



SECRETARY

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

May 29, 2019

COMMISSION VOTING RECORD

DECISION ITEM:           SECY-18-0049

TITLE:                     MANAGEMENT DIRECTIVE AND HANDBOOK 8.4,  
                              "MANAGEMENT OF BACKFITTING, ISSUE FINALITY, AND  
                              INFORMATION COLLECTION"

The Commission acted on the subject paper as recorded in the Staff Requirements Memorandum (SRM) of Month 29, 2019.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

A handwritten signature in black ink, appearing to read "Annette Vietti-Cook", written over a horizontal line.

Annette L. Vietti-Cook  
Secretary of the Commission

Enclosures:

1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Svinicki  
Commissioner Baran  
Commissioner Caputo  
Commissioner Wright  
OGC  
EDO  
PDR

VOTING SUMMARY – SECY-18-0049

RECORDED VOTES

	<u>APPROVED</u>	<u>DISAPPROVED</u>	<u>ABSTAIN</u>	<u>NOT PARTICIPATING</u>	<u>COMMENTS</u>	<u>DATE</u>
Chrm. Svinicki	X				X	02/14/19
Cmr. Baran	X	X			X	12/11/18
Cmr. Caputo	X				X	02/22/19
Cmr. Wright	X				X	02/22/19

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: CHAIRMAN SVINICKI

SUBJECT: SECY-18-0049: Management Directive and Handbook 8.4, "Management of Backfitting, Issue Finality, and Information Collection"

Approved XX Disapproved \_\_\_\_\_ Abstain \_\_\_\_\_ Not Participating \_\_\_\_\_

COMMENTS: Below \_\_\_\_\_ Attached XX None \_\_\_\_\_

  
\_\_\_\_\_  
SIGNATURE

02/ 14 /19  
\_\_\_\_\_  
DATE

Entered on "STARS" Yes  No \_\_\_\_\_

**Chairman Svinicki's Comments on SECY-18-0049  
Management Directive and Handbook 8.4, "Management of Backfitting,  
Issue Finality, and Information Collection"**

I approve the revision to Management Directive 8.4 and its companion Directive Handbook, subject to the attached edits. Substantial efforts have been undertaken by the staff, both in response to the Commission's direction in SRM-COMSECY-16-0200, "Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception to Backfit Rule" and under the staff's own, broader initiative as reflected in the June 2016 tasking from the Executive Director for Operations to the Committee to Review Generic Requirements, to assess the guidance, training, and knowledge management associated with backfitting and issue finality throughout the agency. We learned much in this endeavor: the most revealing lesson being, in my view, the need to require training and the demonstration of competency with respect to the regulatory paradigms underlying the imposition of new requirements by the NRC staff whose job responsibilities require the mastery of those very concepts on a day-to-day basis. This gap has now been remedied with agency-wide training for impacted staff and requirements for follow-on, refresher training.

With this lesson in mind, however, I approached my review of the revised Management Directive and Handbook with an awareness that both documents – the Handbook most especially – best serve the NRC's purposes if they are usable as day-to-day working tools or job aids for the agency staff grappling with these complex regulatory determinations. This is best achieved if these documents help the staff to navigate the complexity of case-specific issues related to the imposition of new requirements, whether that be in the form of backfitting, issue finality, or information requests. To that end, I propose that the Policy section of the Management Directive emphasize – up front – that the regulatory concepts of stability, informed decisionmaking, and transparency, as espoused in the NRC Principles of Good Regulation underpin the Backfit Rule and are reflected in the requirements of the Administrative Procedure Act. Consistent with that focus, and continuing throughout the documents, I propose further edits to reflect the orientation towards a systematic process for assessing the imposition of new requirements, in whatever form the facts of the matter present, to allow NRC staff to navigate to the appropriate agency process and begin to disposition the issue, consistent with applicable policies and practices.

These are complex matters, to be sure. My aim is to provide the staff with a clear compass that can guide them to other references and to other colleagues for further, cross-disciplinary discussions, as necessary and appropriate, with the goal of producing regulatory outcomes that are stable, informed, and transparent by virtue of being well-documented and supported. If successful in this, we will enhance the coherency and replicability of regulatory determinations across the agency, as well as the defensibility and rigor of our conclusions.



Kristine L. Svinicki

02/14/19

<b>MD 8.4</b>	<b>MANAGEMENT OF BACKFITTING, ISSUE FINALITY, AND INFORMATION <u>COLLECTIONREQUESTS</u></b>	<b>DT-XX-XX</b>
<i>Volume 8:</i>	Licensee Oversight Programs	
<i>Approved By:</i>	[Name and Title of Approving Official]	
<i>Date Approved:</i>	Month X, 20 <u>10</u> X [Date of Final Approval]	
<i>Cert. Date:</i>	N/A, for the latest version of any NRC directive or handbook, see the <a href="#">online MD Catalog</a> .	
<i>Issuing Office:</i>	Office of Nuclear Reactor Regulation Division of Inspection and Regional Support	
<i>Contact Name:</i>	Timothy Reed	
<b>EXECUTIVE SUMMARY</b>		
<p>Management Directive (MD) 8.4, “Management of Backfitting, Issue Finality, and Information Collection,” is retitled and revised to clarify <del>the agency’s</del> roles and responsibilities for management of backfitting, issue finality, and information <u>collectionrequests generically and on a facility-specific basis</u>. MD 8.4 describes the roles and responsibilities of various offices and provides the policy to direct the U.S. Nuclear Regulatory Commission implementation of the backfitting provisions of Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) for nuclear power reactor <u>facilities licensees</u> and selected nuclear materials <u>facilitieslicensees</u>; <del>and the issue finality provisions of 10 CFR Part 52 for nuclear power reactors licensees, design certification applicants, and holders of related NRC permits and approvals,; as well asand the specific</del> provisions of 10 CFR 50.54(f) and the corresponding requirements in 10 CFR Parts 70, 72, and 76, <del>and 10 CFR 2.204</del>.</p> <p>Accordingly, MD 8.4 is retitled from “Management of Facility-Specific Backfitting and Information Collection” to “Management of Backfitting, Issue Finality, and Information <u>RequestsCollection</u>” to clarify the intent and the objectives of the program.</p>		

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For updates or revisions to policies contained in this MD that were issued after the MD was signed, please see the Yellow Announcement to Management Directive index ([YA-to-MD index](#)).

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## I. POLICY

It is the policy of the U.S. Nuclear Regulatory Commission to have an effective program that will ensure that backfitting<sup>1</sup> of nuclear power reactor ~~facilities~~licensees<sup>2</sup> and selected nuclear materials ~~licensees and certificate holders~~facilities is appropriately documented and justified based on the backfitting provisions of applicable NRC regulations and the Commission's backfitting policy and guidance. Additionally, the NRC must justify information requests to licensees as required by applicable NRC regulations under 10 CFR 50.54(f), "Conditions of licenses," and 2.204, "Demand for information."

The backfit evaluation and analysis requirements ensure that the NRC demonstrates, before implementing the backfit, that the backfitting action would meet certain standards that vary based on the type of facility. In accordance with the NRC Principles of Good Regulation and the Administrative Procedure Act, the backfitting rules provide the following:

- (a) Regulatory stability, by ensuring that the changes the NRC makes are necessary or provide a substantial safety enhancement;

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<sup>1</sup> In this MD, the NRC uses the terms "backfit" and "backfitting" to mean backfitting as defined in 10 CFR 50.109, 70.76, 72.62, and 76.76 and violations of issue finality under 10 CFR Part 52. 10 CFR Part 52, Parts 50, "Domestic Licensing of Production and Utilization Facilities," Part 52, Part 70, "Domestic Licensing of Special Nuclear Material," Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste," and Part 76, "Certification of Gaseous Diffusion Plants," are the only parts of the NRC's regulations that contain backfitting or issue finality provisions. Backfitting provisions implicitly apply, in part, to applicants for a power reactor renewed license due to the limitation in scope of the NRC's review under 10 CFR Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants. In Title 10 of the Code of Federal Regulations (10 CFR), Section 50.109, "Backfitting," backfitting for a nuclear power reactor is defined as the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position after certain dates. For selected nuclear materials facilities, the backfitting definitions in 10 CFR 70.76, 72.62, and 76.76 are slightly different. The "issue finality" provisions in 10 CFR Part 52 are different from those in 10 CFR 50.109 and the wording and structure between the two groups of provisions differ significantly. The term "backfit" is not normally used in discussions relevant to new power reactors; the concept of "issue finality" is used rather than "backfit." In this MD, the NRC uses the terms "backfit" and "backfitting" to encompass backfits as defined in 10 CFR 50.109, 70.76, 72.62, and 76.76, and issue finality matters under 10 CFR Part 52.

<sup>2</sup> In this MD, the NRC uses the term "nuclear power reactor licensees" to refer to holders of 10 CFR Part 50 or Part 52 licenses, permits, or approvals, including: early site permits (ESPs), standard design approvals (SDAs), combined licenses (COLs), and MLs; design certification (DC) applicants whose designs are certified in final DC rules (DCR); applicants for COLs if the application references an ESP, DCR, or SDA; and applicants for MLs if the application references a DCR or SDA. Specific definitions and terminology are included in 10 CFR Parts 50, 70, 72, and 76.

(b) Reasoned and informed NRC decisionmaking, by requiring the proposed action be properly justified; and

(c) Transparency of NRC decisionmaking, by requiring that the NRC document and make publicly available its analyses and evaluations.

## II. OBJECTIVES

- Ensure NRC-licensed facilities provide adequate protection of public health and safety, promote the common defense and security, and allow for substantial improvements in both safety and security, beyond adequate protection, while minimizing avoiding any unjustified burden on the NRC, the public, or licensees when implementing a backfitting action.
- ~~– Ensure that backfitting considerations are applied to the furtherance of substantive radiological public health and safety, or common defense and security objectives.~~
- Ensure that backfitting applied to a nuclear power reactor licensee facility or nuclear materials licensee facility is appropriately justified and documented.
- Ensure that NRC-proposed changes to previously approved Early Site Permits (ESP), Design Certifications (DC), Standard Design Approvals (SDA), Combined Operating Licenses (COL), and Manufacturing Licenses (ML) (i.e., ~~violations of issue finality under 10 CFR Part 52~~) are appropriately justified and documented.
- Ensure that compliance backfitting justifications include some consideration of costs.
- Ensure that any documented evaluation or backfit analysis is risk-informed.
- Ensure all information requests to licensees are justified as required by applicable NRC regulations.

## III. ORGANIZATIONAL RESPONSIBILITIES AND DELEGATIONS OF AUTHORITY

### A. Executive Director for Operations (EDO)

1. Responsible for the NRC's backfitting process and ensuring proper implementation of the backfitting rules.
2. Authorizes deviations from this MD when in the public interest and when the deviation otherwise complies with applicable Commission policies, NRC regulations, public laws, and Executive Orders.



3. Delegates facility-specific backfitting authority and actions to the program ~~office~~  
Office Directors (ODs) and Regional Administrators (RAs).
4. Delegates information request authority and actions to the program ODs and RAs.
- 4.5. Reviews and modifies any proposed facility-specific backfitting action on his or her own initiative or at the appeal of the affected licensee or stakeholders.

**B. Office of the General Counsel (OGC)**

1. Identifies potential backfitting actions.
2. Advises staff about whether staff's actions meet the applicable definitions of backfit.
3. Advises staff about ~~how whether~~ staff's actions are congruent with issue finality provisions in 10 CFR Part 52.
4. Provides legal advice and assistance during backfitting identification, justification, imposition, and licensee appeal processes.
5. Provides legal advice and assistance for developing ~~backfitting~~ training in accordance with regarding backfitting requirements and agency implementation.
6. Provides legal advice and assistance for information collections.
- 6.7. Maintains a backfitting Community of Practice with office POCs, including a backfitting site.

**C. Committee To Review Generic Requirements (CRGR)**

1. ~~Monitors the overall effectiveness of the NRC's generic backfitting management process, including the effectiveness of administrative controls for facility-specific backfitting. Maintains a Charter that describes the roles, responsibilities, and procedures of the CRGR in accordance with applicable regulations.~~
2. Selects a sample of proposed backfitting actions for audit under 10 CFR Part 50, 10 CFR Part 52, 10 CFR Part 70, 10 CFR Part 72 and 10 CFR Part 76, consistent with its Charter, and ensures the actions are justified in accordance with regulations, guidance, and Commission policies.
3. Reviews potential facility-specific backfits as requested by ~~program office directors~~ program ODs and RAs.
4. Uses its discretion in deciding whether any review should require a formal staff presentation to the CRGR.

- ~~5. Periodically assesses the effectiveness of the NRC's backfitting process implementation as part of its regulatory effectiveness responsibility and provides a report to the EDO.~~
- 6.5. Ensures consistency among the offices and regions in implementing the provisions of the NRC's backfitting rules. The CRGR review focuses on the adequacy of backfitting implementation, interoffice coordination for processing backfitting actions, and staff training.
- 7.6. Verifies that the responsible staff<sup>3</sup> promptly enters backfitting decisions into the Agencywide Documents Access and Management System (ADAMS), and makes them publicly available, consistent with applicable requirements and guidance.
- 8.7. Periodically meets with stakeholders to gain stakeholder views and advise the EDO when modifications to the backfitting processes should be considered.
- 9.8. Participates in Backfitting Review Panels at the request of the EDO.
- 10.9. Coordinates with the Office of the Chief Human Capital Officer (OCHCO), OGC, RES, NSIR, OE, the regions, and program offices to ensure that Human Resources Training and Development (HRTD) provides appropriate training for the NRC staff and that individual office procedures and guidance appropriately reflect the requirements of this MD and other applicable guidance.

**D. Director, Office of Nuclear Regulatory Research (RES)**

1. Identifies potential backfitting actions.
2. Supports the offices and regions by implementing pertinent CRGR recommendations, EDO decisions, staff lessons learned, and Commission directives for enhancing the NRC's backfitting program.
3. Provides administrative support for routine CRGR activities.
- 3.4. Ensures appropriate training is provided to the RES staff.

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<sup>3</sup> The office or the region that initiated the backfitting action supports the program office (the Office of Nuclear Reactor Regulation (NRR), the Office of Nuclear Material Safety and Safeguards (NMSS), or the Office of New Reactors (NRO)) that has the obligation to impose the backfit. The program office is solely responsible for generic backfitting actions. Regions are responsible for facility-specific backfitting actions arising from inspection, and program offices are responsible for facility-specific backfitting actions arising from licensing or other headquarters actions.

- ~~4. Maintains a backfitting Community of Practice with office POCs, including a backfitting SharePoint site.~~

**E. Director, Office of Enforcement (OE)**

1. Defines and implements appropriate administrative controls to support the office and regional staffs in processing compliance backfits that involve enforcement discretion.
2. If an Order, a notice of violation, or enforcement discretion is necessary in relation to a backfitting action, consults with OGC and the responsible office(s) and region(s), on the backfitting action and advises on its imposition, including supporting interactions with licensees to establish a schedule for implementing the compliance backfit, as applicable.

Ensures appropriate training is provided available to the OE staff and ensures OE staff performance is in accordance ~~with NUREG-1409, "Backfitting Guidelines."~~ with current agency policy and guidelines.

3. Designates an office-level POC to coordinate and resolve backfitting questions or concerns from the staff as they relate to the responsibilities of OE.

**F. Director, Office of Nuclear Security and Incident Response (NSIR)**

1. Identifies any potential security-related or emergency preparedness-related backfitting actions.<sup>4</sup>
- ~~2. Coordinates all security-related backfitting with the program offices and the regional offices.~~
- ~~3.2.~~ Designates an NSIR manager (division director or higher) who coordinates with the program offices and OGC to request that the program office propose backfitting actions on nuclear power reactor and nuclear materials licensees facilities that pertain to the common defense and security or emergency preparedness.
- ~~4.3.~~ Ensures consistency of security and emergency preparedness inspection procedures with regulations and current agency guidelines and policies, and NUREG-1409.
- ~~5.4.~~ Consults, coordinates with, and provides support to program ODs, as appropriate necessary, to resolve issues with security-related backfitting actions. The Director, NSIR, must support the program ODs and RAs, as appropriate, in

<sup>4</sup> Throughout this MD, security-related and emergency preparedness-related backfitting may be referred to as security ~~or security-related~~ backfitting.

processing security-related backfits, including the resolution of licensee backfit appeals.<sup>5</sup>

~~6.5.~~ Ensures appropriate training is available to the NSIR staff and ensures that the NSIR staff performance is in accordance with current agency guidelines and policies NUREG-1409.

~~7.6.~~ Designates an office-level POC to coordinate and resolve backfitting questions or concerns from staff as they relate to the responsibilities of NSIR.

~~8.~~ Makes backfitting decisions publicly available, consistent with applicable requirements and guidance.

**G. Director, Office of Nuclear Reactor Regulation (NRR); Director, Office of New Reactors (NRO); and Director, Office of Nuclear Material Safety and Safeguards (NMSS)**

1. Identify backfitting actions applicable to within its-their programs.

2. Coordinate backfitting actions with OGC, other program offices, NSIR, OE, RES, and regional offices to ensure consistency and uniformity.

3. Provide the CRGR with an opportunity to review any required documented evaluation or backfit analysis or any generic communication with backfitting concerns.

4. Request CRGR review of potential facility-specific backfit, as deemed appropriate.

5. After approving supporting documentation, notify, or designate the relevant division director to notify, the affected entity or entities, e.g. the nuclear power reactor or nuclear materials licensee(s), of the backfitting action.

6. Ensure consistency among inspection procedures, regulations, office instructions, and current agency guidelines and policies NUREG-1409.

~~7.~~ Consult and coordinate with the regions, NSIR, RES, OE, and OGC, as appropriate, to resolve issues with backfitting actions for which the program office has oversight responsibility.

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<sup>5</sup> ~~The program OD for the affected facilities imposes facility-specific backfitting actions and forwards licensee appeals on security-related backfitting to the NSIR OD. The NSIR OD will decide on the appeal and coordinate with the program OD. If a licensee refuses to implement an imposed backfitting action, the appropriate program office must issue an Order.~~

- ~~8. Coordinate security-related backfitting with the Director, NSIR, and the affected regional office and approves the supporting documentation for security-related backfitting within the program office's areas of responsibility.~~
- ~~9.7.~~ Decide first-level licensee appeals on the imposition of all backfitting actions within the program office's area of responsibility ~~and coordinates any appeals of security-related backfits with the Director, NSIR.~~
- ~~10.8.~~ During the staff's evaluation and backfitting transmittal process, and any subsequent licensee appeal process, track each facility-specific backfitting action within the affected program office ~~or region.~~
- ~~11.9.~~ Ensure entry into ADAMS, as appropriate, of all documents and records related to backfitting originating in either the program office or the region (within the program office's area of responsibility), including communications, decisionmaking, and the outcome of backfitting appeals. Makes the backfitting decisions publicly available, consistent with applicable requirements and guidance.
- ~~12.10.~~ Ensure appropriate training is available to the program office staff and ensure that the program office staff performance is in accordance with regulations, and current agency guidelines and policies ~~NUREG-1409.~~
- ~~13.11.~~ Designate an office-level POC to coordinate and resolve backfitting questions or concerns from the staff as they relate to the responsibilities of each respective program office.
- ~~14.12.~~ Ensure information collection requested under 10 CFR 50.54(f) ~~and 2.204~~ is appropriately justified.

#### H. Regional Administrators (RAs)

1. Identify backfitting actions applicable to within the regions.
2. Coordinate with OGC, ODs, NSIR and other RAs to ensure consistency in backfitting implementation among the regions and program offices.
3. Provide the CRGR with an opportunity to review any required documented evaluation or backfit analysis before final approval.
4. After approving supporting documentation, notify, or designate the relevant division director to notify, the affected entity, e.g. the nuclear power reactor or nuclear materials licensee(s), of the backfitting action.

- ~~5. Coordinate with other regions and either the Division of Inspection and Regional Support, NRR, or the Division of Construction Inspection and Operational Programs, NRO, as applicable, to ensure consistency among inspection procedures and regulations, and NUREG-1409.~~
- ~~6.5. Consult and coordinate with the Director, NSIR; OGC and/or regional counsel; and the appropriate program OD to resolve security-related, facility-specific backfitting actions.~~
- ~~7.6. Coordinate with the appropriate program office and NSIR, as necessary, to obtain the supporting documentation for proposed backfits.~~
- ~~8.7. Support the appropriate program office in processing licensee backfitting appeals that are within the regional area of responsibility.~~
- ~~9.8. Ensure entry into ADAMS, as appropriate, of all documents and records related to backfitting and originating in the region, including communications, decisionmaking, and the outcome of backfitting appeals. Makes backfitting decisions publicly available, consistent with applicable requirements and guidance.~~
- ~~10.9. Ensure appropriate training is available to the regional staff and ensures that the regional staff performance is in accordance with regulations and current agency guidelines and policies NUREG-1409.~~
- ~~11.10. Designate a regional POC who will be responsible for any specific backfitting activities (generic and facility-specific) as needed, including the coordination and resolution of any backfitting questions or concerns from the staff as they relate to the responsibilities of the respective region. The regional POC also ensures that the associated regional staff is proficient in a training program relevant to backfitting activities and agency information collection processes.~~

#### **I. Chief Human Capital Officer (CHCO)**

1. Develops, maintains, and updates, in consultation with the CRGR and OGC and in coordination with other offices and regions, a backfitting training program for the NRC staff, including generic and facility-specific backfitting training modules and refresher courses.
2. Consults and coordinates with the appropriate contact in the Office of the Chief Information Officer to maintain backfitting training modules ~~online~~.

#### J. Chief Information Officer (CIO)

1. Maintains a repository for backfitting records in ADAMS.
2. Advises the offices and regions on implementing administrative controls to ensure backfitting information is maintained in accordance with Federal and agency recordkeeping requirements.
3. Consults on the agency review of information collections requests to ensure compliance with the Paperwork Reduction Act.

#### IV. APPLICABILITY

The policy in this directive and handbook applies to all NRC employees.

#### V. DIRECTIVE HANDBOOK

For effective regulation of NRC-licensed facilities, it is crucial that the backfitting process be well-defined, that staff members clearly understand their obligation for responsibly implementing all aspects of the backfitting program, and that managers ensure staff performance is in accordance with this MD. Handbook 8.4 explains the components of the NRC backfitting management program. NUREG-1409 provides guidance to the staff implementing backfitting regulations.

#### VI. REFERENCES

##### *Code of Federal Regulations*

10 CFR Part 2, "Agency Rules of Practice and Procedure."

10 CFR 2.202, "Orders."

~~10 CFR 2.204, "Demand for Information."~~

10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

10 CFR 50.2, "Definitions."

10 CFR 50.12, "Specific Exemptions."

10 CFR 50.49, "Environmental Qualification of Electrical Equipment Important to Safety for Nuclear Power Plants."

10 CFR 50.54, "Conditions of Licenses."

10 CFR 50.59, "Changes, Tests, and Experiments."

10 CFR 50.71, "Maintenance of Records; Making of Reports."

- 10 CFR 50.72, "Immediate Notification Requirements for Operating Nuclear Power Reactors."
- 10 CFR 50.73, "License Event Report System."
- 10 CFR 50.109, "Backfitting."
- 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."
- 10 CFR 52.7, "Specific Exemptions."
- 10 CFR 52.31, "Criteria for Renewal."
- 10 CFR 52.39, "Finality of Early Site Permit Determinations."
- 10 CFR 52.59, "Criteria for Renewal."
- 10 CFR 52.63, "Finality of Standard Design Certifications."
- 10 CFR 52.83, "Finality of Referenced NRC Approvals; Partial Initial Decision on Site Suitability."
- 10 CFR 52.98, "Finality of Combined Licenses; Information Requests."
- 10 CFR 52.145, "Finality of Standard Design Approvals; Information Requests."
- 10 CFR 52.171, "Finality of Manufacturing Licenses; Information Requests."
- 10 CFR 52.179, "Criteria for Renewal."
- 10 CFR Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants."
- 10 CFR 54.30, "Matters Not Subject to a Renewal Review."
- 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."
- 10 CFR 70, Subpart B, "Exemptions."
- 10 CFR 70.22, "Contents of Applications."
- 10 CFR 70.76, "Backfitting."
- 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste."
- 10 CFR 72.7, "Specific Exemptions."
- 10 CFR 72.62, "Backfitting."



10 CFR Part 76, "Certification of Gaseous Diffusion Plants."

10 CFR 76.23, "Specific Exemptions."

10 CFR 76.76, "Backfitting."

### ***Nuclear Regulatory Commission Documents***

Charter of the Committee To Review Generic Requirements.

Letter to Ellen Ginsberg from Stephen Burns discussing applicability of the Backfit Rule to NRC interpretive guidance, July 14, 2010 (ADAMS Accession No. [ML101960180](#)).

Memorandum to Edwin Hackett from Andrew Averbach, "Summary of COMSECY-16-0020, Recommendation on Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception to Backfit Rule," December 20, 2016 (ADAMS Accession No. [ML16355A258](#)).

Memorandum to James M. Taylor and William C. Parler from Samuel J. Chilk, "SECY-93-086, Backfit Considerations," June 30, 1993 (ADAMS Accession No. [ML003760758](#)).

Memorandum from Luis A. Reyes, Executive Director for Operations, NRR to Those on the Attached List, "Implementation of an ADAMS-Based Record Access System for Facility-Specific Backfits," February 22, 2006 (ADAMS Accession No. [ML052720147](#)).

NUREG-0910, "NRC Comprehensive Records Disposition Schedule."

NUREG-1409, "Backfitting Guidelines."

NUREG/BR-0058, Revision 45, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," and all Appendices.

SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," dated March 2, 1999 (ADAMS Accession No. [ML992810068](#)).

Staff Requirements Memorandum, COMSECY-16-0020, "Staff Requirements – COMSECY-16-0020 – Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception to Backfit Rule," November 29, 2016 (ADAMS Accession No. [ML16334A462](#)).

Staff Requirements Memorandum, SECY-98-185, "[Staff Requirements](#) - Proposed Rulemaking, - Revised Requirements for the Domestic Licensing of Special Nuclear Material," December 1, 1998 (ADAMS Accession No. [ML991880012](#)).

Staff Requirements Memorandum, SECY-14-0087, "Staff Requirements—  
SECY - 14- 0087-Qualitative Consideration of Factors in the Development of  
Regulatory Analyses and Backfit Analyses," dated March 4, 2015 (ADAMS  
Accession No. [ML15063A568](#)).

"Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities;  
Final Policy Statement," 60 FR 42622, August 16, 1995.

***United States Code***

Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.).

Energy Reorganization Act of 1974, as amended (42 U.S.C. 5801 et seq.).

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

**U.S. NUCLEAR REGULATORY COMMISSION DIRECTIVE HANDBOOK (DH)**

<b>DH 8.4</b>	<b>MANAGEMENT OF BACKFITTING, ISSUE FINALITY, AND INFORMATION COLLECTION REQUESTS</b>	<b>DT-XX-XX</b>
<i>Volume 8:</i>	Licensee Oversight Programs	
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<b>EXECUTIVE SUMMARY</b>		
<p>Management Directive (MD) 8.4, “Management of Backfitting, Issue Finality, and Information Collection,” is retitled and revised to clarify <del>the agency’s</del> roles and responsibilities for management of backfitting, issue finality, and information collection <u>generically and on a facility specific basis</u>. MD 8.4 describes the roles and responsibilities of various offices and provides the policy to direct the U.S. Nuclear Regulatory Commission implementation of the backfitting provisions of Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) for nuclear power reactor <del>facilities-licensees</del>; and selected nuclear materials <del>facilities-licensees</del>; <del>and the issue finality provisions of 10 CFR Part 52 for nuclear power reactors-licensees, design certification applicants, and holders of related NRC permits and approvals;</del> <del>and as well as the specific</del> provisions of 10 CFR 50.54(f) and the corresponding requirements in <del>Parts</del> 10 CFR <del>Parts</del> 70, 10 CFR 72, and 10 CFR 76, and 10 CFR 2.204.</p> <p>Accordingly, MD 8.4 is retitled from “Management of Facility-Specific Backfitting and Information Collection” to “Management of Backfitting, Issue Finality, and Information <u>CollectionRequests</u>” to clarify the intent and the objectives of the program.</p>		

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## I. INTRODUCTION TO BACKFITTING AND INFORMATION COLLECTION REQUESTS<sup>1</sup>

### A. Backfitting

1. Under 10 CFR 50.109, backfitting is “the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position.” Substantially similar definitions are provided in § 70.76, § 72.62, and § 76.76.
2. Backfitting is the process by which the U.S. Nuclear Regulatory Commission imposes new or revised regulatory requirements or new or revised staff positions on nuclear power reactor licensees or selected nuclear materials licensees.<sup>2</sup> Backfitting is an integral part of the regulatory process and is expected to occur. To ensure that proposed changes are adequately justified and defined, a backfitting action is implemented only after formal and systematic review. Backfitting normally occurs in one of two ways: when the agency imposes a new or changed regulation or requirement imposed upon a licensee's facility or facilities (through rulemaking or order); Backfitting concerns also arise when the agency communicates a new or changed staff position interpreting applicable regulations requirements imposed on facilities licensees. A new or changed staff position may arise in a number of regulatory contexts including facility inspections, license amendment reviews, or issuance of guidance documents. In this Directive Handbook (DH), the terms “backfit” and “backfitting” mean backfitting as defined in 10 CFR 50.109, “Backfitting,” 70.76, “Backfitting,” 72.62, “Backfitting,” and 76.76 “Backfitting,” and violations

<sup>1</sup> This section provides a high-level overview of the backfit process, and as such, may simplify some concepts for introductory purposes. If a provision of this section conflicts with a provision in a later section, the later section is controlling.

<sup>2</sup> For purposes of this DH, the term “licensees” includes the holders of power reactor construction permits (CPs) and operating licenses (OLs) under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities;” holders of licenses, permits or approvals under 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants;” holders of licenses for fuel facilities under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” Subpart H, “Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material;” holders of licenses for spent fuel and radioactive waste storage facilities under 10 CFR Part 72, “Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste;” and certificate holders for gaseous diffusion plants under 10 CFR Part 76, “Certification of Gaseous Diffusion Plants.”

of changes affecting issue finality under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." The only parts of the NRC's regulations that contain backfitting or issues finality provisions are 10 CFR Part 50, 10 CFR Part 52, 10 CFR Part 70, 10 CFR Part 72, and 10 CFR Part 76. ~~The backfitting provisions typically do not apply to license applicants. There is no backfitting provision in 10 CFR Part 54, "Requirements for Renewal of Operating Licenses of Nuclear Power Plants," however the scope of the NRC's review under 10 CFR Part 54 is limited. The protections in the backfitting provisions further NRC compliance with the requirements of the Administrative Procedure Act regarding reasoned decisionmaking.~~

3. The backfit evaluation and analysis requirements ensure that the NRC demonstrates, before implementing the backfit, that the backfitting action meets certain standards that vary based on the type of facility. In accordance with the NRC Principles of Good Regulation and the Administrative Procedure Act, the backfitting rules provide the following:
  - (a) Regulatory stability, by ensuring that the changes the NRC makes are necessary or provide a substantial safety enhancement;
  - (b) Reasoned and informed NRC decisionmaking, by requiring that the proposed action be properly justified; and
  - (c) Transparency of NRC decisionmaking, by requiring that the NRC document and make publicly available its analyses and evaluations.

4.4. There are three principal types of backfitting that may be considered justifications the agency relies on to impose a backfit: adequate protection backfitting, compliance backfitting, and a cost-justified substantial increase<sup>3</sup> in protection backfitting.<sup>4</sup> If the NRC is considering a backfitting action, it must first consider whether regulatory action is necessary to ensure adequate protection of public health and safety, and if so whether there is an imminent threat to public health and safety. If regulatory action is not necessary to ensure adequate protection, then the NRC needs to determine if the proposed action satisfies the compliance backfit criteria. If the

<sup>3</sup> See 50 FR 38097, September 20, 1985.

<sup>4</sup> The issue finality provisions of 10 CFR Part 52 include additional backfitting actions justifications for certain types of approval holders. For example, 10 CFR 52.63, "Finality of sStandard dDesign cCertifications," also allows backfitting to, among other things, correct material errors in the certification information for a design certification (DC) or to contribute to the increased standardization of the DC.

proposed action does not satisfy the compliance backfit criteria, then the NRC must consider a cost-justified substantial increase in protection backfit.

~~2. The Supreme Court's decision in *Michigan v. Environmental Protection Agency*, 135 S. Ct. 2699 (2015), reflects the view that, under the Administrative Procedure Act (APA), unless Congress has indicated otherwise, an agency's decisionmaking calculus should include at least some consideration of the cost placed on a licensee to comply with new requirements. In contrast, when the NRC has reached a new or changed position with respect to whether regulatory action is needed to ensure adequate protection under the Atomic Energy Act of 1954 (AEA), as amended, no further explanation, including consideration of cost, is necessary. Otherwise, the APA's reasoned decision making requirement compels some consideration of cost.~~

~~3.5. Regulations in 10 CFR 50.109, define the term backfitting for power reactors under 10 CFR Part 50 (i.e., construction permit (CP) holders and operating license (OL) holders) as the modification of or addition to systems, structures, components (SSCs); or design of a facility; or the design approval or manufacturing license (ML) for a facility; or the procedures or organization required to design, construct, or operate a facility, any of which may result from a new or amended provision in the Commission's regulations or the imposition of a staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position after certain specified dates.<sup>5</sup> Provisions of 10 CFR 50.109 can also~~

<sup>5</sup> ~~Applicable NRC action may be considered backfitting under 10 CFR 50.109 if the agency action occurs after the following:~~

- ~~• the issuance of the CP for the facility (for facilities with CPs issued after October 21, 1985),~~
- ~~• 6 months before the date of docketing of the OL application for the facility (for facilities with CPs issued before October 21, 1985),~~
- ~~• the issuance of the OL for the facility (for facilities having an OL on October 21, 1985),~~
- ~~• the issuance of the design approval under Subpart E, "Standard Design Approvals," of 10 CFR Part 52,~~
- ~~• the issuance of a an ML under Subpart F, "Manufacturing Licenses," of 10 CFR Part 52,~~
- ~~• the issuance of the first CP for a duplicate design under Appendix N, "Standardization of Nuclear Power Plant Designs: Permits To Construct and Licenses to Operate Nuclear Power Reactors of Identical Design at Multiple Sites," of 10 CFR Part 50, or~~
- ~~• the issuance of a COL under Subpart C, "Combined Licenses," of 10 CFR Part 52.~~

~~apply to power reactor licensees under 10 CFR Part 52,<sup>6</sup> but 10 CFR 50.109 is not applicable to non-power production or utilization facilities licensed under 10 CFR Part 50.~~

~~4.6. In 10 CFR Part 52, power reactor licensees are granted “issue finality”<sup>7</sup> exists with respect to prior their NRC approvals, which prevents the NRC from making changes to the approvals without meeting certain criteria as provided in the applicable issue finality regulation. The issue finality requirements are intended to accomplish the same objective as the backfitting requirements by limiting changes to final Commission decisions made as part of the 10 CFR Part 52 licensing process. The standards vary for making changes to renewed and previously approved early site permits (ESPs) (10 CFR 52.31, “Criteria for Renewal,” and 10 CFR 52.39, “Finality of Early Site Permit Determinations”), renewed and previously approved design certification rules (DCRs) (10 CFR 52.59, “Criteria for Renewal,” and 10 CFR 52.63, “Finality of standard design certifications), previously approved combined operating licenses (COLs) (10 CFR 52.83, “Finality of Referenced NRC Approvals; Partial Initial Decision on the Site Suitability,” and 10 CFR 52.98, “Finality of Combined Licenses; Information Requests”), previously approved standard design approvals (SDAs) (10 CFR 52.145, “Finality of Standard Design Approvals; Information Requests”), and renewed and previously approved MLs (10 CFR 52.179, “Criteria for Renewal,” and 10 CFR 52.171, “Finality of Manufacturing Licenses; Information Requests”). The backfitting provisions in 10 CFR 50.109 apply to ESPs, DCs, COLs, SDAs, and MLs to the extent that they do not overlap the applicability of 10 CFR Part 52 issue finality provisions.~~

~~5.7. Section 70.76 of 10 CFR defines the term backfitting for materials licensees authorized to possess greater than a critical mass of special nuclear material as the modification of, or addition to, SSCs of a facility; or to the procedures or organization required to operate a facility. Either of these may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position~~

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~~<sup>6</sup> For purposes of this DH, the term “10 CFR Part 52 power reactor licensees” refers to holders of early site permits (ESPs), standard design approvals (SDAs), combined licenses (COLs), and MLs; DC applicants whose designs are certified in final DC rules (DCRs); applicants for COLs if the application references an ESP, DCR, or SDA; and applicants for MLs if the application references a DCR or SDA.~~

<sup>7</sup> Within this DH, the term “issue finality” encompasses the language of the regulations from 10 CFR 52.39 “Finality of Early Site Permit Determinations,” 10 CFR 52.63, “Finality of standard design certifications,” 10 CFR 52.83, “Finality of Referenced NRC approvals; Partial Initial Decision on Site Suitability,” 10 CFR 52.98, “Finality of Combined Licenses; Information Requests,” 10 CFR 52.145, “Finality of Standard Design Approvals; Information Requests,” 10 CFR 52.171 “Finality of Manufacturing Licenses; Information Requests,” and any other applicable discussion of finality in part 52.



~~interpreting the Commission rules that is either new or different from a previous NRC staff position.~~

~~6.8. Section 72.62 of 10 CFR defines the term backfitting as the addition, elimination, or modification, after the license has been issued, of SSCs of an independent spent fuel storage installation (ISFSI) or monitored retrievable storage (MRS), or the procedures or organization required to operate an ISFSI or MRS.~~

~~7.9. Section 76.76 of 10 CFR defines the term backfitting as the modification of, or addition to, SSCs of a gaseous diffusion plant, or to the procedures or organization required to operate a plant, 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.~~

~~Sections 50.109(a)(4)(i) and (a)(7), 70.76(a)(4)(ii) and (a)(7), 72.62(b), and 76.76(a)(4)(i) of 10 CFR require compliance with "written commitments" and, in the case of 10 CFR 76.76(a)(7), "written Corporation commitments." Within the scope of backfitting, these written commitments mean those commitments that have been incorporated into the license as a means necessary to demonstrate compliance with requirements.~~

~~The licensing basis (LB) for power reactors under Parts 50, 52, and 54 is determined on a case-by-case basis and is commonly referred to as the set of NRC requirements applicable to a specific facility and that licensee's written commitments for ensuring compliance with applicable NRC requirements in the LB and the facility-specific design bases (including all modifications and additions over the life of the license).~~

~~8. Commitments that have been included in a licensee's updated final safety analysis report (UFSAR) that describe a method for complying with regulations or requirements are not enforceable unless they are part of the license. Commitments documented outside of the license only represent acceptable approaches for complying with the governing requirements.~~

~~10. If a licensee voluntarily submits a license amendment request (LAR) or license renewal application (LRA), the NRC, as a condition of its approval, may require that the licensee modify its submittal or adopt new or revised guidance, provided that 1) the new or revised guidance relates to the licensee's request, and 2) the subject matter of the guidance is essential to the NRC staff's determination of the acceptability of the licensee's request. This would not constitute backfitting. It is the licensee's burden to show that the submitted application enables the NRC to make the appropriate findings (e.g., in accordance with 10 CFR 50.40, 50.57, 50.92, or the other applicable regulations). A forward fit is defined as the imposition of a new or~~

modified requirement or regulatory staff interpretation of a requirement that results in the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility as a condition of approval by the NRC of a licensee-initiated request for a licensing action when the underlying request did not propose to comply with the new or revised requirement or interpretation. Such licensing actions may include a license amendment or a license renewal, although the normal application of the process in 10 CFR Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants," does not generally constitute forward fitting. The NRC may condition its approval of such a licensing action on the use of a new or modified regulatory staff position if there is a direct nexus to the licensee's request and the imposition of the new or modified requirement or regulatory staff position is essential to the NRC staff's determination of the acceptability of the licensee's request. In deciding whether a forward fit is appropriate, the NRC staff should also take the following factors into account:

- a) As noted in paragraph I.A.5, when the NRC imposes new requirements or regulatory staff position interpreting requirements not needed to ensure adequate protection, the APA requires some consideration of cost. Thus, if the forward fit is unrelated to adequate protection, the NRC must consider cost before implementing the new or modified requirement or interpretation.
- b) In establishing or modifying the requirement or regulatory staff position interpreting the requirement, the NRC staff had the opportunity to consider whether the resulting position should be imposed as a backfit on existing licensees. Under the mandatory backfitting provisions of §§ 50.109(a)(5), 70.76(a)(5), and 76.76(a)(5), and the portions of 72.62(b) regarding backfitting necessary to assure adequate protection of public health and safety, if such a change were necessary to ensure adequate protection of public health and safety when the new or modified requirement or regulatory staff position was made, the NRC would have been required to impose it as a backfit. Because such a backfit has not been imposed for cases where a forward fit is being considered, it is unlikely that a change could be justified to be necessary to ensure adequate protection of public health and safety.
- c) NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," provides the following guidance on the development of regulatory staff positions:

The NRC performs regulatory analyses to support numerous NRC actions affecting reactor and materials licensees. Executive Order 12866 requires that a regulatory analysis be prepared for all

significant regulatory actions. The NRC requires regulatory analyses for a broader range of regulatory actions than for significant rulemakings as defined in E.O.12866. In general, each NRC office should ensure that all mechanisms used by the NRC staff to establish or communicate generic requirements, guidance, requests or staff positions that would affect a change in the use of resources by its licensees include an accompanying regulatory analysis. This requirement applies to actions initiated internally by the NRC or by a petition to the NRC. These mechanisms include rules, bulletins, generic letters, regulatory guides, orders, standard review plans, branch technical positions and standard technical specifications.

