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United States Nuclear Regulatory Commission
Protecting People and the Environment

NUREG-1409, Revision 1

Backfitting Guidelines

Draft Report for Comment

Office of Nuclear Reactor Regulation

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Backfitting Guidelines

Draft Report for Comment

Manuscript Completed: March 2020
Date Published: March 2020

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Office of Nuclear Reactor Regulation

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Any interested party may submit comments on this report for consideration by the U.S. Nuclear Regulatory Commission (NRC) staff. Comments may be accompanied by additional relevant information or supporting data. Submitted comments need to specify the report number, **"NUREG-1409, Revision 1,"** and be sent by the end of the comment period specified in the *Federal Register* notice announcing the availability of this report.

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ABSTRACT

NUREG-1409, "Backfitting Guidelines," Revision 1, provides guidance to the U.S. Nuclear Regulatory Commission (NRC) staff on the implementation of the backfitting and issue finality provisions in Title 10 of the *Code of Federal Regulations* (10 CFR) Chapter I and the backfitting, issue finality, and forward fitting policies provided in Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," dated September 20, 2019.

Backfitting occurs when the NRC imposes new or changed regulatory requirements or staff interpretations of the regulations or requirements on nuclear power reactor licensees, certain nuclear power reactor applicants, or select nuclear materials licensees. Backfitting is an integral part of the regulatory process and may be needed when the staff addresses safety or security issues. The NRC may take a backfitting action only after conducting a formal, systematic review to ensure that the action is defined and justified. This process ensures discipline, predictability, and optimal use of NRC and licensee resources. The backfitting requirements are in 10 CFR 50.109, "Backfitting," 70.76, "Backfitting," 72.62, "Backfitting," and 76.76, "Backfitting." Provisions analogous to the backfitting requirements, referred to as issue finality provisions, are set forth in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

Forward fitting occurs when the NRC conditions its approval of a licensee-initiated request for a licensing action on the licensee's compliance with a new or modified requirement or staff interpretation of a requirement that the licensee did not request. The new or modified requirement or staff interpretation must result in, generally, a change to the licensee's systems, structures, components, design, approval, procedures, or organization.

The NRC issued the previous version of this NUREG in 1990, but the 1990 document did not address the backfitting requirements in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," 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," or 10 CFR Part 76, "Certification of Gaseous Diffusion Plants"; the issue finality provisions in 10 CFR Part 52; or the Commission's forward fitting policy in Management Directive 8.4, most of which were developed after 1990. This version of NUREG-1409 is a substantial revision of the 1990 version and addresses all backfitting and issue finality provisions in the regulations listed above and the Commission's backfitting, issue finality, and forward fitting policies.

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EXECUTIVE SUMMARY

This document presents guidance on the implementation of the U.S. Nuclear Regulatory Commission (NRC) regulations on backfitting and issue finality and the Commission's policies on backfitting, issue finality, and forward fitting. Backfitting occurs when the NRC imposes certain new or changed regulatory requirements or staff positions interpreting requirements on nuclear power reactor licensees, select nuclear power reactor applicants, or select nuclear materials licensees. Backfitting is an integral part of the regulatory process and may be needed when the staff addresses safety or security issues. Issue finality is a concept similar to backfitting that applies only to the holders of certain nuclear power reactor-related approvals under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." Forward fitting occurs when the NRC imposes on a licensee certain new or revised requirements or staff interpretations of a requirement during its review of a licensee-initiated request for a licensing action. Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," dated September 20, 2019, describes the Commission's policies on backfitting, issue finality, and forward fitting.

Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.109, "Backfitting" (the Backfit Rule), provides backfitting provisions for nuclear power reactor licensees. It is the NRC's policy that nonpower production or utilization facilities licensed under 10 CFR 50.21, "Class 104 licensees; for medical therapy and research and development facilities," paragraphs (a) or (c), or 10 CFR 50.22, "Class 103 licenses; for commercial and industrial facilities," are not within the scope of the backfitting provisions. Backfitting provisions for select nuclear material licensees are contained in 10 CFR 70.76, "Backfitting," 72.62, "Backfitting," and 76.76, "Backfitting." Each of these provisions, as with the issue finality provisions in 10 CFR Part 52, requires that the NRC follow a formal, systematic process before imposing new or changed regulatory requirements or staff positions interpreting requirements on entities that are the subject of these regulations. This process ensures discipline, predictability, and optimal use of NRC and licensee resources.

The backfitting regulations address both generic and facility-specific backfitting actions for power reactor licensees and select materials licensees. The backfitting provision in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," defines a backfitting action 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...." The definitions of "backfitting" in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," and Part 76, "Certification of Gaseous Diffusion Plants," are very similar to the definition in 10 CFR Part 50. The definition of "backfitting" in 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," is limited to changes to the structures, systems, or components of, or the procedures or organization required to operate an independent spent fuel storage installation or monitored retrievable storage installation. Issue finality within 10 CFR Part 52 defines the changes the NRC can require for an approved facility license, permit, or design.

