

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

MD 8.4 MANAGEMENT OF BACKFITTING, DT-19-15
FORWARD FITTING, ISSUE FINALITY,
AND INFORMATION REQUESTS

Volume 8: Licensee Oversight Programs

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EXECUTIVE SUMMARY

Management Directive (MD) 8.4, "Management of Facility-Specific Backfitting and Information Collection," is retitled and revised to clarify roles and responsibilities for management of backfitting, forward fitting, issue finality, and information 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 and select nuclear materials facilities; the issue finality provisions of 10 CFR Part 52 for nuclear power reactors; and the provisions of 10 CFR 50.54(f) and the corresponding requirements in 10 CFR Parts 52, 70, 72, and 76.

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

TABLE OF CONTENTS

I. POLICY.....3

II. OBJECTIVES3

III. ORGANIZATIONAL RESPONSIBILITIES AND DELEGATIONS OF AUTHORITY.....4

A. Executive Director for Operations (EDO).....4

B. Director, Office of Nuclear Reactor Regulation (NRR); Director, Office of New Reactors (NRO); and Director, Office of Nuclear Material Safety and Safeguards (NMSS).....5

C. Regional Administrators (RAs).....6

D. Office of the General Counsel (OGC).....6

E. Committee to Review Generic Requirements (CRGR).....7

F. Director, Office of Nuclear Regulatory Research (RES).....8

G. Director, Office of Enforcement (OE).....8

H. Director, Office of Nuclear Security and Incident Response (NSIR).....9

I. Chief Human Capital Officer (CHCO).....9

J. Chief Information Officer (CIO).....9

IV. APPLICABILITY10

V. DIRECTIVE HANDBOOK10

VI. REFERENCES.....10

I. POLICY

It is the policy of the U.S. Nuclear Regulatory Commission (NRC or the Commission) to have an effective program that will ensure that backfitting¹ and forward fitting² of nuclear power reactor facilities and select nuclear materials facilities are appropriately documented and justified based on the backfitting provisions of applicable NRC regulations and the agency's backfitting and forward fitting policy and guidance. Additionally, the NRC must ensure information requests are appropriate as required by applicable NRC regulations.

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 rules and policies and the forward fitting 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

¹ 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 select nuclear materials facilities, the backfitting definitions in 10 CFR 70.76, "Backfitting," 72.62, "Backfitting," and 76.76, "Backfitting," are slightly different. The "issue finality" provisions in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," 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 Management Directive (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.

² A forward fit is defined in Section 1.B of the attached handbook.

both safety and security, beyond adequate protection, while avoiding any unjustified burden on the NRC, the public, or licensees when implementing a backfitting action.

- Ensure that backfitting applied to a nuclear power reactor facility or nuclear materials facility is appropriately justified and documented.
- Ensure that forward fitting a nuclear power reactor facility or nuclear materials facility is appropriately justified and documented.
- Ensure that NRC-proposed changes to previously approved Early Site Permits, Design Certifications, Standard Design Approvals, Combined Licenses, and Manufacturing Licenses are appropriately justified and documented.
- Ensure that any documented evaluation for an adequate protection backfit includes an imminent threat analysis.
- Ensure that any documented evaluation for a compliance backfit includes some consideration of costs.
- Ensure that any documented evaluation or 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.
2. Responsible for the NRC's forward fitting process and ensuring proper implementation of the forward fitting policy.
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 responsibility for facility-specific backfitting and forward fitting actions to the program Office Directors (ODs) and Regional Administrators (RAs), as appropriate.
5. Delegates information request authority and actions to the program ODs and RAs.
6. 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 and forward fitting analyses while coordinating with the Office of the General Counsel (OGC), other program offices, the Office of Nuclear Security and Incident Response (NSIR), the Office of Enforcement (OE), the Office of Nuclear Regulatory Research (RES), and regional offices, as appropriate.
3. Conduct an imminent threat analysis when the adequate protection exception is applied.
4. Provide the Committee to Review Generic Requirements (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.
5. Request CRGR review of potential facility-specific backfitting or forward fitting actions, as appropriate.
6. 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.
7. Ensure consistency among inspection procedures, regulations, office instructions, and current agency guidelines and policies.
8. Decide first-level licensee appeals on the imposition of all backfitting and forward fitting actions within the program office's area of responsibility.
9. 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.
10. Ensure entry into Agencywide Documents Access and Management System (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 the backfitting and forward fitting decisions publicly available, consistent with applicable requirements and guidance.
11. 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.