If the regulatory analysis developed in support of the new or modified requirement or regulatory staff position (e.g., a revision to regulatory guidance) resulted in an agency decision that the prior regulatory staff position should remain available for use by current licensees and not be withdrawn, the decision on whether to forward fit the new or modified regulatory staff position on an applicant for a licensing action should be informed by a site-specific regulatory analysis.

- d) If a licensee believes that the staff has incorrectly followed this process in imposing a forward fit, the licensee may use the backfitting appeals process described in Section III.F of this Management Directive to challenge the forward fit, as contemplated by the Statement of Considerations for the 1985 Revision of Backfitting Process for Power Reactors.<sup>8</sup>
- e) Forward fits generally do not include instances when an applicant files an initial licensing application for a new facility. However, for light-water reactor (LWR) facilities, § 50.34(d), § 52.17(a)(1)(xii), § 52.47(a)(9), § 52.79(a)(41), § 52.137(a)(9), and § 52.157(f)(30) establish the version of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," (the SRP) that applicants should be anticipated to reasonably rely upon in the development of their applications. Any change in requirements or regulatory staff positions from that version of the SRP interpreting the Commission's requirements should follow the same reasoned decisionmaking process as a forward fit.

~~9. Under 10 CFR 50.40 Common standards, "in determining that a construction permit or OL in this part, or early site permit, combined license, or ML in Part 52 of this chapter will be issued to an applicant, the Commission will be guided by the following~~

<sup>8</sup> 50 FR 38097, 38101, September 20, 1985.

~~considerations: (a) Except for an early site permit or manufacturing license, the processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other technical specifications, or the proposals, in regard to any of the foregoing collectively provide reasonable assurance that the applicant will comply with the regulations in this chapter, including the regulations in Part 20 of this chapter, and that the health and safety of the public will not be endangered."~~

- ~~10. A key aspect of 10 CFR 50.40 is the "collectively" aspect. The licensing (and amendment) finding allows consideration of the collective aspect of the proposed change. For example, if a licensee proposes longer outage time for SSC A, then the staff could rely on 50.40 to say that less outage time for SSC B is needed to give the overall collective reasonable assurance, and doing so is not necessarily a backfit.~~

~~The backfitting rules generally do not apply to voluntary licensee changes, where "voluntary" is defined as any action by the licensee that was made of its own accord, without the force of a legally binding requirement or NRC representation of further licensing or enforcement action. The licensee must not be compelled by the NRC staff to make the change. The NRC staff's requirement that the licensee adopt new or revised guidance that does not directly pertain to the licensee's voluntary request would constitute backfitting. Unless required by the NRC, confirmatory orders that are the result of participation in the alternative dispute resolution (ADR) process, LARs, and LRAs are considered voluntary, and the NRC review process and approval of an ADR, LAR, or LRA generally is not considered backfitting. Furthermore, the backfitting rules do not apply to NRC suggested actions with which licensees are not required to comply, but decide to voluntarily implement. The backfitting rules do not apply to any voluntarily-initiated licensee installation of updated (or additional) equipment to the existing plant, to expand the plant, improve efficiencies, delay its obsolescence, or extend its capabilities.~~

~~Backfitting does not apply to actions that do not have a direct link to, and do not further a substantive radiological public health and safety, or common defense and security, objective. Nevertheless, the NRC must have legal authority to justify taking such actions.~~

- ~~11. For backfitting purposes, staff positions are documented interpretations of the regulations, already specifically imposed upon a licensee or "class" of licensees at the time of the identification of the proposed backfitting and may be contained in documents such as the Statement of Considerations for a final rule, Standard Review Plan (SRP), NUREG, interim staff guidance (ISG), and branch technical position (BTP). A licensee's commitment to guidance, such as regulatory guides (RGs) or NRC-endorsed industry topical reports (TRs), through a licensing action is considered a voluntary action. However, RGs and NRC-endorsed TRs do represent staff positions. Generally, the issuance of or revision to a staff position is considered forward-fitting and the revisions to staff positions do not, in isolation, impose~~

~~anything, and are therefore not (in isolation) backfits. The applicable staff positions for each facility license application, LAR, or LRA includes the safety evaluation reports (SER)<sup>9</sup> and any NRC approvals based on licensees' docketed responses to requests for information. A change in the applicable staff position is referred to as a new or revised staff position.~~

~~12.11.~~ The NRC's backfitting actions can be either generic or facility-specific.<sup>10</sup>

~~(a) Generic backfitting actions affect a class or classes of licensees and can include the imposition of new or revised regulations or requirements (through rulemaking or Orders) or new or revised staff positions interpreting NRC regulations. Generic backfitting actions can be initiated in a number of ways, such as by the staff in rulemaking, the Commission through a staff requirements memorandum (SRM), and the public through a petition for rulemaking. Regardless of whether a generic backfitting action is the result of rulemaking or a new or changed staff interpretation, the new or changed regulation or staff position must be documented, and stakeholders must have had an opportunity to review and provide comments in response to a *Federal Register* (FR) notice. However, time-sensitive, safety-significant, or security-significant NRC actions, such as Orders or Bulletins, do not require public notice and opportunity to comment. In addition, not all previously issued staff positions were provided to the public for comment.~~

~~(b) Facility-specific backfitting issues typically arise through the NRC's inspection or licensing process. In these circumstances, the NRC's regional or headquarters staff may find that a change to a facility's licensing basis (LB) is appropriate. Facility-specific backfitting actions are normally a change in a staff position (the applicable SE) for a specific facility, based on an error or omission in the analysis (compliance backfit) for the implementation of that facility's LB, but they could also be a change to the facility-specific LB deemed necessary to ensure that the facility provides adequate protection. For power reactors, in addition to single unit sites, facility-specific backfitting actions may apply to sites that have multiple units, sites that share a UFSAR, or sites that may have more than one reactor type but share common sections of a UFSAR. Any reference in this DH or in NUREG-1409,~~

<sup>9</sup> — Historically, the NRC has used two terms to describe the document approving a license, amendment, or license renewal: SER or safety evaluation (SE). Throughout this DH, the use of SE will indicate the SER (usually used for approving initial licensing or relicensing actions) or the SE (usually used for approving license amendments).

<sup>10</sup> Hereafter, the term "facility" will be used to mean a nuclear power reactor; an ESP, DCR, COL, SDA, or ML for a power reactor; or a materials facility such as an ISFSI, fuel facility, gaseous diffusion plant, or an MRS installation.

~~“Backfitting and Issue Finality Guidance,” to facility-specific backfitting pertains to facility-specific backfitting actions in this context.~~

~~Unless an exception as described in Section I.A.19 applies, to justify a backfit under 10 CFR 50.109, 10 CFR 70.76, 10 CFR 76.76, and generally 10 CFR 72.62, or, in many cases, to justify a violation of issue finality under 10 CFR Part 52, the NRC must perform and document a backfit analysis in accordance with NUREG-1409 that shows the following:~~

~~The backfitting would result in a substantial increase<sup>11</sup> in overall protection of public health and safety or the common defense and security, and~~

~~The direct and indirect costs of implementing the backfitting are justified in view of the increased protection.~~

~~The backfitting provisions generally contain three exceptions to the backfit analysis requirement described above, such that the analysis is not necessary when the backfitting action—~~

~~Is required for adequate protection,~~

~~Defines or redefines the level of protection that should be regarded as adequate, or is necessary to bring a facility into compliance with applicable requirements in the licensing basis, or into conformance with its written commitments.~~

~~13. Adequate protection backfitting, whether used to ensure that adequate protection is maintained or to define or redefine the level of protection that should be regarded as adequate, does not require a finding of substantial safety or security improvement, nor does it require that costs be considered. If a backfitting action is deemed necessary for adequate protection, it must be implemented, as required by Section 161 of the Atomic Energy Act of 1954, as amended (AEA). Compliance backfitting does not require a finding of substantial safety or security improvement, but does require some consideration of costs. Use of the adequate protection or compliance exception must be explained in a risk-informed, documented evaluation.~~

~~14. The backfit analysis requirement, and the exceptions to that requirement, restrict the ability of the NRC to conduct backfitting by requiring the NRC to demonstrate, before implementing the backfit, that the backfitting action would meet certain standards~~

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<sup>11</sup>—As noted in the Statements of Consideration for the 1985 backfitting final rule (50 FR 38097; September 20, 1985), a “substantial” increase in protection means “important or significant in a large amount, extent, or degree.” Under such a standard, the Commission would not ordinarily expect to justify backfitting plant improvements that result in an insignificant or small benefit to public health and safety or the common defense and security, regardless of costs.

~~that vary based on the type of facility. In this way, the backfitting rules provide the following:~~

- ~~(a) Regulatory stability, by limiting the changes the NRC can make;~~
- ~~(b) Reasoned and informed NRC decisionmaking, by requiring the proposed action to be properly justified; and~~
- ~~(c) Transparency of NRC decisionmaking, by requiring the NRC to document and make publicly available its analyses.~~

~~15.12.~~ This MD and DH reflect NRC policy direction and provide the process for implementing that policy. The MD and DH list the regulations and guidance documents that govern backfitting and describe how the NRC implements those regulations. Backfitting guidance for the NRC staff is available in NUREG-1409. Office or region-specific guidance is not required or desired. Consistency of implementation is assured by the staff's use of NUREG-1409.

~~16.13.~~ Any change to an NRC staff position that the NRC intends to communicate to a licensee(s) as being applicable to their facility by any means may be identified as backfitting either by the staff or by licensees. The means of communication can be through the issuance of regulatory guidance, inspection reports, generic communications, or staff interactions with licensee personnel. The NRR, NRO or NMSS office director (OD) or regional administrator (RA) responsible for the staff position and affected facility or facilities will make the determination as to whether the new or revised staff position constitutes backfitting and whether the backfit should be imposed on the licensee(s).

~~17.14.~~ In support of the Commission's probabilistic risk assessment (PRA) policy statement<sup>12</sup> of August 1995, which encourages the use of PRA "in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy," risk insights must be considered, to the extent practical, as part of all backfitting actions. Risk information should be integrated in a manner that complements traditional regulatory approaches and supports the defense-in-depth philosophy, which would improve the technical basis, increase efficiency, and enhance effectiveness. All backfitting actions must be risk-informed.

~~18.15.~~ Exhibits 1 and 2 in this handbook are flowcharts that illustrate the NRC's program for processing backfits and backfit appeals.

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<sup>12</sup> Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement (60 FR 42622; August 16, 1995).

## B. Information ~~Collection~~ Requests

- ~~1.~~ The provisions of 10 CFR 2.204, "Demand for Information," require that a licensee respond to information requests from the Commission for the purpose of determining if an Order under 10 CFR 2.202, "Orders," should be issued, or whether other actions should be taken.
- ~~2.1.~~ The provisions of 10 CFR 50.54(f) require power reactor licensees to respond to information requests from the ~~staff~~NRC to enable the determination of whether a license should be modified, suspended or revoked. This rule stipulates that, except for information sought to verify licensee compliance with the facility's LB, the NRC must prepare the reasons for the information request to ensure that the burden imposed on licensees is justified based on the potential safety ~~or security~~ significance of the issue to be addressed. For additional information regarding appropriate use of 10 CFR 50.54(f), see Section IV, Information Requests.
- ~~3.2.~~ Requests for information for power reactors to be licensed under 10 CFR Part 52 will be in accordance with the administrative requirements in 10 CFR 50.54(f), and as stated in 10 CFR 52.39(f), 10 CFR 52.98(g), 10 CFR 52.145(c), or 10 CFR 52.171(c), as applicable. The information ~~collection~~ requirements for selected materials licensees are contained in 10 CFR 70.22(d), 10 CFR 72.62(d), and 10 CFR 76.70(e).
- ~~4.3.~~ This MD and DH reflects the policy for ~~all~~ requests for information under these provisions.

## C. Coordination and Communication

For effective implementation of the NRC's backfitting and information ~~collection request~~ programs, the ODs and the RAs must ensure the following:

1. Effective communication and coordination are maintained between their counterparts and among the responsible technical staff within the headquarters and regional offices.
2. Processes, procedures, and programmatic and administrative controls are written in plain English.
3. Formal feedback from the Committee to Review Generic Requirements (CRGR) provided during the review of a proposed rule involving backfitting is addressed as part of the rulemaking package before its submittal to the Executive Director of Operations (EDO).
4. No backfitting actions will be communicated to a licensee unless the appropriate OD or RA has determined whether the position involves backfitting and, if so, has ensured that the position is identified as backfitting, the appropriate material (i.e.,



documented evaluation or backfit analysis) has been prepared and approved, the CRGR was offered an opportunity to review the documentation, and written feedback was considered. NRR shall ensure backfitting actions are consistently implemented throughout the regions.

#### D. Recordkeeping

Offices and regions directly involved in backfitting or information ~~collection~~ requests are responsible for tracking and maintaining associated records originating in that office or region. Documentation of the justification for backfitting or use of a backfit analysis exception is required by 10 CFR 50.109, 10 CFR 70.76, 10 CFR 72.62, and 10 CFR 76.76. Documentation of the justification for information requests under 10 CFR Parts 50 and 52 are required by 10 CFR 50.54(f), 10 CFR 52.39(f), 10 CFR 52.98(g), 10 CFR 52.145(c), or 10 CFR 52.171(c), as applicable.

1. The office or region proposing information ~~collections~~ requests or backfitting actions must administratively manage each ~~collection~~ request or action by maintaining all related records. Records must be maintained in accordance with NUREG-0910, "NRC Comprehensive Records Disposition Schedule," issued March 2005.
2. Backfitting records placed in the Agencywide Documents Access and Management System (ADAMS) must be accessible to all stakeholders by being profiled as publicly available when appropriate, consistent with agency guidance on the release of information to the public.

## II. BACKFITTING APPLICABILITY

### A. Regulatory Changes Subject to the Backfit Rule

1. ~~As defined in Section I.A, a~~An NRC action is considered backfitting when the NRC changes any requirements through rulemaking, ~~an~~ Order, or ~~the~~ imposition of a new or modified staff position that interprets requirements and would result in the modification or addition to SSCs, or the design of a facility, or the design approval or ML for a facility, or the procedures or organization required to design, construct, or operate a facility, after the dates defined in the backfitting requirements.
2. If the NRC staff conveys an expectation that licensees change programs, processes, procedures, or the physical plant by using or committing to use voluntary guidance (e.g., RGs or NRC-endorsed industry TRs) that is not already within the LBlicensing basis for the identified purpose, then the staff's communication of that expectation is may be considered backfitting. As discussed above, in section I.A.11, forward fits do not constitute backfits but must meet additional, specified criteria and are subject to the backfit appeals process. Since there is generally more than one way to achieve compliance with a license or the rules or orders of the Commission, or with written

~~licensee commitments, or there may be more ways to reach a level of protection that is adequate, the applicant or licensee is ordinarily free to choose the way which best suits its purposes. However, this does not apply during the review and consideration of any voluntarily submitted license application, LAR, or LRA, provided the issue in question is somehow associated with, and is within the scope of, the license application, LAR, or LRA under consideration.~~

3. A relaxation is the modification of a regulatory requirement or staff position that reduces ~~requirements~~ the obligations of placed on a licensee or class of licensees. A relaxation may provide licensees the option of continuing as previously licensed (status quo), or adhering to the new “relaxed” regulatory requirement or staff position. If a relaxation does not provide for the status quo option, it is mandatory, and the relaxation is considered backfitting. ~~However, if the implementation of the relaxation is voluntary for the licensee, in that it does provide for the status quo option, then the relaxation is not backfitting, even if the licensee decides to implement the relaxed requirement.~~

## **B. Nonapplicable Regulatory Changes**

1. The ~~NRC’s backfitting rules do not apply to the~~ following regulatory actions generally do not meet the definition for backfitting:
  - (a) Confirmatory action letters (CALs), because CALs involve voluntary actions a licensee commits to take, which are agreed to between the licensee and the NRC;
  - (b) Changes mandated by statute or other Congressional action that preclude agency discretion in their implementation;
  - (c) Changes required by other Federal agencies that preclude agency-NRC discretion in their implementation;
  - (d) Voluntary licensee submittals ~~of an LAR or LRA or subsequent license renewal (SLR) request,~~<sup>13</sup> subject to the limitations discussed above in Section I.A.104, and the NRC’s process (requests for information, licensee engagement, or modifications to the submittal) used during the review and consideration of the LAR, LRA, or SLR request;
  - (e) ~~A licensee’s voluntary implementation of NRC-recommended actions that do not constitute the basis for resolution of a safety, security, or regulatory issue (e.g., a~~

<sup>13</sup> ~~The scope of the NRC’s review of an LR or SLR and, thus, the backfitting of these applicants, is limited by the regulations in 10 CFR 54.30, “Matters Not Subject to a Renewal Review.”~~

~~licensee's decision to follow an NRC RG, or an NRC-endorsed TR, or to make changes based on an NRC Information Notice);~~

~~(f)(e) Issuance of a notice of violation for an improper change~~ Overturning of an improper change implemented under 10 CFR 50.59, "Changes, Tests, and Experiments" resulting in a modification to a facility;

~~(g)(f)~~ Licensee changes or plant modifications that expand the plant capabilities or improve plant efficiencies or performance that are not mandated by the NRC;

~~(h)(g)~~ Non-mandatory relaxations of staff positions or regulations;

~~(i) New or changes to requirements that do not have a direct link to, and do not further a substantive radiological public health and safety or common defense and security objective, such as reporting and recordkeeping requirements (e.g., 10 CFR 50.71, 50.72, "Immediate Notification Requirements for Operating Nuclear Power Reactors") or appeals processes (e.g., 10 CFR 26.39, "Review Process for Fitness For Duty Policy Violations," 10 CFR 73.56(l), "Review Procedures");~~

~~(j)(h)~~ Changes or updates to American Society of Mechanical Engineers Boiler and Pressure Vessel (ASME) Code, Section XI, that are incorporated into 10 CFR 50.55a, "Codes and Standards.";

~~(k)(i)~~ Plant or procedural changes to comply with industry or professional standards not mandated by the NRC;

~~(l)(j)~~ Current and future applications for an NRC license, with two exceptions described in Section II.B.24 below;

~~(m)(k)~~ Voluntary changes made to a plant based on national or international operating experience, including any changes as a direct result of NRC Information Notices;

~~(n)(l)~~ Changes as a result of a licensee's commitment management program;

~~(o)(m)~~ Licensee changes to its plant under 10 CFR 50.59 or other existing change control requirements (see Section II.B.23 below); and

~~(p)(n)~~ Plant or procedural corrective actions to restore the LB or adherence to the license and thereby provide compliance with governing requirements.;

~~2. The issuance of new or updated NRC RGs, as RGs are forward fitting, provided the RGs are not imposed on licensees;~~

~~3. The endorsement of new or updated industry-submitted TRs, because TRs are forward fitting and not imposed by the NRC; and~~

- ~~4. The staff use of documents, such as NUREGs, ISGs, and BTPs, during the review and consideration of any LAR or LRA, as the submission of the LAR or LRA is a voluntary action by a licensee applying for a change to its license, subject to the limitations discussed in Sections I.A.11 and I.A.14.~~
- ~~5. If an existing licensee voluntarily requests a license amendment or change, and (1) the NRC staff's consideration of the request involves a regulatory issue directly relevant to an NRC guidance document (such as an RG) and (2) the specific subject matter of the guidance document is an essential consideration in the staff's determination of the acceptability of the licensee's request, then the staff may request that the licensee either follow that guidance or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements in the licensing basis. This is not considered backfitting.~~
- ~~6. Power reactor licensee implementation of changes to its facility under 10 CFR 50.59 are not subject to the backfitting rules. The NRC has established a process under 10 CFR 50.59 that provides a licensee the authority to make certain changes without NRC approval if the change meets certain specified criteria. Unless the NRC determines that the licensee incorrectly used the 10 CFR 50.59 process, the licensee reasonably can implement the change without the NRC taking enforcement action. This is consistent with the underlying premise of regulatory stability established within the backfitting rules and the principles of good regulation. However if, during any inspection or review of licensee actions implemented in accordance with 10 CFR 50.59, the staff determines that 10 CFR 50.59 was not properly implemented, the staff shall issue a finding or violation in accordance with regulations, and the licensee may be required to "revert" to the previous plant or procedural configuration, or otherwise change the facility to a configuration acceptable to the NRC. This would not be considered backfitting.~~
- 7.2. In general, backfitting provisions do not apply to current and future applicants for an NRC license. Backfitting is not intended to apply to every NRC action that substantially changes the expectations of current and future license applicants. There are two exceptions to this general principle. The first exception occurs when a 10 CFR Part 52 license applicant references a 10 CFR Part 52 license (e.g., an ESP) or NRC regulatory approval (e.g., a DCR), or both, with specified issue finality provisions. The second exception occurs when a 10 CFR Part 50 power reactor OL applicant holds a CP or limited work authorization (LWA). Section 50.109 would apply to the matters covered by the CP or LWA. See also the discussion on the use of the SRP for review of LWR applications in Section I.A.11 of this DH.
- ~~8. Actions proposed or voluntarily implemented by a licensee are not backfits, even though such actions may result from routine discussions between the staff and the licensee concerning an issue, provided that those discussions did not include an NRC expectation that the licensee must implement the action.~~

### III. BACKFITTING POLICY

#### A. Adequate Protection Backfitting

1. For all matters of potential backfitting, including forward fitting, the staff must first consider whether the issue is one of adequate protection.<sup>14</sup> If the NRC staff determines that it must impose a backfitting action to ensure that a facility provides adequate protection to public health and safety and is in accord with the common defense and security, or if the Commission decides that it needs to define or redefine the appropriate level of protection of public health and safety or the common defense and security that should be considered as adequate, then the AEA requires that the backfitting action be implemented. A backfit analysis to justify the determination that a backfitting action is necessary for adequate protection and a consideration of costs are not required (unless the NRC staff identifies more than one means for implementing the new requirement, in which case costs could be considered in deciding which approach is appropriate). Whenever adequate protection is invoked, the NMSS, NRO or NRR OD must approve a risk-informed, documented evaluation of the type discussed in 10 CFR 50.109(a)(6), 10 CFR 70.76(a)(6), and 10 CFR 76.76(a)(6), with a finding that the action is necessary to define or redefine adequate protection or to ensure adequate protection of public health and safety or the common defense and security.<sup>15</sup> The risk-informed, documented evaluation must include a statement of the objectives, the reasons for the action, the basis for invoking adequate protection, and the safety or security risk if action is not taken. The NMSS, NRO or NRR staff should seek advice from the Office of General Counsel (OGC) on the imposition of all adequate protection actions, including the licensee's proposed implementation schedule. NUREG-1409 contains detailed guidance on how to prepare the documented evaluation. For generic backfitting actions that are part of rulemakings, the documented evaluation is provided as part of the rulemaking package that the Commission approves. Generally, adequate

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<sup>14</sup> Instances of adequate protection forward fitting should be extremely rare. This is because the NRC takes into account the potential for the imposition of backfits necessary for adequate protection under its mandatory backfitting provisions ((§§ 50.109(a)(5), 70.76(a)(5), and 76.76(a)(5), and the portions of 72.62(b) regarding backfitting necessary to assure adequate protection of public health and safety) when regulatory staff positions interpreting the Commission's requirements are developed. Once a new or revised regulatory staff position interpreting the Commission's requirements is finalized, the potential for backfitting that is necessary for adequate protection of public health and safety would have been considered and accomplished as appropriate.

<sup>15</sup> It is the policy of the NRC that backfitting actions under 10 CFR 72.62 that are similarly justified must be documented in a manner similar to those under 10 CFR 70.76(a)(6), and 10 CFR 76.76(a)(6).

protection backfits are not included in rulemakings, and instead, result from the issuance of an Order. The rulemaking will subsequently be issued to include the previously imposed adequate protection backfits, given consideration to public comments provided on the proposed rule and to lessons learned through the implementation of the previous Order requirements.

2. To issue the license, the Commission found that operating in accordance with the license would provide reasonable assurance of adequate protection of public health and safety and reasonable assurance that the licensee would meet the regulations. Therefore, licensee compliance with its LB is presumed to provide reasonable assurance of adequate protection of public health and safety and the common defense and security. Thus, for the NRC to impose new or changed requirements on a licensee that are intended to provide for adequate protection of public health and safety or the common defense and security, the NRC must provide, within the documented evaluation, a clear explanation of why, despite the licensee's compliance with the applicable existing regulatory framework (LB), there is not (or will not be) reasonable assurance of adequate protection. This evaluation must include appropriate consideration of risk insights. Typically, a clear basis for invoking the adequate protection exception can be established when the NRC has new information regarding a safety or security issue that creates undue risk to public health and safety that is not addressed through compliance with the current regulatory framework. If the NRC can show that it must take action to provide reasonable assurance of adequate protection of public health and safety and the common defense and security, then the AEA requires the NRC to impose the new or changed requirements.

2.3. Upon determining that a backfit is necessary for adequate protection of public health and safety, the NRC must then consider whether the underlying safety issue presents an imminent threat to public health and safety. If so, the agency must take immediate action.

3.4. It is the NRC's position policy<sup>16</sup> that the agency cannot allow licensees to address issues of adequate protection by a voluntary initiative. Instead, the AEA requires the

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<sup>16</sup> In SRM-SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," dated March 2 May 27, 1999 (ADAMS Accession No. ML003752062992810068) the Commission approved the staff's recommendation ~~agreed~~ that relying on voluntary industry initiatives to ensure adequate protection would be inappropriate "since they would be based on commitments rather than requirements."

NRC to establish requirements that provide reasonable assurance of adequate protection of public health and safety and the common defense and security.

~~4. 5.~~ Under 10 CFR 50.109(a)(5), 70.76(a)(5), 72.62 and 76.76(a)(5), the Commission requires the imposition of a backfit if it finds that the backfit is necessary to ensure adequate protection of occupational or public health and safety.

5. Under 10 CFR 72.62, the Commission requires the imposition of a backfit if it finds that the backfit is necessary to ensure adequate protection of occupational or public health and safety.

## **B. Compliance Backfitting**

1. Compliance backfitting is intended to address situations in which the licensee has failed to meet known and established standards of the Commission because of omission or mistake of fact. New or modified interpretations of what constitutes compliance do not fall within the exception.

2. Before the staff uses the compliance exception, the staff must determine whether the conditions represent an issue of adequate protection. If the issue does not involve adequate protection, then the staff should determine whether the backfitting action is necessary to ensure compliance with regulatory requirements in the licensing basis, or written commitments on how the licensee will comply with a requirement that were in place at the time of the decision at issue. ~~If the backfitting action ensures compliance, a backfit analysis is not required. Instead,~~ The appropriate program office or region prepares a risk-informed, documented evaluation of the type discussed in 10 CFR 50.109(a)(6), 10 CFR 70.76(a)(6), and 10 CFR 76.76(a)(6), with a finding that the action is necessary to ensure compliance as the result of an error of omission or mistake of fact. The documented evaluation must include a statement of the objectives, the reasons for the action, the basis for invoking the compliance exception, and the safety or security risk if action is not taken. NUREG-1409 contains detailed guidance on how to prepare this documented evaluation. The responsible office staff shall seek OGC and the Office of Enforcement (OE) advice on the imposition of all compliance backfitting actions, including the licensee's proposed implementation schedule. The NRC staff's compliance backfitting documentation should include risk insights, including safety margin,<sup>17</sup> to provide the

<sup>17</sup> Safety margin may not be quantifiable. For example, meeting environmental qualification (EQ) requirements in 10 CFR 50.49 "Environmental qualifications of electrical equipment important to safety for nuclear power plants," results in safety margin, but this margin is not readily quantifiable, particularly with regard to public health and safety (i.e., the equipment is robust for performing under events that are important to plant risk and are less severe than the environmental qualifications envelop).

staff sufficient information to determine an acceptable schedule for the licensee to implement the backfit. These risk insights may also indicate that it is appropriate to terminate consideration of a backfitting action as discussed in item 9 of this section.

- 4.3. The phrase “written commitments,” as used within the backfitting provisions, refers to those commitments that have been submitted to the NRC on the docket, have ~~become part of the LB~~been incorporated into the license, and directly relate to the means by which the licensee complies with a requirement.
- 2.4. Under 10 CFR 72.62, the Commission will require the imposition of a backfit if it finds that the backfit is necessary to bring an ISFSI or MRS into compliance with a license or the Commission’s Orders or rules. ~~Under 72.62(b), “The Commission will require backfitting of an ISFSI or MRS if it finds that such action is necessary to assure adequate protection to occupational or public health and safety, or to bring the ISFSI or MRS into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by a licensee.”~~
- 3.5. ~~Because a compliance backfitting action does not require a backfit analysis, the staff need not demonstrate that the direct and indirect costs of implementation are justified in view of the increased protection from the backfit. However, As noted in paragraph I.A.5, when the NRC imposes new requirements not needed to ensure adequate protection, the APA requires some consideration of cost. Thus, the staff must include at least some consideration of costs in its documented evaluation. for a compliance backfit performed under 50.109(a)(4), 70.76(a)(4), or 76.76(a)(4).~~ Although the extent of the consideration required will necessarily be fact- and site-specific, one of the factors that may be relevant is the amount of time that has elapsed since the approval that is now claimed to be the subject of a mistake or omission. When the potential for compliance backfitting is identified relatively soon (within approximately 2 years) after the licensing decision or the imposition of a regulatory requirement, likely all that will be necessary is a simple estimate of the cost of imposing the backfitting action that does not quantify benefits or perform any balancing beyond that which was originally considered. However, when many years have passed (typically more than 10) before the staff determines that a regulation or requirement is not satisfied, identifying the benefits of compliance and comparing them to the cost of implementation will likely be appropriate to ensure that costs have been adequately considered. The staff is afforded ~~a high degree of substantial~~ flexibility, in accordance with Commission direction, to determine how much cost consideration is appropriate based on the specifics of each case and the identified risk.
- 4.6. Use of the compliance exception is limited to the following situations that define “omission or mistake of fact”:



- (a) The NRC staff, whether by its own error or by licensee or third-party error or omission at or before the time of its determination that a known and established standard of the Commission was satisfied, (1) incorrectly perceived facts, (2) performed or failed to recognize flawed analyses, or (3) failed to properly draw inferences from those facts or analyses, as judged by the standards and practices that were prevailing among professionals or experts in the relevant area at the time of the determination in question, and
- (b) Those facts, analyses, or inferences have now been properly perceived, performed, or drawn.
- (c) The error or omission may have been committed by any involved party and must be traced to—
  - (i) The original LB or to a change to the LB, and
  - (ii) The regulations ~~contained-reflected~~ in the LB at the time of implementation that were applicable to the particular licensee whose LB is at issue, and
  - (iii) Any standards and practices in existence at the time the original determination was made.

The understanding for what constituted proper implementation of the regulations, standards, and practices must have been widely known or understood by professionals at the time. This is not restricted to the regulatory positions of the NRC but includes any industry or professional standards and practices in existence at the time the original determination was made.

5.7. The compliance exception should not be applied to the following:

- (d) Failure of the NRC staff to extrapolate conclusions from facts, analyses, and direct inferences in ways that were not commonly recognized under such prevailing professional standards and practices at the time of the NRC determination; or
- (e) Recharacterizations of whether a particular set of otherwise understood circumstances satisfies the standard at issue based upon professional standards and practices developed or accepted after the time of the determination.

6.8. The following policy concerns the use of the compliance exception to mandate consistency with the general design criteria (GDC).

- ~~(a) The GDC are located in Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50 and 10 CFR Part 72, Subpart F, "General Design~~

~~Criteria.” Those design criteria help formulate a plant’s design basis, and the design basis is reflected in the plant’s final engineering drawings. The design basis must be documented in the UFSAR.~~

~~(b) The GDC establish “minimum requirements” for the development of the principal design criteria (PDC). The GDC are intended to provide guidance in establishing the PDC. The licensing process requires approval of an applicant’s PDC as a condition for granting a CP. Before an OL is issued, and as a basis for its finding of reasonable assurance of adequate protection of public health and safety and the common defense and security, the Commission must find that the facility has been built in accordance with the PDC and any NRC-approved changes. Thus, for 10 CFR Part 50 licensees with CPs issued since 1971 (when the GDC were promulgated), the Commission has already necessarily reached the conclusion that the design basis of the plant, as reflected in the PDC, meets or exceeds the minimum criteria set forth in the GDC. The 1992 SRM approved the SECY that concluded that no GDC backfitting was needed, and that all pre-GDC plants meet the intent of the GDC.<sup>18</sup>~~

~~(e)(a) The NRC must not rely on the GDC requirements for pre-GDC licensing actions (those licenses or CPs issued before the issuance of the GDC (before 1971)), unless the NRC has made the GDC a requirement for that licensee.~~

~~(d) Under the provisions of 10 CFR 50.34, “Contents of Applications; Technical Information,” an application for a CP must include the PDC for a proposed facility. Under the provisions of 10 CFR 52.47, “Contents of Applications; Technical Information,” 10 CFR 52.79, “Contents of Applications; Technical Information in Final Safety Analysis Report,” 10 CFR 52.137, “Contents of Applications; Technical Information,” and 10 CFR 52.157, “Contents of Applications; Technical Information in Final Safety Analysis Report,” an application for a DC, COL, SDA, or ML, respectively, must include the PDC for a proposed facility. The PDC establish the necessary design, fabrication, construction, testing, and performance requirements for SSCs important to safety; that is, SSCs that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public.~~

~~(e)(b) The license approval process will typically yield more specific requirements than those set forth in the GDC. However, the NRC is not~~

<sup>18</sup>—SRM was in response to SECY-92-223 “Resolution of Deviations Identified During the Systematic Evaluation Program” and is dated September 18, 1992 (ML12256B290).

precluded from reliance on GDC as the source of a “requirement” for purposes of invoking the compliance exception ~~in those cases where a GDC provides more than just a performance standard and has not been superseded through the approval of the PDC, and requirements derived from those PDC that are clearly meant to address the GDC at issue. Thus, a GDC can be regarded as a requirement in those circumstances in which~~ when the GDC is prescriptive in nature and the technical specifications and other licensee requirements derived from the PDC do not speak to the matter in question.

~~(f) In some cases, conditions not in accordance with the GDC can be properly resolved as a matter of adequate protection if the matter creates undue risk to public health and safety or the common defense and security, without the need to invoke the compliance exception. The extent to which regulatory action is necessary to ensure adequate protection should be evaluated before invoking the compliance exception based on a requirement set forth in the GDC.~~

Use of the compliance exception to support a backfit should not be confused with routine inspection activities related to the LB, as determined by the reactor oversight process or other inspection activities. NRC inspections assess compliance with the requirements in the licensing basis, whereas compliance backfitting is pertinent to those issues where the staff has determined that it is necessary to modify the approved LB because of an error or omission. Thus, it is not expected that findings or violations documented as part of the NRC’s inspection activities would result in compliance backfitting. However, the NRC staff must evaluate each circumstance to ensure the issue is properly assessed against the LB and resolved. For example, the NRC would take enforcement action when a licensee is not in compliance with the NRC-approved method of meeting a requirement, whereas compliance backfitting would occur when a licensee is in compliance with an NRC-approved method but the NRC subsequently determines that the licensee’s method does not result in compliance with the requirement because of an ~~error or omission~~ or mistake of fact at the time of approval.

~~7.1. The NRC staff’s compliance backfitting documentation should include risk insights, including safety margin<sup>19</sup>, to provide the staff sufficient information to determine an acceptable schedule for the licensee to implement the backfit.~~

<sup>19</sup>—Safety margin may not be quantifiable. For example, meeting environmental qualification (EQ) requirements in 10 CFR 50.49 “Environmental qualifications of electrical equipment important to safety for nuclear power plants,” results in safety margin, but this margin is not readily quantifiable.

8.9. At any point during the process, the responsible program office or the region, in consultation with other appropriate offices, including OGC and OE, may decide not to proceed with the backfitting action because further effort is likely to show either of the following:

- (a) Compliance backfitting would not provide any increase in safety or security as compared to the status quo. This is not to say that the increase in safety or security must be substantial, only that there must be some attributable increase.
- (b) An exemption from compliance with the Commission's regulation for which compliance is sought may be granted under 10 CFR 50.12, "Specific eExemptions;" 10 CFR 52.7, "Specific eExemptions;" 10 CFR Part 70 Subpart B, "Exemptions;" 10 CFR 72.7, "Specific eExemptions;" or 10 CFR 76.23, "Specific eExemptions."

9.10. ~~Or, i~~In consultation with OE, the OD or RA may determine that enforcement discretion should be granted to enable the licensee to prepare a systematic and planned approach for implementing a backfitting action. If the OD or RA and OE conclude that enforcement discretion is appropriate or necessary, based on a risk-informed analysis and in consideration of licensee outages and maintenance schedules, OE, with the OD or RA, will normally issue an enforcement guidance memorandum or seek Commission approval for an interim enforcement policy for multifacility compliance backfitting actions, as appropriate.

- (a) An enforcement guidance memorandum is usually the appropriate enforcement discretion for generic or industrywide compliance backfits.
- (b) For individual facility- or site-specific compliance backfitting actions, the exercise of enforcement discretion may be addressed in the Order associated with the compliance backfit.

~~10. If adequate protection is not involved, then a determination must be made to verify there is adequate safety margin with respect to the regulatory requirements. Therefore, consideration of cost is relevant in determining if a backfit is needed to recover the lost safety margin.~~

11. If, after careful consideration of the issue, risk to public health and safety or the common defense and security, safety margin, and licensee costs for implementation of the compliance backfit, the NRC determines that compliance should not be

~~particularly with regard to public health and safety (i.e., the equipment is robust for performing under events that are important to plant risk and are less severe than the environmental qualifications envelop).~~

required, then the NRC will normally grant enforcement discretion until such time as the NRC initiates and issues an exemption in accordance with 10 CFR 50.12, an amendment in accordance with 10 CFR 50.90, a relaxation of an order, or other action as appropriate.