Although the specific backfitting provisions in the various parts of the NRC's regulations differ in detail, they are generally structured to allow backfitting actions, provided the actions are

supported by a backfit analysis or meet one of the exceptions to the requirement to perform a backfit analysis. The three exceptions are: (1) actions necessary to ensure adequate protection; (2) actions defining or redefining the level of protection considered adequate; and (3) actions necessary for compliance with NRC requirements or conformance with written licensee commitments (abbreviated as "the compliance exception"). If the NRC uses one of the exceptions, then it must provide a justification for invoking the exception. Otherwise, a backfit analysis must show that (1) the action will provide a substantial increase in the overall protection of the public health and safety or the common defense and security, and (2) the direct and indirect costs of implementing the backfitting action are justified in view of the increased protection.

The NRC is required under the Atomic Energy Act of 1954, as amended, to impose regulatory requirements that provide for reasonable assurance of adequate protection of public health and safety and the common defense and security. Accordingly, for proposed adequate protection actions that involve backfitting, the NRC does not need to consider other reasons justifying the backfitting action. Additionally, the NRC does not consider costs for these actions or forward fitting actions that involve adequate protection, unless there are multiple ways of implementing the new requirements. If the proposed backfitting action does not involve adequate protection, then the NRC should consider the compliance exception or determine through a backfit analysis whether the action is a cost-justified, substantial increase in overall protection. Backfitting and forward fitting justifications other than adequate protection must consider cost.

The NRC issued the previous version of NUREG-1409 in July 1990 and addressed the backfitting requirements in 10 CFR 50.109 but did not address those in 10 CFR Part 70, Part 72, or Part 76; the issue finality provisions in 10 CFR Part 52; or the forward fitting policy. This version of NUREG-1409 is a substantial revision of the 1990 version and addresses all backfitting and issue finality provisions and the forward fitting policy. References to backfitting in this document also include matters that address issue finality.

ABBREVIATIONS AND ACRONYMS

10 CFR	Title 10 of the *Code of Federal Regulations*
ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act of 1954, as amended
AEC	Atomic Energy Commission
ASME	American Society of Mechanical Engineers
CDF	core damage frequency
CFR	*Code of Federal Regulations*
CoC	Certificate of Compliance
COL	combined license
CRGR	Committee to Review Generic Requirements
DC	design certification
EDO	Executive Director for Operations
ESP	early site permit
FR	*Federal Register*
GDC	general design criterion/criteria
ISFSI	independent spent fuel storage installation
LWR	light-water reactor
MD	Management Directive
ML	manufacturing license
NCV	non-cited violation
NEI	Nuclear Energy Institute
NMSS	Office of Nuclear Material Safety and Safeguards
NOV	notice of violation
NRC	U.S. Nuclear Regulatory Commission
NRR	Office of Nuclear Reactor Regulation
NTTAA	National Technology Transfer and Advancement Act of 1995
NUREG	NRC technical report designation
NUREG/BR	NUREG brochure
OGC	Office of the General Counsel
OMB	Office of Management and Budget
PDC	principal design criteria
PRA	probabilistic risk assessment
SDA	standard design approval
SOC	statement of considerations
SRM	Staff Requirements Memorandum
SRP	Standard Review Plan
SSC	structure, system, and component
U.S.C.	United States Code

1 OVERVIEW OF BACKFITTING AND FORWARD FITTING

1.1 Introduction

This document provides the U.S. Nuclear Regulatory Commission (NRC) staff with guidance to ensure consistent implementation of the backfitting and issue finality provisions in Title 10 of the *Code of Federal Regulations* (10 CFR) Chapter I and the backfitting, issue finality, and forward fitting policies in Management Directive (MD) 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," dated September 20, 2019.[1] This guidance is intended for use by the NRC staff, is not legally binding, and does not contain or imply requirements for any licensee,[2] any holder of a standard design approval, or any design certification applicant after the NRC issues the applicable design certification rule under 10 CFR Part 52.

In 2016, the Executive Director for Operations (EDO) tasked the Committee to Review Generic Requirements (CRGR) with assessing the agency's backfitting requirements, policy, guidance, criteria, training, and knowledge management. In response, the CRGR hosted two public meetings to obtain stakeholder feedback on backfitting and the agency's backfitting process. On June 27, 2017, the CRGR issued a report on the NRC's backfitting process and recommended several actions. Subsequently, the NRC revised MD 8.4, this NUREG, NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," and the CRGR Charter to reflect policy updates, organizational changes, the latest judicial decisions, Commission direction, and the CRGR's process for reviewing backfitting activities.

This NUREG begins by describing the relevant regulations, terminology, policies, and processes associated with backfitting, forward fitting, and issue finality. Chapter 2 explains how to screen and justify potential backfitting actions. Chapter 3 explains how to screen and justify potential forward fitting actions. Chapter 4 sets forth the backfitting and forward fitting appeals process. Chapter 5 describes several NRC actions and processes and whether they may constitute backfitting or forward fitting. Chapter 6 provides the staff's recordkeeping and documentation obligations. Chapter 7 lists the references cited in this document. The appendices contain flowcharts, worksheets, and guides to assist the staff in working through potential backfitting or forward fitting actions.

In this NUREG, the NRC uses the terms "backfit" and "backfitting" generally to mean backfitting actions as defined in 10 CFR 50.109, "Backfitting," 70.76, "Backfitting," 72.62, "Backfitting," and 76.76, "Backfitting," and matters involving issue finality under 10 CFR Part 52.