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12. 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.
 13. Ensure information requests are appropriate as required by applicable NRC regulations.

C. Regional Administrators (RAs)

1. Identify backfitting and forward fitting actions within the regions.
2. Conduct backfitting and forward fitting analyses while coordinating with OGC, NSIR, OE, RES, and the office directors of NRR, NRO, and NMSS, as appropriate.
3. Conduct an imminent threat analysis when the adequate protection exception is applied.
4. Provide the CRGR with an opportunity to review any required documented evaluation or backfit or forward fit analysis before final approval.
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 or forward fitting action.
6. Support the appropriate program office in processing licensee backfitting and forward fitting appeals that are within the regional area of responsibility.
7. 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.
8. 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.
9. 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.

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.
3. Advises staff about 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 during forward fitting identification, justification, imposition, and licensee appeal processes.
6. Provides legal advice and assistance for developing training regarding backfitting requirements and agency implementation.
7. Provides legal advice and assistance for information collections.
8. Maintains a backfitting/forward fitting Community of Practice with office POCs, including a backfitting/forward fitting site.

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.
2. Selects a sample of proposed backfitting and forward fitting actions for audit and ensures the actions are justified in accordance with regulations, guidance, and agency policies.
3. Reviews potential facility-specific backfits and forward fits as requested by program ODs and RAs.
4. Uses its discretion in deciding whether any review should require a formal staff presentation to the CRGR.
5. Ensures consistency among the offices and regions in implementing the provisions of the NRC's backfitting rules and policies and forward fitting 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.
6. Verifies that the responsible staff³ promptly enters backfitting and forward fitting decisions into ADAMS and makes them publicly available, consistent with applicable requirements and guidance.

³ The office or the region that initiated the backfitting action supports the program office (the Office of Nuclear Reactor Regulation, the Office of Nuclear Material Safety and Safeguards, or the Office of New Reactors) 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.

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.
8. Participates in Backfitting Review Panels at the request of the EDO.
9. Coordinates with the Office of the Chief Human Capital Officer, OGC, RES, NSIR, OE, the regions, and program offices to ensure that Human Resources Training and Development 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.

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.
3. Provides administrative support for routine CRGR activities.
4. Ensures appropriate training is available to the RES staff.

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.
3. Ensures appropriate training is available to the OE staff and ensures OE staff performance is in accordance with current agency guidelines and policies.
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.

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

1. Identifies any potential security or emergency preparedness backfitting or forward fitting actions.⁴
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 facilities that pertain to the common defense and security or emergency preparedness.
3. Ensures consistency of security and emergency preparedness inspection procedures with regulations and current agency guidelines and policies.
4. Consults, coordinates with, and provides support to program ODs, as necessary, to resolve issues with security-related backfitting and forward fitting actions. The Director, NSIR, supports the program ODs and RAs, as appropriate, in processing security-related backfits and forward fits, including the resolution of licensee appeals.
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.
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.

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.

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 requests to ensure compliance with the Paperwork Reduction Act.

⁴ Throughout this MD, security- and emergency preparedness-related backfitting may be referred to as security backfitting.

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 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 and forward fitting management programs. 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 Part 50, "Domestic Licensing of Production and Utilization Facilities."
- 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 50.55a, "Codes and Standards."
- 10 CFR 50.59, "Changes, Tests, and Experiments."
- 10 CFR 50.90, "Applications for Amendment of License, Construction Permit, or Early Site Permit."
- 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 Part 70, "Domestic Licensing of Special Nuclear Material."
- 10 CFR Part 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 4, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," and all Appendices.