### C. Cost-Justified Substantial Increase in Protection Backfitting

For all backfitting that does not satisfy the adequate protection exception or compliance exception criteria, the NRC should determine whether to ~~perform~~ impose a backfit ~~analysis~~ by applying the facts of the proposed backfitting against the backfit standard as described below.

#### 1. Backfit or Issue Finality Standard

The backfitting provisions require, first, that the proposed action result in a substantial increase in the overall protection of public health and safety or the common defense and security. If either criterion is met, the standard then requires that the direct and indirect costs are shown to be justified in light of the substantial increase in overall protection. If the proposed action is not shown to result in a substantial increase in safety or security, or the costs are not justified, then the backfit cannot be imposed (unless the Commission exempts itself from the backfitting rule; although as noted in paragraph I.A.5, when the NRC imposes new requirements not needed to ensure adequate protection, the APA requires some consideration of cost.).

In the statement of considerations for the 1985 reactor backfitting rule, the Commission said the following:

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

#### 2. Backfit Analysis

All backfit analyses must be performed in accordance with 10 CFR 50.109 or other applicable regulations and NUREG-1409.

- (a) Once the NRC determines that backfitting ~~must~~ should be pursued, and adequate protection or compliance backfitting are not appropriate, the NRC staff must develop a backfit analysis.
- (b) The staff must demonstrate and document that the backfit standard is met. The staff must consider available quantitative and qualitative data in making this determination. ~~If necessary, relevant, and consistent with SRM-SECY-14-0087, "Staff Requirements – SECY-14-0087- Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," dated March 4, 2015, qualitative considerations may be used to demonstrate a cost-justified increase in protection. As directed, q~~Qualitative factors should be used in a judicious and disciplined manner to inform decisionmaking, in limited cases, when quantitative analyses are not possible or practical (i.e., due to lack of methodologies or data). Accordingly, an analysis should be informed by applicable risk information, including a PRA, to the extent it is available and can be considered without undue use of NRC resources. The staff will also consider information available concerning any of the factors listed in 10 CFR 50.109(c), as may be appropriate, and any other information relevant and material to the proposed backfitting, including NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission."
- (c) ~~Relaxations may not show a substantial increase in safety or security; consequently, implementation of these relaxations are voluntary for the licensees.~~ In most cases, relaxations involve alternative regulatory approaches that licensees can choose to implement, may involve small decreases in safety or security, and are not backfitting actions if options for implementation are offered to the licensees. When such options are offered, the NRC verifies that compliance with the licensee's LB, including the relaxation (if it involves a small decrease in safety or security), continues to provide reasonable assurance of adequate protection.
3. Under 10 CFR 72.62, the Commission can require the backfitting of an ISFSI or MRS installation if it finds that the backfitting action would result in a substantial increase in protection to the occupational or public health and safety whose costs are justified in light of the increased protection.

#### D. Additional Considerations

1. For all backfitting actions, additional procedural factors required by the CRGR Charter for justification must be used if they apply to the issue. Furthermore, as

additional administrative controls, the offices or regions may use reviews by special internal panels, and OE and OGC review and concurrence, as appropriate.

2. The NRC staff should recommend terminating a proposed agency action that would constitute backfitting when the staff concludes that the proposed action is not necessary for adequate protection; the compliance exception to the backfit analysis requirement does not apply; the backfitting action is not likely to result in a substantial increase in safety or security; or, if a substantial increase in safety or security can be demonstrated, the direct and indirect costs of implementation are not likely to be justified. The responsible program OD or RA may approve closing the issue with appropriate notice sent to all applicable parties and recorded in ADAMS.
3. During the course of dispositioning a proposed finding, violation, or licensing action, a licensee may raise concerns that the proposed action is backfitting. The staff will inform divisional management of the concern, before the proposed action is taken, with ensuing discussions considering previous regulatory staff positions and enforcement precedence. A lack of historical staff position could be indicative of a new staff position and therefore subject to backfitting provisions. Informing divisional management and researching historical positions ensures appropriate consideration of licensee concerns and supports agency operation as a stable and reliable regulator.

#### E. Scheduling of Backfitting Implementation

1. After the appropriate OD (NMSS, NRO, or NRR) or RA has approved a facility-specific documented evaluation or backfit analysis, the responsible division director or above must issue the backfitting requirement to the licensee. The licensee may choose to implement the backfitting action or appeal the decision to the program OD or RA.
2. Implementation of a facility-specific backfitting action should be accomplished on a schedule based on the safety or security significance and overall risk of the issue, with the exception of any adequate protection backfits that should must be expeditiously imposed if the NRC finds that an imminent threat to public health and safety exists. Upon determining that a backfit is necessary for adequate protection to public health and safety, the NRC should prepare an imminent threat analysis that determines whether immediate action is necessary. The staff should consult with its regional and program office counterparts and OE to establish the implementation schedule, identify the implementation actions, and determine if and when enforcement action is appropriate. The responsible OD or RA, in collaboration with OE, must determine whether enforcement discretion is appropriate, and how it will be addressed in the facility specific backfit action.

- ~~3. In accordance with the backfitting provisions (e.g., 10 CFR 50.109(c)), scheduling criteria will include the importance of the backfitting action (i.e., safety or security significance, including risk) relative to other safety or security-related activities underway, such as planned construction, outages, or other maintenance.~~
- 4.3. For generic backfitting actions that are part of rulemaking, schedule considerations are addressed as part of the rulemaking process, and are typically included in the new regulations as implementation or scheduling provisions.
- 5.4. A facility-specific backfitting action may be imposed by Order before completing any of these procedures if the OD who authorized the backfitting action determines that immediate imposition is necessary to ensure public health and safety or the common defense and security. In such cases, the appropriate OD must promptly notify the EDO of the action and, if possible, the staff must prepare a documented evaluation in time to be issued with the Order. If the documented evaluation cannot be issued with the Order, the evaluation must be completed as soon as possible after issuance of the Order and made publicly available.

#### F. Appeals of Backfitting Decisions

1. By NRC policy, the NRC affords licensees an opportunity to appeal any staff action that does not comport with agency's backfit rules ~~backfitting action~~ at two levels: a First-Level Appeal to the OD or RA and a Second-Level Appeal to the EDO.
2. The appeal process applies to the following two situations:
  - (a) An applicable staff position that the NRC staff determined was not backfitting, but the licensee believes is backfitting, or
  - (b) An applicable staff position that the NRC staff determined was backfitting, but the licensee believes was not properly justified, ~~including an appeal to modify or withdraw a backfitting action for which a backfit analysis was conducted or an appeal that a backfitting action justified by the adequate protection or compliance exception in fact must be justified through a backfit analysis.~~
3. If at any time during an appeal process, the NRC determines the proposed action is unjustified backfitting, the responsible OD or RA, or designee, must document the decision and inform the licensee.
4. The First-Level Appeal process must be carried out before the Second Level Appeal process. In the event a licensee addresses its initial appeal of a staff action to a level above the OD or RA, the appeal should be assigned to the OD of the program office that oversees the subject of the backfit, who will then oversee the First-Level Appeal process. ~~While a program OD or an RA can issue backfitting actions, a~~ All backfitting appeals are overseen by a program OD, who will coordinate the review with the RA



overseeing the affected facility, and ~~the OD for emergency preparedness or security issues, in the Office of Nuclear Security and Incident Response (NSIR).~~

5. First-Level Appeal:

- (a) The licensee may send a backfitting appeal in writing to the OD or RA whose staff proposed or issued the action. The program OD is responsible for deciding the appeal. This constitutes a First-Level Appeal.
- (b) During the review process, the OD may designate a panel to consider the appeal. A public meeting must be offered at which the licensee may discuss the appeal to ensure the NRC has a full understanding of the appeal. No determinations will be made at this public meeting.
- (c) During the review process and following any public meeting with the licensee, a meeting with the originating staff must be offered to discuss the backfitting action and supporting documentation to ensure a full understanding of the initial action in question.
- (d) After appropriate interoffice coordination and management review of the licensee's appeal, the program OD, working with the responsible RA and the NSIR OD, as applicable, must decide on the appeal. This process should be completed within 90 days of the date the NRC accepts the appeal.
- (e) The ~~applicable~~ Deputy EDO responsible for the issuing office must be informed of the decision before the program OD informs the licensee of the decision in writing.
- (f) If the backfitting action is ~~determined to be the correct regulatory path forward, following the written decision of the appropriate program ODs sustained~~, the licensee may implement the action or submit a Second-Level Appeal.

6. Second-Level Appeal:

- (a) If the licensee does not agree with the outcome of a First-Level Appeal, the licensee may file a second and final appeal to the EDO.
- (b) The EDO may designate a panel to consider the Second-Level Appeal. A public meeting with the licensee must be offered to discuss the licensee's appeal ~~documentation~~ and allow for a full understanding of the licensee's position.
- (c) The EDO's designated panel must consider all supporting staff analyses, submitted licensee analyses, and supplemented staff analyses, as well as any

other information that is relevant and material to the appeal. Meetings with the staff involved in the original action in question and those involved in the First-Level Appeal must be offered to allow a full understanding of the staff position.

- (d) If the EDO determines that the action subject to a backfitting appeal is not considered backfitting, the action must not be treated further within the context of backfitting, but will be processed commensurate with the normal licensing or inspection appeal process.
- (e) If the EDO denies the appeal, the licensee must implement the action. If the licensee fails to implement the backfitting action, the appropriate OD must issue an Order. Once an Order is issued, whether or not it is immediately effective, MD 8.4 no longer applies. At this point, appeals are governed by the provisions of 10 CFR Part 2, "Agency Rules of Practice and Procedure," Subpart B, "Procedure for Imposing Requirements by Order, or for Modification, Suspension, or Revocation of a License, or for Imposing Civil Penalties."

#### **G. Exceptions**

The NRC staff is not required to make facility-specific backfitting findings when generic backfitting actions on the same issue(s) are, or have been, approved by the CRGR and EDO. This is also true for generic backfitting actions approved before November 1981, unless the EDO determines that significant facility-specific backfits were not considered during the prior reviews.

#### **H. Assessment of the Overall Effectiveness of the NRC's Backfit Management Program**

The CRGR assesses, ~~typically every 5 years,~~ the effectiveness of the NRC's administrative controls for backfitting, as part of its regulatory effectiveness responsibility, and provides a report to the EDO.

### **IV. INFORMATION COLLECTION PROCESS REQUESTS**

#### **A. NRC Regulations for Information Collection Requests**

~~1. Demands for information concerning alleged violations or potentially hazardous conditions or other facts are made pursuant to 10 CFR 2.204. Under Section 2.204, the NRC can require a licensee to respond for the purposes of determining if an Order under 10 CFR 2.202 should be issued, or whether other actions should be taken.~~

~~2. Information requests to power reactor licensees are made pursuant to 10 CFR 50.54(f). Under 10 CFR 50.54(f), the NRC can require request its licensees~~

to provide information to enable the Commission to determine whether or not a license should be modified, suspended, or revoked. This rule requires the NRC staff to justify these information requests with supporting analysis that demonstrates that the burden to be imposed on licensees is justified in view of the potential safety significance of the issue for which the information is requested. ~~The exceptions to this requirement to prepare a justification are as follows:~~

- ~~3. No supporting analysis is required whenever there is reason to believe that public health and safety or the common defense and security may not be adequately protected, and information is needed to determine if this is the case and to take any necessary corrective actions.~~
- ~~4. No supporting analysis is necessary if the staff seeks information of a type routinely sought as a part of the standard procedures for the review of applications for licenses or license amendments for facilities under construction, or the conduct of inspection activities for facilities under construction. However, if the request is not part of a routine licensing review (for example, if the staff seeks information to develop a new staff position), then the supporting analysis must include the reasons for the request and justify the estimated burden imposed on the licensee before issuance.~~
- 5.1. No supporting analysis is necessary for licensing reviews or inspection activities for operating facilities, or for information requests sought to verify licensee compliance with the requirements in the LB for the facility. Requests for information made in connection with fact-finding reviews, inspections, and investigations of accidents or incidents are not usually made, pursuant to 10 CFR 50.54(f). Furthermore, such requests are not normally considered within the scope of the backfitting rules.
- 6.2. The requirements for information ~~collection~~ requests for selected materials licensees are contained in 10 CFR 70.22(d), 10 CFR 72.62(d), and 10 CFR 76.70(e).
- 7.3. The requirements for information ~~collection~~ requests for power reactor licensees under 10 CFR Part 52 are contained in 10 CFR 52.39(f), 10 CFR 52.98(g), 10 CFR 52.145(c), and 10 CFR 52.171(c).
- 8.4. The information request sent to the licensee should document the staff's evaluation of the applicable information collection requirements for the request.

## **B. Justification**

1. The program OD and the RAs must ensure that the staff establishes a reasonable basis for all information requests (except in cases that do not require justification). Specifically, the responsible OD or RA must do the following:

- (a) Ensure that the staff has evaluated the request to determine whether the burden imposed on the licensee by the information request is justified, commensurate with the potential safety or security significance of the issue to be addressed. Such justification should consider the following:
    - (i) Whether the NRC already has the information being requested,
    - (ii) Whether the NRC can readily obtain the information absent a formal information request (for example, is the information available in the public domain),
    - (iii) How to minimize the population of entities from whom information is being requested, and
    - (iv) How to obtain the necessary information while minimizing the burden on requested entities.
  - (b) Approve the information request and the staff evaluation before transmittal of the request for information to a licensee.
2. The NRC staff's evaluations to demonstrate that an information request is justified must include at least the following elements:
- (a) A statement of the problem describing the need for the requested information in terms of its potential safety benefit,
  - (b) The licensee actions required and an estimate of the burden on the licensee to develop a response to the information request, and
  - (c) An anticipated schedule for the NRC to analyze and act on the information.

## V. TRAINING PROGRAMS FOR BACKFITTING AND INFORMATION COLLECTION REQUESTS

### A. Backfitting Training

The NRC ODs and RAs, informed by consultation with OGC and agency backfitting POCs, must plan for backfitting training for their staff that incorporates, at a minimum, the agency backfitting training program discussed below. NRC ODs and RAs may also provide additional backfit training that provides additional detail in areas pertinent to the region or office. ~~The agency backfitting training program should include beginner and advanced levels, as well as refresher courses.~~

### **B. Backfitting Agencywide Training Coordination**

The Office of the Chief Human Capital Officer (OCHCO) must maintain and update a backfitting training program for the NRC staff. OCHCO will develop the backfitting training modules in consultation with OGC, CRGR, ~~and~~ program ODs, OE, RES, and NSIR. OCHCO will also consult and coordinate with the appropriate contact in the Office of the Chief Information Officer to ensure backfitting training modules are available online. The agency backfitting training program should include beginner introductory and advanced levels, as well as refresher courses.

### **C. Information Collection Training**

The NRC program offices should maintain information collection training and qualification for project managers with support from OGC. Regional inspection procedures and qualification do not apply to this training requirement.

## **VI. ACRONYMS**

10 CFR	Title 10 of the <i>Code of Federal Regulations</i>
ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act of 1954, as amended
BTP	Branch Technical Position
CAL	Confirmatory Action Letter
COL	Combined License
CP	Construction Permit
CRGR	Committee To Review Generic Requirements
DC	Design Certification
DCR	Design Certification Rule
DEDO	Deputy Executive Director for Operations
DH	Directive Handbook
EDO	Executive Director for Operations
ESP	Early Site Permit
GDC	General Design Criterion/criteria
ISFSI	Independent Spent Fuel Storage Installation

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LAR	License Amendment Request
LB	Licensing Basis
LR	License Renewal
LRA	License Renewal Application
LWA	Limited Work Authorization
MD	Management Directive
ML	Manufacturing License
MRS	Monitored Retrievable Storage
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission
NRO	Office of New Reactors
NRR	Office of Nuclear Reactor Regulation
NSIR	Office of Nuclear Security and Incident Response
NUREG	NRC Technical Report Designation
NUREG/BR	NUREG Brochure
OCHCO	Office of the Chief Human Capital Officer
OD	Office Director
OE	Office of Enforcement
OGC	Office of the General Counsel
OL	Operating License
PDC	Principal Design Criteria
POC	Point of Contact
PRA	Probabilistic Risk Assessment
RA	Regional Administrator
RES	Office of Nuclear Regulatory Research
RG	Regulatory Guide
SDA	Standard Design Approval

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SE	Safety Evaluation
SECY	Office of the Secretary
SER	Safety Evaluation Report
SLR	Subsequent License Renewal
SRM	Staff Requirements Memorandum
SSC	Structure, system, and component
TR	Topical Report
UFSAR	Updated Final Safety Analysis Report

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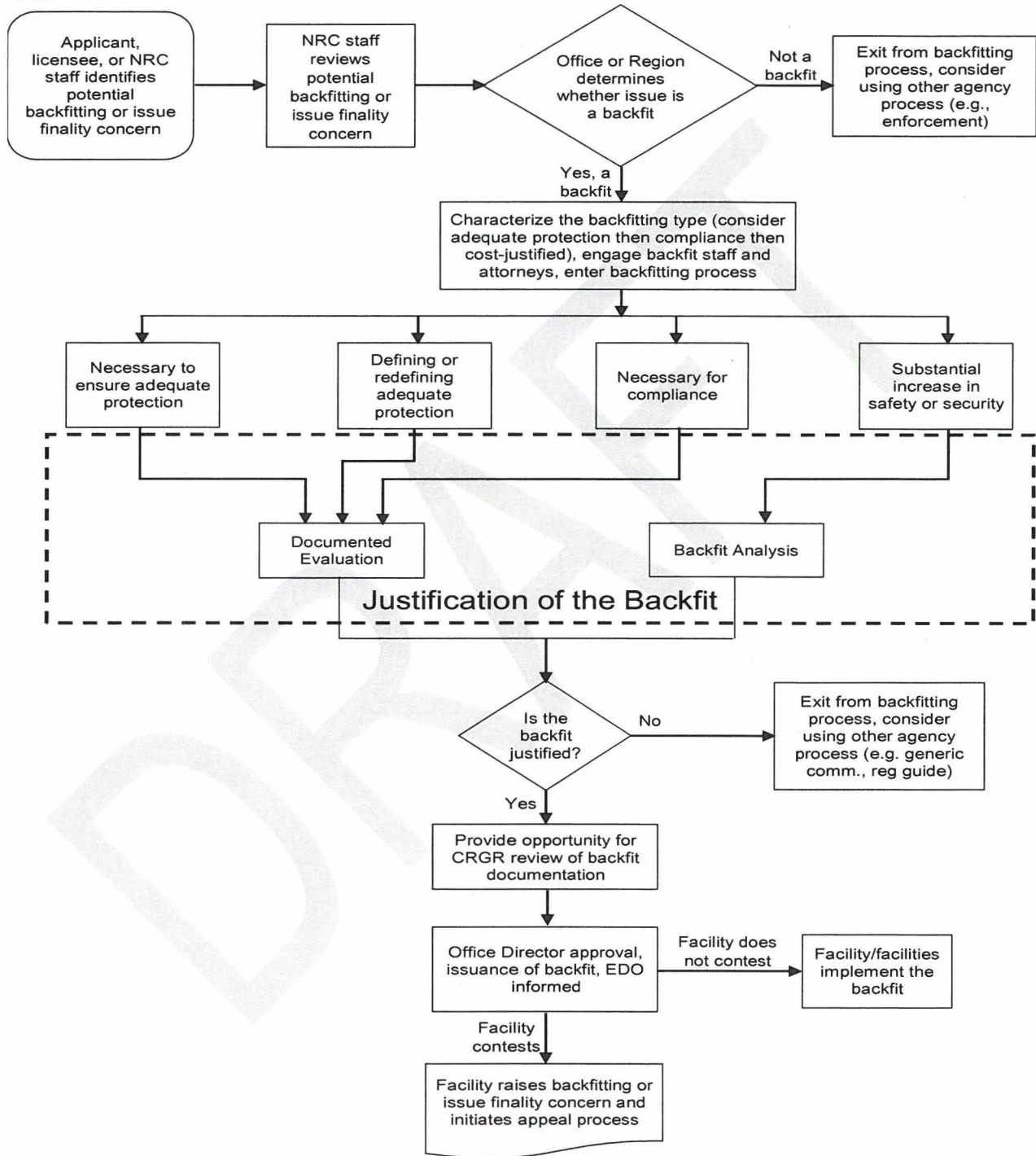
**EXHIBITS**

**EXHIBIT 1 NRC Internal Backfitting and Issue Finality Flowchart**

DRAFT

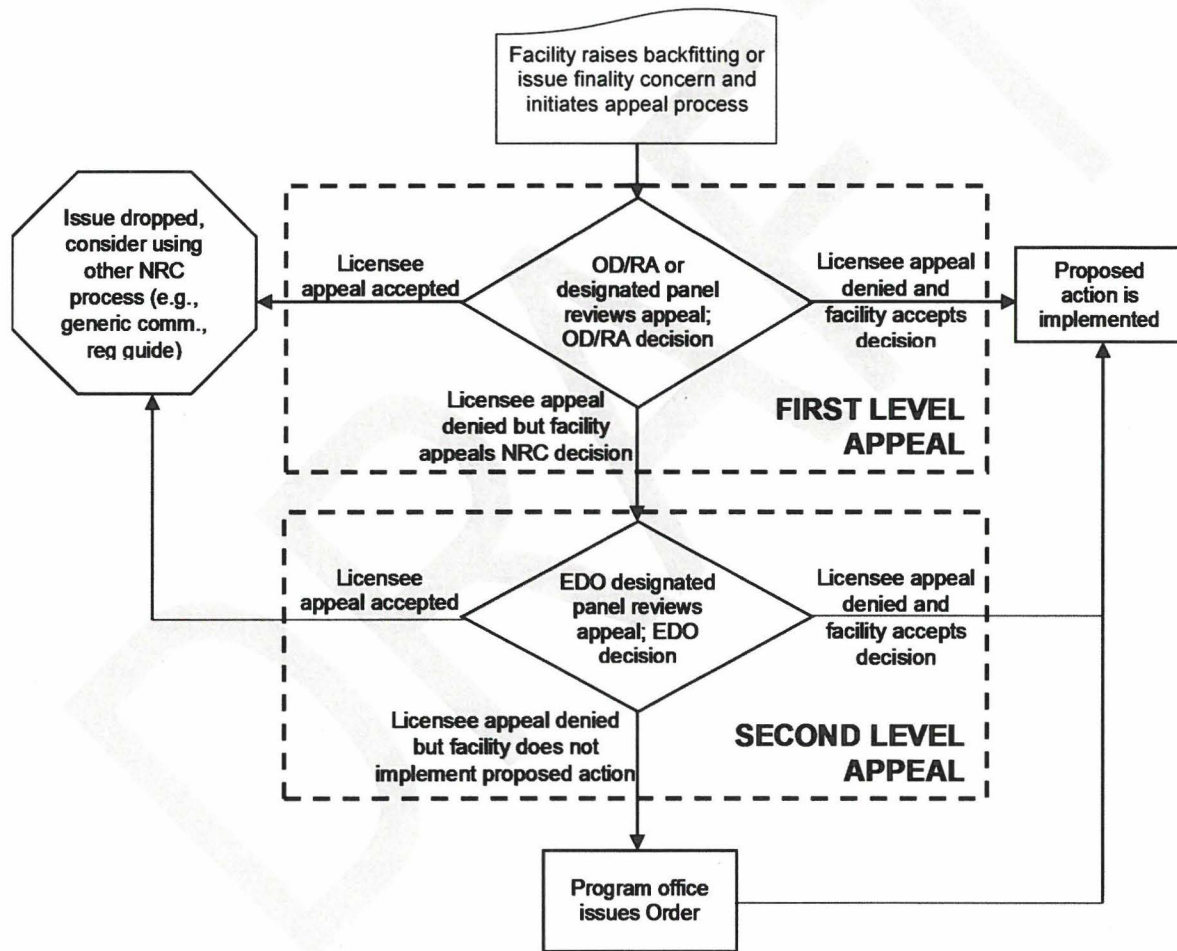


Revise "Exit from backfitting process consider using other . . ." to "Issue dropped: document outcome"



**EXHIBIT 2 NRC Internal Backfitting and Issue Finality Flowchart**

Revise octagon on far left to read "Issue dropped: document outcome."



**EXHIBIT 3 NRC Backfitting Requirements**

<b>Affected Entities</b>	<b>Backfitting/Issue Finality Regulation</b>
Power Reactors (licensed under 10 CFR Part 50)	10 CFR 50.109
Power Reactors (permitted, certified, licensed or approved under 10 CFR Part 52)	10 CFR 50.109 and 10 CFR Part 52 (as noted below)
Early Site Permit (ESP)	10 CFR 52.39 (term of ESP) 10 CFR 52.31 (renewal)
Standard Design Certification Rule (DCR)	10 CFR 52.63 (term of DCR) 10 CFR 52.59 (renewal)
Combined License (COL)	10 CFR 52.83 (referenced NRC approvals) 10 CFR 52.98 (term of COL)
Standard Design Approval	10 CFR 52.145
Manufacturing License (ML)	10 CFR 52.171 (term of ML) 10 CFR 52.179 (renewal)
Licensees authorized to possess special nuclear material above a critical mass	10 CFR 70.76, Subpart H
Independent Spent Fuel Storage Installation	10 CFR 72.62
Gaseous Diffusion Plant	10 CFR 76.76

**RESPONSE SHEET**

**TO:** Annette Vietti-Cook, Secretary  
**FROM:** Commissioner Baran  
**SUBJECT:** SECY-18-0049: Management Directive and Handbook 8.4, "Management of Backfitting, Issue Finality, and Information Collection"

Approved  Disapproved  Abstain  Not Participating

COMMENTS: Below  Attached  None

**Entered in "STARS"**  
Yes   
No

  
\_\_\_\_\_  
**SIGNATURE**  
12/11/18  
\_\_\_\_\_  
**DATE**

**Commissioner Baran's Comments on SECY-18-0049,  
"Management Directive and Handbook 8.4, 'Management of Backfitting, Issue Finality,  
and Information Collection'"**

The NRC staff has provided a recommended revision to the existing NRC guidance on the backfit rule.

I see two main reasons to update the guidance. First, the guidance should make clear that, for a potential backfit, the staff should determine as a threshold matter whether the potential regulatory action is necessary to ensure adequate protection of public health and safety. This change rightly puts the focus of the staff's analysis on safety. Moreover, it ensures that the staff does not consider costs when it is impermissible to do so.

Second, in light of the Supreme Court's decision in *Michigan v. EPA* and the subsequent federal court cases interpreting that decision, the guidance must explain that, when applying the compliance exception to the backfit rule, the staff's evaluation must include at least some consideration of costs.

For these reasons, I approve the revised guidance, subject to the attached edits. I propose several substantive edits to improve the revised guidance.

One edit relates to the new statement that a potential compliance backfitting action must include some consideration of costs. As the Supreme Court explained, "some consideration of cost" does not require an agency to conduct a formal cost-benefit analysis. I propose an edit to make the guidance clear on this point.

Given that the compliance exception has only been used a handful of times during the last decade and will likely be used even less frequently with the new threshold for an initial adequate protection determination, I propose striking the guidance language that would further limit the use of the compliance exception.

For the first time, the revised guidance also would require the evaluations supporting the use of the adequate protection or compliance exception to be risk-informed. While I agree that it often makes sense to take a risk-informed approach to a decision about whether to establish a new regulatory requirement, there are a number of areas where risk information may be limited or unavailable. For example, detailed risk-informed evaluations may be challenging for regulatory decisions regarding physical security, cybersecurity, radiation protection, emergency preparedness, materials licensees, or fuel cycle facilities. I propose to clarify that adequate protection and compliance backfit evaluations should consider risk insights to the extent practical.

Finally, the revision is littered with statements about the need to "justify" the imposition of regulatory "burdens." Using this language in this way represents a significant departure from the actual backfit regulations, which do not use the term "burdens" to characterize the costs of complying with a regulatory requirement. How the agency talks about backfitting matters. Including this kind of language in the revised guidance could suggest an inappropriate bias against regulatory action. As the independent safety and security regulator, NRC should be thoughtful and transparent when determining whether to establish a new regulatory requirement or when making a regulatory decision, but it should not hesitate to act when necessary to protect the public. I propose more neutral, balanced language throughout the revised guidance documents.

U.S. NUCLEAR REGULATORY COMMISSION MANAGEMENT DIRECTIVE (MD)

<b>MD 8.4</b>	<b>MANAGEMENT OF BACKFITTING, ISSUE FINALITY, AND INFORMATION COLLECTION</b>	<b>DT-XX-XX</b>
<i>Volume 8:</i>	Licensee Oversight Programs	
<i>Approved By:</i>	[Name and Title of Approving Official]	
<i>Date Approved:</i>	Month X, 200X [Date of Final Approval]	
<i>Cert. Date:</i>	N/A, for the latest version of any NRC directive or handbook, see the <a href="#">online MD Catalog</a> .	
<i>Issuing Office:</i>	Office of Nuclear Reactor Regulation Division of Inspection and Regional Support	
<i>Contact Name:</i>	Timothy Reed	
<b>EXECUTIVE SUMMARY</b>		
<p>Management Directive (MD) 8.4, "Management of Backfitting, Issue Finality, and Information Collection," is retitled and revised to clarify the agency's roles and responsibilities for management of backfitting, issue finality, and information collection. MD 8.4 describes the roles and responsibilities of various offices and provides the policy to direct the U.S. Nuclear Regulatory Commission implementation of the backfitting provisions of Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) for nuclear power reactor licensees and selected nuclear materials licensees; and the issue finality provisions of 10 CFR Part 52 nuclear power reactor licensees, design certification applicants, and holders of related NRC permits and approvals, as well as specific provisions of 10 CFR 50.54(f) and the corresponding requirements in 10 CFR Parts 70, 72, and 76, and 10 CFR 2.204.</p> <p>Accordingly, MD 8.4 is retitled from "Management of Facility-Specific Backfitting and Information Collection" to "Management of Backfitting, Issue Finality, and Information Collection" to clarify the intent and the objectives of the program.</p>		

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For updates or revisions to policies contained in this MD that were issued after the MD was signed, please see the Yellow Announcement to Management Directive index ([YA-to-MD index](#)).

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## I. POLICY

It is the policy of the U.S. Nuclear Regulatory Commission to have an effective program that will ensure that backfitting<sup>1</sup> of nuclear power reactor licensees<sup>2</sup> and selected nuclear materials licensees and certificate holders is appropriately documented and [analyzed](#)[justified](#) based on the backfitting provisions of applicable NRC regulations and the

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<sup>1</sup> In this MD, the NRC uses the terms “backfit” and “backfitting” to mean backfitting as defined in 10 CFR 50.109, 70.76, 72.62, and 76.76 and violations of issue finality under 10 CFR Part 52. 10 CFR Part 52. Parts 50, “Domestic Licensing of Production and Utilization Facilities,” Part 52, Part 70, “Domestic Licensing of Special Nuclear Material,” Part 72, “Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste,” and Part 76, “Certification of Gaseous Diffusion Plants,” are the only parts of the NRC’s regulations that contain backfitting or issue finality provisions. Backfitting provisions implicitly apply, in part, to applicants for a power reactor renewed license due to the limitation in scope of the NRC’s review under 10 CFR Part 54, “Requirements for Renewal of Operating Licenses for Nuclear Power Plants.

<sup>2</sup> In this MD, the NRC uses the term “nuclear power reactor licensees” to refer to holders of 10 CFR Part 50 or Part 52 licenses, permits, or approvals, including: early site permits (ESPs), standard design approvals (SDAs), combined licenses (COLs), and MLs; design certification (DC) applicants whose designs are certified in final DC rules (DCR); applicants for COLs if the application references an ESP, DCR, or SDA; and applicants for MLs if the application references a DCR or SDA. Specific definitions and terminology are included in 10 CFR Parts 50, 70, 72, and 76.

Commission's backfitting policy and guidance. Additionally, the NRC must [provide a reasonable basis for](#) justify information requests to licensees as required by applicable NRC regulations under 50.54(f), "Conditions of licenses," and 2.204, "Demand for information."

## II. OBJECTIVES

- Ensure NRC-licensed facilities provide adequate protection of public health and safety, promote the common defense and security, and allow for substantial improvements in both safety and security, beyond adequate protection, while minimizing any [unnecessary cost](#) ~~unjustified burden~~ on the NRC, the public, or licensees when implementing a backfitting action.
- Ensure that backfitting considerations are applied to the furtherance of substantive radiological public health and safety, or common defense and security objectives.
- Ensure that backfitting applied to a nuclear power reactor licensee or nuclear materials licensee is appropriately [analyzed](#) ~~justified~~ and documented.
- Ensure that NRC-proposed changes to previously approved ESPs, DCs, SDAs, COLs, and MLs (i.e., violations of issue finality under 10 CFR Part 52) are appropriately [analyzed](#) ~~justified~~ and documented.
- Ensure that compliance backfitting [analyses](#) ~~justifications~~ include some consideration of costs.
- Ensure that any documented evaluation or backfit analysis is risk-informed, [to the extent practical](#).
- Ensure all information requests to licensees are [appropriate](#) ~~justified~~ as required by applicable NRC regulations.

## III. ORGANIZATIONAL RESPONSIBILITIES AND DELEGATIONS OF AUTHORITY

### A. Executive Director for Operations (EDO)

1. Responsible for the NRC's backfitting process and ensuring proper implementation of the backfitting rules.
2. Authorizes deviations from this MD when in the public interest and when the deviation otherwise complies with applicable NRC regulations, public laws, and Executive Orders.
3. Delegates facility-specific backfitting authority and actions to the program office ODs and RAs.
4. Delegates information request authority and actions to the program ODs and RAs.



**B. Office of the General Counsel (OGC)**

1. Identifies potential backfitting actions.
2. Advises staff about whether staff's actions meet the applicable definitions of backfit.
3. Advises staff about how staff's actions are congruent with finality provisions in 10 CFR Part 52.
4. Provides legal advice and assistance during backfitting identification, [analysis](#)justification, imposition, and licensee appeal processes.
5. Provides legal advice and assistance for developing backfitting training in accordance with backfitting requirements and agency implementation.
6. Provides legal advice and assistance for information collections.

**C. Committee To Review Generic Requirements (CRGR)**

1. Maintains a Charter that describes the roles, responsibilities, and procedures of the CRGR in accordance with applicable regulations.
2. Selects a sample of proposed backfitting actions under 10 CFR Part 50, 10 CFR Part 52, 10 CFR Part 70, 10 CFR Part 72 and 10 CFR Part 76, consistent with its Charter and ensures the actions are [analyzed](#)justified in accordance with regulations.
3. Reviews potential facility specific backfits as requested by program office directors.
4. Uses its discretion in deciding whether any review should require a formal staff presentation to the CRGR.
5. Periodically assesses the effectiveness of the NRC's backfitting process implementation as part of its regulatory effectiveness responsibility and provides a report to the EDO.
6. Ensures consistency among the offices and regions in implementing the provisions of the NRC's backfitting rules. The CRGR review focuses on the adequacy of backfitting implementation, interoffice coordination for processing backfitting actions, and staff training.

7. Verifies that the responsible staff<sup>3</sup> promptly enters backfitting decisions into the Agencywide Documents Access and Management System (ADAMS), and makes them publicly available, consistent with applicable requirements and guidance.
8. Periodically meets with stakeholders to gain stakeholder views and advise the EDO when modifications to the backfitting processes should be considered.
9. Participates in Backfitting Review Panels at the request of the EDO.
10. Coordinates with the Office of the Chief Human Capital Officer (OCHCO) to ensure that Human Resources Training and Development (HRTD) provides appropriate training for the NRC staff.

**D. Director, Office of Nuclear Regulatory Research (RES)**

1. Identifies potential backfitting actions.
2. Supports the offices and regions by implementing pertinent CRGR recommendations, EDO decisions, staff lessons-learned, and Commission directives for enhancing the NRC's backfitting program.
3. Provides administrative support for routine CRGR activities.
4. Maintains a backfitting Community of Practice with office POCs, including a backfitting SharePoint site.

**E. Director, Office of Enforcement (OE)**

1. Defines and implements appropriate administrative controls to support the office and regional staffs in processing compliance backfits that involve enforcement discretion.
2. If an Order, a notice of violation, or enforcement discretion is necessary in relation to a backfitting action, consults with OGC and the responsible office(s) and region, on the backfitting action and advises on its imposition, including supporting interactions with licensees to establish a schedule for implementing the compliance backfit, as applicable.

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<sup>3</sup> The office or the region that initiated the backfitting action supports the program office (the Office of Nuclear Reactor Regulation (NRR), the Office of Nuclear Material Safety and Safeguards (NMSS), or the Office of New Reactors (NRO)) that has the obligation to impose the backfit. The program office is solely responsible for generic backfitting actions. Regions are responsible for facility-specific backfitting actions arising from inspection and program offices are responsible for facility-specific backfitting actions arising from licensing or other headquarters actions.

3. Ensures appropriate training is available to the OE staff and ensures OE staff performance is in accordance with NUREG-1409, "Backfitting Guidelines."
4. Designates an office-level POC to coordinate and resolve backfitting questions or concerns from the staff as they relate to the responsibilities of OE.

**F. Director, Office of Nuclear Security and Incident Response (NSIR)**

1. Identifies any potential security-related or emergency preparedness-related backfitting actions.<sup>4</sup>
2. Coordinates all security-related backfitting with the program offices and the regional offices.
3. Designates an NSIR manager (division director or higher) who coordinates with the program offices and OGC to request that the program office propose backfitting actions on nuclear power reactor and nuclear materials licensees that pertain to the common defense and security or emergency preparedness.
4. Ensures consistency of security and emergency preparedness inspection procedures with regulations, and NUREG-1409.
5. Consults, coordinates with, and provides support to program ODs, as appropriate, to resolve issues with security-related backfitting actions. The Director, NSIR, must support the program ODs and RAs, as appropriate, in processing security-related backfits, including the resolution of licensee backfit appeals.<sup>5</sup>
6. Ensures appropriate training is available to the NSIR staff and ensures that the NSIR staff performance is in accordance with NUREG-1409.
7. Designates an office-level POC to coordinate and resolve backfitting questions or concerns from staff as they relate to the responsibilities of NSIR.
8. Makes backfitting decisions publicly available, consistent with applicable requirements and guidance.

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<sup>4</sup> Throughout this MD, security-related and emergency preparedness-related backfitting may be referred to as security or security-related backfitting.

<sup>5</sup> The program OD for the affected facilities imposes facility-specific backfitting actions and forwards licensee appeals on security-related backfitting to the NSIR OD. The NSIR OD will decide on the appeal and coordinate with the program OD. If a licensee refuses to implement an imposed backfitting action, the appropriate program office must issue an Order.

**G. Director, Office of Nuclear Reactor Regulation (NRR); Director, Office of New Reactors (NRO); and Director, Office of Nuclear Material Safety and Safeguards (NMSS)**

1. Identify backfitting actions applicable to its programs.
2. Coordinate backfitting actions with other program offices and regional offices to ensure consistency and uniformity.
3. Provide the CRGR with an opportunity to review any required documented evaluation or backfit analysis or any generic communication with backfitting concerns.
4. Request CRGR review of potential facility specific backfit, as deemed appropriate.
5. After approving supporting documentation, notify, or designate the relevant division director to notify, the nuclear power reactor or nuclear materials licensee of the backfitting action.
6. Ensure consistency among inspection procedures, regulations, and NUREG-1409.
7. Consult and coordinate with the regions, NSIR, RES, OE, and OGC, as appropriate, to resolve issues with backfitting actions for which the program office has oversight responsibility.
8. Coordinate security-related backfitting with the Director, NSIR, and the affected regional office and approves the supporting documentation for security-related backfitting within the program office's areas of responsibility.
9. Decide first-level licensee appeals on the imposition of all backfitting actions within the program office's area of responsibility and coordinates any appeals of security-related backfits with the Director, NSIR.
10. During the staff's evaluation and backfitting transmittal process, and any subsequent licensee appeal process, track each facility-specific backfitting action within the affected program office or region.
11. Ensure entry into ADAMS, as appropriate, of all documents and records related to backfitting originating in either the program office or the region (within the program office's area of responsibility), including communications, decisionmaking, and the outcome of backfitting appeals. Makes the backfitting decisions publicly available, consistent with applicable requirements and guidance.