[1] References to MD 8.4 in this NUREG include the MD and its associated Directive Handbook.

[2] For the purposes of this NUREG, the unqualified term "licensee" includes the holder of a power reactor limited work authorization, construction permit, or power reactor license issued under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities"; the holder of a license or permit issued under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants"; holder of a license for a fuel facility issued 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"; holder of a license for a spent fuel or radioactive waste storage facility issued 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"; holder of a certificate for a gaseous diffusion plant issued under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants"; and holder of one or more of these approvals while its facility is in a decommissioning phase, as applicable.

1.2 Backfitting and Issue Finality

The NRC uses the term "the Backfit Rule" to refer to the provisions in 10 CFR 50.109. The rule defines the term "backfitting" to mean the following for nuclear power reactors licensed under Parts 50 and 52:

> 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....

The Backfit Rule also provides the bases on which the NRC can justify taking backfitting actions. This rule is intended, in part, to provide predictability and stability to the NRC's regulatory processes. Before the NRC can impose certain requirements and positions, the staff must perform a formal, systematic review to ensure that it has properly defined and justified the proposed action. By limiting the changes that the NRC can make to a facility's licensing basis,[3] the Backfit Rule allows a licensee to operate a facility in accordance with its licensing basis and reasonably rely on the NRC to impose only justified changes to its license or facility. This reliability is part of the basis of the NRC's regulatory framework, as explained in the NRC's Principles of Good Regulation, as provided in the NRC's Strategic Plan for Fiscal Years 2018–2022 (NUREG-1614, Volume 7):

> Once established, regulation should be perceived to be reliable and not unjustifiably in a state of transition. Regulatory actions should always be fully consistent with written regulations and should be promptly, fairly, and decisively administered so as to lend stability to the nuclear operational and planning processes.

If the NRC initiates a change to the approved facility or programs described in the licensee's licensing basis, that change could be classified as backfitting.

The Backfit Rule also ensures reasoned and informed NRC decisionmaking, by requiring the NRC to justify the backfitting action, and transparency of the NRC's decisionmaking, by requiring the NRC to document its analysis of the backfitting action.

The U.S. Atomic Energy Commission issued the Backfit Rule for power reactors in 1970. The NRC revised the Backfit Rule in 1985 to provide specific standards for backfitting decisions, such as cost-justification and required documentation. The 1985 rule was vacated by the U.S. Court of Appeals for the D.C. Circuit in 1987 in *Union of Concerned Scientists v. NRC*.

[3] The Office of Nuclear Reactor Regulation (NRR) Office Instruction LIC-100, "Control of Licensing Bases for Operating Reactors," dated January 7, 2004, states that the licensing basis for a nuclear power reactor consists of three categories of information: (1) obligations (also referred to as regulatory requirements), which include regulations, orders, and the license; (2) mandated licensing basis documents (e.g., the updated final safety analysis report, quality assurance program); and (3) regulatory commitments. For Part 70, Subpart H licensees, the licensing basis is defined within each license. For Part 72 licensees, the licensing basis is defined similarly to that for nuclear power reactors but has slightly different terminology (e.g., "final safety evaluation report" instead of "updated final safety analysis report").

The court stated that the 1985 Backfit Rule conflicted with the Atomic Energy Act of 1954, as amended (AEA), by including cost considerations in adequate protection determinations. In 1988, the NRC issued an amended Backfit Rule that was again subject to court review and was upheld. The amended rule does not require a cost justification or analysis of the increase in protection to the public health and safety or the common defense and security in cases of ensuring, defining, or redefining adequate protection, or in cases of ensuring compliance with NRC requirements or conformance with written licensee commitments.[4]

In subsequent years, the NRC issued backfitting rules in 10 CFR 70.76 for entities licensed to possess special nuclear material in quantities greater than a critical mass and engage in specific activities (e.g., fuel facilities), 10 CFR 72.62 for independent spent fuel storage installations (ISFSIs) and monitored retrievable storage installations, and 10 CFR 76.76 for gaseous diffusion plants.[5] These regulations provide definitions of backfitting and related requirements that are similar to those in the Backfit Rule. The NRC also provided issue finality provisions in 10 CFR Part 52 (as listed in Table 1-1) that are analogous to backfitting but apply to only certain holders of Part 52 approvals. The NRC voluntarily self-imposed these backfitting and issue finality regulations. There is no statutory requirement for the agency's backfitting and issue finality requirements.

1.2.1 Backfitting and Issue Finality Regulations

Parts 50, 52, 70, 72, and 76 are the only parts of the NRC's regulations that contain backfitting provisions. As discussed in Section 2.3 of this NUREG, it is the NRC's policy that non-power production or utilization facilities licensed under 10 CFR 50.21, "Class 104 licenses; for medical therapy and research and development facilities," paragraphs (a) or (c), or 10 CFR 50.22, "Class 103 licenses; for commercial and industrial facilities," are outside the scope of the Backfit Rule. For the purposes of this guidance, 10 CFR 50.109, 70.76, 72.62, 76.76, and the issue finality provisions of Part 52 may collectively be referred to as the "backfitting regulations" or "backfitting provisions." Table 1-1 lists the NRC regulations that contain backfitting provisions.

[4] 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 of 1946, 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 Administrative Procedure Act's reasoned decisionmaking requirement compels some consideration of cost.

