressed?
7. Is the NRC resource burden estimate reasonable?

Note: The cost of NRC review may be passed on to the licensee as a Part 171 annual fee.

8. If the backfit is interim, is there a valid justification for its imposition?
9. Is the priority of the backfit assigned by the NRC staff reasonable considering other ongoing regulatory activities at the facility?
10. Are there any other material factors that might make a backfit unnecessary?

Note: The NRC staff is to consider all factors that are relevant and material to the proposed backfit. For example, an NRC-initiated backfit may interfere with other ongoing or planned work at a facility. If the staff has not adequately considered the priorities, the licensee may point this out.

B. Documented Evaluation

NRC staff will conduct a documented evaluation to either achieve regulatory compliance or to achieve adequate protection. Checklists of issues that each should be addressed for each case follow:

Backfit Imposed to Achieve Compliance

1. Did the NRC staff correctly identify a requirement applicable to the facility?
2. Did the staff properly conclude that this requirement was not satisfied? Is the staff's interpretation of the requirement correct? Is it new or different from a previous interpretation?
3. Did the staff (in an SER or otherwise) previously find the facility in compliance with the requirement?
4. Will achievement of the objectives of the backfitting the facility into compliance with this requirement?
5. Is the proposed backfit going to accomplish the objective identified by the staff?
6. Is there any evidence that alternate designs or means of satisfying the requirement have been considered?

Backfit Imposed to Achieve Adequate Protection

1. Did the NRC staff correctly find that the facility will not provide "adequate protection" without imposition of the backfit?
2. Will achievement of the backfit restore adequate protection and resolve the undue risk identified by the staff?
3. Is there evidence that alternate designs or means of restoring "adequate protection" have been considered?

B. NRC Internal Backfit Procedure Checklist

The following internal procedures should be followed by the NRC staff in preparing for a backfit analysis.

- A. 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.
- B. Generally describe the activity that would be required by the licensee in order to complete the backfit.
- C. 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. [Comment: references should be made to the ISA and ISA Summary in this point. The licensee or the NRC will have to conduct an updated ISA or equivalent safety analysis to establish this.]
- D. State whether the proposed backfit is interim or final and, if interim, justify imposing the proposed backfit on an interim basis.
- E. 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. [Comment: an ISA will be required.] This statement should include consideration of at least the following factors:
- i. The potential change in risk to the public from the accidental offsite release of radioactive material.
 - ii. 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. [Comment: the preceding sentence is far too definitive and does not properly interpret the OSHA MOU. Bulk chemical stored on the licensed facility land, but which could not impact the safety of radioactive materials would not be subject to NRC oversight.] 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.
 - iii. The installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay.
 - iv. The estimated resource burden on the NRC associated with the proposed backfit and the availability of these resources.
- F. 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.
- G. Prepare a statement affirming interoffice (e.g. regions if needed) coordination related to the proposed backfit and the plan for its implementation.
- H. 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.
- I. Establish a schedule for staff actions involved in the implementation and verifying the implementation of the backfit, as appropriate.

- J. Determine the importance of the proposed backfit activities considered in light of other safety/safeguards-related activities underway at the affected facility.
- K. Consider whether the proposed facility-specific backfit is, or could be, a potential generic backfit.

APPENDIX 7: APPEAL PROCESS - SUGGESTED PROCEDURES

[Comment: For completeness, this PPL should also mention the desirability of resolving backfit disputes through informal procedures. NEI recommends addition of a third section of this Appendix.]

For resolution of backfit issues and disagreements with staff positions, a licensee may make use of formal claim and appeal procedures. Alternatively, informal discussions with the staff may prove most expedient for resolving such matters.

I. *Informal Resolution of Backfit Issues*

NRC management and Part 50 licensees have found that one of the most efficient ways to use the 10 CFR 50.109 rule is to do so informally (e.g. during meetings and discussions with the staff on technical issues, during inspections, etc.). In this way potential backfitting issues can be discussed and possibly resolved without resort to a written claim or appeal. An identical informal approach should also be used by Part 70 licensees.