12. Ensure appropriate training is available to the program office staff and ensure that the program office staff performance is in accordance with regulations, and NUREG-1409.
13. Designate an office-level POC to coordinate and resolve backfitting questions or concerns from the staff as they relate to the responsibilities of each respective program office.
14. Ensure information collection under 10 CFR 50.54(f) and 2.204 is appropriately **justified**.

#### H. Regional Administrators (RAs)

1. Identify backfitting actions applicable to the regions.
2. Coordinate with ODs and other RAs to ensure consistency in backfitting implementation among the regions and program offices.
3. Provide the CRGR with an opportunity to review any required documented evaluation or backfit analysis before final approval.
4. After approving supporting documentation, notify, or designate the relevant division director to notify, the nuclear power reactor or nuclear materials licensee of the backfitting action.
5. Coordinate with other regions and either the Division of Inspection and Regional Support, NRR, or the Division of Construction Inspection and Operational Programs, NRO, as applicable, to ensure consistency among inspection procedures and regulations, and NUREG-1409.
6. Consult and coordinate with the Director, NSIR; OGC and/or regional counsel; and the appropriate program OD to resolve security-related, facility-specific backfitting actions.
7. Coordinate with the appropriate program office and NSIR, as necessary, to obtain the supporting documentation for proposed backfits.
8. Support the appropriate program office in processing licensee backfitting appeals that are within the regional area of responsibility.
9. Ensure entry into ADAMS, as appropriate of all documents and records related to backfitting and originating in the region, including communications, decisionmaking, and the outcome of backfitting appeals. Makes backfitting decisions publicly available, consistent with applicable requirements and guidance.

10. Ensure appropriate training is available to the regional staff and ensures that the regional staff performance is in accordance with regulations and NUREG-1409.
11. Designate a regional POC who will be responsible for any specific backfitting activities (generic and facility-specific) as needed, including the coordination and resolution of any backfitting questions or concerns from the staff as they relate to the responsibilities of the respective region. The regional POC also ensures that the associated regional staff is proficient in a training program relevant to backfitting activities and agency information collection processes.

**I. Chief Human Capital Officer (CHCO)**

1. Develops, maintains, and updates, in consultation with OGC and in coordination with other offices and regions, a backfitting training program for the NRC staff, including generic and facility-specific backfitting training modules and refresher courses.
2. Consults and coordinates with the appropriate contact in the Office of the Chief Information Officer to maintain backfitting training modules online.

**J. Chief Information Officer (CIO)**

1. Maintains a repository for backfitting records in ADAMS.
2. Advises the offices and regions on implementing administrative controls to ensure backfitting information is maintained in accordance with Federal and agency recordkeeping requirements.
3. Consults on the agency review of information collections to ensure compliance with the Paperwork Reduction Act.

**IV. APPLICABILITY**

The policy in this directive and handbook applies to all NRC employees.

**V. DIRECTIVE HANDBOOK**

For effective regulation of NRC-licensed facilities, it is ~~important~~**crucial** that the backfitting process be well-defined, that staff members clearly understand their ~~roles in the process~~**obligation for responsibly implementing all aspects of the backfitting program**, and that managers ensure staff performance is in accordance with this MD. Handbook 8.4 explains the components of the NRC backfitting management program. NUREG-1409 provides guidance to the staff implementing backfitting regulations.

## VI. REFERENCES

### *Code of Federal Regulations*

- 10 CFR Part 2, "Agency Rules of Practice and Procedure."
- 10 CFR 2.202, "Orders."
- 10 CFR 2.204, "Demand for Information."
- 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."
- 10 CFR 50.2, "Definitions."
- 10 CFR 50.12, "Specific Exemptions."
- 10 CFR 50.49, "Environmental Qualification of Electrical Equipment Important to Safety for Nuclear Power Plants."
- 10 CFR 50.54, "Conditions of Licenses."
- 10 CFR 50.59, "Changes, Tests, and Experiments."
- 10 CFR 50.71, "Maintenance of Records; Making of Reports."
- 10 CFR 50.72, "Immediate Notification Requirements for Operating Nuclear Power Reactors."
- 10 CFR 50.73, "License Event Report System."
- 10 CFR 50.109, "Backfitting."
- 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."
- 10 CFR 52.7, "Specific Exemptions."
- 10 CFR 52.31, "Criteria for Renewal."
- 10 CFR 52.39, "Finality of Early Site Permit Determinations."
- 10 CFR 52.59, "Criteria for Renewal."
- 10 CFR 52.63, "Finality of Standard Design Certifications."
- 10 CFR 52.83, "Finality of Referenced NRC Approvals; Partial Initial Decision on Site Suitability."
- 10 CFR 52.98, "Finality of Combined Licenses; Information Requests."
- 10 CFR 52.145, "Finality of Standard Design Approvals; Information Requests."
- 10 CFR 52.171, "Finality of Manufacturing Licenses; Information Requests."

- 10 CFR 2.179, "Criteria for Renewal."
- 10 CFR Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants."
- 10 CFR 54.30, "Matters Not Subject to a Renewal Review."
- 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."
- 10 CFR 70, Subpart B, "Exemptions."
- 10 CFR 70.22, "Contents of Applications."
- 10 CFR 70.76, "Backfitting."
- 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste."
- 10 CFR 72.7, "Specific Exemptions."
- 10 CFR 72.62, "Backfitting."
- 10 CFR Part 76, "Certification of Gaseous Diffusion Plants."
- 10 CFR 76.23, "Specific Exemptions."
- 10 CFR 76.76, "Backfitting."

***Nuclear Regulatory Commission Documents***

Charter of the Committee To Review Generic Requirements.

Letter to Ellen Ginsberg from Stephen Burns discussing applicability of the Backfit Rule to NRC interpretive guidance, July 14, 2010 (ADAMS Accession No. [ML101960180](#)).

Memorandum to Edwin Hackett from Andrew Averbach, "Summary of COMSECY-16-0020, Recommendation on Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception to Backfit Rule," December 20, 2016 (ADAMS Accession No. [ML16355A258](#)).

Memorandum to James M. Taylor and William C. Parler from Samuel J. Chilk, "SECY-93-086, Backfit Considerations," June 30, 1993 (ADAMS Accession No. [ML003760758](#)).

Memorandum from Luis A. Reyes, Executive Director for Operations, NRR to Those on the Attached List, "Implementation of an ADAMS-Based Record Access System for Facility-Specific Backfits," February 22, 2006 (ADAMS Accession No. [ML052720147](#)).



NUREG-0910, "NRC Comprehensive Records Disposition Schedule."

NUREG-1409, "Backfitting Guidelines."

NUREG/BR-0058, Revision 5, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," and all Appendices.

SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," dated March 2, 1999 (ADAMS Accession No. [ML992810068](#)).

Staff Requirements Memorandum, COMSECY-16-0020, "Staff Requirements – COMSECY-16-0020 – Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception to Backfit Rule," November 29, 2016 (ADAMS Accession No. [ML16334A462](#)).

Staff Requirements Memorandum, SECY-98-185, Proposed Rulemaking, "Revised Requirements for the Domestic Licensing of Special Nuclear Material," December 1, 1998 (ADAMS Accession No. [ML991880012](#)).

Staff Requirements Memorandum, SECY-14-0087, "Staff Requirements— SECY - 14- 0087-Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," dated March 4, 2015 (ADAMS Accession No. [ML15063A568](#)).

"Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement," 60 FR 42622, August 16, 1995.

***United States Code***

Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.).

Energy Reorganization Act of 1974, as amended (42 U.S.C. 5801 et seq.).

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

U.S. NUCLEAR REGULATORY COMMISSION DIRECTIVE HANDBOOK (DH)

<b>DH 8.4</b>	<b>MANAGEMENT OF BACKFITTING, ISSUE FINALITY, AND INFORMATION COLLECTION</b>	<b>DT-XX-XX</b>
<i>Volume 8:</i>	Licensee Oversight Programs	
<i>Approved By:</i>	[Name and Title of Approving Official]	
<i>Date Approved:</i>	Month X, 200X [Date of Final Approval]	
<i>Cert. Date:</i>	N/A, for the latest version of any NRC directive or handbook, see the <a href="#">online MD Catalog.</a>	
<i>Issuing Office:</i>	Office of Nuclear Reactor Regulation Division of Inspection and Regional Support	
<i>Contact Name:</i>	Timothy Reed	
<b>EXECUTIVE SUMMARY</b>		
<p>Management Directive (MD) 8.4, “Management of Backfitting, Issue Finality, and Information Collection,” is retitled and revised to clarify the agency’s roles and responsibilities for management of backfitting, issue finality, and information collection. MD 8.4 describes the roles and responsibilities of various offices and provides the policy to direct the U.S. Nuclear Regulatory Commission implementation of the backfitting provisions of Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) for nuclear power reactor licensees; and selected nuclear materials licensees; and the issue finality provisions of 10 CFR Part 52 nuclear power reactor licensees, design certification applicants, and holders of related NRC permits and approvals, as well as the specific provisions of 10 CFR 50.54(f) and the corresponding requirements in Parts 10 CFR 70, 10 CFR 72, and 10 CFR 76, and 10 CFR 2.204.</p> <p>Accordingly, MD 8.4 is retitled from “Management of Facility-Specific Backfitting and Information Collection” to “Management of Backfitting, Issue Finality, and Information Collection” to clarify the intent and the objectives of the program.</p>		

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## I. INTRODUCTION TO BACKFITTING AND INFORMATION COLLECTION

### A. Backfitting

1. Backfitting is the process by which the U.S. Nuclear Regulatory Commission imposes new or revised regulatory requirements or new or revised staff positions on nuclear power reactor licensees or selected nuclear materials licensees.<sup>1</sup> Backfitting is an integral part of the regulatory process and is expected to occur. To ensure that proposed changes are adequately analyzed ~~justified~~ and defined, a backfitting action is implemented only after formal and systematic review. Backfitting normally occurs in one of two ways: a new or changed regulation or requirement imposed upon licensees (through rulemaking or order), or a new or changed staff position interpreting applicable regulations imposed on licensees. In this Directive Handbook (DH), the terms “backfit” and “backfitting” mean backfitting as defined in 10 CFR 50.109, “Backfitting,” 70.76, “Backfitting,” 72.62, “Backfitting,” and 76.76 “Backfitting,” and ~~violations inconsistencies of~~ with issue finality under 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.”<sup>2</sup> The only parts of the NRC’s regulations that contain backfitting or ~~issues~~ finality provisions are 10 CFR Part 50, 10 CFR Part 52, 10 CFR Part 70, 10 CFR Part 72, and 10 CFR Part 76. The backfitting provisions typically do not apply to license applicants. There is no backfitting provision in 10 CFR Part 54, “Requirements for Renewal of Operating Licenses of Nuclear Power Plants,” ~~however the scope of the NRC’s review under 10 CFR Part 54 is limited.~~
2. ~~There are three principal types of backfitting that may be considered: adequate protection backfitting, compliance backfitting, and cost-justified substantial increase~~<sup>3</sup>

<sup>1</sup> For purposes of this DH, the term “licensees” includes the holders of power reactor construction permits (CPs) and operating licenses (OLs) under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities;” holders of licenses, permits or approvals under 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants;” holders of licenses for fuel facilities under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” Subpart H, “Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material;” holders of licenses for spent fuel and radioactive waste storage facilities under 10 CFR Part 72, “Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste;” and certificate holders for gaseous diffusion plants under 10 CFR Part 76, “Certification of Gaseous Diffusion Plants.”

<sup>2</sup> The issue finality provisions of 10 CFR Part 52 include additional backfitting actions for certain types of approval holders. For example, 10 CFR 52.63, “Finality of Standard Design Certifications,” also allows backfitting to, among other things, correct material errors in the certification information for a design certification (DC) or to contribute to the increased standardization of the DC.

<sup>3</sup> ~~See 50 FR 38097, September 20, 1985.~~

~~in protection backfitting.~~<sup>4</sup> If the NRC is considering a backfitting action, it must first consider whether regulatory action is necessary to ensure adequate protection. If regulatory action is not necessary to ensure adequate protection, then the NRC needs to determine if the proposed action satisfies the compliance backfit criteria. If the proposed action does not satisfy the compliance backfit criteria, then the NRC must consider a cost-justified substantial increase<sup>5</sup> in protection backfit.

3. Regulations in 10 CFR 50.109, define the term backfitting for power reactors under 10 CFR Part 50 (i.e., construction permit (CP) holders and operating license (OL) holders) as the modification of or addition to systems, structures, components (SSCs); or design of a facility; or the design approval or manufacturing license (ML) for a facility; or the procedures or organization required to design, construct, or operate a facility, any of which may result from a new or amended provision in the Commission's regulations or the imposition of a staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position after certain specified dates.<sup>6</sup> Provisions of 10 CFR 50.109 can also

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~~<sup>4</sup>—The issue finality provisions of 10 CFR Part 52 include additional backfitting actions for certain types of approval holders. For example, 10 CFR 52.63, "Finality of Standard Design Certifications," also allows backfitting to, among other things, correct material errors in the certification information for a design certification (DC) or to contribute to the increased standardization of the DC.~~

<sup>5</sup> [See 50 FR 38097, September 20, 1985.](#)

<sup>6</sup> Applicable NRC action may be considered backfitting under 10 CFR 50.109 if the agency action occurs after the following:

- the issuance of the CP for the facility (for facilities with CPs issued after October 21, 1985),
- 6 months before the date of docketing of the OL application for the facility (for facilities with CPs issued before October 21, 1985),
- the issuance of the OL for the facility (for facilities having an OL on October 21, 1985),
- the issuance of the design approval under Subpart E, "Standard Design Approvals." of 10 CFR Part 52,
- the issuance of a an ML under Subpart F, "Manufacturing Licenses," of 10 CFR Part 52,
- the issuance of the first CP for a duplicate design under Appendix N, "Standardization of Nuclear Power Plant Designs: Permits To Construct and Licenses to Operate Nuclear Power Reactors of Identical Design at Multiple Sites," of 10 CFR Part 50, or
- the issuance of a COL under Subpart C, "Combined Licenses," of 10 CFR Part 52.

apply to power reactor licensees under 10 CFR Part 52,<sup>7</sup> but 10 CFR 50.109 is not applicable to non-power production or utilization facilities licensed under 10 CFR Part 50.

4. In 10 CFR Part 52, power reactor licensees are granted “issue finality”<sup>8</sup> with their NRC approvals, which prevents the NRC from making changes to the approvals without meeting certain criteria as provided in the applicable issue finality regulation. The issue finality requirements are intended to accomplish the same objective as the backfitting requirements by limiting changes to final Commission decisions made as part of the 10 CFR Part 52 licensing process. The standards vary for making changes to renewed and previously approved early site permits (ESPs) (10 CFR 52.31, “Criteria for Renewal,” and 10 CFR 52.39, “Finality of Early Site Permit Determinations”), renewed and previously approved design certification rules (DCRs) (10 CFR 52.59, “Criteria for Renewal,” and 10 CFR 52.63, “Finality of standard design certifications), previously approved combined operating licenses (COLs) (10 CFR 52.83, “Finality of Referenced NRC Approvals; Partial Initial Decision on the Site Suitability,” and 10 CFR 52.98, “Finality of Combined Licenses; Information Requests”), previously approved standard design approvals (SDAs) (10 CFR 52.145, “Finality of Standard Design Approvals; Information Requests”), and renewed and previously approved MLs (10 CFR 52.179, “Criteria for Renewal,” and 10 CFR 52.171, “Finality of Manufacturing Licenses; Information Requests”). The backfitting provisions in 10 CFR 50.109 apply to ESPs, DCs, COLs, SDAs, and MLs to the extent that they do not overlap the applicability of 10 CFR Part 52 issue finality provisions.
5. Section 70.76 of 10 CFR defines the term backfitting for materials licensees authorized to possess greater than a critical mass of special nuclear material as the modification of, or addition to, SSCs of a facility; or to the procedures or organization required to operate a facility. Either of these may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position

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<sup>7</sup> For purposes of this DH, the term “10 CFR Part 52 power reactor licensees” refers to holders of early site permits (ESPs), standard design approvals (SDAs), combined licenses (COLs), and MLs; DC applicants whose designs are certified in final DC rules (DCRs); applicants for COLs if the application references an ESP, DCR, or SDA; and applicants for MLs if the application references a DCR or SDA.

<sup>8</sup> Within this DH, the term “issue finality” encompasses the language of the regulations from 10 CFR 52.39 “Finality of Early Site Permit Determinations,” 10 CFR 52.63, “Finality of standard design certifications,” 10 CFR 52.83, “Finality of Referenced NRC approvals; Partial Initial Decision on Site Suitability,” 10 CFR 52.98, “Finality of Combined Licenses; Information Requests,” 10 CFR 52.145, “Finality of Standard Design Approvals; Information Requests,” 10 CFR 52.171 “Finality of Manufacturing Licenses; Information Requests,” and any other applicable discussion of finality in part 52.

- interpreting the Commission rules that is either new or different from a previous NRC staff position.
6. Section 72.62 of 10 CFR defines the term backfitting as the addition, elimination, or modification, after the license has been issued, of SSCs of an independent spent fuel storage installation (ISFSI) or monitored retrievable storage (MRS), or the procedures or organization required to operate an ISFSI or MRS.
  7. Section 76.76 of 10 CFR defines the term backfitting as the modification of, or addition to, SSCs of a gaseous diffusion plant, or to the procedures or organization required to operate a plant, 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.
  8. Sections 50.109(a)(4)(i) and (a)(7), 70.76(a)(4)(ii) and (a)(7), 72.62(b), and 76.76(a)(4)(i) of 10 CFR require compliance with "written commitments" and, in the case of 10 CFR 76.76(a)(7), "written Corporation commitments." Within the scope of backfitting, these written commitments mean those commitments that have been incorporated into the license as a means necessary to demonstrate compliance with requirements.
  9. The licensing basis (LB) for power reactors under Parts 50, 52, and 54 is determined on a case-by-case basis and is commonly referred to as the set of NRC requirements applicable to a specific facility and that licensee's written commitments for ensuring compliance with applicable NRC requirements in the LB and the facility-specific design bases (including all modifications and additions over the life of the license).
  10. Commitments that have been included in a licensee's updated final safety analysis report (UFSAR) that describe a method for complying with regulations or requirements are not enforceable unless they are part of the license. Commitments documented outside of the license only represent acceptable approaches for complying with the governing requirements.
  11. If a licensee voluntarily submits a license amendment request (LAR) or license renewal application (LRA), the NRC, as a condition of its approval, may require that the licensee modify its submittal or adopt new or revised guidance, provided that 1) the new or revised guidance relates to the licensee's request, and 2) the subject matter of the guidance is essential to the NRC staff's determination of the acceptability of the licensee's request. This would not constitute backfitting. It is the licensee's burden to show that the submitted application enables the NRC to make the appropriate findings (e.g.; in accordance with 10 CFR 50.40, 50.57, 50.92, or the other applicable regulations).

12. Under 10 CFR 50.40 Common standards, “in determining that a construction permit or OL in this part, or early site permit, combined license, or ML in Part 52 of this chapter will be issued to an applicant, the Commission will be guided by the following considerations: (a) Except for an early site permit or manufacturing license, the processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other technical specifications, or the proposals, in regard to any of the foregoing collectively provide reasonable assurance that the applicant will comply with the regulations in this chapter, including the regulations in Part 20 of this chapter, and that the health and safety of the public will not be endangered.”
13. A key aspect of 10 CFR 50.40 is the “collectively” aspect. The licensing (and amendment) finding allows consideration of the collective aspect of the proposed change. For example, if a licensee proposes longer outage time for SSC A, then the staff could rely on 50.40 to say that less outage time for SSC B is needed to give the overall collective reasonable assurance, and doing so is not necessarily a backfit.
14. The backfitting rules generally do not apply to voluntary licensee changes, where “voluntary” is defined as any action by the licensee that was made of its own accord, without the force of a legally binding requirement or NRC representation of further licensing or enforcement action. The licensee must not be compelled by the NRC staff to make the change. The NRC staff’s requirement that the licensee adopt new or revised guidance that does not directly pertain to the licensee’s voluntary request would constitute backfitting. Unless required by the NRC, confirmatory orders that are the result of participation in the alternative dispute resolution (ADR) process, LARs, and LRAs are considered voluntary, and the NRC review process and approval of an ADR, LAR, or LRA generally is not considered backfitting. Furthermore, the backfitting rules do not apply to NRC suggested actions with which licensees are not required to comply, but decide to voluntarily implement. The backfitting rules do not apply to any voluntarily-initiated licensee installation of updated (or additional) equipment to the existing plant, to expand the plant, improve efficiencies, delay its obsolescence, or extend its capabilities.
- ~~15. Backfitting does not apply to actions that do not have a direct link to, and do not further a substantive radiological public health and safety, or common defense and security, objective. Nevertheless, the NRC must have legal authority to justify taking such actions.~~
- 16.15. For backfitting purposes, staff positions are documented interpretations of the regulations, already specifically imposed upon a licensee or “class” of licensees at the time of the identification of the proposed backfitting and may be contained in documents such as the Statement of Considerations for a final rule, Standard Review Plan (SRP), NUREG, interim staff guidance (ISG), and branch technical position (BTP). A licensee’s commitment to guidance, such as regulatory guides (RGs) or NRC-endorsed industry topical reports (TRs), through a licensing action is considered a voluntary action. However, RGs and NRC-endorsed TRs do represent



staff positions. Generally, the issuance of or revision to a staff position is considered forward-fitting and the revisions to staff positions do not, in isolation, impose anything, and are therefore not (in isolation) backfits. The applicable staff positions for each facility license application, LAR, or LRA includes the safety evaluation reports (SER)<sup>9</sup> and any NRC approvals based on licensees' docketed responses to requests for information. A change in the applicable staff position is referred to as a new or revised staff position.

47.16. The NRC's backfitting actions can be either generic or facility-specific.<sup>10</sup>

- (a) Generic backfitting actions affect a class or classes of licensees and can include the imposition of new or revised regulations or requirements (through rulemaking or Orders) or new or revised staff positions interpreting NRC regulations. Generic backfitting actions can be initiated in a number of ways, such as by the staff in rulemaking, the Commission through a staff requirements memorandum (SRM), and the public through a petition for rulemaking. Regardless of whether a generic backfitting action is the result of rulemaking or a new or changed staff interpretation, the new or changed regulation or staff position must be documented, and stakeholders must have had an opportunity to review and provide comments in response to a *Federal Register* (FR) notice. However, time-sensitive, safety-significant, or security-significant NRC actions, such as Orders or Bulletins, do not require public notice and opportunity to comment. In addition, not all previously issued staff positions were provided to the public for comment.
- (b) Facility-specific backfitting issues typically arise through the NRC's inspection or licensing process. In these circumstances, the NRC's regional or headquarters staff may find that a change to a LB is necessary. Facility-specific backfitting actions are normally a change in a staff position (the applicable SE) for a specific facility, based on an error or omission in the analysis (compliance backfit) for the implementation of that facility's LB, but they could also be a change to the facility-specific LB deemed necessary to ensure that the facility provides adequate protection. For power reactors, in addition to single unit sites, facility-specific backfitting actions may apply to sites that have multiple units, sites that share a UFSAR, or sites that may have more than one reactor type but share common sections of a UFSAR. Any reference in this DH or in

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<sup>9</sup> Historically, the NRC has used two terms to describe the document approving a license, amendment, or license renewal: SER or safety evaluation (SE). Throughout this DH, the use of SE will indicate the SER (usually used for approving initial licensing or relicensing actions) or the SE (usually used for approving license amendments).

<sup>10</sup> Hereafter, the term "facility" will be used to mean a nuclear power reactor; an ESP, DCR, COL, SDA, or ML for a power reactor; or a materials facility such as an ISFSI, fuel facility, gaseous diffusion plant, or a MRS installation.

NUREG-1409, "Backfitting and Issue Finality Guidance," to facility-specific backfitting pertains to facility-specific backfitting actions in this context.

~~18.17.~~ Unless an exception as described in Section I.A. ~~19-18~~ applies, to ~~require~~ justify a backfit under 10 CFR 50.109, 10 CFR 70.76, 10 CFR 76.76, and generally 10 CFR 72.62, or, in many cases, to ~~justify a violation of~~ address an inconsistency with issue finality under 10 CFR Part 52, the NRC must perform and document a backfit analysis in accordance with NUREG-1409 that shows the following:

- (a) The backfitting would result in a substantial increase<sup>11</sup> in overall protection of public health and safety or the common defense and security, and
- (b) The direct and indirect costs of implementing the backfitting are justified in view of the increased protection.

~~19.18.~~ The backfitting provisions generally contain three exceptions to the backfit analysis requirement described above, such that the analysis is not necessary when the backfitting action—

- (a) Is required for adequate protection,
- (b) Defines or redefines the level of protection that should be regarded as adequate, or
- (c) is necessary to bring a facility into compliance with applicable requirements in the licensing basis, or into conformance with its written commitments.

~~20.19.~~ Adequate protection backfitting, whether used to ensure that adequate protection is maintained or to define or redefine the level of protection that should be regarded as adequate, does not require a finding of substantial safety or security improvement, ~~nor does it require that~~ and costs cannot be considered. If a backfitting action is deemed necessary for adequate protection, it must be implemented, as required by Section 161 of the Atomic Energy Act of 1954, as amended (AEA). Compliance backfitting does not require a finding of substantial safety or security improvement, but does require some consideration of costs. Use of the adequate protection or compliance exception must be explained in a ~~risk-informed,~~ documented evaluation.

~~21. The backfit analysis requirement, and the exceptions to that requirement, restrict the ability of the NRC to conduct backfitting by requiring the NRC to demonstrate, before~~

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<sup>11</sup> As noted in the Statements of Consideration for the 1985 backfitting final rule (50 FR 38097; September 20, 1985), a "substantial" increase in protection means "important or significant in a large amount, extent, or degree." ~~Under such a standard, the Commission would not ordinarily expect to justify backfitting plant improvements that result in an insignificant or small benefit to public health and safety or the common defense and security, regardless of costs.~~

~~implementing the backfit, that the backfitting action would meet certain standards that vary based on the type of facility. In this way, the backfitting rules provide the following:~~

- ~~(a) Regulatory stability, by limiting the changes the NRC can make;~~
- ~~(b) Reasoned and informed NRC decisionmaking, by requiring the proposed action to be properly justified; and~~
- ~~(c) Transparency of NRC decisionmaking, by requiring the NRC to document and make publicly available its analyses.~~

~~22.20.~~ This MD and DH reflect NRC policy direction and provide the process for implementing that policy. The MD and DH list the regulations and guidance documents that govern backfitting and describe how the NRC implements those regulations. Backfitting guidance for the NRC staff is available in NUREG-1409 and should be used by all offices and regions. ~~Office or region-specific guidance is not required or desired. Consistency of implementation is assured by the staff's use of NUREG-1409.~~

~~23.21.~~ Any change to an NRC staff position may be identified as backfitting either by the staff or by licensees. The NRR, NRO or NMSS office director (OD) or regional administrator (RA) responsible for the staff position and affected facility or facilities will make the determination as to whether the new or revised staff position constitutes backfitting and whether the backfit should be imposed on the licensee(s).

~~24.22.~~ In support of the Commission's probabilistic risk assessment (PRA) policy statement<sup>12</sup> of August 1995, which encourages the use of PRA "in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy," risk insights should ~~must~~ be considered, to the extent practical, as part of ~~all~~ backfitting actions. Risk information should be integrated in a manner that complements traditional regulatory approaches and supports the defense-in-depth philosophy, which would improve the technical basis, increase efficiency, and enhance effectiveness. ~~All backfitting actions must be risk-informed.~~

~~25.23.~~ Exhibits 1 and 2 in this handbook are flowcharts that illustrate the NRC's program for processing backfits and backfit appeals.

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<sup>12</sup> Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement (60 FR 42622; August 16, 1995).

## B. Information Collection Requests

1. The provisions of 10 CFR 2.204, "Demand for Information," require that a licensee respond to information requests from the Commission for the purpose of determining if an Order under 10 CFR 2.202, "Orders," should be issued, or whether other actions should be taken.
2. The provisions of 10 CFR 50.54(f) require power reactor licensees to respond to information requests from the staff. This rule stipulates that, except for information sought to verify licensee compliance with the facility's LB, the NRC must prepare the reasons for the information request to ensure that the ~~costs to burden imposed on~~ licensees ~~are necessary~~ is justified based on the potential safety or security significance of the issue to be addressed.
3. Requests for information for power reactors to be licensed under 10 CFR Part 52 will be in accordance with the administrative requirements in 10 CFR 50.54(f), and as stated in 10 CFR 52.39(f), 10 CFR 52.98(g), 10 CFR 52.145(c), or 10 CFR 52.171(c), as applicable. The information collection requirements for selected materials licensees are contained in 10 CFR 70.22(d), 10 CFR 72.62(d), and 10 CFR 76.70(e).
4. This MD and DH reflects the policy for all requests for information.

## C. Coordination and Communication

For effective implementation of the NRC's backfitting and information collection programs, the ODs and the RAs must ensure the following:

1. Effective communication and coordination are maintained between their counterparts and among the responsible technical staff within the headquarters and regional offices.
2. Processes, procedures, and programmatic and administrative controls are written in plain English.
3. Formal feedback from the Committee to Review Generic Requirements (CRGR) provided during the review of a proposed rule involving backfitting is addressed as part of the rulemaking package before its submittal to the Executive Director of Operations (EDO).
4. No backfitting actions will be communicated to a licensee unless the appropriate OD or RA has determined whether the position involves backfitting and, if so, has ensured that the position is identified as backfitting, the appropriate material (i.e., documented evaluation or backfit analysis) has been prepared and approved, the CRGR was offered an opportunity to review the documentation, and written feedback was considered. NRR shall ensure reactor backfitting actions are consistently implemented throughout the regions.

#### D. Recordkeeping

Offices and regions directly involved in backfitting or information collection requests are responsible for tracking and maintaining associated records originating in that office or region. Documentation of the ~~justification~~ reasonable basis for backfitting or use of a backfit analysis exception is required by 10 CFR 50.109, 10 CFR 70.76, 10 CFR 72.62, and 10 CFR 76.76.

1. The office or region proposing information collections or backfitting actions must administratively manage each collection or action by maintaining all related records. Records must be maintained in accordance with NUREG-0910, "NRC Comprehensive Records Disposition Schedule," issued March 2005.
2. Backfitting records placed in the Agencywide Documents Access and Management System (ADAMS) must be accessible to all stakeholders by being profiled as publicly available when appropriate, consistent with agency guidance on the release of information to the public.

## II. BACKFITTING APPLICABILITY

### A. Regulatory Changes Subject to the Backfit Rule

1. As defined in Section I.A, an NRC action is considered backfitting when the NRC changes any requirements through rulemaking, an Order, or the imposition of a new or modified staff position that interprets requirements and would result in the modification or addition to SSCs, or the design of a facility, or the design approval or ML for a facility, or the procedures or organization required to design, construct, or operate a facility, after the dates defined in the backfitting requirements.
- ~~2. If the NRC staff conveys an expectation that licensees change programs, processes, procedures, or the physical plant by using or committing to use voluntary guidance (e.g., RGs or NRC endorsed industry TRs) that is not already within the LB for the identified purpose, then the staff's communication of that expectation may be considered backfitting. Since there is generally more than one way to achieve compliance with a license or the rules or orders of the Commission, or with written licensee commitments, or there may be more ways to reach a level of protection that is adequate, the applicant or licensee is ordinarily free to choose the way which best suits its purposes. However, this does not apply during the review and consideration of any voluntarily submitted license application, LAR, or LRA, provided the issue in question is somehow associated with, and is within the scope of, the license application, LAR, or LRA under consideration.~~
- 3-2. A relaxation is the modification of a regulatory requirement or staff position that reduces requirements placed on a licensee or class of licensees. A relaxation may provide licensees the option of continuing as previously licensed (status quo), or adhering to the new "relaxed" regulatory requirement or staff position. If a relaxation

does not provide for the status quo option, it is mandatory, and the relaxation is considered backfitting. However, if the implementation of the relaxation is voluntary for the licensee, in that it does provide for the status quo option, then the relaxation is not backfitting, even if the licensee decides to implement the relaxed requirement.

## B. Nonapplicable Regulatory Changes

1. The NRC's backfitting rules do not apply to the following actions:
  - (a) Confirmatory action letters (CALs), because CALs involve voluntary actions a licensee commits to take, which are agreed to between the licensee and the NRC;
  - (b) Changes mandated by statute or other Congressional action that preclude agency discretion in their implementation;
  - (c) Changes required by other Federal agencies that preclude agency discretion in their implementation;
  - (d) Voluntary licensee submittals of an LAR or LRA or subsequent license renewal (SLR) request,<sup>13</sup> subject to the limitations discussed above in Section I.A.14, and the NRC's process (requests for information, licensee engagement, or modifications to the submittal) used during the review and consideration of the LAR, LRA, or SLR request;
  - (e) A licensee's voluntary implementation of NRC-recommended actions that do not constitute the basis for resolution of a safety, security, or regulatory issue (e.g., a licensee's decision to follow an NRC RG, or an NRC-endorsed TR, or to make changes based on an NRC Information Notice);
  - (f) Overturning of an improper change implemented under 10 CFR 50.59, "Changes, Tests, and Experiments";
  - (g) Licensee changes or plant modifications that expand the plant capabilities or improve plant efficiencies or performance that are not mandated by the NRC, [such as voluntary industry initiatives](#);
  - (h) Non-mandatory relaxations of staff positions or regulations;
  - (i) New [requirements](#) or changes to requirements that do not have a direct link to, and do not further a substantive radiological public health and safety or common defense and security objective, such as reporting and recordkeeping requirements (e.g., 10 CFR 50.71, 50.72, "Immediate Notification Requirements for Operating Nuclear Power Reactors") or appeals processes (e.g., 10 CFR

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<sup>13</sup> The scope of the NRC's review of an LR or SLR and, thus, the backfitting of these applicants, is limited by the regulations in 10 CFR 54.30, "Matters Not Subject to a Renewal Review."

- 26.39, "Review Process for Fitness-For-Duty Policy Violations," 10 CFR 73.56(l), "Review Procedures");
- (j) Changes or updates to American Society of Mechanical Engineers Boiler and Pressure Vessel (ASME) Code, Section XI, that are incorporated into 10 CFR 50.55a, "Codes and Standards";
  - (k) Plant or procedural changes to comply with industry or professional standards not mandated by the NRC;
  - (l) Current and future applications for an NRC license, with two exceptions described in Section II.B.4 below;
  - (m) Voluntary changes made to a plant based on national or international operating experience, including any changes as a direct result of NRC Information Notices;
  - (n) Changes as a result of a licensee's commitment management program;
  - (o) Licensee changes to its plant under 10 CFR 50.59 or other existing change control requirements (see Section II.B.3 below);
  - (p) Plant or procedural corrective actions to restore the LB or adherence to the license and thereby provide compliance with governing requirements;
  - (q) The issuance of new or updated NRC RGs, as RGs are forward fitting, provided the RGs are not imposed on licensees;
  - (r) The endorsement of new or updated industry-submitted TRs, because TRs are forward fitting and not imposed by the NRC; and
  - (s) The staff use of documents, such as NUREGs, ISGs, and BTPs, during the review and consideration of any LAR or LRA, as the submission of the LAR or LRA is a voluntary action by a licensee applying for a change to its license, subject to the limitations discussed in Sections I.A.11 and I.A.14.
2. If an existing licensee voluntarily requests a license amendment or change, and (1) the NRC staff's consideration of the request involves a regulatory issue directly relevant to an NRC guidance document (such as an RG) and (2) the specific subject matter of the guidance document is an essential consideration in the staff's determination of the acceptability of the licensee's request, then the staff may request that the licensee either follow that guidance or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements in the licensing basis. This is not ~~considered~~ backfitting.
3. Power reactor licensee implementation of changes to its facility under 10 CFR 50.59 are not subject to the backfitting rules. The NRC has established a process under 10 CFR 50.59 that provides a licensee the authority to make certain changes without NRC approval if the change meets certain specified criteria. ~~Unless the NRC~~

~~determines that the licensee incorrectly used the 10 CFR 50.59 process, the licensee reasonably can implement the change without the NRC taking enforcement action. This is consistent with the underlying premise of regulatory stability established within the backfitting rules and the principles of good regulation.~~ However if, during any inspection or review of licensee actions implemented in accordance with 10 CFR 50.59, the staff determines that 10 CFR 50.59 was not properly implemented, the staff shall issue a finding or violation in accordance with regulations, and the licensee may be required to “revert” to the previous plant or procedural configuration, or otherwise change the facility to a configuration acceptable to the NRC. This would not be ~~considered~~ backfitting.

4. In general, backfitting provisions do not apply to current and future applicants for an NRC license. Backfitting is not intended to apply to every NRC action that substantially changes the expectations of current and future license applicants. There are two exceptions to this general principle. The first exception occurs when a 10 CFR Part 52 license applicant references a 10 CFR Part 52 license (e.g., an ESP) or NRC regulatory approval (e.g., a DCR), or both, with specified issue finality provisions. The second exception occurs when a 10 CFR Part 50 power reactor OL applicant holds a CP or limited work authorization (LWA). Section 50.109 would apply to the matters covered by the CP or LWA.
5. Actions proposed or voluntarily implemented by a licensee are not backfits, even though such actions may result from routine discussions between the staff and the licensee concerning an issue, ~~provided that those discussions did not include an NRC expectation that the licensee must implement the action.~~

### III. BACKFITTING POLICY

#### A. Adequate Protection Backfitting

1. For all matters of potential backfitting, the staff must first consider whether the issue is one of adequate protection. If the NRC staff determines that it must impose a backfitting action to ensure that a facility provides adequate protection to public health and safety and is in accord with the common defense and security, or if the Commission decides that it needs to define or redefine the appropriate level of protection of public health and safety or the common defense and security that should be considered as adequate, then the AEA requires that the backfitting action be implemented. If a backfitting action is determined to be a backfit analysis to justify the determination that a backfitting action is necessary for adequate protection, a backfit analysis is not required and costs cannot be considered and a consideration of costs are not required (unless the NRC staff identifies more than one means for implementing the new requirement, in which case costs could be considered in deciding which approach is appropriate). Whenever adequate protection is invoked,



the NMSS, NRO or NRR OD must approve a documented evaluation of the type discussed in 10 CFR 50.109(a)(6), 10 CFR 70.76(a)(6), and 10 CFR 76.76(a)(6), with a finding that the action is necessary to define or redefine adequate protection or to ensure adequate protection of public health and safety or the common defense and security. The documented evaluation must include a statement of the objectives, the reasons for the action, the basis for invoking adequate protection, and the safety or security risk if action is not taken. The NMSS, NRO or NRR staff should seek advice from the Office of General Counsel (OGC) on the imposition of all adequate protection actions, including the licensee's proposed implementation schedule. NUREG-1409 contains detailed guidance on how to prepare the documented evaluation. For generic backfitting actions that are part of rulemakings, the documented evaluation is provided as part of the rulemaking package that the Commission approves. ~~Generally, adequate protection backfits are not included in rulemakings, and instead, result from the issuance of an Order. The rulemaking will subsequently be issued to include the previously imposed adequate protection backfits, given consideration to public comments provided on the proposed rule and to lessons learned through the implementation of the previous Order requirements.~~

2. To issue the license, the Commission found that operating in accordance with the license would provide reasonable assurance of adequate protection and reasonable assurance the licensee would meet the regulations. Therefore, licensee compliance with its LB is presumed to provide reasonable assurance of adequate protection of public health and safety and the common defense and security. Thus, for the NRC to impose new or changed requirements on a licensee that are intended to provide for adequate protection of public health and safety or the common defense and security, the NRC must provide, within the documented evaluation, a clear explanation of why, despite the licensee's compliance with the applicable existing regulatory framework (LB), there is not (or will not be) reasonable assurance of adequate protection. Typically, a clear basis for invoking the adequate protection exception can be established when the NRC has new information regarding a safety or security issue that creates undue risk to public health and safety that is not addressed through compliance with the current regulatory framework. If the NRC can show that it must take action to provide reasonable assurance of adequate protection of public health and safety and the common defense and security, then the AEA requires the NRC to impose the new or changed requirements.
3. It is the NRC's position<sup>14</sup> that the agency cannot allow licensees to address issues of adequate protection by a voluntary initiative. Instead, the AEA requires the NRC to

<sup>14</sup> In SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," dated March 2, 1999 (ADAMS Accession No. ML992810068) the staff agreed that relying on voluntary

establish requirements that provide reasonable assurance of adequate protection of public health and safety and the common defense and security.