[5] Because no gaseous diffusion plants are currently operating, and the NRC does not expect to licensee any such plants in the foreseeable future, this NUREG does not provide specific guidance for implementation of 10 CFR 76.76.

Table 1-1. NRC Backfitting and Issue Finality Requirements[6]

Affected Entities	Backfitting/Issue Finality Regulation
Power Reactor (licensed under 10 CFR Part 50)	10 CFR 50.109
Power Reactor (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 52.31 10 CFR 52.39
Standard Design Certification (DC)	10 CFR 52.63 10 CFR Part 52, DC Rule Appendices 10 CFR 52.59
Combined License (COL)	10 CFR 52.83 10 CFR 52.98 10 CFR 50.109
Standard Design Approval (SDA)	10 CFR 52.145 10 CFR 50.109
Manufacturing License (ML)	10 CFR 52.171 10 CFR 52.179 10 CFR 50.109
Fuel Cycle Facility (authorized to possess special nuclear material above a critical mass and engaged in activities specified in 10 CFR 70.60)	10 CFR 70.76
Independent Spent Fuel Storage or Monitored Retrievable Storage Installation	10 CFR 72.62
Gaseous Diffusion Plant	10 CFR 76.76

1.2.2 Terminology

Under the backfitting regulations, backfitting can "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." To ensure the consistent implementation of the backfitting regulations, the following discussion describes the fundamental backfitting terms.

1.2.2.1 Requirements

In Directive Handbook Section I.A.4 of MD 8.4, the Commission clarified that, although 10 CFR 50.109(a)(1) refers to only regulations, backfitting can result from new or changed requirements—beyond regulations—or regulatory staff positions interpreting those requirements. For backfitting and forward fitting[7] purposes, the following contain the legally binding requirements on a licensee:

- the license, which ensures compliance with and operation within applicable NRC requirements and the facility-specific design bases as well as all modifications and

[6] Section 2.3 of this NUREG provides a more detailed list of the entities that are within the scope of backfitting or issue finality provisions.

[7] Forward fitting is discussed in more detail in Section 1.3 of this NUREG.

additions over the life of the facility that are docketed and in effect, including any NRC-approved license amendments, license renewals, license conditions, and license appendices such as technical specifications and an environmental protection plan;

- the regulations as they apply to the licensee; and
- orders.

1.2.2.2 Staff Positions

For backfitting and forward fitting purposes, staff positions are those documented interpretations of the Commission's regulations applicable to a licensee or "class" of licensees at the time of the identification of the proposed backfitting or forward fitting. Staff positions can be facility-specific or generic.

The NRC establishes facility-specific staff positions through licensing actions (i.e., NRC approvals) or NRC-issued facility-specific correspondence discussing the NRC's regulatory bases for its decisions (e.g., inspection reports (see **caution** below) or safety evaluations, which may or may not be related to a requested licensing action). Staff positions in safety evaluations are not requirements; rather, they are the NRC's regulatory bases for its decisions or interpretations. Safety evaluations (or safety evaluation reports) provide the staff position on whether a licensee's proposed means for implementing or complying with a governing requirement is acceptable and results in compliance with the requirement. The safety evaluation is generally not part of the licensing basis unless specifically incorporated by the licensee or required as a condition of approval by the staff. If the NRC subsequently decides that a staff position in a safety evaluation is incorrect, then agency actions related to that decision are subject to backfitting assessment.[8]

> **Caution:** Inspection reports can contain staff positions, but the staff must not use inspection reports to create staff positions about the adequacy of the licensing basis (e.g., "the licensee is in compliance"), although some exceptions may apply depending on the type of inspection. If an inspector does not identify any findings, the current practice of stating, "The NRC inspectors did not identify any findings or violations of more than minor significance," in the inspection report does not create a staff position. This language acknowledges the possibility that there were non-compliances but that the inspectors did not identify them in the report (e.g., because of the sampling nature of the inspection process, or because any identified non-compliances were found to be minor). However, if the inspection report states, "The licensee complied with [Requirement X]," then that language would constitute a staff position. If the NRC subsequently determines there is a non-compliance with "Requirement X" related to the inspected sample, then the NRC may need to consider that discovery a change in staff position subject to the backfitting provisions.

The staff's response to a technical assistance request is not a staff position. The response could become a staff position if it is used as the documented basis for further staff action. Until or unless it is used for that purpose, it is an internal agency communication. In general, internal

[8] The NRR Office Instruction LIC-100 states that NRC staff safety evaluations are not part of a plant's licensing basis. However, this does not obviate the fact that changes to staff positions established in safety evaluations (and other correspondence) are subject to the backfitting and forward fitting provisions and policy.

agency communications are not staff positions. Section 5.21 of this NUREG provides more information about the technical assistance request process.

Generic staff positions may be contained in documents such as regulatory guides, standard review plans, NUREGs, interim staff guidance, branch technical positions, and NRC endorsed-industry topical reports. However, these generic staff positions do not apply to individual licensees until or unless the licensee incorporates them into its licensing basis as a means for meeting or complying with a governing requirement, the NRC imposes generic positions on specific licensees through orders or rulemakings, or the NRC approves licensing actions involving the generic positions. Chapter 5 of this NUREG has additional guidance on the relationship between backfitting and generic communications.