"Revision of Backfitting Process for Power Reactors," 50 FR 38097 (September 20, 1985).

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 – 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](#)).

Staff Requirements Memorandum, SECY-18-0049, "Staff Requirements— SECY-18-0049 – Management Directive and Handbook 8.4, Management of Backfitting, Issue finality, and Information Collection," dated May 29, 2019 (ADAMS Accession No. [ML19149A294](#)).

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

United States Code

Administrative Procedure Act (5 U.S.C. 551 et seq.).

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

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

United States Supreme Court Decision

Michigan v. Environmental Protection Agency, 135 S. Ct. 2699 (2015).

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

TABLE OF CONTENTS

I. INTRODUCTION TO BACKFITTING, FORWARD FITTING, AND INFORMATION REQUESTS..... 3

A. Backfitting 3

B. Forward Fitting 6

C. Information Requests..... 8

D. Coordination and Communication 9

E. Recordkeeping..... 9

II. BACKFITTING APPLICABILITY..... 10

A. Regulatory Changes Subject to the Backfit Rule..... 10

B. Nonapplicable Regulatory Changes 10

III. BACKFITTING POLICY..... 12

A. Adequate Protection Backfitting..... 12

B. Compliance Backfitting 14

C. Cost-Justified Substantial Increase in Protection Backfitting 18

D. Additional Considerations for Backfitting and Forward Fitting..... 19

E. Scheduling of Backfitting and Forward Fitting Implementation 20

F. Appeals of Backfitting and Forward Fitting Decisions 20

G. Exceptions 22

H. Assessment of the Overall Effectiveness of the NRC’s Backfit and Forward Fit Management Program 22

IV. INFORMATION REQUESTS 23

A. NRC Regulations for Information Requests 23

B. Evaluation 23

V. TRAINING PROGRAMS FOR BACKFITTING, FORWARD FITTING, AND INFORMATION REQUESTS..... 24

A. Backfitting and Forward Fitting Training 24

B. Backfitting/Forward Fitting Agencywide Training Coordination 24

C. Information Collection Training 24

VI. ACRONYMS..... 25

VII. EXHIBITS 27

EXHIBIT 1 NRC Internal Backfitting and Issue Finality Flowchart 27

EXHIBIT 2 NRC Internal Backfitting and Issue Finality Flowchart 28

EXHIBIT 3 NRC Backfitting Requirements..... 29

I. INTRODUCTION TO BACKFITTING, FORWARD FITTING, AND INFORMATION REQUESTS¹

A. Backfitting

1. Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.109, “Backfitting,” provides the following definition of “backfitting”:

Backfitting 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

2. Substantially similar definitions are provided in § 70.76, “Backfitting,” § 72.62, “Backfitting,” and § 76.76, “Backfitting.” 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. Section 72.62 of 10 CFR defines the term backfitting for an independent spent fuel storage installation (ISFSI) or monitored retrievable storage (MRS). Section 76.76 of 10 CFR defines the term backfitting for a gaseous diffusion plant.
3. In 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” “issue finality” exists with respect to prior U.S. Nuclear Regulatory Commission (NRC or the Commission) 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.
4. Backfitting is an integral part of the regulatory process. To ensure that proposed changes are adequately justified and defined, a backfitting action is implemented only after formal and systematic review. Backfitting normally occurs when the agency imposes a new or changed regulation or requirement upon a facility or facilities through rulemaking or order. Backfitting concerns also arise when the agency communicates a new or changed staff position interpreting applicable requirements imposed on facilities. A new or changed staff position may arise in several regulatory contexts, including facility inspections, license amendment reviews, or issuance of guidance documents. In this Directive Handbook (DH), the

¹ This section provides a high-level overview of the backfit and forward fit processes 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.