4. Under 10 CFR 72.62, the Commission requires the imposition of a backfit if it finds that the backfit is necessary to ensure adequate protection of occupational or public health and safety.

## B. Compliance Backfitting

1. Before the staff uses the compliance exception, the staff must determine whether the conditions represent an issue of adequate protection. If the issue does not involve adequate protection, then the staff should determine whether the backfitting action is necessary to ensure compliance with regulatory requirements in the licensing basis, or written commitments on how the licensee will comply with a requirement that were in place at the time of the decision at issue. If the backfitting action ensures compliance, a backfit analysis is not required. Instead, the appropriate program office or region prepares a documented evaluation of the type discussed in 10 CFR 50.109(a)(6), 10 CFR 70.76(a)(6), and 10 CFR 76.76(a)(6), with a finding that the action is necessary to ensure compliance as the result of an error or omission. The documented evaluation must include a statement of the objectives, the reasons for the action, the basis for invoking the compliance exception, and the safety or security risk if action is not taken. NUREG-1409 contains detailed guidance on how to prepare this documented evaluation. The responsible office staff shall seek OGC and the Office of Enforcement (OE) advice on the imposition of all compliance backfitting actions, including the licensee's proposed implementation schedule.
- ~~2. The phrase "written commitments," as used within the backfitting provisions, refers to those commitments that have been submitted to the NRC on the docket, have become part of the LB, and directly relate to the means by which the licensee complies with a requirement.~~
- 3.2. Under 10 CFR 72.62, the Commission will require the imposition of a backfit if it finds that the backfit is necessary to bring an ISFSI or MRS into compliance with a license or the Commission's Orders or rules. Under 72.62(b), "The Commission will require backfitting of an ISFSI or MRS if it finds that such action is necessary to assure adequate protection to occupational or public health and safety, or to bring the ISFSI or MRS into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by a licensee."

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industry initiatives to ensure adequate protection would be inappropriate "since they would be based on commitments rather than requirements."

4.3. Because a compliance backfitting action does not require a backfit analysis, the staff need not demonstrate that the direct and indirect costs of implementation are justified in view of the increased protection from the backfit. In other words, a full cost-benefit analysis is not required. However, the staff must include at least some consideration of costs in its documented evaluation. ~~Although the extent of the consideration required will necessarily be fact- and site-specific, one of the factors that may be relevant is the amount of time that has elapsed since the approval that is now claimed to be the subject of a mistake or omission. When the potential for compliance backfitting is identified relatively soon (within approximately 2 years) after the licensing decision or the imposition of a regulatory requirement, likely all that will be necessary is a simple estimate of the cost imposing the backfitting action that does not quantify benefits or perform any balancing beyond that which was originally considered. However, when many years have passed (typically more than 10) before the staff determines that a regulation or requirement is not satisfied, identifying the benefits of compliance and comparing them to the cost of implementation will likely be appropriate to ensure that costs have been adequately considered.~~ The staff is afforded a high degree of flexibility, in accordance with Commission direction, to determine how much cost consideration is appropriate based on the specifics of each case and the identified risk.

~~5. Use of the compliance exception is limited to the following situations that define "omission or mistake of fact":~~

~~(a) The NRC staff, whether by its own error or by licensee or third-party error or omission at or before the time of its determination that a known and established standard of the Commission was satisfied, (1) incorrectly perceived facts, (2) performed or failed to recognize flawed analyses, or (3) failed to properly draw inferences from those facts or analyses, as judged by the standards and practices that were prevailing among professionals or experts in the relevant area at the time of the determination in question, and~~

~~(b) Those facts, analyses, or inferences have now been properly perceived, performed, or drawn.~~

~~(c) The error or omission may have been committed by any involved party and must be traced to—~~

~~(i) The original LB or to a change to the LB, and~~

~~(i) The regulations contained in the LB at the time of implementation that were applicable to the particular licensee whose LB is at issue, and~~

~~(ii) Any standards and practices in existence at the time the original determination was made.~~

~~The understanding for what constituted proper implementation of the regulations, standards, and practices must have been widely known or understood by professionals at the time. This is not restricted to the regulatory positions of the NRC but includes any industry or professional standards and practices in existence at the time the original determination was made.~~

~~6. The compliance exception should not be applied to the following:~~

~~(d) Failure of the NRC staff to extrapolate conclusions from facts, analyses, and direct inferences in ways that were not commonly recognized under such prevailing professional standards and practices at the time of the NRC determination; or~~

~~(e) Recharacterizations of whether a particular set of otherwise understood circumstances satisfies the standard at issue based upon professional standards and practices developed or accepted after the time of the determination.~~

~~7. The following policy concerns the use of the compliance exception to mandate consistency with the general design criteria (GDC):~~

~~(a) The GDC are located in Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50 and 10 CFR Part 72, Subpart F, "General Design Criteria." Those design criteria help formulate a plant's design basis, and the design basis is reflected in the plant's final engineering drawings. The design basis must be documented in the UFSAR.~~

~~(b) The GDC establish "minimum requirements" for the development of the principal design criteria (PDC). The GDC are intended to provide guidance in establishing the PDC. The licensing process requires approval of an applicant's PDC as a condition for granting a CP. Before an OL is issued, and as a basis for its finding of reasonable assurance of adequate protection of public health and safety and the common defense and security, the Commission must find that the facility has been built in accordance with the PDC and any NRC-approved changes. Thus, for 10 CFR Part 50 licensees with CPs issued since 1971 (when the GDC were promulgated), the Commission has already necessarily reached the conclusion that the design basis of the plant, as reflected in the PDC, meets or exceeds the minimum criteria set forth in the GDC. The 1992 SRM approved the SECY that concluded that no GDC backfitting was needed, and that all pre-GDC plants meet the intent of the GDC.<sup>15</sup>~~

<sup>15</sup> SRM was in response to SECY-92-223 "Resolution of Deviations Identified During the Systematic Evaluation Program" and is dated September 18, 1992 (ML12256B290).

- ~~(c) The NRC must not rely on the GDC requirements for pre-GDC licensing actions (those licenses or CPs issued before the issuance of the GDC (before 1971)), unless the NRC has made the GDC a requirement for that licensee.~~
- ~~(d) Under the provisions of 10 CFR 50.34, "Contents of Applications; Technical Information," an application for a GP must include the PDC for a proposed facility. Under the provisions of 10 CFR 52.47, "Contents of Applications; Technical Information," 10 CFR 52.79, "Contents of Applications; Technical Information in Final Safety Analysis Report," 10 CFR 52.137, "Contents of Applications; Technical Information," and 10 CFR 52.157, "Contents of Applications; Technical Information in Final Safety Analysis Report," an application for a DC, COL, SDA, or ML, respectively, must include the PDC for a proposed facility. The PDC establish the necessary design, fabrication, construction, testing, and performance requirements for SSCs important to safety; that is, SSCs that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public.~~
- ~~(e) The license approval process will typically yield more specific requirements than those set forth in the GDC. However, the NRC is not precluded from reliance on GDC as the source of a "requirement" for purposes of invoking the compliance exception in those cases where a GDC provides more than just a performance standard and has not been superseded through the approval of the PDC, and requirements derived from those PDC that are clearly meant to address the GDC at issue. Thus, a GDC can be regarded as a requirement in those circumstances in which the GDC is prescriptive in nature and the technical specifications and other licensee requirements derived from the PDC do not speak to the matter in question.~~
- ~~(f) In some cases, conditions not in accordance with the GDC can be properly resolved as a matter of adequate protection if the matter creates undue risk to public health and safety or the common defense and security, without the need to invoke the compliance exception. The extent to which regulatory action is necessary to ensure adequate protection should be evaluated before invoking the compliance exception based on a requirement set forth in the GDC.~~

- 8.4. Use of the compliance exception to support a backfit should not be confused with routine inspection activities related to the LB, as determined by the reactor oversight process or other inspection activities. NRC inspections assess compliance with the requirements in the licensing basis, whereas compliance backfitting is pertinent to those issues where the staff has determined that it is necessary to modify the approved LB because of an error or omission. Thus, it is not expected that findings or violations documented as part of the NRC's inspection activities would result in

compliance backfitting. However, the NRC staff must evaluate each circumstance to ensure the issue is properly assessed against the LB and resolved. For example, the NRC would take enforcement action when a licensee is not in compliance with the NRC-approved method of meeting a requirement, whereas compliance backfitting would occur when a licensee is in compliance with an NRC-approved method but the NRC subsequently determines that the licensee's method does not result in compliance with the requirement because of an error or omission at the time of approval.

- 9.5. To the extent practical, ~~t~~The NRC staff's compliance backfitting documentation should include risk insights, including safety margin<sup>16</sup>, to provide the staff sufficient information to determine an appropriate~~acceptable~~ schedule for the licensee to implement the backfit.
- 10.6. At any point during the process, the responsible program office or the region, in consultation with other appropriate offices, including OGC and OE, may decide not to proceed with the backfitting action because further effort is likely to show either of the following:
- (a) Compliance backfitting would not provide any increase in safety or security as compared to the status quo. This is not to say that the increase in safety or security must be substantial, only that there must be some attributable increase.
  - (b) An exemption from compliance with the Commission's regulation for which compliance is sought may be granted under 10 CFR 50.12, "Specific Exemptions;" 10 CFR 52.7, "Specific Exemptions;" 10 CFR Part 70 Subpart B, "Exemptions;" 10 CFR 72.7, "Specific Exemptions;" or 10 CFR 76.23, "Specific Exemptions."
- 11.7. Or~~Additionally~~, in consultation with OE, the OD or RA may determine that enforcement discretion should be granted to enable the licensee to prepare a systematic and planned approach for implementing a backfitting action. If the OD or RA and OE conclude that enforcement discretion is appropriate or necessary, based on a risk-informed analysis and in consideration of licensee outages and maintenance schedules, OE, with the OD or RA, will normally issue an enforcement guidance memorandum or seek Commission approval for an interim enforcement policy for multifacility compliance backfitting actions, as appropriate.

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<sup>16</sup> Safety margin may not be quantifiable. For example, meeting environments qualification (EQ) requirements in 10 CFR 50.49 "Environmental qualifications of electrical equipment important to safety for nuclear power plants," results in safety margin, but this margin is not readily quantifiable, particularly with regard to public health and safety (i.e., the equipment is robust for performing under events that are important to plant risk and are less severe than the environmental qualifications envelop).

- (a) An enforcement guidance memorandum is usually the appropriate enforcement discretion for generic or industrywide compliance backfits.
  - (b) For individual facility- or site-specific compliance backfitting actions, the exercise of enforcement discretion may be addressed in the Order associated with the compliance backfit.
- ~~12. If adequate protection is not involved, then a determination must be made to verify there is adequate safety margin with respect to the regulatory requirements. Therefore, consideration of cost is relevant in determining if a backfit is needed to recover the lost safety margin.~~
- ~~13.8. If, after careful consideration of the issue, risk to public health and safety or the common defense and security, safety margin, and licensee costs for implementation of the compliance backfit, the NRC determines that compliance should not be required, then the NRC will normally grant enforcement discretion until such time as the NRC initiates and issues an exemption in accordance with 10 CFR 50.12, an amendment in accordance with 10 CFR 50.90, a relaxation of an order, or other action as appropriate.~~

### C. Cost-Justified Substantial Increase in Protection Backfitting

For all backfitting that does not satisfy the adequate protection exception or compliance exception criteria, the NRC should determine whether to perform a backfit analysis by applying the facts of the proposed backfitting against the backfit standard as described below.

#### 1. Backfit or Issue Finality Standard

The backfitting provisions require, first, that the proposed action result in a substantial increase in the overall protection of public health and safety or the common defense and security. If either criterion is met, the standard then requires that the direct and indirect costs are shown to be justified in light of the substantial increase in overall protection. If the proposed action is not shown to result in a substantial increase in safety or security, or the costs are not justified, then the backfit should ~~can~~ not be imposed (unless the Commission exempts itself from the backfitting rule).

#### 2. Backfit Analysis

All backfit analyses must be performed in accordance with 10 CFR 50.109 or other applicable regulations and NUREG-1409.

- (a) Once the NRC determines that backfitting must be pursued, and adequate protection or compliance backfitting are not appropriate, the NRC staff must develop a backfit analysis.

- (b) The staff must demonstrate and document that the backfit standard is met. The staff must consider available quantitative and qualitative data in making this determination. If necessary, relevant, and consistent with SRM-SECY-14-0087, "Staff Requirements – SECY-14-0087-Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," dated March 4, 2015, qualitative considerations may be used to demonstrate a cost-justified increase in protection. As directed, qualitative factors should be used in a judicious and disciplined manner to inform decisionmaking, in limited cases, when quantitative analyses are not possible or practical (i.e., due to lack of methodologies or data). Accordingly, an analysis should be informed by applicable risk information, including a PRA, to the extent it is available and can be considered without undue use of NRC resources. The staff will also consider information available concerning any of the factors listed in 10 CFR 50.109(c), as may be appropriate, and any other information relevant and material to the proposed backfitting, including NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission."
- (c) Relaxations may not show a substantial increase in safety or security; consequently, implementation of these relaxations are voluntary for the licensees. In most cases, relaxations involve alternative regulatory approaches that licensees can choose to implement, may involve small decreases in safety or security, and are not backfitting actions if options for implementation are offered to the licensees. When such options are offered, the NRC verifies that compliance with the licensee's LB, including the relaxation (if it involves a small decrease in safety or security), continues to provide reasonable assurance of adequate protection.
3. Under 10 CFR 72.62, the Commission can require the backfitting of an ISFSI or MRS installation if it finds that the backfitting action would result in a substantial increase in protection to the occupational or public health and safety whose costs are justified in light of the increased protection.

#### D. Additional Considerations

1. For all backfitting actions, additional procedural factors required by the CRGR Charter for [a systematic analysis justification](#) must be used if they apply to the issue. Furthermore, as additional administrative controls, the offices or regions may use reviews by special internal panels, and OE and OGC review and concurrence, as appropriate.
2. The NRC staff [may should](#) recommend terminating a proposed agency action that would constitute backfitting when the staff concludes that the proposed action is not necessary for adequate protection; the compliance exception to the backfit analysis



requirement does not apply; the backfitting action is not likely to result in a substantial increase in safety or security; or, ~~if a substantial increase in safety or security can be demonstrated~~, the direct and indirect costs of implementation are not likely to be justified. The responsible program OD or RA may approve closing the issue with appropriate notice sent to all applicable parties and recorded in ADAMS.

3. During the course of dispositioning a proposed finding, violation, or licensing action, a licensee may raise concerns that the proposed action is backfitting. The staff will inform divisional management of the concern and, ~~before the proposed action is taken, with ensuing discussions considering~~ previous regulatory staff positions and enforcement precedents~~see~~. A lack of historical staff position could be indicative of a new staff position that would trigger ~~and therefore subject to~~ backfitting provisions. ~~Informing divisional management and researching historical positions ensures appropriate consideration of licensee concerns and supports agency operation as a stable and reliable regulator.~~

#### E. Scheduling of Backfitting Implementation

1. After the appropriate OD (NMSS, NRO, or NRR) or RA has approved a facility-specific documented evaluation or backfit analysis, the responsible division director or above must issue the backfitting requirement to the licensee. The licensee may choose to implement the backfitting action or appeal the decision to the program OD or RA.
2. Implementation of a facility-specific backfitting action should be accomplished on a schedule based on the safety or security significance and overall risk of the issue, with the exception of any adequate protection backfits that should be expeditiously imposed. The staff should consult with its regional and program office counterparts and OE to establish the implementation schedule, identify the implementation actions, and determine if and when enforcement action is appropriate. The responsible OD or RA, in collaboration with OE, must determine whether enforcement discretion is appropriate, and how it will be addressed in the facility specific backfit action.
3. In accordance with the backfitting provisions (e.g., 10 CFR 50.109(c)), scheduling criteria will include the importance of the backfitting action (i.e., safety or security significance, including risk) relative to other safety- or security-related activities underway, such as planned construction, outages, or other maintenance.
4. For generic backfitting actions that are part of rulemaking, schedule considerations are addressed as part of the rulemaking process, and are typically included in the new regulations as implementation or scheduling provisions.
5. A facility-specific backfitting action may be imposed by Order before completing any of these procedures if the OD who authorized the backfitting action determines that

immediate imposition is necessary to ensure public health and safety or the common defense and security. In such cases, the appropriate OD must promptly notify the EDO of the action and, if possible, the staff must prepare a documented evaluation in time to be issued with the Order. If the documented evaluation cannot be issued with the Order, the evaluation must be completed as soon as possible after issuance of the Order and made publicly available.

#### F. Appeals of Backfitting Decisions

1. By NRC policy, the NRC affords licensees an opportunity to appeal a backfitting action at two levels: a First-Level Appeal to the OD or RA and a Second-Level Appeal to the EDO.
2. The appeal process applies to the following two situations:
  - (a) An applicable staff position that the NRC staff determined was not backfitting, but the licensee believes is backfitting, or
  - (b) An applicable staff position that the NRC staff determined was backfitting, but the licensee believes was not properly ~~required~~justified, including an appeal to modify or withdraw a backfitting action for which a backfit analysis was conducted or an appeal that a backfitting action ~~based on~~justified by the adequate protection or compliance exception in fact must be ~~analyzed~~justified through a backfit analysis.
3. If at any time during an appeal process, the NRC determines the proposed action is ~~unjustified~~backfitting ~~that was not properly analyzed~~, the responsible OD or RA, or designee, must document the decision and inform the licensee.
4. The First-Level Appeal process must be ~~carried out~~completed before the Second Level Appeal process ~~begins~~. In the event a licensee addresses its initial appeal of a staff action to a level above the OD or RA, the appeal should be assigned to the OD of the program office that oversees the subject of the backfit, who will then oversee the First-Level Appeal process. While a program OD or an RA can issue backfitting actions, all backfitting appeals are overseen by a program OD, who will coordinate the review with the RA overseeing the affected facility, and the OD for emergency preparedness or security issues, in the Office of Nuclear Security and Incident Response (NSIR).
5. First-Level Appeal:
  - (a) The licensee may send a backfitting appeal in writing to the OD or RA whose staff proposed or issued the action. The program OD is responsible for deciding the appeal. This constitutes a First-Level Appeal.

- (b) During the review process, the OD may designate a panel to consider the appeal. A public meeting must be offered at which the licensee may discuss the appeal to ensure the NRC has a full understanding of the appeal. No determinations will be made at this public meeting.
  - (c) During the review process and following any public meeting with the licensee, a meeting with the originating staff must be offered to discuss the backfitting action and supporting documentation to ensure a full understanding of the initial action in question.
  - (d) After appropriate interoffice coordination and management review of the licensee's appeal, the program OD, working with the responsible RA and the NSIR OD, as applicable, must decide on the appeal. This process should be completed within 90 days of the date the NRC accepts the appeal.
  - (e) The applicable Deputy EDO must be informed of the decision before the program OD informs the licensee of the decision in writing.
  - (f) If the backfitting action is determined to be the correct regulatory path forward, following the written decision of the appropriate program OD, the licensee may implement the action or submit a Second-Level Appeal.
6. Second-Level Appeal:
- (a) If the licensee does not agree with the outcome of a First-Level Appeal, the licensee may file a second and final appeal to the EDO.
  - (b) The EDO may designate a panel to consider the Second-Level Appeal. A public meeting with the licensee must be offered to discuss the licensee's appeal documentation and allow for a full understanding of the licensee's position.
  - (c) The EDO's designated panel must consider all supporting staff analyses, submitted licensee analyses, and supplemented staff analyses, as well as any other information that is relevant and material to the appeal. Meetings with the staff involved in the original action in question and those involved in the First-Level Appeal must be offered to allow a full understanding of the staff position.
  - (d) If the EDO determines that the action subject to a backfitting appeal is not considered backfitting, the action must not be treated further within the context of backfitting, but will be processed commensurate with the normal licensing or inspection appeal process.
  - (e) If the EDO denies the appeal, the licensee must implement the action. If the licensee fails to implement the backfitting action, the appropriate OD must issue

an Order. Once an Order is issued, whether or not it is immediately effective, MD 8.4 no longer applies. At this point, appeals are governed by the provisions of 10 CFR Part 2, "Agency Rules of Practice and Procedure," Subpart B, "Procedure for Imposing Requirements by Order, or for Modification, Suspension, or Revocation of a License, or for Imposing Civil Penalties."

### G. Exceptions

The NRC staff is not required to make facility-specific backfitting findings when generic backfitting actions on the same issue(s) are, or have been, approved by the CRGR and EDO. This is also true for generic backfitting actions approved before November 1981, unless the EDO determines that significant facility-specific backfits were not considered during the prior reviews.

### H. Assessment of the Overall Effectiveness of the NRC's Backfit Management Program

The CRGR assesses, typically every 5-years, the effectiveness of the NRC's administrative controls for backfitting, as part of its regulatory effectiveness responsibility, and provides a report to the EDO.

## IV. INFORMATION COLLECTION PROCESS

### A. NRC Regulations for Information Collection

1. Demands for Information concerning alleged violations or potentially hazardous conditions or other facts are made pursuant to 10 CFR 2.204. Under Section 2.204, the NRC can require a licensee to respond for the purposes of determining if an Order under 10 CFR 2.202 should be issued, or whether other actions should be taken.

2. Information requests to power reactor licensees are made pursuant to 10 CFR 50.54(f). Under 10 CFR 50.54(f), the NRC can require its licensees to provide information to enable the Commission to determine whether or not a license should be modified, suspended, or revoked. This rule requires the NRC staff to provide a reasonable basis for justify these information requests with supporting analysis that demonstrates that the cost burden to be imposed on licensees is justified in view of the potential safety significance of the issue for which the information is requested. The exceptions to this requirement to prepare an analysis justification are as follows:

- (a) No supporting analysis is required whenever there is reason to believe that public health and safety or the common defense and security may not be adequately protected, and information is needed to determine if this is the case and to take any necessary corrective actions.

- (b) No supporting analysis is necessary if the staff seeks information of a type routinely sought as a part of the standard procedures for the review of applications for licenses or license amendments for facilities under construction, or the conduct of inspection activities for facilities under construction. However, if the request is not part of a routine licensing review (for example, if the staff seeks information to develop a new staff position), then the supporting analysis must include the reasons for the request and provide a reasonable basis for justify the estimated costburden imposed on the licensee before issuance.
- (c) No supporting analysis is necessary for licensing reviews or inspection activities for operating facilities, or for information requests sought to verify licensee compliance with the requirements in the LB for the facility. Requests for information made in connection with fact-finding reviews, inspections, and investigations of accidents or incidents are not usually made, pursuant to 10 CFR 50.54(f). Furthermore, such requests are not normally considered within the scope of the backfitting rules.
3. The requirements for information collection requests for selected materials licensees are contained in 10 CFR 70.22(d), 10 CFR 72.62(d), and 10 CFR 76.70(e).
  4. The requirements for information collection requests for power reactor licensees under 10 CFR Part 52 are contained in 10 CFR 52.39(f), 10 CFR 52.98(g), 10 CFR 52.145(c), and 10 CFR 52.171(c).
  5. The information request sent to the licensee should document the staff's evaluation of the applicable information collection requirements for the request.

#### B. EvaluationJustification

1. The program OD and the RAs must ensure that the staff establishes a reasonable basis for all information requests (except in cases that do not require an analysisjustification). Specifically, the responsible OD or RA must do the following:
  - (a) Ensure that the staff has evaluated the request to determine whether the burden cost imposed on the licensee by the information request is justified, commensurate with the potential safety or security significance of the issue to be addressed. Such evaluationjustification should consider the following:
    - (i) Whether the NRC already has the information being requested,
    - (ii) Whether the NRC can readily obtain the information absent a formal information request (for example, is the information available in the public domain),

- (iii) How to minimize the population of entities from whom information is being requested, and
  - (iv) How to obtain the necessary information while minimizing the ~~burden on~~ cost to requested entities.
- (b) Approve the information request and the staff evaluation before transmittal of the request for information to a licensee.
2. The NRC staff's evaluations to demonstrate that an information request is justified appropriate must include at least the following elements:
- (a) A statement of the problem describing the need for the requested information in terms of its potential benefit,
  - (b) The licensee actions required and an estimate of the cost to~~burden on~~ the licensee to develop a response to the information request, and
  - (c) An anticipated schedule for the NRC to analyze and act on the information.

## V. TRAINING PROGRAMS FOR BACKFITTING AND INFORMATION COLLECTION

### A. Backfitting Training

The NRC ODs and RAs, informed by consultation with OGC and agency backfitting POCs, must plan for backfitting training for their staff that incorporates the agency backfitting training program. The agency backfitting training program should include beginner and advanced levels, as well as refresher courses.

### B. Backfitting Agencywide Training Coordination

The Office of the Chief Human Capital Officer (OCHCO) must maintain and update a backfitting training program for the NRC staff. OCHCO will develop the backfitting training modules in consultation with OGC, CRGR, and program ODs. OCHCO will also consult and coordinate with the appropriate contact in the Office of the Chief Information Officer to ensure backfitting training modules are available online.

### C. Information Collection Training

The NRC program offices should maintain information collection training and qualification for project managers with support from OGC. Regional inspection procedures and qualification do not apply to this training requirement.

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## VI. ACRONYMS

10 CFR	Title 10 of the <i>Code of Federal Regulations</i>
ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act of 1954, as amended
BTP	Branch Technical Position
CAL	Confirmatory Action Letter
COL	Combined License
CP	Construction Permit
CRGR	Committee To Review Generic Requirements
DC	Design Certification
DCR	Design Certification Rule
DEDO	Deputy Executive Director for Operations
DH	Directive Handbook
EDO	Executive Director for Operations
ESP	Early Site Permit
GDC	General Design Criterion/criteria
ISFSI	Independent Spent Fuel Storage Installation
LAR	License Amendment Request
LB	Licensing Basis
LR	License Renewal
LRA	License Renewal Application
LWA	Limited Work Authorization
MD	Management Directive
ML	Manufacturing License
MRS	Monitored Retrievable Storage
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission

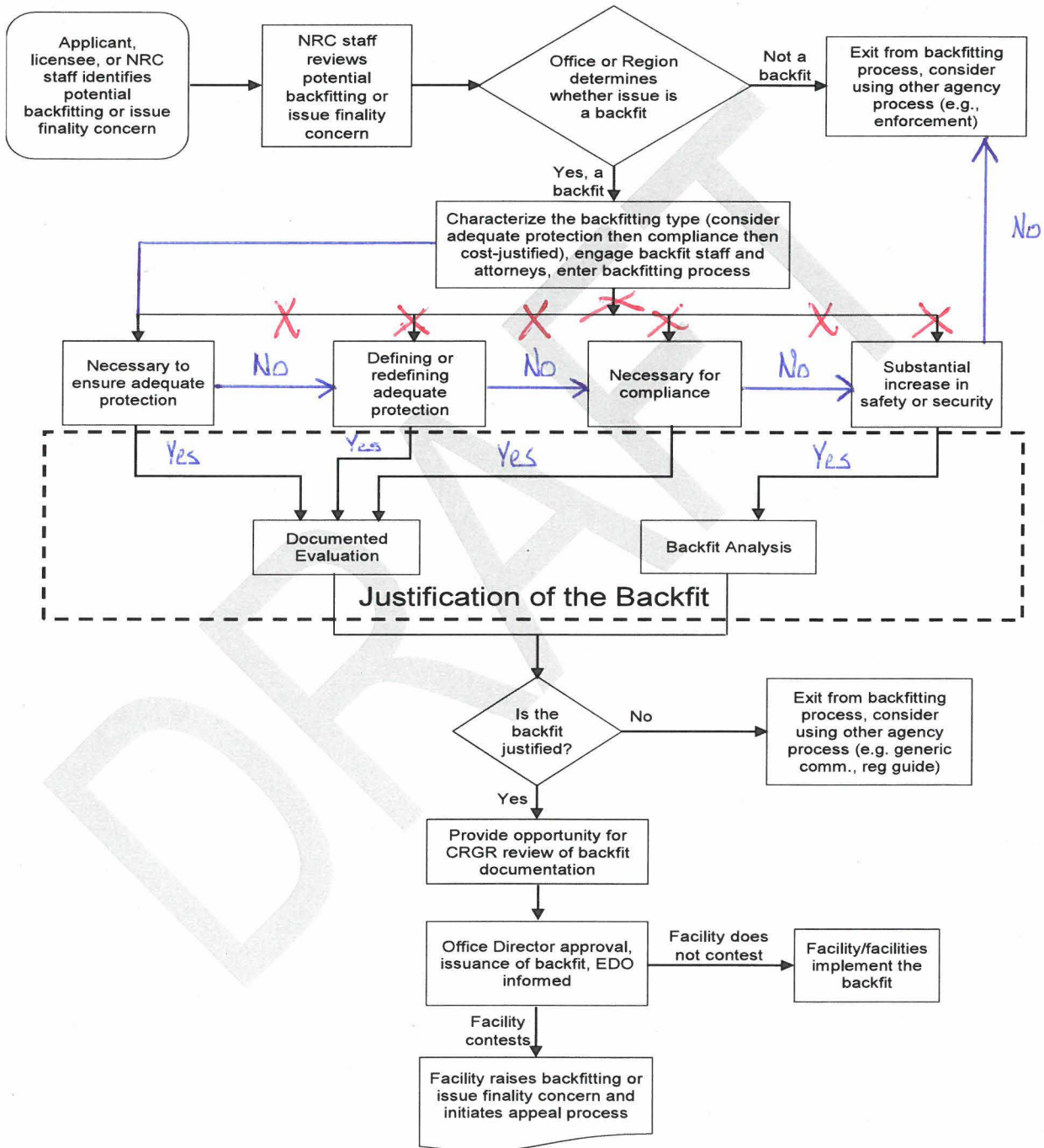
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NRO	Office of New Reactors
NRR	Office of Nuclear Reactor Regulation
NSIR	Office of Nuclear Security and Incident Response
NUREG	NRC Technical Report Designation
NUREG/BR	NUREG Brochure
OCHCO	Office of the Chief Human Capital Officer
OD	Office Director
OE	Office of Enforcement
OGC	Office of the General Counsel
OL	Operating License
PDC	Principal Design Criteria
POC	Point of Contact
PRA	Probabilistic Risk Assessment
RA	Regional Administrator
RES	Office of Nuclear Regulatory Research
RG	Regulatory Guide
SDA	Standard Design Approval
SE	Safety Evaluation
SECY	Office of the Secretary
SER	Safety Evaluation Report
SLR	Subsequent License Renewal
SRM	Staff Requirements Memorandum
SSC	Structure, system, and component
TR	Topical Report
UFSAR	Updated Final Safety Analysis Report

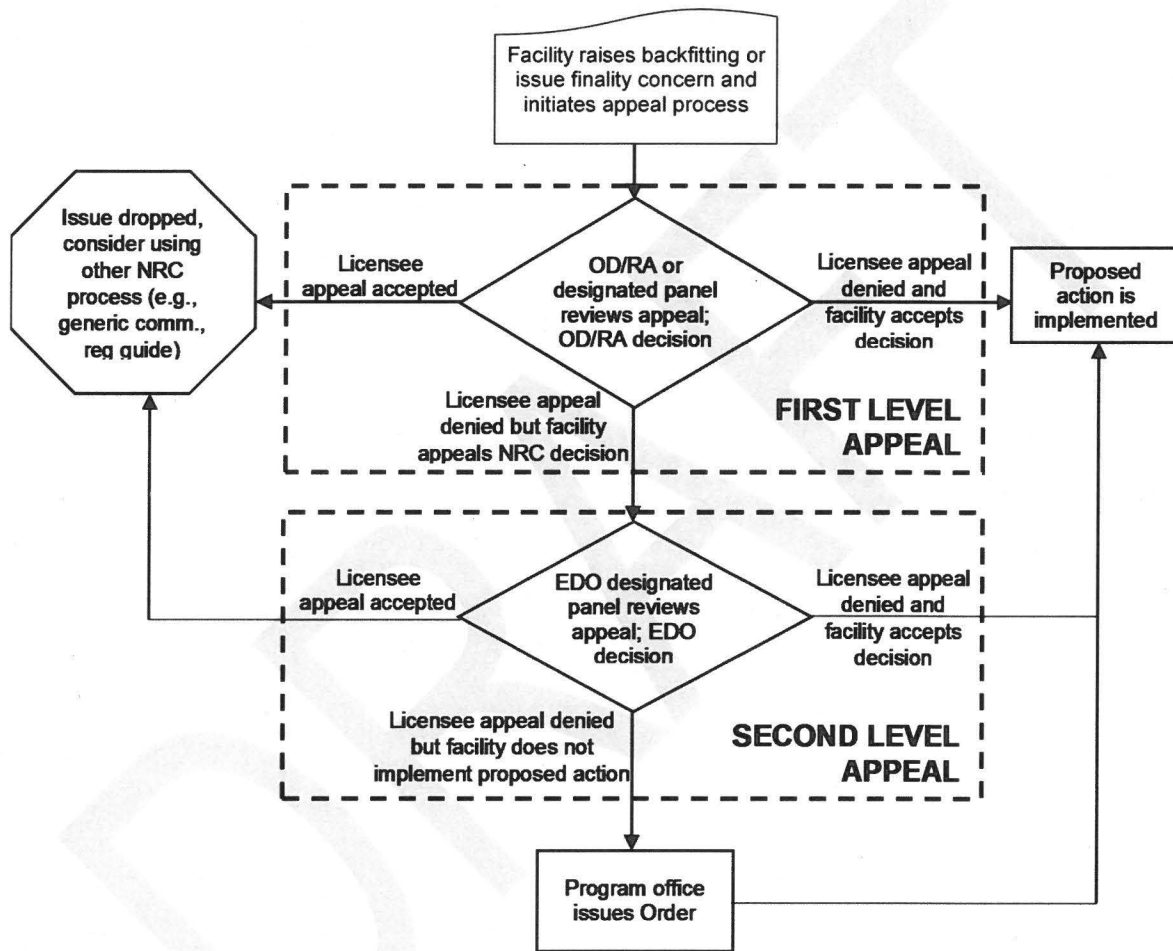


EXHIBITS

EXHIBIT 1 NRC Internal Backfitting and Issue Finality Flowchart



**EXHIBIT 2 NRC Internal Backfitting and Issue Finality Flowchart**



**EXHIBIT 3 NRC Backfitting Requirements**

Affected Entities	Backfitting/Issue Finality Regulation
Power Reactors (licensed under 10 CFR Part 50)	10 CFR 50.109
Power Reactors (permitted, certified, licensed or approved under 10 CFR Part 52)	10 CFR 50.109 and 10 CFR Part 52 (as noted below)
Early Site Permit (ESP)	10 CFR 52.39 (term of ESP) 10 CFR 52.31 (renewal)
Standard Design Certification Rule (DCR)	10 CFR 52.63 (term of DCR) 10 CFR 52.59 (renewal)
Combined License (COL)	10 CFR 52.83 (referenced NRC approvals) 10 CFR 52.98 (term of COL)
Standard Design Approval	10 CFR 52.145
Manufacturing License (ML)	10 CFR 52.171 (term of ML) 10 CFR 52.179 (renewal)
Licensees authorized to possess special nuclear material above a critical mass	10 CFR 70.76, Subpart H
Independent Spent Fuel Storage Installation	10 CFR 72.62
Gaseous Diffusion Plant	10 CFR 76.76

**RESPONSE SHEET**

**TO:** Annette Vietti-Cook, Secretary  
**FROM:** Commissioner Caputo  
**SUBJECT:** SECY-18-0049: Management Directive and Handbook 8.4, "Management of Backfitting, Issue Finality, and Information Collection"


Approved XX Disapproved \_\_\_\_\_ Abstain \_\_\_\_\_ Not Participating \_\_\_\_\_

COMMENTS: Below \_\_\_\_\_ Attached XX None \_\_\_\_\_

Entered in STARS

Yes X

No \_\_\_\_\_

  
\_\_\_\_\_  
Signature

2-22-19  
\_\_\_\_\_  
Date

Commissioner Caputo's Comments on SECY-18-0049  
Management Directive and Handbook 8.4, "Management of Backfitting,  
Issue Finality, and Information Collection"

The Staff has presented for the Commission's consideration revisions to Management Directive 8.4, Management of Backfitting, Issue Finality, and Information Collection, and its related Handbook (MD 8.4). The Staff's efforts stem from Commission direction in SRM-COMSECY-16-0020, which instructed the Staff to revise agency guidance concerning consideration of cost and application of the compliance exception to the Backfit Rule consistent with recent legal developments and clarifications. I thank the Staff for the significant time and effort spent in addressing the Commission's direction.

The Backfit Rule provides licensees with assurance that regulatory changes or modifications will not be implemented unless they are necessary for adequate protection, are needed to correct an error or mistake of fact that causes a licensee to be out of compliance with the agency's requirements, or substantially increase the overall public health and safety or common defense and security and are cost-justified. It is important that the agency consistently follow its own rules. Moreover, adherence to the Backfit Rule ensures that agency action is consistent with agency goals and objectives, including our Principles of Good Regulation.

This vital link between adherence to the Backfit Rule and adherence to our Principles of Good Regulation strongly influenced my consideration of modifications to Management Directive 8.4. The staff's proposed revision and the expansion of its scope is one step toward achieving consistency across the agency for implementing backfitting and issue finality requirements. The previous version of MD 8.4 and its Handbook applied to facility-specific backfitting and information requests only. The staff proposes to change the title and expand the scope of MD 8.4 to apply to facility-specific and generic backfitting and issue finality actions. I approve this change.

I also approve the Staff's proposed restructuring of MD 8.4 to specify that consideration of whether a change is necessary for adequate protection, as defined by the Commission, is the first step in the Staff's backfit analysis. This determination should not be made lightly or used as a means for avoiding a more rigorous regulatory analysis. An adequate protection determination is a necessarily high standard as it indicates that existing protections are inadequate, contrary to the agency's statutory mandate. If a regulatory change or modification is considered necessary for adequate protection, it is common-sense that the next question would be whether the change would need to be immediately effective. The Statements of Consideration accompanying the 1985 revisions to the Backfit Rule recognize circumstances where changes necessary for adequate protection may or may not require "immediately effective regulatory action."<sup>1</sup> However, the MD as presented to the Commission does not instruct the Staff to conduct an imminent threat analysis. Accordingly, I support the Chairman's proposal that where the Staff determines a change is necessary for adequate protection, their determination should be accompanied by an imminent threat analysis. That analysis should be provided to the Commission for consideration in its review of the proposed action. Anything less

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<sup>1</sup> Revision of Backfitting Process for Power Reactors, 50 Fed. Reg. 38097, 38103 (Sept. 20, 1985).

than this disciplined approach risks a decision that is subjective, poorly documented, and inconsistent with the risk reduction achieved.