The NRC's acknowledgment of a licensee's response to a 10 CFR 50.54(f) request for information does not establish a staff position. If the NRC subsequently sends the licensee written correspondence about the acceptability of the information for some regulatory purpose, then that correspondence would constitute an NRC position for that regulatory purpose. Subsequent revisions of a generic staff position are not applicable to a licensee unless or until that licensee specifically incorporates it into its licensing basis or the NRC imposes it through a backfitting or forward fitting action.

1.2.3 Backfitting Justifications

Under 10 CFR 50.109, 70.76, and 76.76, every backfitting action must be justified in one of four ways. The default justification is known as a "cost-justified substantial increase in overall protection," in which the NRC must prepare a backfit analysis showing that (1) the backfitting action will provide a substantial increase in the overall protection of the public health and safety or the common defense and security and (2) the direct and indirect costs of implementing the backfitting action are justified in view of the increased protection.

The other justifications do not require a backfit analysis. These exceptions to the requirement to perform a backfit analysis can be invoked if the proposed action meets one or more of the following criteria:

- The action is necessary to ensure that the facility provides adequate protection of the public health and safety and is in accord with the common defense and security.
- The action involves defining or redefining the level of protection to public health and safety or the common defense and security that should be regarded as adequate.
- The action is necessary to bring a facility into compliance with applicable requirements or into conformance with written commitments by the licensee.

When the action is justified based on one or more of these exceptions, the NRC completes a documented evaluation in lieu of the more detailed backfit analysis. A documented evaluation includes a statement of the backfitting action's objectives, the reasons for the backfitting action, the basis for invoking the exception, and the safety or security risk if the action is not taken. No finding of a substantial increase in overall protection is necessary.

The AEA requires the NRC to approve, among other things, the possession and use of radioactive materials only when the NRC has reasonable assurance that such possession and use will provide adequate protection of the public health and safety and the common defense

and security (i.e., no undue risk). Thus, when an issue exists such that the NRC no longer has reasonable assurance of adequate protection, the AEA requires the NRC to take an action necessary to provide reasonable assurance of adequate protection of the public health and safety and the common defense and security. If that action would constitute backfitting, then the AEA requires the NRC to nevertheless take the action to address the issue. For this reason, as directed by the Commission in Staff Requirements Memorandum (SRM) COMSECY-16-0020, dated November 29, 2016, and explained in an NRC memorandum dated December 20, 2016, from the NRC Solicitor to the Chair of the CRGR, the staff must consider whether any proposed backfitting action can be justified as an issue of adequate protection before considering other justifications. Because the NRC is mandated to take an action involving adequate protection, the NRC does not need to consider the costs of the action unless the NRC has identified more than one method of achieving adequate protection and prescribes one of those methods. In that situation, the NRC may consider the costs of each method when selecting the method. If the NRC does not prescribe the method of achieving adequate protection, then the NRC does not consider the costs of the method(s). Also, upon determining that a backfit is necessary for adequate protection to public health and safety, the NRC must prepare an imminent threat analysis that determines whether immediate action is necessary.

Only after determining that a proposed backfitting action does not meet the adequate protection exception can the staff consider whether the compliance exception applies. If the proposed action cannot be justified by one of the adequate protection or compliance exceptions, then the staff must complete a backfit analysis showing that the proposed action represents a cost-justified substantial increase in overall protection. If the proposed backfitting action cannot be justified by any of these means, then the action cannot be pursued through backfitting, and the staff can consider other agency processes.

The provisions of 10 CFR Part 70, Subpart H, including the backfitting provisions in 10 CFR 70.76, apply to certain licensees that are engaged in specific operations and are authorized to possess an amount of special nuclear material greater than a critical mass (e.g., nuclear fuel cycle facilities). Subpart H also includes specific requirements for adequate protection of workers. These requirements include protection from nuclear-related hazards (e.g., criticality, radiation) and chemical hazards that are comingled or resultant from nuclear processes or events. The backfitting provisions for these licensees in 10 CFR 70.76 consider these worker protection aspects as part of the overall protection of public health and safety or the common defense and security.

The backfitting provisions in 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,” contain justification concepts similar to the other backfitting regulations but apply those concepts differently. Under 10 CFR 72.62(b), the NRC will require backfitting of an ISFSI or monitored retrievable storage installation if the NRC finds that backfitting is necessary to ensure adequate protection of occupational or public health and safety. Also, under 10 CFR 72.62(b), the NRC will require backfitting to bring the ISFSI or monitored retrievable storage installation into compliance with applicable requirements or into conformance with written commitments by the licensee. Under 10 CFR 72.62(c), if the staff cannot justify the backfitting action as necessary for adequate protection or compliance, but the staff can justify the backfitting as a cost-justified, substantial increase in overall protection, then the NRC may require backfitting. The “substantial increase” test of the Part 72 backfit analysis also considers occupational health and safety derived from the backfitting action. Commission policy in MD 8.4 requires backfitting actions under 10 CFR 72.62 that are justified under an adequate protection or compliance exception to be supported by a documented evaluation

similar to those under 10 CFR 70.76 and 10 CFR 76.76. Consistent with 10 CFR 50.109(a), 70.76(a), and 76.76(a) and the transparency and reasoned decision-making objectives of the Backfit Rule, the NRC should prepare a backfit analysis for all proposed backfitting actions under 10 CFR 72.62(c).