- terms “backfit” and “backfitting” mean backfitting as defined in 10 CFR 50.109, 70.76, 72.62, and 76.76, and changes affecting issue finality under 10 CFR Part 52. The only parts of the NRC’s regulations that contain backfitting or issue finality provisions are 10 CFR Part 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.” The protections in the backfitting provisions further NRC compliance with the requirements of the Administrative Procedure Act (APA) regarding reasoned decisionmaking.
5. 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 APA, 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.
 6. The NRC’s backfitting actions can be either generic or facility-specific.²
 - (a) Generic backfitting actions affect a class or classes of licensees and can include the imposition of new or revised requirements through rulemaking, 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.

² Hereafter, the term “facility” will be used to mean a nuclear power reactor; an early site permit, design certification, combined license, standard design approval, or manufacturing license for a power reactor; or a materials facility such as an ISFSI, fuel facility, gaseous diffusion plant, or an MRS installation.

7. There are three principal justifications the agency relies on to impose a backfit: adequate protection, compliance, and a cost-justified substantial increase³ in protection.⁴ 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.
8. The Supreme Court's decision in *Michigan v. Environmental Protection Agency*, 135 S. Ct. 2699 (2015), reflects the view that, under the 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 decisionmaking requirement compels some consideration of cost.
9. The backfitting provisions in 10 CFR 50.109 apply to combined licenses, standard design approvals, and manufacturing licenses to the extent that they do not overlap the applicability of 10 CFR Part 52 issue finality provisions.
10. This Management Directive (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 to ensure consistent implementation.
11. Any change to an NRC staff position that the NRC intends to communicate by any means to a licensee(s) as being applicable to its 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, or generic communications or through staff interactions with licensee personnel. The Office of Nuclear Reactor Regulation (NRR), Office of New Reactors (NRO), or Office of Nuclear Material Safety and Safeguards (NMSS) office director (OD) or regional administrator (RA) responsible for the staff position and affected facility or facilities

³ See 50 *Federal Register* (FR) 38097, September 20, 1985.

⁴ The issue finality provisions of 10 CFR Part 52 include additional justifications 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 or to contribute to the increased standardization of the design certification.

- 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).
12. In support of the Commission's probabilistic risk assessment (PRA) policy statement⁵ 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.
 13. Exhibits 1 and 2 in this handbook are flowcharts that illustrate the NRC's program for processing backfits and backfit appeals.

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.
2. In deciding whether a forward fit is appropriate, the NRC staff should also take the following factors into account:
 - (a) As noted in Section I.A.8 of this DH, when the NRC imposes new requirements or regulatory staff positions interpreting requirements not needed to ensure adequate protection, the APA requires some consideration of cost. Thus, if the

⁵ Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement (60 FR 42622; August 16, 1995).

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 facilities. 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 10 CFR 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," Revision 4 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 [E.O.] 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 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, then 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, then 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 and forward fitting appeals process described in Section III.F of this DH to challenge the forward fit, as contemplated by the Statement of Considerations for the 1985 Revision of Backfitting Process for Power Reactors final rule.⁶
- (e) Forward fits generally do not include instances when an applicant files an initial licensing action for a new facility. For light-water reactor (LWR) facilities, § 50.34(h), § 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 [SRP] for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," 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.

C. Information Requests

1. The provisions of 10 CFR 50.54(f) require power reactor licensees to respond to information requests from the 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 significance of the issue to be addressed. For additional information regarding appropriate use of 10 CFR 50.54(f), see Section IV of this DH.
2. Requests for information for power reactors 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 requirements for select materials licensees are contained in 10 CFR 70.22(d), 10 CFR 72.62(d), and 10 CFR 76.70(e).
3. This MD and DH reflect the policy for requests for information under these provisions.

⁶ 50 FR 38097, 38101, September 20, 1985.

D. Coordination and Communication

For effective implementation of the NRC's backfitting, forward fitting, and information 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 for 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, backfit analysis, or forward fit analysis) has been prepared and approved, the CRGR was offered an opportunity to review the documentation, and written feedback was considered. Program ODs shall ensure backfitting and forward fitting actions are consistently implemented throughout the regions.