The next question in a backfit evaluation is whether the proposed regulatory change or modification is needed to correct an error or mistake of fact that causes a licensee to be out of compliance with the agency's requirements. A logical, substantive, and disciplined answer to this question is essential for regulatory reliability. Subjectively reinterpreting previous agency decisions and licensing bases, either outside or within the backfit process, suggests indecisive administration of our regulations. Such a dynamic creates the perception that our regulations are subject to unpredictable and unjustified change, contrary to the principle of Reliability.

Many of the revisions to MD 8.4 stem from the Supreme Court's decision in *Michigan v. EPA*, where the court determined that an agency's decision-making process should include at least some consideration of the cost incurred by a licensee to comply with a new regulation. The Staff in the past had not considered costs when applying the compliance exception. I recognize the Staff's efforts to address the Court's decision and I support the Chairman's edits that further clarify the interpretation of the use of the compliance exception.

The last step of a backfit evaluation is to determine whether the proposed regulatory change or modification would provide a substantial increase in safety or security, and, if so, whether the change is cost-justified. This crucial step ensures our actions are consistent with the degree of risk reduction they achieve, which is one of the most valuable purposes of the Backfit Rule. Regulatory changes and modifications are ultimately sorted based on risk significance by determining whether they are necessary for adequate protection or provide a cost-justified substantial increase in safety. Thus, the backfit process is a tool for risk-informing whether to impose regulatory changes or modifications.

Connected to the consideration of cost in regulatory decision-making is the concept of "forward fits." While I consider a forward fit to simply be a regulatory change and disagree with the need to create a defined term for what essentially constitutes a new requirement, it has nonetheless crept into our lexicon. Since the term appears in the Staff's proposed revisions to MD 8.4, it becomes necessary to address this new term. A forward fit is similar to a backfit in that it is the imposition of a new or modified requirement or regulatory interpretation. But it is applied as a condition of approval by the NRC of a licensee-initiated request for a licensing action when the underlying request did not propose to comply with the new or revised requirement or interpretation. In either case, a licensee would be compelled to comply with a regulatory change or new interpretation.

I am concerned that the forward fit process provides an avenue for requirements to be imposed on licensees without the advantage of determining whether the new requirement will provide a substantial safety improvement or a cost-benefit analysis. In other words, to suggest that regulatory changes imposed on existing licensees must be justified, but that future applicants can be subjected to unjustified regulatory changes is contrary to the principles of Independence, Efficiency, Clarity, and Reliability. For example, subjecting licensees of comparable facilities to different requirements based solely on the timing of their respective applications without justifying those differences would be subjective, illogical, impractical, and unfair.

I therefore propose that the forward fit process include the same regulatory analysis and scrutiny as employed under the backfit process. Specifically, for forward fits unrelated to adequate protection the Staff must demonstrate 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 forward fit, and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection. Further, forward fits should be limited to situations where: 1) there is a direct nexus to the licensee's request, and 2) the imposition of a new or modified requirement or regulatory Staff position is essential to the Staff's determination of the acceptability of the licensee's request. I also support the Chairman's proposal that the Staff should establish an appeals process for forward fits that is similar to the process provided for backfits. This will enable a continuous and transparent dialogue between Staff and licensees regarding new requirements.

Finally, I propose a clarification in the MD of the responsibilities of each office regarding conducting backfit and forward fit reviews, including those for security related changes. The Directors of NRR, NRO, and NMSS and the Regional Administrators have primary responsibility to conduct backfit evaluations for the facilities within their programs and regions. These offices will be supported by and coordinate with other agency offices—such as OGC, NSIR, OE, and RES—for their input and concurrence on these determinations. This process will enable consistency and uniformity in our backfit and forward fit processes.

Our regulatory framework has been developed over the past 64 years, reflecting the efforts of thousands of agency experts and over 4,500 years of operational experience in nuclear power. Based on this wealth of experience and institutional knowledge, changes should be made only after robust and careful analysis and consideration to ensure that these changes are truly warranted. Rigorous adherence to and consistent application of the Backfit Rule is necessary to provide the agency's stakeholders with necessary regulatory stability and transparency in the NRC's reasoned and informed decision-making process. The Backfit Rule should not be viewed as a barrier to regulatory change, it should be viewed as a tool to ensure we are making sound, justified, safety- and security-beneficial changes in keeping with our Principles of Good Regulation.

<b>MD 8.4</b>	<b>MANAGEMENT OF BACKFITTING, <u>FORWARD FITTING</u>, ISSUE FINALITY, AND INFORMATION <u>COLLECTION REQUESTS</u></b>	<b>DT-XX-XX</b>
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<i>Volume 8:</i>	Licensee Oversight Programs
<i>Approved By:</i>	[Name and Title of Approving Official]
<i>Date Approved:</i>	Month X, 2010X [Date of Final Approval]
<i>Cert. Date:</i>	N/A, for the latest version of any NRC directive or handbook, see the <a href="#">online MD Catalog</a> .
<i>Issuing Office:</i>	Office of Nuclear Reactor Regulation Division of Inspection and Regional Support
<i>Contact Name:</i>	Timothy Reed

**EXECUTIVE SUMMARY**

Management Directive (MD) 8.4, “Management of Backfitting, Issue Finality, and Information Collection,” is retitled and revised to clarify ~~the agency’s~~ roles and responsibilities for management of backfitting, issue finality, forward fitting, and information ~~collection requests~~ generically and on a facility-specific basis. MD 8.4 describes the roles and responsibilities of various offices and provides the policy to direct the U.S. Nuclear Regulatory Commission implementation of the backfitting provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) for nuclear power reactor ~~facilities licensees~~ and selected nuclear materials ~~facilities licensees~~; ~~and~~ the issue finality provisions of 10 CFR Part 52 ~~for~~ nuclear power reactors ~~licensees, design certification applicants, and holders of related NRC permits and approvals;~~ ~~as well as~~ ~~and~~ the ~~specific~~ provisions of 10 CFR 50.54(f) and the corresponding requirements in 10 CFR Parts 70, 72, and 76, ~~and 10 CFR 2.204~~.

Accordingly, MD 8.4 is retitled from “Management of Facility-Specific Backfitting and Information Collection” to “Management of Backfitting, Issue Finality, and Information Requests Collection” to clarify the intent and the objectives of the program.

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For updates or revisions to policies contained in this MD that were issued after the MD was signed, please see the Yellow Announcement to Management Directive index ([YA-to-MD index](#)).



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## I. POLICY

It is the policy of the U.S. Nuclear Regulatory Commission to have an effective program that will ensure that backfitting<sup>1</sup> and forward fitting<sup>2</sup> of nuclear power reactor facilities~~licensees~~<sup>3</sup> and selected nuclear materials ~~licensees and certificate holders~~facilities is appropriately documented and justified based on the backfitting provisions of applicable NRC regulations and the ~~Commission's agency's~~ backfitting and forward fitting policy and guidance. Additionally, the NRC must justify information requests to licensees as required by

<sup>1</sup> In this MD, the NRC uses the terms "backfit" and "backfitting" to mean backfitting as defined in 10 CFR 50.109, 70.76, 72.62, and 76.76 and violations of issue finality under 10 CFR Part 52. 10 CFR Part 52, Parts 50, "Domestic Licensing of Production and Utilization Facilities," Part 52, Part 70, "Domestic Licensing of Special Nuclear Material," Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste," and Part 76, "Certification of Gaseous Diffusion Plants," are the only parts of the NRC's regulations that contain backfitting or issue finality provisions. Backfitting provisions implicitly apply, in part, to applicants for a power reactor renewed license due to the limitation in scope of the NRC's review under 10 CFR Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants." In Title 10 of the Code of Federal Regulations (10 CFR), Section 50.109, "Backfitting," backfitting for a nuclear power reactor is defined as the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position after certain dates. For selected nuclear materials facilities, the backfitting definitions in 10 CFR 70.76, 72.62, and 76.76 are slightly different. The "issue finality" provisions in 10 CFR Part 52 are different from those in 10 CFR 50.109 and the wording and structure between the two groups of provisions differ significantly. The term "backfit" is not normally used in discussions relevant to new power reactors; the concept of "issue finality" is used rather than "backfit." In this MD, the NRC uses the terms "backfit" and "backfitting" to encompass backfits as defined in 10 CFR 50.109, 70.76, 72.62, and 76.76, and issue finality matters under 10 CFR Part 52.

<sup>2</sup> A forward fit is defined as the imposition of a new or modified requirement or regulatory staff interpretation of a requirement that results in the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility as a condition of approval by the NRC of a licensee-initiated request for a licensing action when the underlying request did not propose to comply with the new or revised requirement or interpretation. Such licensing actions may include a license amendment or a license renewal, although the normal application of the process in 10 CFR Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants," does not generally constitute forward fitting. The NRC may condition its approval of such a licensing action on the use of a new or modified regulatory staff position only if 1) there is a direct nexus to the licensee's request and 2) the imposition of the new or modified requirement or regulatory staff position is essential to the NRC staff's determination of the acceptability of the licensee's request.

applicable NRC regulations under 10 CFR 50.54(f), “Conditions of licenses,” and 2.204, “Demand for information.”

The backfit and forward fit evaluation and analysis requirements ensure that the NRC demonstrates, before implementing the backfit or forward fit, that the action would meet certain standards that vary based on the type of facility. In accordance with the NRC Principles of Good Regulation and the Administrative Procedure Act, the backfitting and forward fitting rules and policies provide the following:

- (a) Regulatory stability, by ensuring that the changes the NRC makes are necessary or provide a substantial safety enhancement;
- (b) Reasoned and informed NRC decisionmaking, by requiring the proposed action be properly justified; and
- (c) Transparency of NRC decisionmaking, by requiring that the NRC document and make publicly available its analyses and evaluations.

## II. OBJECTIVES

- Ensure NRC-licensed facilities provide adequate protection of public health and safety, promote the common defense and security, and allow for substantial improvements in both safety and security, beyond adequate protection, while minimizing-avoiding any unjustified burden on the NRC, the public, or licensees when implementing a backfitting or forward fitting action.
- ~~– Ensure that backfitting considerations are applied to the furtherance of substantive radiological public health and safety, or common defense and security objectives.~~
- ~~– Ensure that backfitting applied to a nuclear power reactor licensee facility or nuclear materials licensee facility is appropriately justified and documented.~~
- ~~– Ensure that forward fitting a nuclear power reactor facility or nuclear materials facility are appropriately justified and documented.~~
- ~~– Ensure that NRC-proposed changes to previously approved Early Site Permits (ESP), Design Certifications (DC), Standard Design Approvals (SDA), Combined Operating~~

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<sup>3</sup> ~~In this MD, the NRC uses the term “nuclear power reactor licensees” to refer to holders of 10 CFR Part 50 or Part 52 licenses, permits, or approvals, including: early site permits (ESPs), standard design approvals (SDAs), combined licenses (COLs), and MLs; design certification (DC) applicants whose designs are certified in final DC rules (DCR); applicants for COLs if the application references an ESP, DCR, or SDA; and applicants for MLs if the application references a DCR or SDA. Specific definitions and terminology are included in 10 CFR Parts 50, 70, 72, and 76.~~

Licenses (COL), and Manufacturing Licenses (ML) (i.e., violations of issue finality under 10 CFR Part 52) are appropriately justified and documented.

- Ensure that adequate protection backfitting justifications include an imminent threat analysis.
- Ensure that compliance backfitting justifications include some consideration of costs.
- Ensure that any documented evaluation, ~~of~~ backfit, or forward fit analysis is risk-informed.
- Ensure all information requests to licensees are justified as required by applicable NRC regulations.

### III. ORGANIZATIONAL RESPONSIBILITIES AND DELEGATIONS OF AUTHORITY

#### A. Executive Director for Operations (EDO)

1. Responsible for the NRC's backfitting process and ensuring proper implementation of the backfitting rules.
- 1.2. Responsible for the NRC's forward fitting process and ensuring proper implementation of the forward fitting policy.
- 2.3. Authorizes deviations from this MD when in the public interest and when the deviation otherwise complies with applicable agency guidelines and policies, NRC regulations, public laws, and Executive Orders.
4. Delegates facility-specific backfitting authority and actions to the program ~~office~~ Office Directors (ODs) and Regional Administrators (RAs).
- 3.5. Delegates facility-specific forward fitting authority and actions to the program Office Directors (ODs) and Regional Administrators (RAs).
6. Delegates information request authority and actions to the program ODs and RAs.
- 4.7. Reviews and modifies any proposed facility-specific backfitting or forward fitting action on his or her own initiative or at the appeal of the affected licensee or stakeholders.

#### B. Director, Office of Nuclear Reactor Regulation (NRR); Director, Office of New Reactors (NRO); and Director, Office of Nuclear Material Safety and Safeguards (NMSS)

1. Identify backfitting and forward fitting actions within their programs.

2. Conduct backfitting analyses while coordinating with OGC, other program offices, NSIR, OE, RES, and regional offices, who will be operating in a support role, to ensure consistency and uniformity.
3. Conduct forward fitting analyses while coordinating with OGC, other program offices, NSIR, OE, RES, and regional offices, who will be operating in a support role, to ensure consistency and uniformity.
4. Conduct an imminent threat analysis when the adequate protection exception is applied.
5. Provide the CRGR with an opportunity to review any required documented evaluation, backfit, or forward fit analysis or any generic communication with backfitting or forward fitting concerns.
6. Request CRGR review of potential facility-specific backfit or forward fit, as appropriate.
7. After approving supporting documentation, notify, or designate the relevant division director to notify, the affected entity or entities, e.g. the nuclear power reactor or nuclear materials licensee(s), of the backfitting or forward fitting action.
8. Ensure consistency among inspection procedures, regulations, office instructions, and current agency guidelines and policies.
9. Decide first-level licensee appeals on the imposition of all backfitting and forward fitting actions within the program office's area of responsibility.
10. During the staff's evaluation and backfitting or forward fitting transmittal process, and any subsequent licensee appeal process, track each facility-specific backfitting or forward fitting action within the affected program office.
11. Ensure entry into ADAMS, as appropriate, of all documents and records related to backfitting and forward fitting originating in either the program office or the region (within the program office's area of responsibility), including communications, decisionmaking, and the outcome of appeals. Make backfitting and forward fitting decisions publicly available, consistent with applicable requirements and guidance.
12. Ensure appropriate training is available to the program office staff and ensure that the program office staff performance is in accordance with regulations, and current agency guidelines and policies.

13. Designate an office-level Point of Contact (POC) to coordinate and resolve backfitting and forward fitting questions or concerns from the staff as they relate to the responsibilities of each respective program office.
14. Ensure information requested under 10 CFR 50.54(f) is appropriately justified.

**C. Regional Administrators (RAs)**

1. Identify backfitting and forward fitting actions within the regions.
2. Conduct backfitting analyses while coordinating with OGC, other program offices, NSIR, OE, RES, and the office directors of NRR, NRO, and NMSS, who will be operating in a support role, to ensure consistency and uniformity.
3. Conduct forward fitting analyses while coordinating with OGC, other program offices, NSIR, OE, RES, and the office directors of NRR, NRO, and NMSS, who will be operating in a support role, to ensure consistency and uniformity.
4. Conduct an imminent threat analysis when the adequate protection exception is applied.
5. Provide the CRGR with an opportunity to review any required documented evaluation, backfit, or forward fit analysis before final approval.
6. After approving supporting documentation, notify, or designate the relevant division director to notify, the affected entity, e.g. the nuclear power reactor or nuclear materials licensee(s), of the backfitting or forward fitting action.
7. Support the appropriate program office in processing licensee backfitting and forward fitting appeals that are within the regional area of responsibility.
8. Ensure entry into ADAMS, as appropriate, of all documents and records related to backfitting and forward fitting and originating in the region, including communications, decisionmaking, and the outcome of appeals. Make backfitting and forward fitting decisions publicly available, consistent with applicable requirements and guidance.
9. Ensure appropriate training is available to the regional staff and ensure that the regional staff performance is in accordance with regulations and current agency guidelines and policies.
10. Designate a regional POC who will be responsible for any specific backfitting and forward fitting activities (generic and facility-specific) as needed, including the

coordination and resolution of any backfitting and forward fitting questions or concerns from the staff as they relate to the responsibilities of the respective region.

**B.D. Office of the General Counsel (OGC)**

1. Identifies potential backfitting and forward fitting actions.
2. Advises staff about whether staff's actions meet the applicable definitions of backfit.
- 2.3. Advises staff about whether staff's actions meet the applicable definitions of forward fit.
- 3.4. Advises staff about how whether staff's actions are congruent with issue finality provisions in 10 CFR Part 52.
5. Provides legal advice and assistance during backfitting identification, justification, imposition, and licensee appeal processes.
- 4.6. Provides legal advice and assistance during forward fitting identification, justification, imposition, and licensee appeal processes.
- 5.7. Provides legal advice and assistance for developing backfitting training in accordance with regarding backfitting requirements and agency implementation.
8. Provides legal advice and assistance for information collections.
- 6.9. Maintains a backfitting/forward fitting Community of Practice with office POCs, including a backfitting/forward fitting site.

**C.E. Committee To Review Generic Requirements (CRGR)**

1. Monitors the overall effectiveness of the NRC's generic backfitting and forward fitting management process, including the effectiveness of administrative controls for facility-specific backfitting and forward fitting. Maintains a Charter that describes the roles, responsibilities, and procedures of the CRGR in accordance with applicable regulations.
2. Selects a sample of proposed backfitting and forward fitting actions for audit under 10 CFR Part 50, 10 CFR Part 52, 10 CFR Part 70, 10 CFR Part 72 and 10 CFR Part 76, consistent with its Charter, and ensures the actions are justified in accordance with regulations and agency guidelines and policies.
3. Reviews potential facility-specific backfits and forward fits as requested by program office directors program ODs and RAs.

4. Uses its discretion in deciding whether any review should require a formal staff presentation to the CRGR.
- ~~5. Periodically assesses the effectiveness of the NRC's backfitting process implementation as part of its regulatory effectiveness responsibility and provides a report to the EDO.~~
- ~~6.5.~~ Ensures consistency among the offices and regions in implementing the provisions of the NRC's backfitting and forward fitting rules and policies. The CRGR review focuses on the adequacy of backfitting and forward fitting implementation, interoffice coordination for processing backfitting and forward fitting actions, and staff training.
- ~~7.6.~~ Verifies that the responsible staff<sup>4</sup> promptly enters backfitting and forward fitting decisions into the Agencywide Documents Access and Management System (ADAMS), and makes them publicly available, consistent with applicable requirements and guidance.
- ~~8.7.~~ Periodically meets with stakeholders to gain stakeholder views and advise the EDO when modifications to the backfitting and forward fitting processes should be considered.
- ~~9.8.~~ Participates in Backfitting Review Panels at the request of the EDO.
- ~~10.9.~~ Coordinates with the Office of the Chief Human Capital Officer (OCHCO), OGC, RES, NSIR, OE, the regions, and program offices to ensure that Human Resources Training and Development (HRTD) provides appropriate training for the NRC staff and that individual office procedures and guidance appropriately reflect the requirements of this MD and other applicable guidance.

**~~D.F.~~ Director, Office of Nuclear Regulatory Research (RES)**

1. Identifies potential backfitting and forward fitting actions.
2. Supports the offices and regions by implementing pertinent CRGR recommendations, EDO decisions, staff lessons learned, and Commission directives for enhancing the NRC's backfitting program.

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<sup>4</sup> The office or the region that initiated the backfitting action supports the program office (the Office of Nuclear Reactor Regulation (NRR), the Office of Nuclear Material Safety and Safeguards (NMSS), or the Office of New Reactors (NRO)) that has the obligation to impose the backfit. The program office is solely responsible for generic backfitting actions. Regions are responsible for facility-specific backfitting actions arising from inspection, and program offices are responsible for facility-specific backfitting actions arising from licensing or other headquarters actions.



3. Provides administrative support for routine CRGR activities.

~~3.4.~~ Ensures appropriate training is provided to the RES staff.

~~4.~~ Maintains a backfitting Community of Practice with office POCs, including a backfitting SharePoint site.

**E.G. Director, Office of Enforcement (OE)**

1. Defines and implements appropriate administrative controls to support the office and regional staffs in processing compliance backfits that involve enforcement discretion.
2. If an Order, a notice of violation, or enforcement discretion is necessary in relation to a backfitting action, consults with OGC and the responsible office(s) and region(s), on the backfitting action and advises on its imposition, including supporting interactions with licensees to establish a schedule for implementing the compliance backfit, as applicable.

Ensures appropriate training is provided available to the OE staff and ensures OE staff performance is in accordance ~~with NUREG-1409, "Backfitting Guidelines."~~ with current agency policy and guidelines.

3. Designates an office-level POC to coordinate and resolve backfitting questions or concerns from the staff as they relate to the responsibilities of OE.

**F.H. Director, Office of Nuclear Security and Incident Response (NSIR)**

1. Identifies any potential security-~~related~~ or emergency preparedness-~~related~~ backfitting or forward fitting actions.<sup>5</sup>

~~2.~~ Coordinates all security-related backfitting with the program offices and the regional offices.

3.2. Designates an NSIR manager (division director or higher) who coordinates with the program offices and OGC to request that the program office propose backfitting or forward fitting actions on nuclear power reactor and nuclear materials ~~licensees~~ facilities that pertain to the common defense and security or emergency preparedness.

<sup>5</sup> Throughout this MD, security-~~related~~ and emergency preparedness-related backfitting may be referred to as security-or security-related backfitting.

- ~~4.3.~~ Ensures consistency of security and emergency preparedness inspection procedures with regulations and current agency guidelines and policies, and NUREG-1409.
- ~~5.4.~~ Consults, coordinates with, and provides support to program ODs, as appropriate necessary, to resolve issues with security-related backfitting and forward fitting actions. The Director, NSIR, must support the program ODs and RAs, as appropriate, in processing security-related backfits and forward fits, including the resolution of licensee backfit appeals.<sup>6</sup>
- ~~6.5.~~ Ensures appropriate training is available to the NSIR staff and ensures that the NSIR staff performance is in accordance with current agency guidelines and policies NUREG-1409.
- ~~7.6.~~ Designates an office-level POC to coordinate and resolve backfitting and forward fitting questions or concerns from staff as they relate to the responsibilities of NSIR.
- ~~8.~~ Makes backfitting decisions publicly available, consistent with applicable requirements and guidance.
- ~~G.~~ Director, Office of Nuclear Reactor Regulation (NRR); Director, Office of New Reactors (NRO); and Director, Office of Nuclear Material Safety and Safeguards (NMSS)
- ~~1.~~ Identify backfitting actions applicable to its programs.
  - ~~2.~~ Coordinate backfitting actions with other program offices and regional offices to ensure consistency and uniformity.
  - ~~3.~~ Provide the CRGR with an opportunity to review any required documented evaluation or backfit analysis or any generic communication with backfitting concerns.
  - ~~4.~~ Request CRGR review of potential facility specific backfit, as deemed appropriate.
  - ~~5.~~ After approving supporting documentation, notify, or designate the relevant division director to notify, the nuclear power reactor or nuclear materials licensee of the backfitting action.
  - ~~6.~~ Ensure consistency among inspection procedures, regulations, and NUREG-1409.

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<sup>6</sup> ~~The program OD for the affected facilities imposes facility-specific backfitting actions and forwards licensee appeals on security-related backfitting to the NSIR OD. The NSIR OD will decide on the appeal and coordinate with the program OD. If a licensee refuses to implement an imposed backfitting action, the appropriate program office must issue an Order.~~

- ~~7. Consult and coordinate with the regions, NSIR, RES, OE, and OGC, as appropriate, to resolve issues with backfitting actions for which the program office has oversight responsibility.~~
- ~~8. Coordinate security-related backfitting with the Director, NSIR, and the affected regional office and approves the supporting documentation for security-related backfitting within the program office's areas of responsibility.~~
- ~~9. Decide first-level licensee appeals on the imposition of all backfitting actions within the program office's area of responsibility and coordinates any appeals of security-related backfits with the Director, NSIR.~~
- ~~10. During the staff's evaluation and backfitting transmittal process, and any subsequent licensee appeal process, track each facility-specific backfitting action within the affected program office or region.~~
- ~~11. Ensure entry into ADAMS, as appropriate, of all documents and records related to backfitting originating in either the program office or the region (within the program office's area of responsibility), including communications, decisionmaking, and the outcome of backfitting appeals. Makes the backfitting decisions publicly available, consistent with applicable requirements and guidance.~~
- ~~12. Ensure appropriate training is available to the program office staff and ensure that the program office staff performance is in accordance with regulations, and NUREG-1409.~~
- ~~13. Designate an office-level POC to coordinate and resolve backfitting questions or concerns from the staff as they relate to the responsibilities of each respective program office.~~
- ~~14. Ensure information collection under 10 CFR 50.54(f) and 2.204 is appropriately justified.~~

#### ~~H. Regional Administrators (RAs)~~

- ~~1. Identify backfitting actions applicable to the regions.~~
- ~~2. Coordinate with ODs and other RAs to ensure consistency in backfitting implementation among the regions and program offices.~~
- ~~3. Provide the CRGR with an opportunity to review any required documented evaluation or backfit analysis before final approval.~~

- ~~4. After approving supporting documentation, notify, or designate the relevant division director to notify, the nuclear power reactor or nuclear materials licensee of the backfitting action.~~
- ~~5. Coordinate with other regions and either the Division of Inspection and Regional Support, NRR, or the Division of Construction Inspection and Operational Programs, NRO, as applicable, to ensure consistency among inspection procedures and regulations, and NUREG-1409.~~
- ~~6. Consult and coordinate with the Director, NSIR; OGC and/or regional counsel; and the appropriate program OD to resolve security-related, facility-specific backfitting actions.~~
- ~~7. Coordinate with the appropriate program office and NSIR, as necessary, to obtain the supporting documentation for proposed backfits.~~
- ~~8. Support the appropriate program office in processing licensee backfitting appeals that are within the regional area of responsibility.~~
- ~~9. Ensure entry into ADAMS, as appropriate of all documents and records related to backfitting and originating in the region, including communications, decisionmaking, and the outcome of backfitting appeals. Makes backfitting decisions publicly available, consistent with applicable requirements and guidance.~~
- ~~10. Ensure appropriate training is available to the regional staff and ensures that the regional staff performance is in accordance with regulations and NUREG-1409.~~
- ~~11. Designate a regional POC who will be responsible for any specific backfitting activities (generic and facility-specific) as needed, including the coordination and resolution of any backfitting questions or concerns from the staff as they relate to the responsibilities of the respective region. The regional POC also ensures that the associated regional staff is proficient in a training program relevant to backfitting activities and agency information collection processes.~~

#### **I. Chief Human Capital Officer (CHCO)**

1. Develops, maintains, and updates, in consultation with the CRGR and OGC and in coordination with other offices and regions, a backfitting training program for the NRC staff, including generic and facility-specific backfitting training modules and refresher courses.

2. Consults and coordinates with the appropriate contact in the Office of the Chief Information Officer to maintain backfitting training modules ~~online~~.

#### J. Chief Information Officer (CIO)

1. Maintains a repository for backfitting and forward fitting records in ADAMS.
2. Advises the offices and regions on implementing administrative controls to ensure backfitting and forward fitting information is maintained in accordance with Federal and agency recordkeeping requirements.
3. Consults on the agency review of information collections-requests to ensure compliance with the Paperwork Reduction Act.

### IV. APPLICABILITY

The policy in this directive and handbook applies to all NRC employees.

### V. DIRECTIVE HANDBOOK

For effective regulation of NRC-licensed facilities, it is crucial that the backfitting and forward fitting processes be well-defined, that staff members clearly understand their obligation for responsibly implementing all aspects of the backfitting program, and that managers ensure staff performance is in accordance with this MD. Handbook 8.4 explains the components of the NRC backfitting management program. NUREG-1409 provides guidance to the staff implementing backfitting regulations.

### VI. REFERENCES

#### *Code of Federal Regulations*

10 CFR Part 2, "Agency Rules of Practice and Procedure."

10 CFR 2.202, "Orders."

~~10 CFR 2.204, "Demand for Information."~~

10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

10 CFR 50.2, "Definitions."

10 CFR 50.12, "Specific Exemptions."

10 CFR 50.49, "Environmental Qualification of Electrical Equipment Important to Safety for Nuclear Power Plants."

10 CFR 50.54, "Conditions of Licenses."

- 10 CFR 50.59, "Changes, Tests, and Experiments."
- 10 CFR 50.71, "Maintenance of Records; Making of Reports."
- 10 CFR 50.72, "Immediate Notification Requirements for Operating Nuclear Power Reactors."
- 10 CFR 50.73, "License Event Report System."
- 10 CFR 50.109, "Backfitting."
- 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."
- 10 CFR 52.7, "Specific Exemptions."
- 10 CFR 52.31, "Criteria for Renewal."
- 10 CFR 52.39, "Finality of Early Site Permit Determinations."
- 10 CFR 52.59, "Criteria for Renewal."
- 10 CFR 52.63, "Finality of Standard Design Certifications."
- 10 CFR 52.83, "Finality of Referenced NRC Approvals; Partial Initial Decision on Site Suitability."
- 10 CFR 52.98, "Finality of Combined Licenses; Information Requests."
- 10 CFR 52.145, "Finality of Standard Design Approvals; Information Requests."
- 10 CFR 52.171, "Finality of Manufacturing Licenses; Information Requests."
- 10 CFR 52.179, "Criteria for Renewal."
- 10 CFR Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants."
- 10 CFR 54.30, "Matters Not Subject to a Renewal Review."
- 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."
- 10 CFR 70, Subpart B, "Exemptions."
- 10 CFR 70.22, "Contents of Applications."
- 10 CFR 70.76, "Backfitting."
- 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste."

10 CFR 72.7, "Specific Exemptions."

10 CFR 72.62, "Backfitting."

10 CFR Part 76, "Certification of Gaseous Diffusion Plants."

10 CFR 76.23, "Specific Exemptions."

10 CFR 76.76, "Backfitting."

### ***Nuclear Regulatory Commission Documents***

Charter of the Committee To Review Generic Requirements.

Letter to Ellen Ginsberg from Stephen Burns discussing applicability of the Backfit Rule to NRC interpretive guidance, July 14, 2010 (ADAMS Accession No. [ML101960180](#)).

Memorandum to Edwin Hackett from Andrew Averbach, "Summary of COMSECY-16-0020, Recommendation on Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception to Backfit Rule," December 20, 2016 (ADAMS Accession No. [ML16355A258](#)).

Memorandum to James M. Taylor and William C. Parler from Samuel J. Chilk, "SECY-93-086, Backfit Considerations," June 30, 1993 (ADAMS Accession No. [ML003760758](#)).

Memorandum from Luis A. Reyes, Executive Director for Operations, NRR to Those on the Attached List, "Implementation of an ADAMS-Based Record Access System for Facility-Specific Backfits," February 22, 2006 (ADAMS Accession No. [ML052720147](#)).

NUREG-0910, "NRC Comprehensive Records Disposition Schedule."

NUREG-1409, "Backfitting Guidelines."

NUREG/BR-0058, Revision 45, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," and all Appendices.

SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," dated March 2, 1999 (ADAMS Accession No. [ML992810068](#)).

Staff Requirements Memorandum, COMSECY-16-0020, "Staff Requirements – COMSECY-16-0020 – Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception to Backfit Rule," November 29, 2016 (ADAMS Accession No. [ML16334A462](#)).

Staff Requirements Memorandum, SECY-98-185, "Staff Requirements - Proposed Rulemaking," "Revised Requirements for the Domestic Licensing of Special Nuclear Material," December 1, 1998 (ADAMS Accession No. [ML991880012](#)).

Staff Requirements Memorandum, SECY-14-0087, "Staff Requirements— SECY - 14- 0087-Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," dated March 4, 2015 (ADAMS Accession No. [ML15063A568](#)).

"Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement," 60 FR 42622, August 16, 1995.

***United States Code***

Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.).

Energy Reorganization Act of 1974, as amended (42 U.S.C. 5801 et seq.).

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).



U.S. NUCLEAR REGULATORY COMMISSION DIRECTIVE HANDBOOK (DH)

AC Edits

<b>DH 8.4</b>	<b>MANAGEMENT OF BACKFITTING, <u>FORWARD FITTING</u>, ISSUE FINALITY, AND INFORMATION <u>COLLECTION REQUESTS</u></b>	<b>DT-XX-XX</b>
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<i>Volume 8:</i>	Licensee Oversight Programs
<i>Approved By:</i>	[Name and Title of Approving Official]
<i>Date Approved:</i>	Month X, 200X [Date of Final Approval]
<i>Cert. Date:</i>	N/A, for the latest version of any NRC directive or handbook, see the <a href="#">online MD Catalog.</a>
<i>Issuing Office:</i>	Office of Nuclear Reactor Regulation Division of Inspection and Regional Support
<i>Contact Name:</i>	Timothy Reed

**EXECUTIVE SUMMARY**

Management Directive (MD) 8.4, “Management of Backfitting, Issue Finality, and Information Collection,” is retitled and revised to clarify ~~the agency’s~~ roles and responsibilities for management of backfitting, forward fitting, issue finality, and information collection generically and on a facility specific basis. MD 8.4 describes the roles and responsibilities of various offices and provides the policy to direct the U.S. Nuclear Regulatory Commission implementation of the backfitting provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) for nuclear power reactor ~~facilities licensees~~; and selected nuclear materials ~~facilities licensees~~; ~~and~~ the issue finality provisions of 10 CFR Part 52 for nuclear power reactors ~~licensees, design certification applicants, and holders of related NRC permits and approvals;~~ ~~and as well as~~ the specific provisions of 10 CFR 50.54(f) and the corresponding requirements in ~~Parts~~ 10 CFR Parts 70, ~~10 CFR~~ 72, and ~~10 CFR~~ 76, ~~and 10 CFR 2.204~~.

Accordingly, MD 8.4 is retitled from “Management of Facility-Specific Backfitting and Information Collection” to “Management of Backfitting, Issue Finality, and Information Collection Requests” to clarify the intent and the objectives of the program.

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## I. INTRODUCTION TO BACKFITTING FORWARD FITTING, AND INFORMATION COLLECTION REQUESTS<sup>1</sup>

### A. Backfitting

1. Under 10 CFR 50.109, backfitting is “the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position.” Substantially similar definitions are provided in § 70.76, § 72.62, and § 76.76.
2. Backfitting is the process by which the U.S. Nuclear Regulatory Commission imposes new or revised regulatory requirements or new or revised staff positions on nuclear power reactor licensees or selected nuclear materials licensees.<sup>2</sup> Backfitting is an integral part of the regulatory process and is expected to occur. To ensure that proposed changes are adequately justified and defined, a backfitting action is implemented only after formal and systematic review. Backfitting normally occurs in one of two ways: when the agency imposes a new or changed regulation or requirement imposed upon a licensee's facility or facilities (through rulemaking or order); Backfitting concerns also arise when the agency communicates a new or changed staff position interpreting applicable regulations requirements imposed on facilities licensees. A new or changed staff position may arise in a number of regulatory contexts including facility inspections, license amendment reviews, or issuance of guidance documents. In this Directive Handbook (DH), the terms

<sup>1</sup> This section provides a high-level overview of the backfit process, and as such, may simplify some concepts for introductory purposes. If a provision of this section conflicts with a provision in a later section, the later section is controlling.

<sup>2</sup> For purposes of this DH, the term “licensees” includes the holders of power reactor construction permits (CPs) and operating licenses (OLs) under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities;” holders of licenses, permits or approvals under 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants;” holders of licenses for fuel facilities under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” Subpart H, “Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material;” holders of licenses for spent fuel and radioactive waste storage facilities under 10 CFR Part 72, “Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste;” and certificate holders for gaseous diffusion plants under 10 CFR Part 76, “Certification of Gaseous Diffusion Plants.”

“backfit” and “backfitting” mean backfitting as defined in 10 CFR 50.109, “Backfitting,” 70.76, “Backfitting,” 72.62, “Backfitting,” and 76.76 “Backfitting,” and violations of changes affecting issue finality under 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.” The only parts of the NRC’s regulations that contain backfitting or issues finality provisions are 10 CFR Part 50, 10 CFR Part 52, 10 CFR Part 70, 10 CFR Part 72, and 10 CFR Part 76. ~~The backfitting provisions typically do not apply to license applicants. There is no backfitting provision in 10 CFR Part 54, “Requirements for Renewal of Operating Licenses of Nuclear Power Plants,” however the scope of the NRC’s review under 10 CFR Part 54 is limited. The protections in the backfitting provisions further NRC compliance with the requirements of the Administrative Procedure Act regarding reasoned decisionmaking.~~

3. The backfit evaluation and analysis requirements ensure that the NRC demonstrates, before implementing the backfit, that the backfitting action meets certain standards that vary based on the type of facility. In accordance with the NRC Principles of Good Regulation and the Administrative Procedure Act, the backfitting rules provide the following:
  - (a) Regulatory stability, by ensuring that the changes the NRC makes are necessary or provide a substantial safety enhancement;
  - (b) Reasoned and informed NRC decisionmaking, by requiring that the proposed action be properly justified; and
  - (c) Transparency of NRC decisionmaking, by requiring that the NRC document and make publicly available its analyses and evaluations.
4. The NRC’s backfitting actions can be either generic or facility-specific.<sup>3</sup>
  - (a) Generic backfitting actions affect a class or classes of licensees and can include the imposition of new or revised requirements through rulemaking or Orders or new or revised staff positions interpreting NRC regulations.
  - (b) Facility-specific backfitting issues typically arise through the NRC’s inspection or licensing process. In these circumstances, the NRC’s regional or headquarters staff may find that a change to a facility’s licensing basis (LB) is appropriate.

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<sup>3</sup> Hereafter, the term “facility” will be used to mean a nuclear power reactor; an ESP, DCR, COL, SDA, or ML for a power reactor; or a materials facility such as an ISFSI, fuel facility, gaseous diffusion plant, or an MRS installation.

- 1.5. There are three principal ~~types of backfitting that may be considered~~ justifications the agency relies on to impose a backfit: adequate protection ~~backfitting~~, compliance ~~backfitting~~, and a cost-justified substantial increase<sup>4</sup> in protection ~~backfitting~~.<sup>5</sup> If the NRC is considering a backfitting action, it must first consider whether regulatory action is necessary to ensure adequate protection of public health and safety, and if so whether there is an imminent threat to public health and safety. If regulatory action is not necessary to ensure adequate protection, then the NRC needs to determine if the proposed action satisfies the compliance backfit criteria. If the proposed action does not satisfy the compliance backfit criteria, then the NRC must consider a cost-justified substantial increase in protection backfit.
2. The Supreme Court's decision in *Michigan v. Environmental Protection Agency*, 135 S. Ct. 2699 (2015), reflects the view that, under the Administrative Procedure Act (APA), unless Congress has indicated otherwise, an agency's decisionmaking calculus should include at least some consideration of the cost placed on a licensee to comply with new requirements. In contrast, when the NRC has reached a new or changed position with respect to whether regulatory action is needed to ensure adequate protection under the Atomic Energy Act of 1954 (AEA), as amended, no further explanation, including consideration of cost, is necessary. Otherwise, the APA's reasoned decision making requirement compels some consideration of cost.
- 3.6. Regulations in 10 CFR 50.109, define the term backfitting for power reactors under 10 CFR Part 50 (i.e., construction permit (CP) holders and operating license (OL) holders) as the modification of or addition to systems, structures, components (SSCs); or design of a facility; or the design approval or manufacturing license (ML) for a facility; or the procedures or organization required to design, construct, or operate a facility, any of which may result from a new or amended provision in the Commission's regulations or the imposition of a staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position after certain specified dates.<sup>6</sup> Provisions of 10 CFR 50.109 can also

<sup>4</sup> See 50 FR 38097, September 20, 1985.