1.2.4 Administrative Exemption

If the Commission needs to impose an action that meets the definition of "backfitting" but cannot meet the backfitting requirements, then the Commission can exempt itself from the applicable backfitting provisions. The Commission described this concept in SRM-SECY-93-086, dated June 30, 1993, and in greater detail in the statement of considerations (SOC) for the Aircraft Impact Assessment Rule (codified at 10 CFR 50.150). As a practical matter, an administrative exemption should be considered only when none of the criteria for justifying the backfitting action can be met and either the Commission or the EDO has indicated a desire to proceed with the proposed backfitting after being informed by the NRC staff that it was unable to justify the proposed backfitting in accordance with any of the applicable backfitting provisions.

The agency has used the administrative exemption only twice since the Commission first articulated the concept in 1993. The first use of this exemption was for the Aircraft Impact Assessment Rule, which followed the events of September 11, 2001. The second time was for Order EA-12-051, dated March 19, 2012, issued after the accident at the Fukushima nuclear reactors in Japan in 2011. As these examples show, the NRC should employ the exemption only in very significant circumstances.

In rulemaking, the Commission may implement the administrative exemption by making a finding in a proposed rule's SOC, thereby providing the public with notice and an opportunity to comment. Although not an administrative exemption, the Commission can also change the applicable backfitting or issue finality provision through a rulemaking, which would also provide the public with notice and an opportunity to comment.

In other circumstances (e.g., the issuance of orders), to implement the administrative exemption, the Commission should, unless immediate action is necessary, provide the public with an opportunity to comment on the proposed action.

1.2.5 Generic and Facility-Specific Backfitting Actions

There are two types of backfitting actions: generic and facility-specific.

1.2.5.1 Generic Backfitting Actions

Generic backfitting actions apply to more than one licensee (typically a class of licensees) and can include the imposition of new or revised requirements (e.g., rulemaking or orders) or the publication of new or revised staff positions interpreting NRC regulations (e.g., regulatory guides, NUREGs) that are imposed on licensees. Generic backfitting actions can be initiated in several ways, such as by an NRC staff recommendation to the Commission, Commission direction to the staff, and petitions for rulemaking submitted by members of the public.

Regardless of whether a generic backfitting action is the result of an order, rulemaking, or a new or changed staff interpretation, the staff must document its justification. Stakeholders must generally have had an opportunity to review and provide comments in response to a *Federal Register* notice. Because the NRC does not typically notice draft orders for public comment in

the *Federal Register*, the staff should hold a public meeting to provide an opportunity for public comment when the generic backfitting action is the result of an order. However, significant safety or security generic backfitting actions requiring timely action may not allow for prior public notice and opportunity to comment.

In most cases, the Commission will review generic backfitting actions unless the Commission has delegated the Commission's authority to the EDO (although the Commission must review all proposed backfits invoking the adequate protection exception). This authority may have been redelegated to a program office director (e.g., Section III.B.8 of MD 6.3, "The Rulemaking Process," dated July 3, 2019, lists the rulemakings under 10 CFR 50.55a, "Codes and standards," as being delegated from the EDO to the NRR Office Director.).

The backfitting appeals process described in Chapter 4 of this NUREG is not applicable to generic backfitting actions. Licensees have opportunities to raise backfitting concerns during the development of typical generic backfitting actions. For example, in rulemaking, stakeholders can comment on a proposed rule and the agency's discussion of backfitting in the proposed rule's SOC. A final rule is a final agency action that can be appealed in court. Orders can be challenged through the NRC's hearing process.

1.2.5.2 Facility-Specific Backfitting Actions

Backfitting actions that apply to a single unit, a single licensee, a site that has multiple units of similar design, sites that share an updated final safety analysis report, or sites that may have more than one reactor type but where the reactors share common sections of an updated final safety analysis report, are considered facility-specific backfitting actions. The staff properly imposes a backfitting action on a specific facility through a letter communicating a change in staff position or an order imposing a new or changed requirement. Each communication of a backfitting action issued to a licensee should include the justification for the action (i.e., documented evaluation or backfit analysis) and must include instructions on the use of the appeals process (see Chapter 4 of this NUREG for more information on the appeals process). The staff should avoid backfitting through safety evaluations for requested licensing actions, staff assessments, inspection reports, and oral communications with licensees. Section 1.5 of this NUREG contains additional information on communications with licensees.

To determine an acceptable schedule for a licensee to implement a facility-specific backfitting action, the staff must consider the significance of the safety or security concern and the timing of other ongoing regulatory activities at the facility, such as planned construction, outages, or other maintenance, in accordance with the applicable backfitting regulations (e.g., 10 CFR 50.109(c)).