Before written appeals are generated, the NMSS staff and licensee should attempt to resolve potential backfitting issues through informal discussions. Licensees should not be reluctant to discuss potential backfitting issues openly with the staff, and the staff should not resent it when a licensee does so. Open communications on a potential backfitting issue can help ensure that the respective positions of the staff and licensee are properly understood so that resolution of issues can be achieved short of a written appeal.

II. *Backfit Appeal Process*

When a proposed staff position has not been identified as a backfit by the staff, the licensee may file a written claim with the Director of NMSS (with copies to the FCSS Division Director and the EDO) that the staff position should be classified as a backfit. This claim of backfit, which should be filed within 60 days of receipt of an NRC Notice of Backfitting, should provide the licensee's arguments for why the staff's position constitutes a backfit. The claim should show how the staff position goes beyond existing regulatory requirements and applicable staff positions. A denial of the licensee's claim may be appealed to successively higher levels of NRC management as described in §4.3 below.

(a) APPEAL TO MODIFY OR WITHDRAW A BACKFIT

This appeal is made to the Director of NMSS to modify or withdraw a proposed backfit which has been identified, and for which a Backfit Regulatory Analysis has been prepared and transmitted to the licensee. The appeal may also be made to implement the backfit in a less burdensome that dictated by the NRC. A licensee's appeal should provide arguments against the rationale for imposing the backfit as presented in the staff's backfitting analysis. The decision of the Director of NMSS on an appeal of a facility-specific backfit may be appealed further to the EDO unless resolution is achieved at a lower management level. The EDO is required to resolve the appeal promptly and must state his reasons therefor. Summaries of all appeal meetings must be prepared promptly, provided to the licensee and made publicly available.

During the appeal process primary consideration must 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 backfitting regulatory analysis as well as any other information that is relevant and material to the proposed backfit. In short, this type of appeal involves a challenge to the merits of the staff's underlying analysis and justification for the backfit.

The following procedures should be followed to appeal or modify 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 plans.

- 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.

(b) APPEAL TO REVERSE DENIAL OF A LICENSEE CLAIM

[Comment: for consistency in the PPL the title of this section (b) should be modified as shown.]

This type of claim is made to the Director of NMSS to reverse a denial of a prior license claim either that a staff position, not identified by the NRC as a backfit, is one, or that a backfit that the staff believes falls within one of the exceptions from the requirement for a regulatory analysis does not come within such an exception.

This type of appeal should generally be addressed to, and will be decided by, the director of the program office having responsibility for the program area relevant to the staff position or the Director of NMSS. A copy of the appeal should also be sent 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 may review and may modify a decision either at his own initiative or at the request of the licensee. Backfit claims and resultant staff determinations that are reevaluated in response to an appeal, and that are determined by the NRC not to be backfits, or are excepted from the requirement for a backfit regulatory analysis, are not to be treated further.

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.

APPENDIX 8: EXAMPLES OF BACKFIT SITUATIONS

This appendix presents seven examples of regulatory activities in the two general areas of 'licensing actions' and 'inspection and enforcement.' Each example includes an analysis of whether the action should be considered a backfit. As in any situation of this nature, judgment will play a role in the final determination. However, there are specific regulatory documents and positions that should be considered in making that judgment.

A facility-specific backfit is a change from an already established practice for complying with an applicable requirement. An "applicable requirement" is defined as one from the body of requirements established before certain defined milestones in the facility's operating history are met. If the NRC staff requests or directs a change to the design, construction or operation of a facility, this is not a backfit. A suggestion asking a licensee to consider a proposed action may not be a backfit.

Actions proposed by a licensee are not backfits. Even if the change or addition meets the definition of backfit and arises from an information exchange between the licensee and staff, it is not a backfit. The critical element is the imposition of a change in any way by the staff that would force the licensee to change the operation of its facility or to make modification(s).

I. Licensing Actions

Standard Review Plan (SRP)

An SRP delineates the scope and depth of staff review of licensee submittals associated with various licensing activities. It is a definitive NRC staff interpretation of measures that, if taken, will satisfy the requirements of legally binding regulations, primarily found in Title 10 CFR.