<sup>5</sup> The issue finality provisions of 10 CFR Part 52 include additional backfitting actions justifications for certain types of approval holders. For example, 10 CFR 52.63, "Finality of sStandard dDesign cCertifications," also allows backfitting to, among other things, correct material errors in the certification information for a design certification (DC) or to contribute to the increased standardization of the DC.

<sup>6</sup> Applicable NRC action may be considered backfitting under 10 CFR 50.109 if the agency action occurs after the following:

~~apply to power reactor licensees under 10 CFR Part 52,<sup>7</sup> but 10 CFR 50.109 is not applicable to non-power production or utilization facilities licensed under 10 CFR Part 50.~~

~~4.7. In 10 CFR Part 52, power reactor licensees are granted~~ “issue finality”<sup>8</sup> ~~exists~~ with ~~respect to prior their~~ NRC approvals, which prevents the NRC from making changes to the approvals without meeting certain criteria as provided in the applicable issue finality regulation. The issue finality requirements are intended to accomplish the same objective as the backfitting requirements by limiting changes to final Commission decisions made as part of the 10 CFR Part 52 licensing process. ~~The standards vary for making changes to renewed and previously approved early site permits (ESPs) (10 CFR 52.31, “Criteria for Renewal,” and 10 CFR 52.39, “Finality of Early Site Permit Determinations”), renewed and previously approved design certification rules (DCRs) (10 CFR 52.59, “Criteria for Renewal,” and 10 CFR 52.63, “Finality of standard design certifications), previously approved combined operating~~

- ~~▪ the issuance of the CP for the facility (for facilities with CPs issued after October 21, 1985),~~
- ~~▪ 6 months before the date of docketing of the OL application for the facility (for facilities with CPs issued before October 21, 1985),~~
- ~~▪ the issuance of the OL for the facility (for facilities having an OL on October 21, 1985),~~
- ~~▪ the issuance of the design approval under Subpart E, “Standard Design Approvals,” of 10 CFR Part 52,~~
- ~~▪ the issuance of a an ML under Subpart F, “Manufacturing Licenses,” of 10 CFR Part 52,~~
- ~~▪ the issuance of the first CP for a duplicate design under Appendix N, “Standardization of Nuclear Power Plant Designs: Permits To Construct and Licenses to Operate Nuclear Power Reactors of Identical Design at Multiple Sites,” of 10 CFR Part 50, or~~
- ~~▪ the issuance of a COL under Subpart C, “Combined Licenses,” of 10 CFR Part 52.~~

~~<sup>7</sup> For purposes of this DH, the term “10 CFR Part 52 power reactor licensees” refers to holders of early site permits (ESPs), standard design approvals (SDAs), combined licenses (COLs), and MLs; DC applicants whose designs are certified in final DC rules (DCRs); applicants for COLs if the application references an ESP, DCR, or SDA; and applicants for MLs if the application references a DCR or SDA.~~

~~<sup>8</sup> Within this DH, the term “issue finality” encompasses the language of the regulations from 10 CFR 52.39 “Finality of Early Site Permit Determinations,” 10 CFR 52.63, “Finality of standard design certifications,” 10 CFR 52.83, “Finality of Referenced NRC approvals; Partial Initial Decision on Site Suitability,” 10 CFR 52.98, “Finality of Combined Licenses; Information Requests,” 10 CFR 52.145, “Finality of Standard Design Approvals; Information Requests,” 10 CFR 52.171 “Finality of Manufacturing Licenses; Information Requests,” and any other applicable discussion of finality in part 52.~~

~~licenses (COLs) (10 CFR 52.83, "Finality of Referenced NRC Approvals; Partial Initial Decision on the Site Suitability," and 10 CFR 52.98, "Finality of Combined Licenses; Information Requests"), previously approved standard design approvals (SDAs) (10 CFR 52.145, "Finality of Standard Design Approvals; Information Requests"), and renewed and previously approved MLs (10 CFR 52.179, "Criteria for Renewal," and 10 CFR 52.171, "Finality of Manufacturing Licenses; Information Requests").~~ The backfitting provisions in 10 CFR 50.109 apply to ESPs, DCs, COLs, SDAs, and MLs to the extent that they do not overlap the applicability of 10 CFR Part 52 issue finality provisions.

- ~~5.8.~~ Section 70.76 of 10 CFR defines the term backfitting for materials licensees authorized to possess greater than a critical mass of special nuclear material ~~as the modification of, or addition to, SSCs of a facility; or to the procedures or organization required to operate a facility. Either of these 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.~~
- ~~6.9.~~ Section 72.62 of 10 CFR defines the term backfitting ~~as the addition, elimination, or modification, after the license has been issued, of SSCs of or~~ an independent spent fuel storage installation (ISFSI) or monitored retrievable storage (MRS), ~~or the procedures or organization required to operate an ISFSI or MRS.~~
- ~~7.10.~~ Section 76.76 of 10 CFR defines the term backfitting ~~as the modification of, or addition to, SSCs of or~~ a gaseous diffusion plant, ~~or to the procedures or organization required to operate a plant, 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.~~
- ~~11.~~ Sections 50.109(a)(4)(i) and (a)(7), 70.76(a)(4)(ii) and (a)(7), 72.62(b), and 76.76(a)(4)(i) of 10 CFR ~~require compliance with "written commitments" and, in the case of 10 CFR 76.76(a)(7), "written Corporation commitments." Within the scope of backfitting, these written commitments mean those commitments that have been incorporated into the license as a means necessary to demonstrate compliance with requirements. This MD and DH reflect NRC policy direction and provide the process for implementing that policy. The MD and DH list the regulations and guidance documents that govern backfitting and describe how the NRC implements those regulations. Backfitting guidance for the NRC staff is available in NUREG-1409. Office or region-specific guidance is not required or desired. Consistency of implementation is assured by the staff's use of NUREG-1409.~~
- ~~12.~~ Any change to an NRC staff position that the NRC intends to communicate by any means to a licensee(s) as being applicable to their facility may be identified as

backfitting either by the staff or by licensees. The means of communication can be through the issuance of regulatory guidance, inspection reports, generic communications, or staff interactions with licensee personnel. The NRR, NRO or NMSS office director (OD) or regional administrator (RA) responsible for the staff position and affected facility or facilities will make the determination as to whether the new or revised staff position constitutes backfitting and whether the backfit should be imposed on the licensee(s).

- ~~8. In support of the Commission's probabilistic risk assessment (PRA) policy statement<sup>9</sup> of August 1995, which encourages the use of PRA "in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy," risk insights must be considered, to the extent practical, as part of all backfitting actions. Risk information should be integrated in a manner that complements traditional regulatory approaches and supports the defense-in-depth philosophy, which would improve the technical basis, increase efficiency, and enhance effectiveness. All backfitting actions must be risk-informed.~~

~~Exhibits 1 and 2 in this handbook are flowcharts that illustrate the NRC's program for processing backfits, forward fits, and appeals. The licensing basis (LB) for power reactors under Parts 50, 52, and 54 is determined on a case-by-case basis and is commonly referred to as the set of NRC requirements applicable to a specific facility and that licensee's written commitments for ensuring compliance with applicable NRC requirements in the LB and the facility-specific design bases (including all modifications and additions over the life of the license).~~

- ~~9. Commitments that have been included in a licensee's updated final safety analysis report (UFSAR) that describe a method for complying with regulations or requirements are not enforceable unless they are part of the license. Commitments documented outside of the license only represent acceptable approaches for complying with the governing requirements.~~
- ~~13. If a licensee voluntarily submits a license amendment request (LAR) or license renewal application (LRA), the NRC, as a condition of its approval, may require that the licensee modify its submittal or adopt new or revised guidance, provided that 1) the new or revised guidance relates to the licensee's request, and 2) the subject matter of the guidance is essential to the NRC staff's determination of the acceptability of the licensee's request. This would not constitute backfitting. It is the~~

<sup>9</sup> Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement (60 FR 42622; August 16, 1995).



~~licensee's burden to show that the submitted application enables the NRC to make the appropriate findings (e.g.; in accordance with 10 CFR 50.40, 50.57, 50.92, or the other applicable regulations).~~

## **B. Forward Fitting**

1. A forward fit is defined as the imposition of a new or modified requirement or regulatory staff interpretation of a requirement that results in the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility as a condition of approval by the NRC of a licensee-initiated request for a licensing action when the underlying request did not propose to comply with the new or revised requirement or interpretation. Such licensing actions may include a license amendment or a license renewal, although the normal application of the process in 10 CFR Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants," does not generally constitute forward fitting. The NRC may condition its approval of such a licensing action on the use of a new or modified regulatory staff position only if 1) there is a direct nexus to the licensee's request and 2) the imposition of the new or modified requirement or regulatory staff position is essential to the NRC staff's determination of the acceptability of the licensee's request. Staff must address these two elements in its analysis and adequately justify why each one is independently met.

In situations where a forward fit is not necessary for adequate protection,<sup>10</sup> the NRC staff should proceed along the same path as that established in the backfit rule. Specifically, the staff should require forward fitting of a facility only when it determines, based on an analysis similar to that required for backfitting in 10 CFR § 50.109(c), that there is a substantial increase in the overall protection of the public health and safety of 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. The Staff should also take the following factors into account in deciding whether a forward fit is appropriate:

- a) In establishing or modifying the requirement or regulatory staff position interpreting the requirement, the NRC staff had the opportunity to consider whether the resulting position should be imposed as a backfit on existing licensees. Under the mandatory backfitting provisions of 10 CFR 50.109(a)(5), 70.76(a)(5), and 76.76(a)(5), and the portions of 72.62(b) regarding backfitting necessary to ensure adequate protection of public health and safety, if such a change were necessary to ensure adequate

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<sup>10</sup> Instances of adequate protection forward fitting should be extremely rare, as discussed in Section III.A.

protection of public health and safety when the new or modified requirement or regulatory staff position was made, the NRC would have been required to impose it as a backfit. Because such a backfit has not been imposed for cases where a forward fit is being considered, it is unlikely that a change could be justified to be necessary to ensure adequate protection of public health and safety.

- b) NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," provides the following guidance on the development of regulatory staff positions:

The NRC performs regulatory analyses to support numerous NRC actions affecting reactor and materials licensees. Executive Order 12866 requires that a regulatory analysis be prepared for all significant regulatory actions. The NRC requires regulatory analyses for a broader range of regulatory actions than for significant rulemakings as defined in E.O.12866. In general, each NRC office should ensure that all mechanisms used by the NRC staff to establish or communicate generic requirements, guidance, requests or staff positions that would affect a change in the use of resources by its licensees include an accompanying regulatory analysis. This requirement applies to actions initiated internally by the NRC or by a petition to the NRC. These mechanisms include rules, bulletins, generic letters, regulatory guides, orders, standard review plans, branch technical positions and standard technical specifications.

If the regulatory analysis developed in support of the new or modified requirement or regulatory staff position (e.g., a revision to regulatory guidance) resulted in an agency decision that the prior regulatory staff position should remain available for use by current licensees and not be withdrawn, the decision on whether to forward fit the new or modified regulatory staff position on an applicant for a licensing action should be informed by a site-specific regulatory analysis.

- c) If a licensee believes that the staff has incorrectly followed this process in imposing a forward fit, the licensee may use the backfitting appeals process described in Section III.F of this Management Directive to challenge the forward fit, as contemplated by the Statement of Considerations for the 1985 Revision of Backfitting Process for Power Reactors.<sup>11</sup>

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<sup>11</sup> 50 FR 38097, 38101, September 20, 1985.

- ~~—For light-water reactor (LWR) facilities, § 50.34(d), § 52.17(a)(1)(xii), § 52.47(a)(9), § 52.79(a)(41), § 52.137(a)(9), and § 52.157(f)(30) establish the version of NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,” (the SRP) that applicants should be anticipated to reasonably rely upon in the development of their applications. Any change in requirements or regulatory staff positions from that version of the SRP interpreting the Commission’s requirements should follow the same reasoned decisionmaking process as a forward fit.~~
- ~~a) Under 10 CFR 50.40 Common standards, “in determining that a construction permit or OL in this part, or early site permit, combined license, or ML in Part 52 of this chapter will be issued to an applicant, the Commission will be guided by the following considerations: (a) Except for an early site permit or manufacturing license, the processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other technical specifications, or the proposals, in regard to any of the foregoing collectively provide reasonable assurance that the applicant will comply with the regulations in this chapter, including the regulations in Part 20 of this chapter, and that the health and safety of the public will not be endangered.”~~
- ~~b) A key aspect of 10 CFR 50.40 is the “collectively” aspect. The licensing (and amendment) finding allows consideration of the collective aspect of the proposed change. For example, if a licensee proposes longer outage time for SSC A, then the staff could rely on 50.40 to say that less outage time for SSC B is needed to give the overall collective reasonable assurance, and doing so is not necessarily a backfit.~~
- ~~c) The backfitting rules generally do not apply to voluntary licensee changes, where “voluntary” is defined as any action by the licensee that was made of its own accord, without the force of a legally binding requirement or NRC representation of further licensing or enforcement action. The licensee must not be compelled by the NRC staff to make the change. The NRC staff’s requirement that the licensee adopt new or revised guidance that does not directly pertain to the licensee’s voluntary request would constitute backfitting. Unless required by the NRC, confirmatory orders that are the result of participation in the alternative dispute resolution (ADR) process LARs, and LRAs are considered voluntary, and the NRC review process and approval of an ADR, LAR, or LRA generally is not considered backfitting. Furthermore, the backfitting rules do not apply to NRC suggested actions with which licensees are not required to comply, but decide to voluntarily implement. The backfitting rules do not apply to any voluntarily-initiated licensee installation of updated (or additional) equipment to the existing plant,~~

~~to expand the plant, improve efficiencies, delay its obsolescence, or extend its capabilities.~~

- ~~d) Backfitting does not apply to actions that do not have a direct link to, and do not further a substantive radiological public health and safety, or common defense and security, objective. Nevertheless, the NRC must have legal authority to justify taking such actions.~~
- ~~e) For backfitting purposes, staff positions are documented interpretations of the regulations, already specifically imposed upon a licensee or "class" of licensees at the time of the identification of the proposed backfitting and may be contained in documents such as the Statement of Considerations for a final rule, Standard Review Plan (SRP), NUREG, interim staff guidance (ISG), and branch technical position (BTP). A licensee's commitment to guidance, such as regulatory guides (RGs) or NRC-endorsed industry topical reports (TRs), through a licensing action is considered a voluntary action. However, RGs and NRC-endorsed TRs do represent staff positions. Generally, the issuance of or revision to a staff position is considered forward-fitting and the revisions to staff positions do not, in isolation, impose anything, and are therefore not (in isolation) backfits. The applicable staff positions for each facility license application, LAR, or LRA includes the safety evaluation reports (SER)<sup>12</sup> and any NRC approvals based on licensees' docketed responses to requests for information. A change in the applicable staff position is referred to as a new or revised staff position.~~
- ~~f) The NRC's backfitting actions can be either generic or facility-specific.<sup>13</sup>~~
- ~~g) (a) Generic backfitting actions affect a class or classes of licensees and can include the imposition of new or revised regulations or requirements (through rulemaking or Orders) or new or revised staff positions interpreting NRC regulations. Generic backfitting actions can be initiated in a number of ways, such as by the staff in rulemaking, the Commission through a staff requirements memorandum (SRM), and the public through a petition for rulemaking. Regardless of whether a generic backfitting action is the result of rulemaking or a new or changed staff interpretation, the new or changed regulation or staff position must be documented, and stakeholders must have had an opportunity to review and provide comments in response to a *Federal*~~

<sup>12</sup>—Historically, the NRC has used two terms to describe the document approving a license, amendment, or license renewal: SER or safety evaluation (SE). Throughout this DH, the use of SE will indicate the SER (usually used for approving initial licensing or relicensing actions) or the SE (usually used for approving license amendments).

<sup>13</sup>—Hereafter, the term "facility" will be used to mean a nuclear power reactor; an ESP, DCR, COL, SDA, or ML for a power reactor; or a materials facility such as an ISFSI, fuel facility, gaseous diffusion plant, or a MRS installation.

~~Register (FR) notice. However, time-sensitive, safety-significant, or security-significant NRC actions, such as Orders or Bulletins, do not require public notice and opportunity to comment. In addition, not all previously issued staff positions were provided to the public for comment.~~

- ~~h) (b) Facility-specific backfitting issues typically arise through the NRC's inspection or licensing process. In these circumstances, the NRC's regional or headquarters staff may find that a change to a facility's licensing basis (LB) is appropriate. Facility-specific backfitting actions are normally a change in a staff position (the applicable SE) for a specific facility, based on an error or omission in the analysis (compliance backfit) for the implementation of that facility's LB, but they could also be a change to the facility-specific LB deemed necessary to ensure that the facility provides adequate protection. For power reactors, in addition to single unit sites, facility-specific backfitting actions may apply to sites that have multiple units, sites that share a UFSAR, or sites that may have more than one reactor type but share common sections of a UFSAR. Any reference in this DH or in NUREG-1409, "Backfitting and Issue Finality Guidance," to facility-specific backfitting pertains to facility-specific backfitting actions in this context.~~
- ~~i) Unless an exception as described in Section I.A.19 applies, to justify a backfit under 10 CFR 50.109, 10 CFR 70.76, 10 CFR 76.76, and generally 10 CFR 72.62, or, in many cases, to justify a violation of issue finality under 10 CFR Part 52, the NRC must perform and document a backfit analysis in accordance with NUREG-1409 that shows the following:~~
- ~~j) The backfitting would result in a substantial increase<sup>14</sup> in overall protection of public health and safety or the common defense and security, and~~
- ~~k) The direct and indirect costs of implementing the backfitting are justified in view of the increased protection.~~
- ~~l) The backfitting provisions generally contain three exceptions to the backfit analysis requirement described above, such that the analysis is not necessary when the backfitting action—~~
- ~~m) Is required for adequate protection,~~

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<sup>14</sup>—As noted in the Statements of Consideration for the 1985 backfitting final rule (50 FR 38097; September 20, 1985), a "substantial" increase in protection means "important or significant in a large amount, extent, or degree." Under such a standard, the Commission would not ordinarily expect to justify backfitting plant improvements that result in an insignificant or small benefit to public health and safety or the common defense and security, regardless of costs.

- ~~n) Defines or redefines the level of protection that should be regarded as adequate, or~~
- ~~e)d) is necessary to bring a facility into compliance with applicable requirements in the licensing basis, or into conformance with its written commitments.~~
- ~~10. Adequate protection backfitting, whether used to ensure that adequate protection is maintained or to define or redefine the level of protection that should be regarded as adequate, does not require a finding of substantial safety or security improvement, nor does it require that costs be considered. If a backfitting action is deemed necessary for adequate protection, it must be implemented, as required by Section 161 of the Atomic Energy Act of 1954, as amended (AEA). Compliance backfitting does not require a finding of substantial safety or security improvement, but does require some consideration of costs. Use of the adequate protection or compliance exception must be explained in a risk-informed, documented evaluation.~~
- ~~11. The backfit analysis requirement, and the exceptions to that requirement, restrict the ability of the NRC to conduct backfitting by requiring the NRC to demonstrate, before implementing the backfit, that the backfitting action would meet certain standards that vary based on the type of facility. In this way, the backfitting rules provide the following:~~
- ~~(a) Regulatory stability, by limiting the changes the NRC can make;~~
- ~~(b) Reasoned and informed NRC decisionmaking, by requiring the proposed action to be properly justified; and~~
- ~~(c) Transparency of NRC decisionmaking, by requiring the NRC to document and make publicly available its analyses.~~
- ~~12. This MD and DH reflect NRC policy direction and provide the process for implementing that policy. The MD and DH list the regulations and guidance documents that govern backfitting and describe how the NRC implements those regulations. Backfitting guidance for the NRC staff is available in NUREG-1409. Office or region-specific guidance is not required or desired. Consistency of implementation is assured by the staff's use of NUREG-1409.~~
- 13.2. Any change to an NRC staff position that the NRC intends to communicate by any means to a licensee(s) as being applicable to their facility may be identified as backfitting forward fitting either by the staff or by licensees. The means of communication can be through the issuance of regulatory guidance, inspection reports, generic communications, or staff interactions with licensee personnel. The NRR, NRO or NMSS office director (OD) or regional administrator (RA) responsible for the staff position and affected facility or facilities will make the determination as to

whether the new or revised staff position constitutes backfitting-forward fitting and whether the backfit-forward fit should be imposed on the licensee(s).

- 14.3. In support of the Commission's probabilistic risk assessment (PRA) policy statement<sup>15</sup> of August 1995, which encourages the use of PRA "in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy," risk insights must be considered, to the extent practical, as part of all backfitting and forward fitting actions. Risk information should be integrated in a manner that complements traditional regulatory approaches and supports the defense-in-depth philosophy, which would improve the technical basis, increase efficiency, and enhance effectiveness. All backfitting and forward fitting actions must be risk-informed.
- 15.4. Exhibits 1 and 2 in this handbook are flowcharts that illustrate the NRC's program for processing backfits, forward fits, and backfit appeals.

#### B.C. Information Collection Requests

- ~~1. The provisions of 10 CFR 2.204, "Demand for Information," require that a licensee respond to information requests from the Commission for the purpose of determining if an Order under 10 CFR 2.202, "Orders," should be issued, or whether other actions should be taken.~~
- 2.1. The provisions of 10 CFR 50.54(f) require power reactor licensees to respond to information requests from the staff NRC to enable the determination of whether a license should be modified, suspended or revoked. This rule stipulates that, except for information sought to verify licensee compliance with the facility's LB, the NRC must prepare the reasons for the information request to ensure that the burden imposed on licensees is justified based on the potential safety or security significance of the issue to be addressed. For additional information regarding appropriate use of 10 CFR 50.54(f), see Section IV, Information Requests.
- 3.2. Requests for information for power reactors to be licensed under 10 CFR Part 52 will be in accordance with the administrative requirements in 10 CFR 50.54(f), and as stated in 10 CFR 52.39(f), 10 CFR 52.98(g), 10 CFR 52.145(c), or 10 CFR 52.171(c), as applicable. The information request collection requirements for selected materials licensees are contained in 10 CFR 70.22(d), 10 CFR 72.62(d), and 10 CFR 76.70(e).

<sup>15</sup> Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement (60 FR 42622; August 16, 1995).

4.3. This MD and DH reflects the policy for ~~all~~ requests for information under these provisions.

#### **C.D. Coordination and Communication**

For effective implementation of the NRC's backfitting, forward fitting, and information collection request programs, the ODs and the RAs must ensure the following:

1. Effective communication and coordination are maintained between their counterparts and among the responsible technical staff within the headquarters and regional offices.
2. Processes, procedures, and programmatic and administrative controls are written in plain English.
3. Formal feedback from the Committee to Review Generic Requirements (CRGR) provided during the review of a proposed rule involving backfitting or forward fitting is addressed as part of the rulemaking package before its submittal to the Executive Director of Operations (EDO).
4. No backfitting or forward fitting actions will be communicated to a licensee unless the appropriate OD or RA has determined whether the position involves backfitting or forward fitting and, if so, has ensured that the position is identified as backfitting or forward fitting, the appropriate material (i.e., documented evaluation or backfit analysis) has been prepared and approved, the CRGR was offered an opportunity to review the documentation, and written feedback was considered. NRR shall ensure backfitting and forward fitting actions are consistently implemented throughout the regions.

#### **D.E. Recordkeeping**

Offices and regions directly involved in backfitting, forward fitting, or information collection requests are responsible for tracking and maintaining associated records originating in that office or region. Documentation of the justification for backfitting or use of a backfit analysis exception is required by 10 CFR 50.109, 10 CFR 70.76, 10 CFR 72.62, and 10 CFR 76.76. Documentation of the justification for information requests under 10 CFR Parts 50 and 52 are required by 10 CFR 50.54(f), 10 CFR 52.39(f), 10 CFR 52.98(g), 10 CFR 52.145(c), or 10 CFR 52.171(c), as applicable.



1. The office or region proposing information ~~collections requests, or~~ backfitting actions, or forward fitting actions must administratively manage each ~~collection request~~ or action by maintaining all related records. Records must be maintained in accordance with NUREG-0910, "NRC Comprehensive Records Disposition Schedule," issued March 2005.
2. Backfitting and forward fitting records placed in the Agencywide Documents Access and Management System (ADAMS) must be accessible to all stakeholders by being profiled as publicly available when appropriate, consistent with agency guidance on the release of information to the public.

## II. BACKFITTING APPLICABILITY

### A. Applicability of the Backfit process to Forward Fitting

As explained in Section I.B.1 above, the Staff should conduct the same evaluation for forward fitting and proceed along the same path as it does for backfitting. As such, all references, direction, and processes in this section that apply to backfitting also apply to forward fitting.

### A.B. Regulatory Changes Subject to the Backfit Rule

1. ~~As defined in Section I.A, a~~An NRC action is considered backfitting when the NRC changes any requirements through rulemaking, ~~an O~~order, or ~~the imposition of~~ a new or modified staff position that interprets requirements and would result in the modification or addition to SSCs, or the design of a facility, or the design approval or ML for a facility, or the procedures or organization required to design, construct, or operate a facility, after the dates defined in the backfitting requirements.
2. If the NRC staff conveys an expectation that licensees change programs, processes, procedures, or the physical plant by using or committing to use voluntary guidance (e.g., RGs or NRC-endorsed industry TRs) that is not already within the LB for the identified purpose, then the staff's communication of that expectation is may be considered backfitting or forward fitting. ~~Since there is generally more than one way to achieve compliance with a license or the rules or orders of the Commission, or with written licensee commitments, or there may be more ways to reach a level of protection that is adequate, the applicant or licensee is ordinarily free to choose the way which best suits its purposes. However, this does not apply during the review and consideration of any voluntarily submitted license application, LAR, or LRA, provided the issue in question is somehow associated with, and is within the scope of, the license application, LAR, or LRA under consideration.~~
3. A relaxation is the modification of a regulatory requirement or staff position that reduces requirements the obligations of placed on a licensee or class of licensees. A

relaxation may provide licensees the option of continuing as previously licensed (status quo), or adhering to the new “relaxed” regulatory requirement or staff position. If a relaxation does not provide for the status quo option, it is mandatory, and the relaxation is considered backfitting. ~~However, if the implementation of the relaxation is voluntary for the licensee, in that it does provide for the status quo option, then the relaxation is not backfitting, even if the licensee decides to implement the relaxed requirement.~~

### B.C. Nonapplicable Regulatory Changes

1. The ~~NRC’s backfitting rules do not apply to the~~ following regulatory actions generally do not meet the definition for backfitting:
  - (a) Confirmatory action letters (CALs), because CALs involve voluntary actions a licensee commits to take, which are agreed to between the licensee and the NRC;
  - (b) Changes mandated by statute or other Congressional action that preclude agency discretion in their implementation;
  - (c) Changes required by other Federal agencies that preclude ~~agency~~ NRC discretion in their implementation;
  - (d) Voluntary licensee submittals ~~of an LAR or LRA or subsequent license renewal (SLR) request,<sup>16</sup> subject to the limitations discussed above in Section I.A.104, and the NRC’s process (requests for information, licensee engagement, or modifications to the submittal) used during the review and consideration of the LAR, LRA, or SLR request;~~
  - ~~(e) A licensee’s voluntary implementation of NRC recommended actions that do not constitute the basis for resolution of a safety, security, or regulatory issue (e.g., a licensee’s decision to follow an NRC RG, or an NRC endorsed TR, or to make changes based on an NRC Information Notice);~~
  - ~~(f)~~ (e) Issuance of a notice of violation for an improper change ~~Overturning of an improper change implemented~~ under 10 CFR 50.59, “Changes, Tests, and Experiments” resulting in a modification to a facility;
  - ~~(g)~~ (f) Licensee changes or plant modifications that expand the plant capabilities or improve plant efficiencies or performance that are not mandated by the NRC;
  - ~~(h)~~ (g) Non-mandatory relaxations of staff positions or regulations;

<sup>16</sup> ~~The scope of the NRC’s review of an LR or SLR and, thus, the backfitting of these applicants, is limited by the regulations in 10 CFR 54.30, “Matters Not Subject to a Renewal Review.”~~

- ~~(i) New or changes to requirements that do not have a direct link to, and do not further a substantive radiological public health and safety or common defense and security objective, such as reporting and recordkeeping requirements (e.g., 10 CFR 50.71, 50.72, "Immediate Notification Requirements for Operating Nuclear Power Reactors") or appeals processes (e.g., 10 CFR 26.39, "Review Process for Fitness For Duty Policy Violations," 10 CFR 73.56(l), "Review Procedures");~~
  - ~~(j)(h) \_\_\_\_\_ Changes or updates to American Society of Mechanical Engineers Boiler and Pressure Vessel (ASME) Code, Section XI, that are incorporated into 10 CFR 50.55a, "Codes and Standards.";~~
  - ~~(k)(i) \_\_\_\_\_ Plant or procedural changes to comply with industry or professional standards not mandated by the NRC;~~
  - ~~(l) Current and future applications for an NRC license, with two exceptions described in Section II.B.4 below;~~
  - ~~(m)(j) \_\_\_\_\_ Voluntary changes made to a plant based on national or international operating experience, including any changes as a direct result of NRC Information Notices;~~
  - ~~(n)(k) \_\_\_\_\_ Changes as a result of a licensee's commitment management program;~~
  - ~~(o)(l) \_\_\_\_\_ Licensee changes to its plant under 10 CFR 50.59 or other existing change control requirements (see Section II.BC.23 below); and~~
  - ~~(p)(m) \_\_\_\_\_ Plant or procedural corrective actions to restore the LB or adherence to the license and thereby provide compliance with governing requirements.;~~
- ~~2. The issuance of new or updated NRC RGs, as RGs are forward fitting, provided the RGs are not imposed on licensees;~~
  - ~~3. The endorsement of new or updated industry-submitted TRs, because TRs are forward fitting and not imposed by the NRC; and~~
  - ~~4. The staff use of documents, such as NUREGs, ISGs, and BTPs, during the review and consideration of any LAR or LRA, as the submission of the LAR or LRA is a voluntary action by a licensee applying for a change to its license, subject to the limitations discussed in Sections I.A.11 and I.A.14.~~
  - ~~5. If an existing licensee voluntarily requests a license amendment or change, and (1) the NRC staff's consideration of the request involves a regulatory issue directly relevant to an NRC guidance document (such as an RG) and (2) the specific subject matter of the guidance document is an essential consideration in the staff's determination of the acceptability of the licensee's request, then the staff may~~

~~request that the licensee either follow that guidance or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements in the licensing basis. This is not considered backfitting.~~

~~6. Power reactor licensee implementation of changes to its facility under 10 CFR 50.59 are not subject to the backfitting rules. The NRC has established a process under 10 CFR 50.59 that provides a licensee the authority to make certain changes without NRC approval if the change meets certain specified criteria. Unless the NRC determines that the licensee incorrectly used the 10 CFR 50.59 process, the licensee reasonably can implement the change without the NRC taking enforcement action. This is consistent with the underlying premise of regulatory stability established within the backfitting rules and the principles of good regulation. However if, during any inspection or review of licensee actions implemented in accordance with 10 CFR 50.59, the staff determines that 10 CFR 50.59 was not properly implemented, the staff shall issue a finding or violation in accordance with regulations, and the licensee may be required to “revert” to the previous plant or procedural configuration, or otherwise change the facility to a configuration acceptable to the NRC. This would not be considered backfitting.~~

~~7.2. In general, backfitting provisions do not apply to current and future applicants for an NRC license. Backfitting is not intended to apply to every NRC action that substantially changes the expectations of current and future license applicants. There are two exceptions to this general principle. The first exception occurs when a 10 CFR Part 52 license applicant references a 10 CFR Part 52 license (e.g., an ESP) or NRC regulatory approval (e.g., a DCR), or both, with specified issue finality provisions. The second exception occurs when a 10 CFR Part 50 power reactor OL applicant holds a CP or limited work authorization (LWA). 10 CFR Section 50.109 would apply to the matters covered by the CP or LWA. See also the discussion on the use of the SRP for review of LWR applications in Section I.A.11 of this DH.~~

~~8. Actions proposed or voluntarily implemented by a licensee are not backfits, even though such actions may result from routine discussions between the staff and the licensee concerning an issue, provided that those discussions did not include an NRC expectation that the licensee must implement the action.~~

### III. BACKFITTING POLICY

#### A. Adequate Protection Backfitting

1. For all matters of potential backfitting, including forward fitting, the staff must first consider whether the issue is one of adequate protection.<sup>17</sup> If the NRC staff

<sup>17</sup> Instances of adequate protection forward fitting should be extremely rare. This is because the NRC takes into account the potential for the imposition of backfits necessary for adequate protection under

determines that it must impose a backfitting or forward fitting action to ensure that a facility provides adequate protection to public health and safety and is in accord with the common defense and security, or if the Commission decides that it needs to define or redefine the appropriate level of protection of public health and safety or the common defense and security that should be considered as adequate, then the AEA requires that the backfitting action be implemented. An backfit analysis must be completed to justify the determination that a backfitting or forward fitting action is necessary for adequate protection and a consideration of costs are not required (unless the NRC staff identifies more than one means for implementing the new requirement, in which case costs could be considered in deciding which approach is appropriate). Whenever adequate protection is invoked, the NMSS, NRO or NRR OD must approve a risk-informed, documented evaluation of the type discussed in 10 CFR 50.109(a)(6), 10 CFR 70.76(a)(6), and 10 CFR 76.76(a)(6), with a finding that the action is necessary to define or redefine adequate protection or to ensure adequate protection of public health and safety or the common defense and security.<sup>18</sup> The risk-informed, documented evaluation must include a statement of the objectives, the reasons for the action, the basis for invoking adequate protection, and the safety or security risk if action is not taken. The NMSS, NRO or NRR staff should seek advice from the Office of General Counsel (OGC) on the imposition of all adequate protection actions, including the licensee's proposed implementation schedule. NUREG-1409 contains detailed guidance on how to prepare the documented evaluation. For generic backfitting actions that are part of rulemakings, the documented evaluation is provided as part of the rulemaking package that the Commission approves. Generally, adequate protection backfits are not included in rulemakings, and instead, result from the issuance of an Order. The rulemaking will subsequently be issued to include the previously imposed adequate protection backfits, given consideration to public comments provided on the proposed rule and to lessons learned through the implementation of the previous Order requirements.

2. To issue the license, the Commission found that operating in accordance with the license would provide reasonable assurance of adequate protection of public health

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its mandatory backfitting provisions ((§§ 50.109(a)(5), 70.76(a)(5), and 76.76(a)(5), and the portions of 72.62(b) regarding backfitting necessary to ensure adequate protection of public health and safety) when regulatory staff positions interpreting the Commission's requirements are developed. Once a new or revised regulatory staff position interpreting the Commission's requirements is finalized, the potential for backfitting that is necessary for adequate protection of public health and safety would have been considered and accomplished as appropriate.

<sup>18</sup> It is the policy of the NRC that backfitting actions under 10 CFR 72.62 that are similarly justified must be documented in a manner similar to those under 10 CFR 70.76(a)(6), and 10 CFR 76.76(a)(6).

and safety and reasonable assurance that the licensee would meet the regulations. Therefore, licensee compliance with its LB is presumed to provide reasonable assurance of adequate protection of public health and safety and the common defense and security. Thus, for the NRC to impose new or changed requirements on a licensee that are intended to provide for adequate protection of public health and safety or the common defense and security, the NRC must provide, within the documented evaluation, a clear explanation of why, despite the licensee's compliance with the applicable existing regulatory framework (LB), there is not (or will not be) reasonable assurance of adequate protection. This evaluation must include appropriate consideration of risk insights. Typically, a clear basis for invoking the adequate protection exception can be established when the NRC has new information regarding a safety or security issue that creates undue risk to public health and safety that is not addressed through compliance with the current regulatory framework. If the NRC can show that it must take action to provide reasonable assurance of adequate protection of public health and safety and the common defense and security, then the AEA requires the NRC to impose the new or changed requirements.

2.3. Upon determining that a backfit or forward fit is necessary for adequate protection of public health and safety, the NRC must prepare an imminent threat analysis to consider whether the underlying safety issue presents an imminent threat to public health and safety. If so, the agency must take immediate action. In these situations, the staff must provide its determination, including the imminent threat analysis, to the Commission for consideration in its review of the proposed regulatory change or modification.

3.4. It is the NRC's position policy<sup>19</sup> that the agency cannot allow licensees to address issues of adequate protection by a voluntary initiative. Instead, the AEA requires the NRC to establish requirements that provide reasonable assurance of adequate protection of public health and safety and the common defense and security.

4. 5. Under 10 CFR 50.-109(a)(5), 70.76(a)(5), 72.62 and 76.76(a)(5), the Commission requires the imposition of a backfit if it finds that the backfit is necessary to ensure adequate protection of occupational or public health and safety.

<sup>19</sup> In SRM-SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," dated March 2 May 27, 1999 (ADAMS Accession No. ML003752062992840068) the Commission approved the staff's recommendation agreed that relying on voluntary industry initiatives to ensure adequate protection would be inappropriate "since they would be based on commitments rather than requirements."

5. Under 10 CFR 72.62, the Commission requires the imposition of a backfit if it finds that the backfit is necessary to ensure adequate protection of occupational or public health and safety.

## B. Compliance Backfitting

1. Compliance backfitting is intended to address situations in which the licensee has failed to meet known and established standards of the Commission because of omission or mistake of fact. New or modified interpretations of what constitutes compliance do not fall within the exception.
2. Before the staff uses the compliance exception, the staff must determine whether the conditions represent an issue of adequate protection. If the issue does not involve adequate protection, then the staff should determine whether the backfitting action is necessary to ensure compliance with regulatory requirements in the licensing basis, or written commitments on how the licensee will comply with a requirement that were in place at the time of the decision at issue. ~~If the backfitting action ensures compliance, a backfit analysis is not required. Instead,~~ The appropriate program office or region prepares a risk-informed, documented evaluation of the type discussed in 10 CFR 50.109(a)(6), 10 CFR 70.76(a)(6), and 10 CFR 76.76(a)(6), with a finding that the action is necessary to ensure compliance as the result of ~~an~~ error or omission or mistake of fact. The documented evaluation must include a statement of the objectives, the reasons for the action, the basis for invoking the compliance exception, and the safety or security risk if action is not taken. NUREG-1409 contains detailed guidance on how to prepare this documented evaluation. The responsible office staff shall seek OGC and the Office of Enforcement (OE) advice on the imposition of all compliance backfitting actions, including the licensee's proposed implementation schedule. The NRC staff's compliance backfitting documentation should include risk insights, including safety margin,<sup>20</sup> to provide the staff sufficient information to determine an acceptable schedule for the licensee to implement the backfit. These risk insights may also indicate that it is appropriate to terminate consideration of a backfitting action as discussed in item 9 of this section.

- 1.3. The phrase "written commitments," as used within the backfitting provisions, refers to those commitments that have been submitted to the NRC on the docket, have

<sup>20</sup> Safety margin may not be quantifiable. For example, meeting environmental qualification (EQ) requirements in 10 CFR 50.49 "Environmental qualifications of electrical equipment important to safety for nuclear power plants," results in safety margin, but this margin is not readily quantifiable, particularly with regard to public health and safety (i.e., the equipment is robust for performing under events that are important to plant risk and are less severe than the environmental qualifications envelop).

~~become part of the LB~~ been incorporated into the license, and directly relate to the means by which the licensee complies with a requirement.