E. Recordkeeping

1. Offices and regions directly involved in backfitting, forward fitting, or information 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.
2. The office or region proposing information requests, backfitting actions, or forward fitting actions must administratively manage each 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.
3. 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. Regulatory Changes Subject to the Backfit Rule

1. An NRC action is considered backfitting when the NRC changes any requirements through rulemaking or order, or imposes a new or modified staff position that interprets requirements and would result in the modification or addition to structures, systems, and components, the design of a facility, the design approval or manufacturing license 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., Regulatory Guides or NRC-endorsed industry topical reports) that is not already within the LB for the identified purpose, then the staff's communication of that expectation is considered backfitting or forward fitting. As discussed in Section I.B of this DH, forward fits do not constitute backfits but must meet additional specified criteria and are subject to the backfit appeals process.
3. A relaxation is the modification of a regulatory requirement or staff position that reduces the obligations of a licensee or class of licensees. A relaxation may provide licensees the option of continuing as previously licensed (i.e., status quo) or adhering to the new "relaxed" regulatory requirement or staff position. If a relaxation does not provide for the status quo option, then it is mandatory, and the relaxation is considered backfitting.

B. Nonapplicable Regulatory Changes

1. The following is a non-exhaustive list of examples of regulatory actions that generally do not meet the definition for backfitting:
 - (a) Confirmatory action letters because they involve voluntary actions a licensee commits to take, which are agreed upon by 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 NRC discretion in their implementation;
 - (d) Voluntary licensee submittals subject to the limitations discussed in Section I.B. of this DH;
 - (e) Issuance of a notice of violation for an improper change under 10 CFR 50.59, "Changes, Tests, and Experiments," resulting in a modification to a facility;
 - (f) Licensee changes or plant modifications that expand the plant capabilities or improve plant efficiencies or performance that are not mandated by the NRC;

- (g) Non-mandatory relaxations of staff positions or regulations;
 - (h) Changes or updates to American Society of Mechanical Engineers Boiler and Pressure Vessel Code, Section XI, that are incorporated into 10 CFR 50.55a, "Codes and Standards;"
 - (i) Plant or procedural changes to comply with industry or professional standards not mandated by the NRC;
 - (j) Current and future applications for an NRC license, with two exceptions described in Section II.B.2 of this DH;
 - (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;
 - (l) Changes resulting from a licensee's commitment management program;
 - (m) Licensee changes to its plant under 10 CFR 50.59 or other existing change control requirements; and
 - (n) Plant or procedural corrective actions to restore the LB or adherence to the license and thereby provide compliance with governing requirements.
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 early site permit) or NRC regulatory approval (e.g., a design certification), or both, with specified issue finality provisions. The second exception occurs when a 10 CFR Part 50 power reactor operating license applicant holds a construction permit or limited work authorization. Section 50.109 would apply to the matters covered by the construction permit or limited work authorization. See also the discussion on the use of the SRP for review of LWR applications in Section I.B.2(e) of this DH.

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.⁷ 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 necessary for adequate protection, a backfit analysis is not required and costs cannot be considered (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.⁸ 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 the 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

⁷ Like backfitting, for matters of potential forward fitting the staff must first consider whether the issue is one of adequate protection. Instances of adequate protection forward fitting should be extremely rare. This is because the NRC considers 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.

⁸ 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).

backfits, considering public comments provided on the proposed rule and the lessons learned through the implementation of the previous order requirements.

2. To issue each 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 (i.e., the applicable portions of its 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 act 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. 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.
4. It is the NRC's policy⁹ 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.
5. Under 10 CFR 50.109(a)(5), 52.39(a)(ii), 52.63(a)(1)(ii), 52.171(a)(1), 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 public health and safety.

⁹ In Staff Requirements Memorandum-SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," dated May 27, 1999 (ADAMS Accession No. ML003752062), the Commission approved the staff's recommendation that relying on voluntary industry initiatives to ensure adequate protection would be inappropriate since they would be based on commitments rather than requirements.