1.2.6 Issue Finality Provisions

Issue finality describes the treatment of a final Commission or staff decision on an approval under 10 CFR Part 52. Approvals under 10 CFR Part 52 include ESPs, DCs, COLs, SDAs, MLs, and renewals of these approvals. Once the final decision has been made, all matters and issues associated with the decision are resolved and final. The Part 52 licensing process enables an applicant to incorporate by reference, as part of its application, certain previous Part 52 approvals in which the referenced approval is afforded issue finality. Similar to the Backfit Rule, if the NRC, or an applicant referencing a 10 CFR Part 52 approval in its application, proposes to change an existing Part 52 approval, the NRC or applicant must follow a disciplined process. Issue finality provisions in 10 CFR Part 52 provide criteria that the NRC

or applicant must satisfy to change an ESP, DC, COL, SDA, or ML. Issue finality provides a degree of stability to these approvals just as backfitting provides regulatory stability in Parts 50, 70, 72, and 76. It also provides greater certainty and efficiency in the licensing process for those applicants choosing to incorporate by reference a Part 52 approval.

Each of the 10 CFR Part 52 approvals has a unique set of issue finality requirements. The staff should be aware of the differences in requirements among the various approvals and between 10 CFR Part 52 provisions and 10 CFR 50.109 when dealing with any final approval. For example, the DC issue finality regulations have criteria in addition to the adequate protection, compliance, or substantial increase in overall protection concepts found in the Backfit Rule. Where the issue finality regulations for these approvals have analogous requirements to the Backfit Rule (e.g., adequate protection exception), the staff must follow the Commission's policy describing the order in which the requirements are considered (i.e., consider adequate protection before considering any of the other issue finality provisions).

The DC issue finality regulations recognize that there may be additional reasons to amend DC information. Such additional reasons could include providing detailed design information to replace design acceptance criteria, reducing unnecessary regulatory burden, contributing to increased standardization of the design, or correcting material errors. Although the issue finality regulations ensure that the NRC will maintain the stability of the licensing process by preserving the safety conclusions reached in the DC rulemaking, they also provide flexibility for amendments to the design.

In addition, as reflected in 10 CFR 52.98, "Finality of combined licenses; information requests," and 10 CFR 50.109(a)(1)(vii), different backfitting criteria might apply to different portions of a COL holder's licensing basis. For example, if a COL holder references an approved ESP and a DC, then: (1) 10 CFR 50.109 would apply to the portions of the licensing basis outside the scope of the referenced ESP and DC; (2) 10 CFR 52.39, "Finality of early site permit determinations," would apply with respect to the site characteristics, design parameters, and terms and conditions in the ESP; and (3) 10 CFR 52.63, "Finality of standard design certifications," would apply to design matters resolved in the DC, unless the DC includes specific issue finality provisions, in which case those specific provisions will govern.

The nature of issue finality may differ depending on the regulation and the information in question. For example, 10 CFR Part 52, Appendix D, "Design Certification Rule for the AP1000 Design," Section VI, provides that nuclear safety issues within the scope of the certified design are resolved and that "additional or alternative structures, systems, components, design features, design criteria, testing, analyses, acceptance criteria, or justifications" are unnecessary. However, Section VI does not accord such finality to operational requirements in the design control document. For ESPs, 10 CFR 52.39 provides issue finality, but a COL, construction permit, or operating license applicant referencing the ESP must "update the emergency preparedness information that was provided under 10 CFR 52.17(b), and discuss whether the updated information materially changes the bases for compliance with applicable NRC requirements." For DC renewal, the NRC must meet the backfit-like criteria of 10 CFR 52.59(b) to impose other requirements, but to renew the DC, 10 CFR 52.59(a) requires a finding of, among other things, compliance with the regulations in effect at initial certification.

1.2.7 Independent Spent Fuel Storage Installations

Part 72 of the NRC's regulations contains requirements for, among other things, ISFSIs and Certificates of Compliance (CoCs) approving spent fuel storage cask designs. Typically, for an

ISFSI associated with a nuclear power plant, the licensee for the nuclear power plant is licensed to operate the ISFSI. The NRC issues a CoC to the vendor of the associated cask design. The Part 72 backfitting provisions in 10 CFR 72.62 involve the ISFSI but do not address CoCs. This means that the user of the cask—the ISFSI licensee—is within the scope of 10 CFR 72.62 but the CoC holder—the vendor—is not.

If the CoC holder decides to revise its NRC-approved cask design, or the NRC determines that a change must be made to the design, such action would not constitute backfitting for the CoC holder because the backfitting provisions do not apply to the CoC holder. The potential backfitting would involve the ISFSI licensee using that particular cask and would depend on whether the change is an "administrative correction," an "amendment," or a "revision." Administrative corrections and amendments to CoCs have no backfitting implications. Corrections, which are of an administrative or editorial nature and do not change the substantive technical information of the CoC, are not the type of changes that were intended to be included in the definition of backfitting. Users of previous versions of that cask can choose to apply the administrative corrections or other changes authorized by a CoC amendment, but their decision is entirely voluntary.

Revisions to CoCs are technical changes and supersede the CoC and, therefore, qualify as backfitting for any licensee using the applicable cask. If an ISFSI licensee has purchased a cask for which a revision is sought and the ISFSI licensee is made aware of the revision and voluntarily agrees to implement the change, then the NRC would not be imposing the revised technical change on the licensee, thereby eliminating the potential backfitting. If the ISFSI licensee does not agree to implement the revision, then the staff would need to perform a backfit analysis under 10 CFR 72.62 to impose the revision.

Regulatory Issue Summary 2017-05, "Administration of 10 CFR Part 72 Certificate of Compliance Corrections and Revisions," dated September 13, 2017, contains more detail about the CoC change process and backfitting considerations for administrative corrections and revisions to CoCs.