The SRP is not a substitute for regulations and compliance is not a requirement.

Questions intended only to enable staff understanding of proposed actions, in order to determine whether the actions will meet the intent of the SRP are not a backfit.

Acceptance criteria that appear more stringent than those contained in the SRP or that are in addition to those specified in the SRP, whether in writing or verbal, are backfits. Actions volunteered by a licensee that exceed the SRP acceptance criteria generally do not constitute facility-specific backfits. However, if staff implies or states that a specific action in excess of already applicable requirements is the only way for the staff to be satisfied, the action is a facility-specific backfit.

Application of an SRP to an operating plant after the license is granted constitutes a backfit unless the SRP was approved specifically for operating plant implementation and is applicable to such operating plant. However, in order to issue an amendment to a license, the staff must reach a current finding of compliance with regulations applicable to the amendment. Review to new SRP revisions is not permitted to determine current compliance with regulations. For example, use of a new process control system constitutes a clear advance in design and operation that may warrant review against the criteria used to approve the initial license issuance. This is not considered a backfit. (Such review to newer SRP revisions is not necessarily required to determine current compliance with regulations.)

Licensees should assure that revisions in plant design, operation or modification that may affect the margin of safety are reviewed by reanalysis of the same accident sequences and associated assumptions as analyzed in the ISA and reported in the ISA Summary and as approved in the SER for the Initial license issuance.

SRP COMPLIANCE EXAMPLE

Issue: NUREG-1520, the Part 70 SRP, directs an analysis to be performed in a particular fashion. However due to changes in technology and state-of-the-art knowledge, the licensee performs a different analysis which the licensee believes will meet the 'Acceptance Criteria' of the SRP. Upon receipt of the licensee's analysis the staff has no procedures or comparable analytical tools to evaluate the analysis. Thus, the staff took the position that they would not evaluate the analysis because it is not consistent with the SRP. They requested the licensee to perform the analysis according to the SRP methodology based on the reasoning that no backfit is required (since it was in the SRP initially). Is this a backfit?

Resolution: Yes. 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 the change in position that the SRP is now a requirement (even though the licensee's analysis demonstrates conformance with the regulations called out in the SRP and thereby fulfills the regulatory purpose).

The licensee should file a backfit claim in accordance with 10 CFR 70.76.

Regulatory Guides

A proposal by the NRC staff to implement a Regulatory Guide provision for a facility that is not encompassed by the generic implication determination is a facility-specific backfit. A staff action with respect to a specific licensee that expands upon, adds to, or modifies a generically approved regulatory guide, such that the position taken is more demanding than intended in the generic positions, is a facility-specific backfit.

Backfit Orders

An order issued to a licensee to take actions that are not otherwise applicable requirement is a facility-specific backfit. An order causing prompt imposition of a backfit may be issued prior to completing any of the procedures set forth in the rule provided that the Director of NMSS determines that prompt imposition is necessary and a justification for prompt imposition is approved.

An order issued to confirm commitments to take specific actions, even if the action is in excess of previously applicable requirements, is not a facility-specific backfit, provided the commitment was

not obtained by the staff as the only alternative in order to gain staff approval. Discussion or comments by the NRC staff identifying deficiencies observed, whether in meetings or in written reports, do not constitute requirements and thus, are generally not backfits. Definitive statements directing specific actions to satisfy staff positions are backfits unless the action is explicitly an already applicable requirement for the facility in question.

REGULATORY GUIDE COMPLIANCE EXAMPLE

Issue: The licensee commits to meet the provisions of Reg. Guide 8.10, "*Operating Philosophy for Maintaining Occupational Radiation Exposures as Low As Reasonably Achievable*." As part of Reg. Guide 8.10 compliance, the licensee commits to provide adequate equipment and supplies for radiation protection and to maintain them, and any equipment designated as an IROFS, in good working order. After several years of operation the staff recommends replacement of certain radiation protection equipment with newer technology and that applicable operating and maintenance procedures be updated. The NRC contends that the original commitment to Reg. Guide 8.10 requires use by the licensee of any equipment and supplies that can reduce occupational exposures at a reasonable cost. By not endorsing use of the modern technologies, the NRC claims the licensee is meeting neither its license commitment nor ALARA goals as best as could be expected. Is this a backfit?