- ~~2.4.~~ Under 10 CFR 72.62, the Commission will require the imposition of a backfit if it finds that the backfit is necessary to bring an ISFSI or MRS into compliance with a license or the Commission's Orders or rules. ~~Under 72.62(b), "The Commission will require backfitting of an ISFSI or MRS if it finds that such action is necessary to assure adequate protection to occupational or public health and safety, or to bring the ISFSI or MRS into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by a licensee."~~
- ~~3.5.~~ ~~Because a compliance backfitting action does not require a backfit analysis, the staff need not demonstrate that the direct and indirect costs of implementation are justified in view of the increased protection from the backfit. However, As noted in paragraphs I.A.5 and I.A.6, when the NRC imposes new requirements not needed to ensure adequate protection, the APA requires some consideration of cost. Thus, the staff must include at least some consideration of costs in its documented evaluation- for a compliance backfit performed under 10 CFR 50.109(a)(4), 70.76(a)(4), or 76.76(a)(4).~~ Although the extent of the consideration required will necessarily be fact- and site-specific, one of the factors that may be relevant is the amount of time that has elapsed since the approval that is now claimed to be the subject of a mistake or omission. When the potential for compliance backfitting is identified relatively soon (within approximately 2 years) after the licensing decision or the imposition of a regulatory requirement, likely all that will be necessary is a simple estimate of the cost of imposing the backfitting action that does not quantify benefits or perform any balancing beyond that which was originally considered. However, when many years have passed (typically more than 10) before the staff determines that a regulation or requirement is not satisfied, identifying the benefits of compliance and comparing them to the cost of implementation will likely be appropriate to ensure that costs have been adequately considered. The staff is afforded ~~a high degree of~~ flexibility, in accordance with Commission direction regarding qualitative and quantitative factors in line with direction given to staff in SRM-14-0087, to determine how much cost consideration is appropriate based on the specifics of each case and the identified risk.
- ~~4.6.~~ Use of the compliance exception is limited to the following situations that define "omission or mistake of fact":
- (a) The NRC staff, whether by its own error or by licensee or third-party error or omission at or before the time of its determination that a known and established standard of the Commission was satisfied, (1) incorrectly perceived facts, (2) performed or failed to recognize flawed analyses, or (3) failed to properly draw inferences from those facts or analyses, as judged by the standards and



practices that were prevailing among professionals or experts in the relevant area at the time of the determination in question, and

- (b) Those facts, analyses, or inferences have now been properly perceived, performed, or drawn.
- (c) The error or omission may have been committed by any involved party and must be traced to—
  - (i) The original LB or to a change to the LB, and
  - (ii) The regulations ~~contained~~ reflected in the LB at the time of implementation that were applicable to the particular licensee whose LB is at issue, and
  - (iii) Any standards and practices in existence at the time the original determination was made.

The understanding for what constituted proper implementation of the regulations, standards, and practices must have been widely known or understood by professionals at the time. This is not restricted to the regulatory positions of the NRC but includes any industry or professional standards and practices in existence at the time the original determination was made.

~~5.7.~~ The compliance exception should not be applied to the following:

- (d) Failure of the NRC staff to extrapolate conclusions from facts, analyses, and direct inferences in ways that were not commonly recognized under such prevailing professional standards and practices at the time of the NRC determination; or
- (e) Recharacterizations of whether a particular set of otherwise understood circumstances satisfies the standard at issue based upon professional standards and practices developed or accepted after the time of the determination.

~~6.8.~~ The following policy concerns the use of the compliance exception to mandate consistency with the general design criteria (GDC).

- ~~(a) The GDC are located in Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50 and 10 CFR Part 72, Subpart F, "General Design Criteria." Those design criteria help formulate a plant's design basis, and the design basis is reflected in the plant's final engineering drawings. The design basis must be documented in the UFSAR.~~

~~(b) The GDC establish “minimum requirements” for the development of the principal design criteria (PDC). The GDC are intended to provide guidance in establishing the PDC. The licensing process requires approval of an applicant’s PDC as a condition for granting a CP. Before an OL is issued, and as a basis for its finding of reasonable assurance of adequate protection of public health and safety and the common defense and security, the Commission must find that the facility has been built in accordance with the PDC and any NRC approved changes. Thus, for 10 CFR Part 50 licensees with CPs issued since 1971 (when the GDC were promulgated), the Commission has already necessarily reached the conclusion that the design basis of the plant, as reflected in the PDC, meets or exceeds the minimum criteria set forth in the GDC. The 1992 SRM approved the SECY that concluded that no GDC backfitting was needed, and that all pre-GDC plants meet the intent of the GDC.<sup>24</sup>~~

~~(e)(a)~~ The NRC must not rely on the GDC requirements for pre-GDC licensing actions (those licenses or CPs issued before the issuance of the GDC (before 1971)), unless the NRC has made the GDC a requirement for that licensee.

~~(d) Under the provisions of 10 CFR 50.34, “Contents of Applications; Technical Information,” an application for a CP must include the PDC for a proposed facility. Under the provisions of 10 CFR 52.47, “Contents of Applications; Technical Information,” 10 CFR 52.79, “Contents of Applications; Technical Information in Final Safety Analysis Report,” 10 CFR 52.137, “Contents of Applications; Technical Information,” and 10 CFR 52.157, “Contents of Applications; Technical Information in Final Safety Analysis Report,” an application for a DC, COL, SDA, or ML, respectively, must include the PDC for a proposed facility. The PDC establish the necessary design, fabrication, construction, testing, and performance requirements for SSCs important to safety; that is, SSCs that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public.~~

~~(e)(b)~~ The license approval process will typically yield more specific requirements than those set forth in the GDC. However, the NRC is not precluded from reliance on GDC as the source of a “requirement” for purposes of invoking the compliance exception ~~in those cases where a GDC provides more than just a performance standard and has not been superseded through the approval of the PDC, and requirements derived from those PDC that are clearly~~

<sup>24</sup>—SRM was in response to SECY-92-223 “Resolution of Deviations Identified During the Systematic Evaluation Program” and is dated September 18, 1992 (ML12256B290).

~~meant to address the GDC at issue. Thus, a GDC can be regarded as a requirement in those circumstances in which when the GDC is prescriptive in nature and the technical specifications and other licensee requirements derived from the PDC do not speak to the matter in question.~~

- ~~(f) In some cases, conditions not in accordance with the GDC can be properly resolved as a matter of adequate protection if the matter creates undue risk to public health and safety or the common defense and security, without the need to invoke the compliance exception. The extent to which regulatory action is necessary to ensure adequate protection should be evaluated before invoking the compliance exception based on a requirement set forth in the GDC.~~

Use of the compliance exception to support a backfit should not be confused with routine inspection activities related to the LB, as determined by the reactor oversight process or other inspection activities. NRC inspections assess compliance with the requirements in the ~~licensing basis~~ LB, whereas compliance backfitting is pertinent to those issues where the staff has determined that it is necessary to modify the approved LB because of an error or omission. Thus, it is not expected that findings or violations documented as part of the NRC's inspection activities would result in compliance backfitting. However, the NRC staff must evaluate each circumstance to ensure the issue is properly assessed against the LB and resolved. For example, the NRC would take enforcement action when a licensee is not in compliance with the NRC-approved method of meeting a requirement, whereas compliance backfitting would occur when a licensee is in compliance with an NRC-approved method but the NRC subsequently determines that the licensee's method does not result in compliance with the requirement because of an ~~error or omission~~ or mistake of fact at the time of approval.

- ~~7.1. The NRC staff's compliance backfitting documentation should include risk insights, including safety margin<sup>22</sup>, to provide the staff sufficient information to determine an acceptable schedule for the licensee to implement the backfit.~~

<sup>22</sup> ~~Safety margin may not be quantifiable. For example, meeting environments qualification (EQ) requirements in 10 CFR 50.49 "Environmental qualifications of electrical equipment important to safety for nuclear power plants," results in safety margin, but this margin is not readily quantifiable, particularly with regard to public health and safety (i.e., the equipment is robust for performing under events that are important to plant risk and are less severe than the environmental qualifications envelop).~~

~~8.9.~~ At any point during the process, the responsible program office or the region, in consultation with other appropriate offices, including OGC and OE, may decide not to proceed with the backfitting action because further effort is likely to show either of the following:

- (a) Compliance backfitting would not provide any increase in safety or security as compared to the status quo. This is not to say that the increase in safety or security must be substantial, only that there must be some attributable increase.
- (b) An exemption from compliance with the Commission's regulation for which compliance is sought may be granted under 10 CFR 50.12, "Specific ~~e~~Exemptions;" 10 CFR 52.7, "Specific ~~e~~Exemptions;" 10 CFR Part 70 Subpart B, "Exemptions;" 10 CFR 72.7, "Specific ~~e~~Exemptions;" or 10 CFR 76.23, "Specific ~~e~~Exemptions."

~~9.10.~~ ~~Of, i~~n consultation with OE, the OD or RA may determine that enforcement discretion should be granted to enable the licensee to prepare a systematic and planned approach for implementing a compliance backfitting action. If the OD or RA and OE conclude that enforcement discretion is appropriate or necessary, based on a risk-informed analysis and in consideration of licensee outages and maintenance schedules, OE, with the OD or RA, will normally issue an enforcement guidance memorandum or seek Commission approval for an interim enforcement policy for multifacility compliance backfitting actions, as appropriate.

- (a) An enforcement guidance memorandum is usually the appropriate enforcement discretion for generic or industrywide compliance backfits.
- (b) For individual facility- or site-specific compliance backfitting actions, the exercise of enforcement discretion may be addressed in the Order associated with the compliance backfit.

~~10. If adequate protection is not involved, then a determination must be made to verify there is adequate safety margin with respect to the regulatory requirements. Therefore, consideration of cost is relevant in determining if a backfit is needed to recover the lost safety margin.~~

11. If, after careful consideration of the issue, risk to public health and safety or the common defense and security, safety margin, and licensee costs for implementation of the compliance backfit, the NRC determines that compliance should not be required, then the NRC will normally grant enforcement discretion until such time as the NRC initiates and issues an exemption in accordance with 10 CFR 50.12, an amendment in accordance with 10 CFR 50.90, a relaxation of an order, or other action as appropriate.

### C. Cost-Justified Substantial Increase in Protection Backfitting and Forward Fitting

For all backfitting that does not satisfy the adequate protection exception or compliance exception criteria, the NRC should determine whether to ~~perform~~impose a backfit ~~analysis~~ by applying the facts of the proposed backfitting against the backfit standard as described below. As explained in I.B.1 above, the Staff should conduct the same evaluation for forward fitting and proceed along the same path as it does for backfitting. As such, all references, direction, and processes in this section that apply to backfitting also apply to forward fitting.

#### 1. Backfit or Issue Finality Standard

The backfitting provisions require, first, that the proposed action result in a substantial increase in the overall protection of public health and safety or the common defense and security. If either criterion is met, the standard then requires that the direct and indirect costs are shown to be justified in light of the substantial increase in overall protection. If the proposed action is not shown to result in a substantial increase in safety or security, or the costs are not justified, then the backfit cannot be imposed (unless the Commission exempts itself from the backfitting rule; although as noted in paragraph I.A.5, when the NRC imposes new requirements not needed to ensure adequate protection, the APA requires some consideration of cost.).

In the statement of considerations for the 1985 reactor backfitting rule, the Commission said the following:

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

#### 2. Backfit Analysis

All backfit analyses must be performed in accordance with 10 CFR 50.109 or other applicable regulations and NUREG-1409.

- (a) Once the NRC determines that backfitting ~~must~~should be pursued, and adequate protection or compliance backfitting are not appropriate, the NRC staff must develop a backfit analysis.

(b) The staff must demonstrate and document that the backfit standard is met. The staff must consider available quantitative and qualitative data in making this determination. ~~If necessary, relevant, and consistent with SRM-SECY-14-0087, "Staff Requirements – SECY-14-0087- Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," dated March 4, 2015, qualitative considerations may be used to demonstrate a cost-justified increase in protection. As directed, q~~Qualitative factors should be used in a judicious and disciplined manner to inform decisionmaking, in limited cases, when quantitative analyses are not possible or practical (i.e., due to lack of methodologies or data). Accordingly, an analysis should be informed by applicable risk information, including a PRA, to the extent it is available and can be considered without undue use of NRC resources. The staff will also consider information available concerning any of the factors listed in 10 CFR 50.109(c), as may be appropriate, and any other information relevant and material to the proposed backfitting, including NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission."

(c) ~~Relaxations may not show a substantial increase in safety or security; consequently, implementation of these relaxations are voluntary for the licensees.~~ In most cases, relaxations involve alternative regulatory approaches that licensees can choose to implement, may involve small decreases in safety or security, and are not backfitting actions if options for implementation are offered to the licensees. When such options are offered, the NRC verifies that compliance with the licensee's LB, including the relaxation (if it involves a small decrease in safety or security), continues to provide reasonable assurance of adequate protection.

3. Under 10 CFR 72.62, the Commission can require the backfitting of an ISFSI or MRS installation if it finds that the backfitting action would result in a substantial increase in protection to the occupational or public health and safety whose costs are justified in light of the increased protection.

#### D. Additional Considerations

1. For all backfitting and forward fitting actions, additional procedural factors required by the CRGR Charter for justification must be used if they apply to the issue. Furthermore, as additional administrative controls, the offices or regions may use reviews by special internal panels, and OE and OGC review and concurrence, as appropriate.
2. The NRC staff should recommend terminating a proposed agency action that would constitute backfitting or forward fitting when the staff concludes that the proposed

action is not necessary for adequate protection; the compliance exception to the backfit analysis requirement does not apply; the backfitting action is not likely to result in a substantial increase in safety or security; or, if a substantial increase in safety or security can be demonstrated, the direct and indirect costs of implementation are not likely to be justified. The responsible program OD or RA may approve closing the issue with appropriate notice sent to all applicable parties and recorded in ADAMS.

3. During the course of dispositioning a proposed finding, violation, or licensing action, a licensee may raise concerns that the proposed action is either backfitting or forward fitting. The staff will inform divisional management of the concern, before the proposed action is taken, with ensuing discussions considering previous regulatory staff positions and enforcement precedence. A lack of historical staff position could be indicative of a new staff position and therefore subject to backfitting and forward fitting provisions. Informing divisional management and researching historical positions ensures appropriate consideration of licensee concerns and supports agency operation as a stable and reliable regulator.

#### E. Scheduling of Backfitting Implementation

1. After the appropriate OD (NMSS, NRO, or NRR) or RA has approved a facility-specific documented evaluation, ~~or~~ backfit analysis, or forward fit analysis, the responsible division director or above must issue the backfitting or forward fitting requirement to the licensee. The licensee may choose to implement the backfitting or forward fitting action or appeal the decision to the program OD or RA.
2. Implementation of a facility-specific backfitting action should be accomplished on a schedule based on the safety or security significance and overall risk of the issue, ~~with the exception of any a~~adequate protection backfits ~~that should must~~ be expeditiously imposed if the NRC finds that an imminent threat to public health and safety exists. Upon determining that a backfit is necessary for adequate protection to public health and safety, the NRC should prepare an imminent threat analysis that determines whether immediate action is necessary. The staff should consult with its regional and program office counterparts and OE to establish the implementation schedule, identify the implementation actions, and determine if and when enforcement action is appropriate. The responsible OD or RA, in collaboration with OE, must determine whether enforcement discretion is appropriate, and how it will be addressed in the facility specific backfit action. In these situations, the staff must provide its determination, including the imminent threat analysis, to the Commission for consideration in its review of the proposed regulatory change or modification.
3. ~~In accordance with the backfitting provisions (e.g., 10 CFR 50.109(c)), scheduling criteria will include the importance of the backfitting action (i.e., safety or security~~

~~significance, including risk) relative to other safety or security-related activities underway, such as planned construction, outages, or other maintenance.~~

4.3. For generic backfitting actions that are part of rulemaking, schedule considerations are addressed as part of the rulemaking process, and are typically included in the new regulations as implementation or scheduling provisions.

5.4. A facility-specific backfitting action may be imposed by Order, following review and approval by the Commission, before completing any of these procedures if the OD who authorized the backfitting action determines that immediate imposition is necessary to ensure public health and safety or the common defense and security. In such cases, the appropriate OD must promptly notify the EDO of the action and, if possible, the staff must prepare a documented evaluation in time to be issued with the Order. If the documented evaluation cannot be issued with the Order, the evaluation must be completed as soon as possible after issuance of the Order and made publicly available.

#### F. Appeals of Backfitting and Forward Fitting Decisions

1. As stated in Section I.B.1.c above, if a licensee believes that the staff has incorrectly followed the outlined process for imposing a forward fit, the licensee may use the backfitting appeals process described below to challenge the forward fit, as contemplated by the Statement of Considerations for the 1985 Revision of Backfitting Process for Power Reactors.<sup>23</sup>

1.2. By NRC policy, the NRC affords licensees an opportunity to appeal any staff action a licensee believes does not comport with agency's backfit rules backfitting action at two levels: a First-Level Appeal to the OD or RA and a Second-Level Appeal to the EDO.

2.3. The appeal process applies to the following two situations:

(a) An applicable staff position that the NRC staff determined was not backfitting, but the licensee believes is backfitting, or

(b) An applicable staff position that the NRC staff determined was backfitting, but the licensee believes was not properly justified, ~~including an appeal to modify or withdraw a backfitting action for which a backfit analysis was conducted or an appeal that a backfitting action justified by the adequate protection or compliance exception in fact must be justified through a backfit analysis.~~

<sup>23</sup> 50 FR 38097, 38101, September 20, 1985.



- 3.4. If at any time during an appeal process, the NRC determines the proposed action is unjustified backfitting, the responsible OD or RA, or designee, must document the decision and inform the licensee.
- 4.5. The First-Level Appeal process must be carried out before the Second Level Appeal process. In the event a licensee addresses its initial appeal of a staff action to a level above the OD or RA, the appeal should be assigned to the OD of the program office that oversees the subject of the backfit, who will then oversee the First-Level Appeal process. ~~While a program OD or an RA can issue backfitting actions, a~~ All backfitting appeals are overseen by a program OD, who will coordinate the review with the RA overseeing the affected facility, and ~~the OD for emergency preparedness or security issues, in the Office of Nuclear Security and Incident Response (NSIR).~~
- 5.6. First-Level Appeal:
- (a) The licensee may send a backfitting appeal in writing to the OD or RA whose staff proposed or issued the action. The program OD is responsible for deciding the appeal. This constitutes a First-Level Appeal.
  - (b) During the review process, the OD may designate a panel to consider the appeal. A public meeting must be offered at which the licensee may discuss the appeal to ensure the NRC has a full understanding of the appeal. No determinations will be made at this public meeting.
  - (c) During the review process and following any public meeting with the licensee, a meeting with the originating staff must be offered to discuss the backfitting action and supporting documentation to ensure a full understanding of the initial action in question.
  - (d) After appropriate interoffice coordination and management review of the licensee's appeal, the program OD, working with the responsible RA and the NSIR OD, as applicable, must decide on the appeal. This process should be completed within 90 days of the date the NRC accepts the appeal.
  - (e) The ~~applicable~~ Deputy EDO responsible for the issuing office must be informed of the decision before the program OD informs the licensee of the decision in writing.
  - (f) If the backfitting action is ~~determined to be the correct regulatory path forward, following the written decision of the appropriate program OD~~ sustained, the licensee may implement the action or submit a Second-Level Appeal.

6.7. Second-Level Appeal:

- (a) If the licensee does not agree with the outcome of a First-Level Appeal, the licensee may file a second and final appeal to the EDO.
- (b) The EDO may designate a panel to consider the Second-Level Appeal. A public meeting with the licensee must be offered to discuss the licensee's appeal ~~documentation~~ and allow for a full understanding of the licensee's position.
- (c) The EDO's designated panel must consider all supporting staff analyses, submitted licensee analyses, and supplemented staff analyses, as well as any other information that is relevant and material to the appeal. Meetings with the staff involved in the original action in question and those involved in the First-Level Appeal must be offered to allow a full understanding of the staff position.
- (d) If the EDO determines that the action subject to a backfitting appeal is not considered backfitting, the action must not be treated further within the context of backfitting, but will be processed commensurate with the normal licensing or inspection appeal process.
- (e) If the EDO denies the appeal, the licensee must implement the action. If the licensee fails to implement the backfitting action, the appropriate OD must issue an Order. Once an Order is issued, whether or not it is immediately effective, MD 8.4 no longer applies. At this point, appeals are governed by the provisions of 10 CFR Part 2, "Agency Rules of Practice and Procedure," Subpart B, "Procedure for Imposing Requirements by Order, or for Modification, Suspension, or Revocation of a License, or for Imposing Civil Penalties."

#### **G. Exceptions**

The NRC staff is not required to make facility-specific backfitting findings when generic backfitting actions on the same issue(s) are, or have been, approved by the CRGR and EDO. This is also true for generic backfitting actions approved before November 1981, unless the EDO determines that significant facility-specific backfits were not considered during the prior reviews.

#### **H. Assessment of the Overall Effectiveness of the NRC's Backfit and Forward Fit Management Program**

The CRGR assesses, ~~typically every 5 years~~, the effectiveness of the NRC's administrative controls for backfitting and forward fitting, as part of its regulatory effectiveness responsibility, and provides a report to the EDO.

#### IV. INFORMATION COLLECTION PROCESS REQUESTS

##### A. NRC Regulations for Information Collection Requests

- ~~1. Demands for Information concerning alleged violations or potentially hazardous conditions or other facts are made pursuant to 10 CFR 2.204. Under Section 2.204, the NRC can require a licensee to respond for the purposes of determining if an Order under 10 CFR 2.202 should be issued, or whether other actions should be taken.~~
2. Information requests to power reactor licensees are made pursuant to 10 CFR 50.54(f). Under 10 CFR 50.54(f), the NRC can require request its licensees to provide information to enable the Commission to determine whether or not a license should be modified, suspended, or revoked. This rule requires the NRC staff to justify these information requests with supporting analysis that demonstrates that the burden to be imposed on licensees is justified in view of the potential safety significance of the issue for which the information is requested. ~~The exceptions to this requirement to prepare a justification are as follows:~~
- ~~3. No supporting analysis is required whenever there is reason to believe that public health and safety or the common defense and security may not be adequately protected, and information is needed to determine if this is the case and to take any necessary corrective actions.~~
- ~~4. No supporting analysis is necessary if the staff seeks information of a type routinely sought as a part of the standard procedures for the review of applications for licenses or license amendments for facilities under construction, or the conduct of inspection activities for facilities under construction. However, if the request is not part of a routine licensing review (for example, if the staff seeks information to develop a new staff position), then the supporting analysis must include the reasons for the request and justify the estimated burden imposed on the licensee before issuance.~~
- 5.1. No supporting analysis is necessary for licensing reviews or inspection activities for operating facilities, or for information requests sought to verify licensee compliance with the requirements in the LB for the facility. Requests for information made in connection with fact-finding reviews, inspections, and investigations of accidents or incidents are not usually made, pursuant to 10 CFR 50.54(f). Furthermore, such requests are not normally considered within the scope of the backfitting rules.
- 6.2. The requirements for information collection requests for selected materials licensees are contained in 10 CFR 70.22(d), 10 CFR 72.62(d), and 10 CFR 76.70(e).

7.3. The requirements for information ~~collection~~ requests for power reactor licensees under 10 CFR Part 52 are contained in 10 CFR 52.39(f), 10 CFR 52.98(g), 10 CFR 52.145(c), and 10 CFR 52.171(c).

8.4. The information request sent to the licensee should document the staff's evaluation of the applicable information collection requirements for the request.

## **B. Justification**

1. The program OD and the RAs must ensure that the staff establishes a reasonable basis for all information requests (except in cases that do not require justification). Specifically, the responsible OD or RA must do the following:
  - (a) Ensure that the staff has evaluated the request to determine whether the burden imposed on the licensee by the information request is justified, commensurate with the potential safety or security significance of the issue to be addressed. Such justification should consider the following:
    - (i) Whether the NRC already has the information being requested,
    - (ii) Whether the NRC can readily obtain the information absent a formal information request (for example, is the information available in the public domain),
    - (iii) How to minimize the population of entities from whom information is being requested, and
    - (iv) How to obtain the necessary information while minimizing the burden on requested entities.
  - (b) Approve the information request and the staff evaluation before transmittal of the request for information to a licensee.
2. The NRC staff's evaluations to demonstrate that an information request is justified must include at least the following elements:
  - (a) A statement of the problem describing the need for the requested information in terms of its potential safety benefit,
  - (b) The licensee actions required and an estimate of the burden on the licensee to develop a response to the information request, and
  - (c) An anticipated schedule for the NRC to analyze and act on the information.

## V. TRAINING PROGRAMS FOR BACKFITTING, FORWARD FITTING, AND INFORMATION COLLECTION REQUESTS

### A. Backfitting and Forward Fitting Training

The NRC ODs and RAs, informed by consultation with OGC and agency backfitting/forward fitting POCs, must plan for ~~backfitting~~ training for their staff that incorporates, at a minimum, the agency backfitting/forward fitting training program discussed below. NRC ODs and RAs may also provide additional backfit/forward fit training that provides additional detail in areas pertinent to the region or office. ~~The agency backfitting training program should include beginner and advanced levels, as well as refresher courses.~~

### B. Backfitting/Forward Fitting Agencywide Training Coordination

The Office of the Chief Human Capital Officer (OCHCO) must maintain and update a backfitting/forward fitting training program for the NRC staff. OCHCO will develop the backfitting/forward fitting training modules in consultation with OGC, CRGR, ~~and~~ program ODs, OE, RES, and NSIR. OCHCO will also consult and coordinate with the appropriate contact in the Office of the Chief Information Officer to ensure backfitting/forward fitting training modules are available online. The agency backfitting/forward fitting training program should include beginner introductory and advanced levels, as well as refresher courses.

### C. Information Collection Training

The NRC program offices should maintain information collection training and qualification for project managers with support from OGC. Regional inspection procedures and qualification do not apply to this training requirement.

## VI. ACRONYMS

10 CFR	Title 10 of the <i>Code of Federal Regulations</i>
ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act of 1954, as amended
BTP	Branch Technical Position
CAL	Confirmatory Action Letter
COL	Combined License
CP	Construction Permit
CRGR	Committee To Review Generic Requirements

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DC	Design Certification
DCR	Design Certification Rule
DEDO	Deputy Executive Director for Operations
DH	Directive Handbook
EDO	Executive Director for Operations
ESP	Early Site Permit
GDC	General Design Criterion/criteria
ISFSI	Independent Spent Fuel Storage Installation
LAR	License Amendment Request
LB	Licensing Basis
LR	License Renewal
LRA	License Renewal Application
LWA	Limited Work Authorization
MD	Management Directive
ML	Manufacturing License
MRS	Monitored Retrievable Storage
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission
NRO	Office of New Reactors
NRR	Office of Nuclear Reactor Regulation
NSIR	Office of Nuclear Security and Incident Response
NUREG	NRC Technical Report Designation
NUREG/BR	NUREG Brochure
OCHCO	Office of the Chief Human Capital Officer
OD	Office Director
OE	Office of Enforcement
OGC	Office of the General Counsel

OL	Operating License
PDC	Principal Design Criteria
POC	Point of Contact
PRA	Probabilistic Risk Assessment
RA	Regional Administrator
RES	Office of Nuclear Regulatory Research
RG	Regulatory Guide
SDA	Standard Design Approval
SE	Safety Evaluation
SECY	Office of the Secretary
SER	Safety Evaluation Report
SLR	Subsequent License Renewal
SRM	Staff Requirements Memorandum
SSC	Structure, system, and component
TR	Topical Report
UFSAR	Updated Final Safety Analysis Report

## EXHIBITS

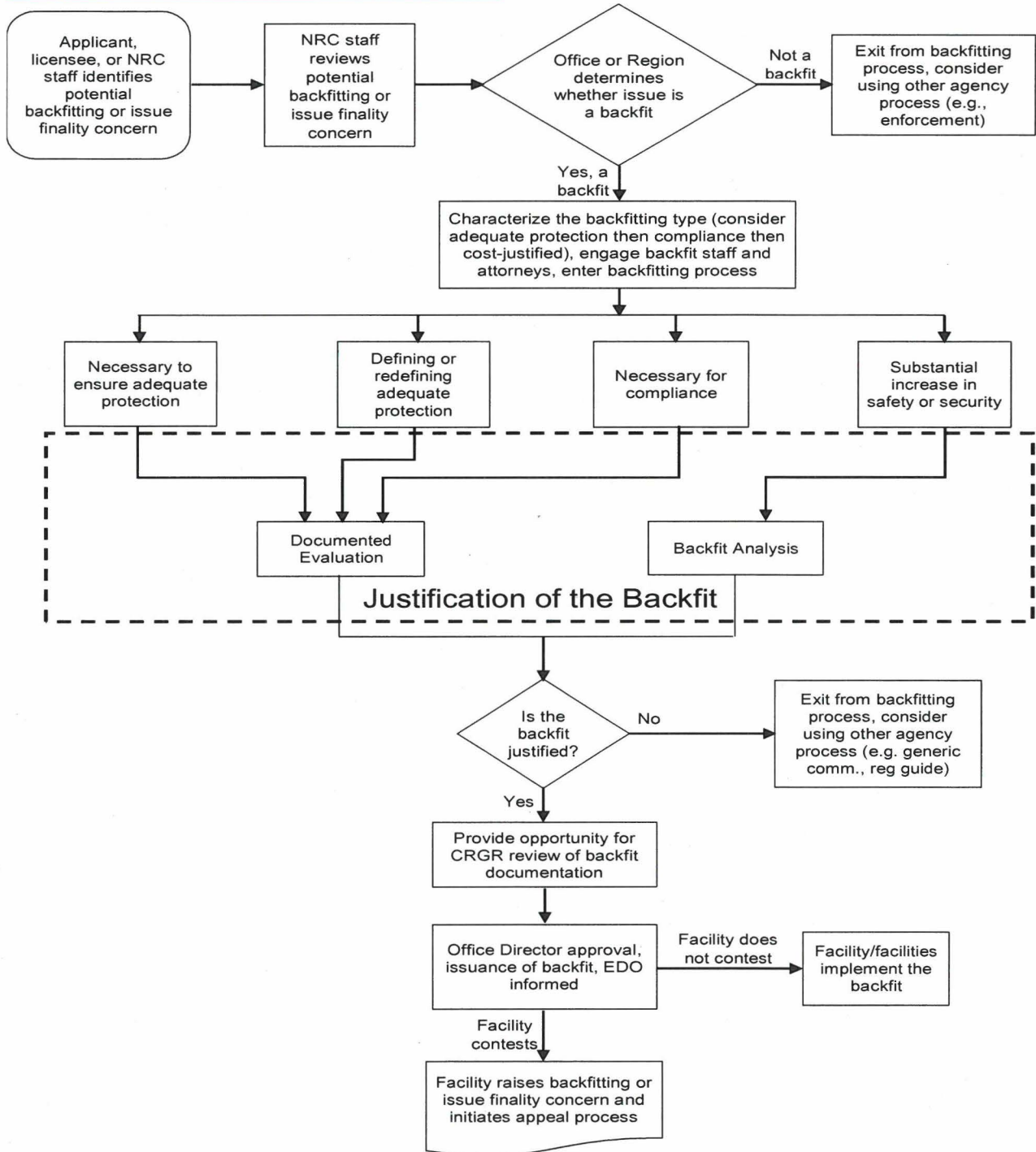
### EXHIBIT 1 NRC Internal Backfitting, Forward Fitting, and Issue Finality Flowchart

Revise "Exit from backfitting process consider using other . . ." to "Issue dropped: document outcome"

Include "forward fitting" each time "backfitting" is used.



Include "forward fit" each time "backfit" is used.

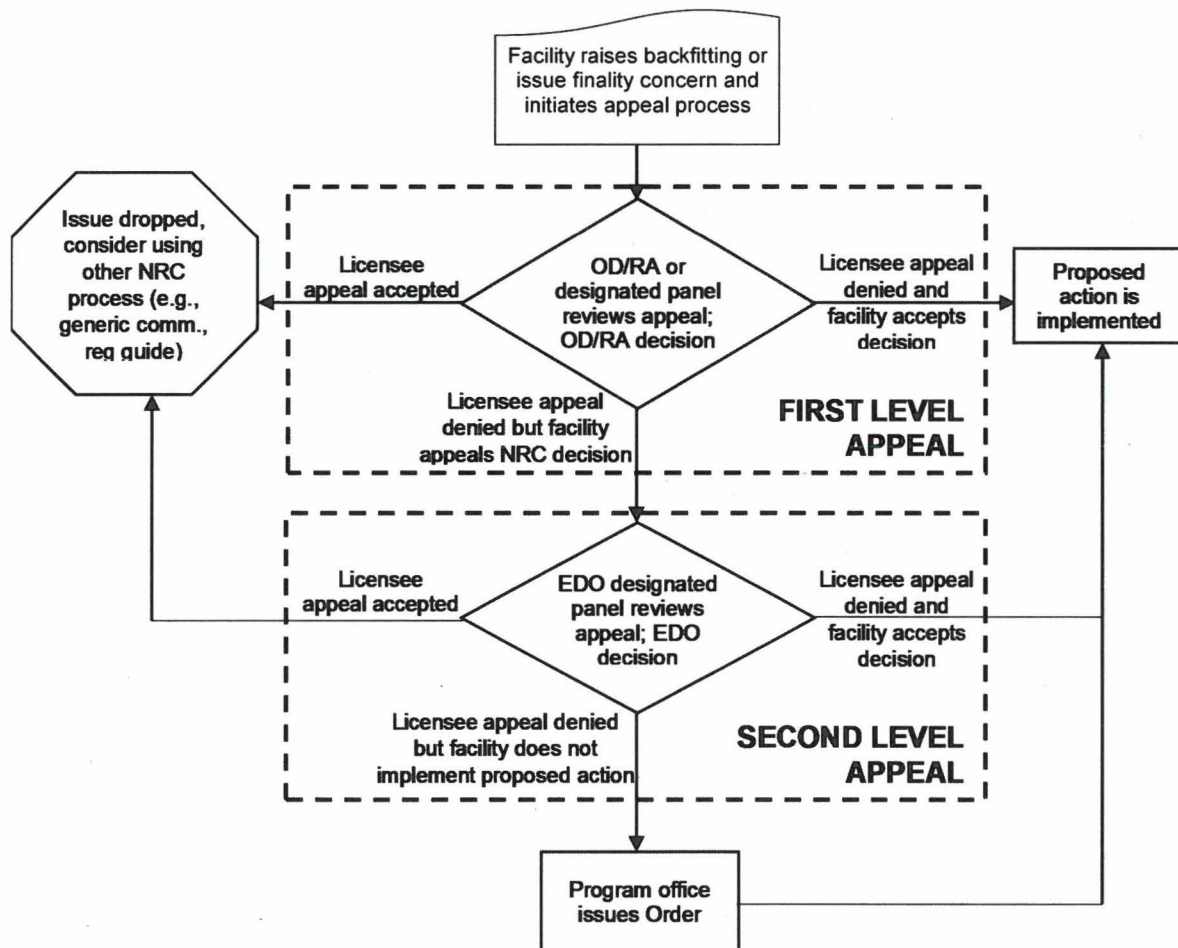


**EXHIBIT 2 NRC Internal Backfitting and Issue Finality Flowchart**

Revise octagon on far left to read "Issue dropped: document outcome."

Include "forward fitting" each time "backfitting" is used.

Include "forward fit" each time "backfit" is used.



**EXHIBIT 3 NRC Backfitting Requirements**

<b>Affected Entities</b>	<b>Backfitting/Issue Finality Regulation</b>
Power Reactors (licensed under 10 CFR Part 50)	10 CFR 50.109
Power Reactors (permitted, certified, licensed or approved under 10 CFR Part 52)	10 CFR 50.109 and 10 CFR Part 52 (as noted below)
Early Site Permit (ESP)	10 CFR 52.39 (term of ESP) 10 CFR 52.31 (renewal)
Standard Design Certification Rule (DCR)	10 CFR 52.63 (term of DCR) 10 CFR 52.59 (renewal)
Combined License (COL)	10 CFR 52.83 (referenced NRC approvals) 10 CFR 52.98 (term of COL)
Standard Design Approval	10 CFR 52.145
Manufacturing License (ML)	10 CFR 52.171 (term of ML) 10 CFR 52.179 (renewal)
Licensees authorized to possess special nuclear material above a critical mass	10 CFR 70.76, Subpart H
Independent Spent Fuel Storage Installation	10 CFR 72.62
Gaseous Diffusion Plant	10 CFR 76.76

**RESPONSE SHEET**

**TO:** Annette Vietti-Cook, Secretary  
**FROM:** Commissioner Wright  
**SUBJECT:** SECY-18-0049: Management Directive and Handbook 8.4, "Management of Backfitting, Issue Finality, and Information Collection"

Approved  X  Disapproved      Abstain      Not Participating    

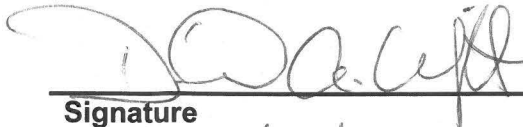
**COMMENTS:** Below  X  Attached  X  None    

I appreciate the staff's efforts to revise Management Directive (MD) 8.4 and its companion Directive Handbook (DH) to ensure consistent implementation of the agency's backfitting requirements. The staff's proposed revisions generally accomplish the objectives of providing regulatory stability, ensuring appropriate application of the backfit and issue finality rules, supporting reasoned and informed decision-making, and improving transparency. However, I believe the MD and DH should be further streamlined, more fully incorporate the guidelines and interpretations outlined in COMSECY-16-0020, and provide guidance on the application of forward-fits. The Chairman's proposed edits address these areas. Therefore, I approve the Chairman's edits to the MD and DH. I also believe further clarification on forward-fits would promote regulatory stability and transparency and have included additional edits on forward-fits, as indicated in the attached.

I view these edits as a continuation of the significant efforts made over the past three years related to backfit. I appreciate the staff's comprehensive efforts in this area, including providing backfit refresh training, implementing the Committee to Review Generic Requirements' assessment, and documenting necessary updates and improvements to the backfitting process.

**Entered in STARS**

Yes  ✓   
No    

  
\_\_\_\_\_  
Signature  
 2/22/19   
\_\_\_\_\_  
Date

significant regulatory actions. The NRC requires regulatory analyses for a broader range of regulatory actions than for significant rulemakings as defined in E.O. 12866. In general, each NRC office should ensure that all mechanisms used by the NRC staff to establish or communicate generic requirements, guidance, requests or staff positions that would affect a change in the use of resources by its licensees include an accompanying regulatory analysis. This requirement applies to actions initiated internally by the NRC or by a petition to the NRC. These mechanisms include rules, bulletins, generic letters, regulatory guides, orders, standard review plans, branch technical positions and standard technical specifications.

If the agency issues a new or modified regulatory staff position (e.g., a revision to regulatory guidance) and the prior regulatory staff position is no longer available for use by current licensees, the new or modified regulatory staff position should include a regulatory analysis.

If the staff imposes a new or modified regulatory staff position as part of the approval of a licensing action for a current licensee, and the prior regulatory staff position is available for use by current licensees and applicable to the licensing action under review, the staff should perform a site-specific regulatory analysis.

- d) If a licensee believes that the staff has incorrectly followed this process in imposing a forward fit, the licensee may use the backfitting appeals process described in Section III.F of this Management Directive to challenge the forward fit, as contemplated by the Statement of Considerations for the 1985 Revision of Backfitting Process for Power Reactors.<sup>8</sup>
- e) Forward fits generally do not include instances when an applicant files an initial licensing application for a new facility. However, for light-water reactor (LWR) facilities, § 50.34(d), § 52.17(a)(1)(xii), § 52.47(a)(9), § 52.79(a)(41), § 52.137(a)(9), and § 52.157(f)(30) establish the version of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," (the SRP) that applicants should be anticipated to reasonably rely upon in the development of their applications. Any change in requirements or regulatory staff positions from that version of the SRP interpreting the Commission's requirements should follow the same reasoned decisionmaking process as a forward fit.

<sup>8</sup> 50 FR 38097, 38101, September 20, 1985.