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6. 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 was in place at the time of the decision at issue. 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 omission or mistake of fact (see item 6 of this section). 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,¹⁰ 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.
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 been incorporated into the license, and directly relate to how the licensee complies with a requirement.

¹⁰ Safety margin may not be quantifiable. For example, meeting environmental qualification 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 during events that are important to plant risk and are less severe than what the environmental qualifications envelop).

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.
5. As noted in paragraph I.A.8, 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 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.
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,
 - (ii) The regulations reflected in the LB at the time of implementation that were applicable to the 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.

7. The compliance exception should not be applied to the following:
 - (a) 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
 - (b) Recharacterizations of whether a 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.
8. The following policy concerns the use of the compliance exception to mandate consistency with the general design criteria (GDC).
 - (a) The NRC must not rely on the GDC requirements for pre-GDC licensing actions (those licenses or construction permits issued before the issuance of the GDC (before 1971)), unless the NRC has made the GDC a requirement for that licensee.
 - (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 when the GDC is prescriptive in nature and the technical specifications and other licensee requirements derived from the principal design criteria do not speak to the matter in question.

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, in part, compliance with the requirements in the 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 omission or mistake of fact. 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 omission or mistake of fact at the time of approval.

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 an 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 the applicable exemption provision, such as 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."
10. 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 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.
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, "Applications for Amendment of License, Construction Permit, or Early Site Permit," 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 impose a backfit 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 considering 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 Section I.A.8 of this DH, 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 the applicable backfitting or issue finality regulations and NUREG-1409.

- (a) Once the NRC determines that backfitting 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. 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.

- (c) 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 considering the increased protection.

D. Additional Considerations for Backfitting and Forward Fitting

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 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 and discuss previous regulatory staff positions and enforcement precedent. A lack of historical staff position could be indicative of a new staff position and therefore subject to backfitting and forward fitting provisions and guidance. 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 and Forward Fitting Implementation

1. After the appropriate OD (NRR, NRO, or NMSS) or RA has approved a facility-specific documented evaluation, 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. Adequate protection backfits 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 or 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. 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.
4. A facility-specific backfitting action may be imposed by an 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 and Forward Fitting Decisions

1. As stated in Section I.B.2(d) of this DH, 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.¹¹
2. By NRC policy, the NRC affords licensees an opportunity to appeal any staff action that does not comport with the agency's backfit rules at two levels: a First-Level Appeal to the OD or RA and a Second-Level Appeal to the EDO.

¹¹ 50 FR 38097, 38101, September 20, 1985.

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.
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.
5. The First-Level Appeal process must be 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. All backfitting appeals are overseen by a program OD, who will coordinate the review with the RA overseeing the affected facility, and the Office of Nuclear Security and Incident Response (NSIR), as applicable.
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 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 sustained, the licensee may implement the action or submit a Second-Level Appeal.

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 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, then the action must not be treated further within the context of backfitting and 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, regardless of whether 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 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 REQUESTS

A. NRC Regulations for Information Requests

1. Information requests to power reactor licensees are made pursuant to 10 CFR 50.54(f). Under 10 CFR 50.54(f), the NRC can request its licensees to provide information to enable the Commission to determine whether 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.
2. 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 requests for select 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 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. Evaluation

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 evaluation 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 cost to 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 REQUESTS

A. Backfitting and Forward Fitting Training

The NRC ODs and RAs, informed by consultation with OGC and agency backfitting/forward fitting points-of-contact, must plan for 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 training that provides additional detail in areas pertinent to the region or office.