Resolution: Yes. The facility has not degraded its original ALARA commitment and the original level of safety is still present. More modern technology may facilitate achievement of ALARA, but the cost-effectiveness of its installation and operation may not justify its selection. The licensee must file a backfit claim.

ORDER EXAMPLE

Issue: In a written response to an NRC request, a licensee commits to install certain plant modifications to reduce the risks posed by electrical power interruptions. The staff then issues an order confirming this commitment, and in the order, directs the licensee to adopt specific technical provisions relating to the modifications. Does the order constitute a backfit in whole or in part?

Resolution: That part of the order that confirms the licensee's commitment is not a backfit. However, to the extent the order went beyond the licensee's commitment and directed adoption of specific technical provisions, it does constitute a backfit.

Because the backfit was imposed by order, the licensee would generally have to follow the procedures on 10 CFR Part 2 and request a hearing. However, in practice, the licensee should consider filing a written request with the staff (essentially a backfit claim) to reconsider the order based on the backfitting implications of the directive to add the prescriptive technical details.

II. Inspection and Enforcement

Inspections

NRC inspection procedures govern the scope and depth of staff inspection of activities such as operation, repair or modification. They define those items the staff is to consider in its determination of whether the licensee is conducting activities in a safe manner. The conduct of an inspection establishes no new requirements and is not a facility-specific backfit.

Staff interpretation that the contents of an NRC inspection procedure are positions that must be met by the licensee constitutes a facility-specific backfit. Discussion or comments by an inspector regarding deficiencies observed in the conduct of the inspection, whether in meetings or in written inspection reports, do not constitute requirements. Staff requests that specific actions be taken as a result of inspections, where those actions are different from ones previously taken, are backfits (assuming previous compliance). Discussion of inspector comments in technical areas wherein prior NRC requirements or licensee commitments do not exist are not regulatory requirements. If, during such discussions, the licensee elects to take actions in response to the inspector's comments, these are done at the licensee's initiative and, therefore, are not a backfit, provided the inspector does not indicate that the specific actions are the only way to resolve a particular issue. If the inspector indicates that a specific action must be taken, such action is a backfit unless the measure is remedial for compliance with an existing requirement.

For example, if the licensee has committed to ANSI/ANS-8.1 (*Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors*) and the inspector finds that implementing procedures do not contain all of the elements required by ANSI/ANS-8.1, direction from the staff that all these elements must be included in the implementing procedures is not a backfit. If an inspector finds all the required elements of ANSI/ANS-8.1 are included, but certain of the optional elements are not in the implementing procedures and he indicates that the implementing procedures must include any or all of the optional elements, this is a backfit whether or not the licensee agrees to include these elements. 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.

Notice of Violation

A Notice of Violation (NOV) requesting description of proposed corrective actions is not a backfit. Commitments by the licensee in the description of corrective actions to be taken are not backfits. A request by the staff to consider some specific action in response to a NOV is not a backfit. However, if the staff is not satisfied with the proposed corrective actions and requests alternate or additional actions, those requested actions, whether requested orally or in writing, are backfits.

Discussions during enforcement conferences in response to requests for advice regarding corrective actions are not backfits. However, definitive statements directing specific actions to satisfy the staff are backfits.

INSPECTION VIOLATION EXAMPLE

Issue: Assume that during an inspection the NRC inspector notes repeated instances in which a plant effluent stream has been analyzed to contain elevated radionuclide concentrations. Although the concentrations do not exceed the 10 CFR 20 Appendix B discharge limits, the inspector states that the licensee must conduct more frequent analyses of the effluent and leak testing of containment isolation valves on certain uranyl nitrate storage tanks which are believed to be the source of the contamination. One of the licensee's managers agrees to do so. The inspector then documents this agreement in the Inspection Report. Is this a backfit?

Resolution: This would represent a potential backfit in that the inspector had directed a specific type of corrective action (accelerated testing and surveillance maintenance). If an inspector imposes a new interpretation of the regulations or indicates that a specific corrective action is the only way to satisfy the staff, a backfit arises. In this example the NRC might well take the position that the licensee waived its backfitting rights by making a voluntary commitment. This example points up the need for the licensee to have controls in place concerning authority to make commitments on its behalf. Otherwise backfitting protection can be eroded by unauthorized "commitments" during inspections.

A NOV may constitute a backfit if it reflects the imposition of a new staff position. More specifically, if the alleged violation goes beyond what is explicitly required by the underlying regulatory requirement, this is a plant-specific backfit. However, as a general rule, the licensee's recourse to challenge a perceived backfit imposed by a NOV is not through the Backfit Provision claim or appeal process, but rather through the normal enforcement process. Thus, in response to a NOV the licensee may argue that the alleged violation goes beyond regulatory requirements and hence represents a backfit.

NOTICE OF VIOLATION EXAMPLE

Issue: A licensee receives a NOV based on a finding that a change was made to an IROFS under 10 CFR 70.72 in a manner that did not address equivalent replacement of its safety function. The licensee removed an administrative control (not listed in the ISA Summary) from a process but retained double contingency through continued use of engineered safety controls. The licensee thereby did not compromise its license commitment to maintain double contingency protection and did not materially reduce the process's margin of safety. Is this NOV a backfit?

Resolution: The NOV constitutes a backfit. As the alleged violation goes beyond the specific regulatory requirements, the NOV represents imposition of a new staff position (need for greater protection than double contingency specified in the Reg. Guide). The licensee should file a response to the NOV (as is called for in the normal enforcement process) and contest in that response the alleged violation on the grounds that it goes beyond existing requirements, and thus is a backfit.

Bulletins and Generic Letters

Bulletins and Generic Letters are *not* requirements and a licensee is free to take whatever actions he believes are appropriate. However, it is generally useful to provide the staff justification for cases in which a staff-recommended action or schedule will not be followed. If the NMSS staff expands the actions requested by a Bulletin or Generic Letter during its application to a specific facility, such expansion is considered a backfit and would have to be justified in accordance with applicable plant-specific backfitting procedures.

The staff does not need to apply the plant-specific backfit process to the actions requested in a bulletin or generic letter, as these documents are issued after generic backfitting reviews. However, if the staff expands the action requested by a bulletin or generic letter during its application, such action is a backfit. In addition, if the staff is not satisfied with a licensee's response (and commitments) to a bulletin or generic letter, the staff may be required to follow the plant-specific backfitting process to direct (i.e. by order) further specific actions by the licensee. In this connection, where a particular plant falls outside the "envelope" of the generic backfitting analysis prepared for the bulletin or generic letter, the licensee may point this out as justification for why the recommended actions are not justified for its plant.

BULLETIN AND GENERIC LETTER EXAMPLE

Issue: Assume the staff issues a generic letter requesting all operating plants east of the Rocky Mountains to conduct a review of the seismic design of safety-related systems in light of new data on the magnitude of seismic hazards for eastern plants. A generic backfitting analysis was performed to justify the generic letter. A licensee whose plant is located in the Atlantic piedmont in an area of low seismicity does not believe such a review is justified for its facility. What action should the licensee take?

Resolution: In response to the generic letter the licensee may indicate its position that such a review is not warranted for its facility and explain its technical basis for the position. If the staff does not accept the licensee's position and requests that the review be conducted, the licensee may submit a plant-specific backfitting appeal or present an informal appeal (e.g. request a meeting with the staff to explain the basis for its position). Before the staff may direct specific action by the licensee, the licensee should be able to insist that a plant-specific backfitting analysis be performed to justify the action for its facility.

Staff Re-analysis of Positions

Throughout the lifetime of a Part 70 facility many NMSS staff members have an opportunity to review the requirements and commitments applicable to a licensee. Undoubtedly, there will be occasions when a reviewer concludes that a previously NRC-approved program in a specific area does not satisfy a regulation, a license condition, compliance plan or a commitment. If the staff previously accepted the program as adequate, any staff-specified change in the program is a backfit.