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, program ODs, OE, the Office of Nuclear Regulatory Research, 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 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
APA	Administrative Procedure Act
COL	Combined License
CRGR	Committee to Review Generic Requirements
DC	Design Certification
DH	Directive Handbook
EDO	Executive Director for Operations
ESP	Early Site Permit
GDC	General Design Criterion/criteria
ISFSI	Independent Spent Fuel Storage Installation
LB	Licensing Basis
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

PRA	Probabilistic Risk Assessment
RA	Regional Administrator
SECY	Office of the Secretary

VII. EXHIBITS

EXHIBIT 1 NRC Internal Backfitting and Issue Finality Flowchart

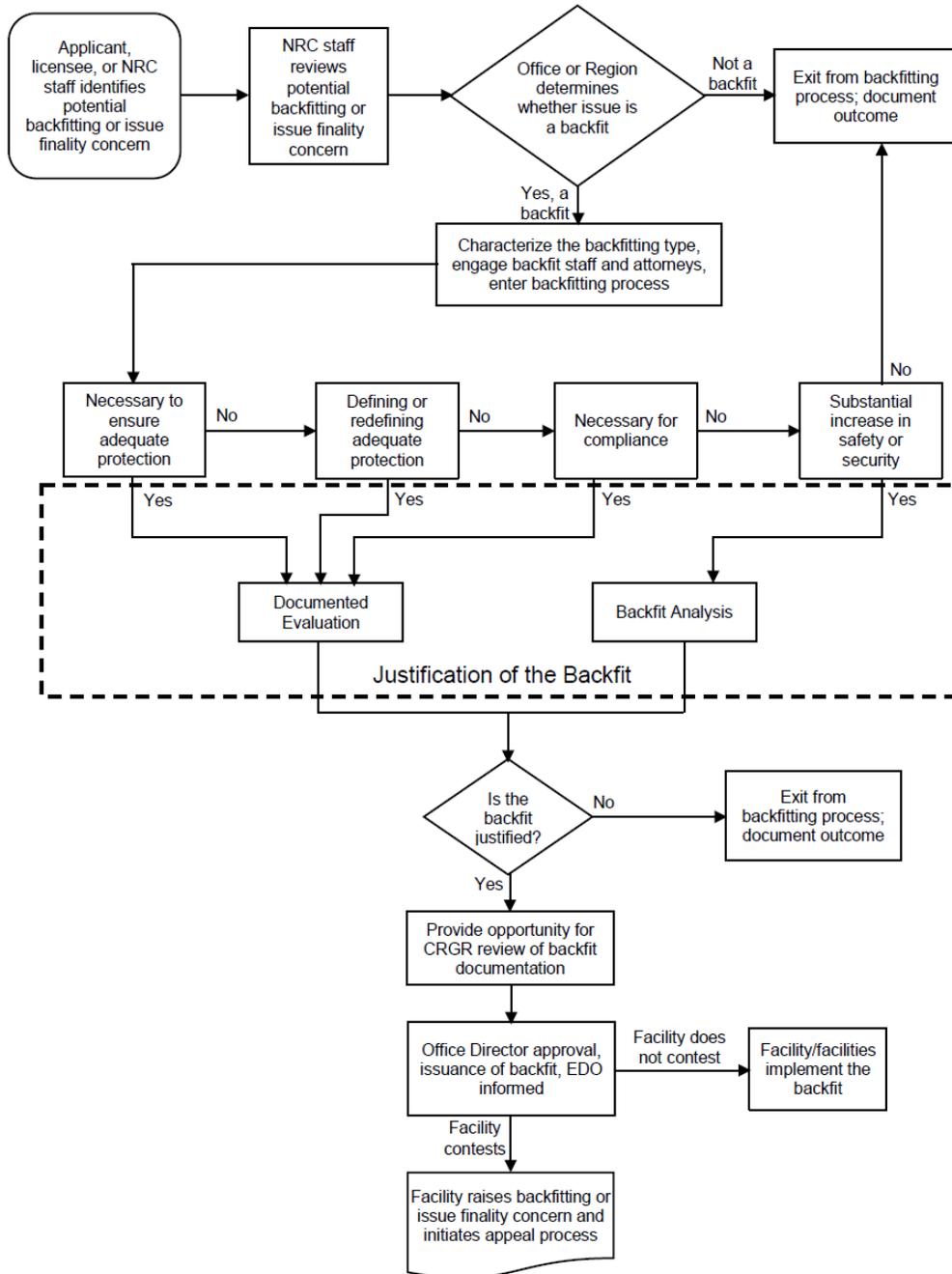


EXHIBIT 2 NRC Internal Backfitting and Issue Finality Flowchart

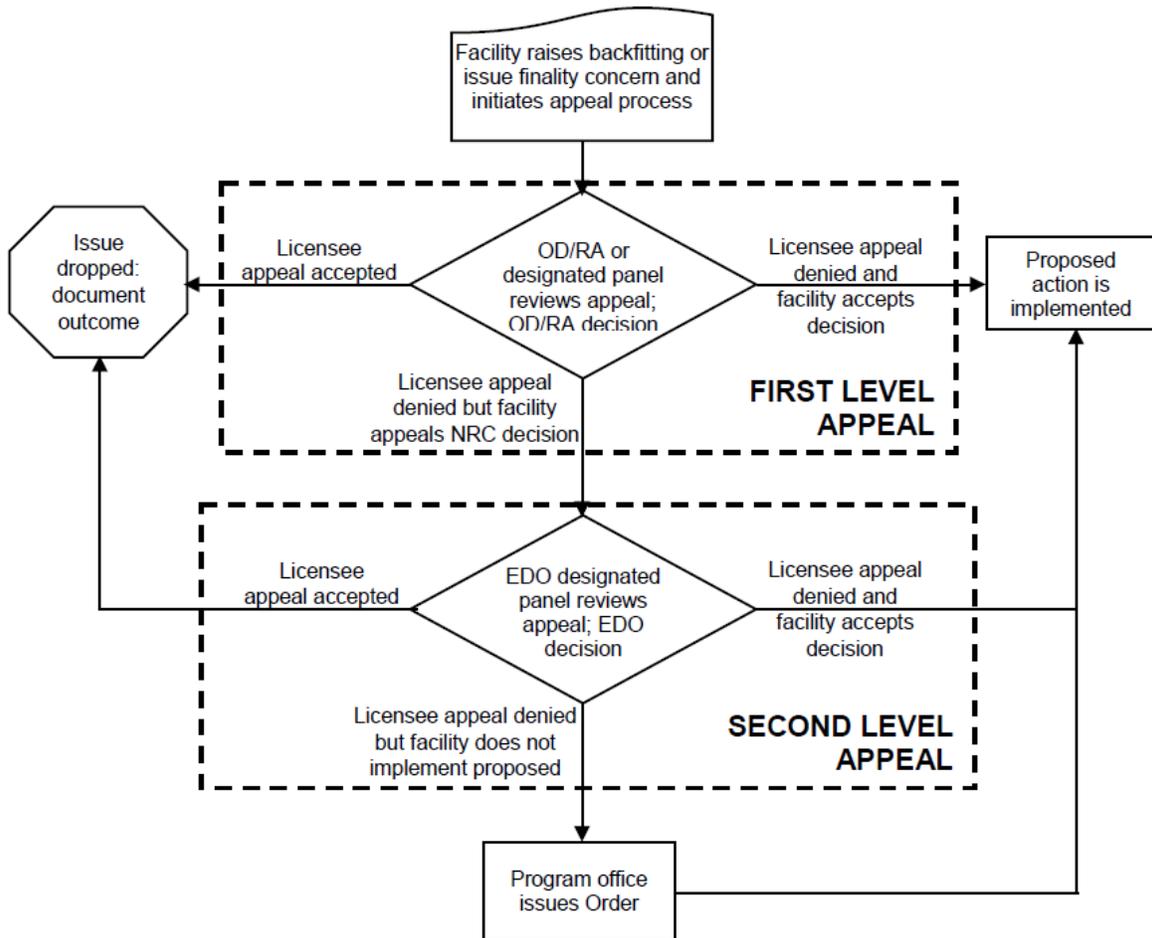


EXHIBIT 3 NRC Backfitting Requirements

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 (DC)	10 CFR 52.63 (term of DC) 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