1.3 Forward Fitting

1.3.1 Definition

The NRC does not have a regulation regarding forward fitting requirements. The Commission's policy on forward fitting is reflected in MD 8.4. Forward fitting is similar to backfitting in that the NRC imposes on a licensee a new or modified requirement or staff interpretation of a requirement (i.e., a staff position, as defined in Section 1.2.2.2 of this NUREG) that results in a modification of or addition to the 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. The fundamental difference between backfitting and forward fitting is that backfitting modifies NRC regulatory approvals already held by a licensee, whereas a forward fit happens when the NRC's approval of a licensee-initiated request for a licensing action includes a condition that the licensee comply with a new or modified requirement or regulatory staff position that the licensee did not request.

1.3.2 Forward Fitting Justifications

Like the backfitting requirements, the forward fitting policy requires the NRC to justify and document its analysis of the forward fitting action to ensure reasoned and informed NRC

decisionmaking and transparency. MD 8.4 states that the analysis must demonstrate that (1) there is a direct nexus between the new or modified requirement or regulatory staff position and 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. The staff must adequately explain why each of these two elements is independently met. Then, the staff must consider the costs of the proposed forward fitting action unless the forward fit would be necessary for adequate protection. Section 3.3 of this NUREG describes how to conduct the cost evaluation that supports a proposed forward fitting action.

1.4 Risk Considerations and Safety Significance

In Directive Handbook Section I.A.4 of MD 8.4, the Commission requires the NRC staff to consider risk insights, to the extent practical, for any proposed backfitting or forward fitting action. Because risk information forms part of the basis for any backfitting or forward fitting action, the staff should document any risk information or analysis as part of the basis for that action. For power reactor licensees, probabilistic risk assessment (PRA) information should be included to the extent practical. In its 1995 PRA policy statement, the Commission encouraged 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." PRA may aid the staff in quantifying the change in the overall protection of the public, but a PRA is not a singular basis for backfit or forward fit analyses or justifications. A quantitative estimate of risk is just one of the possible considerations that can support an integrated and risk-informed justification.

When the staff identifies an issue and is considering a backfitting or forward fitting action, the staff must also determine the safety significance of the issue. This determination should be made before considering whether the issue presents a backfitting or forward fitting concern. Safety significance can weigh heavily on proposed backfitting actions that rely on the compliance exception justification. This may be true if a licensee has incurred costs because of a staff position that the NRC seeks to change and implement through the compliance exception. After many years of safe operation, it may be less obvious as to why such a change is warranted when compliance was not previously mandated. If the licensee has incurred costs in reasonable reliance on a particular NRC position, then the need to provide a justification becomes more important. The fact that a plant has operated safely for a period of years does not mean, in and of itself, that a condition that has persisted for years should not be re-evaluated. But when many years have passed before the NRC determines that a regulation or requirement is not satisfied, and when the agency cannot demonstrate that compliance is necessary for adequate protection, identifying the safety significance should be the first step in ensuring that the change is still warranted.

1.5 Communications with Licensees

In Directive Handbook Section I.A.11 of MD 8.4, the Commission emphasized how staff discussions with licensees can raise backfitting issues: "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." Furthermore, in Directive Handbook Section II.A.2 of MD 8.4, the Commission said that communicating staff expectations to a licensee can constitute backfitting or forward fitting: "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 [licensing basis] for the identified purpose, then the staff's communication of that expectation is considered backfitting or forward fitting."

Definitive statements made by the staff to a licensee that a specific action is needed to comply with NRC requirements or to satisfy existing applicable staff positions may be perceived as backfitting. In a similar manner, if during a licensing review of a voluntary submittal, the licensee perceives that the staff is pressuring the licensee to adopt a specific staff position, then the licensee would generally be expected to raise this concern to the staff. If the staff desires to impose the specific staff position, then the staff should follow the guidance in this NUREG to determine whether the position would constitute backfitting or forward fitting.

In contrast, during the conduct of normal agency regulatory functions, the staff might suggest that licensees consider various actions (e.g., the staff may suggest various corrective actions for licensee consideration to address performance deficiencies). Discussion or comments by the staff that constitute suggestions and considerations for licensees, whether in meetings or written reports, if made in a neutral context (i.e., not suggesting a licensee must take an action that goes beyond its current requirements), do not constitute backfitting actions. Suggestions for consideration do not constitute backfitting, and licensees may consider the suggestions and choose whether to implement them. An example would be a discussion of an NRC information notice describing operating experience that may apply to the facility. When discussing corrective actions required by 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," Criterion XVI, "Corrective Action," the staff should be careful to ensure any specific corrective actions are discussed as considerations, without implication that a particular action must be taken. However, the staff must not act in a "consulting" capacity. The staff can avoid this by cautioning the licensee that the suggestions or considerations from individual staff members have not gone through formal agency review and approval for that licensee and that the licensee is responsible for meeting its licensing basis.

The NRC staff should not attempt to impose or suggest requirements through informal communications. A licensee is not obligated to conform to staff suggestions; however, if it chooses to do so, the licensee should understand that it is doing this voluntarily and that the suggestion does not constitute the imposition of a requirement. If the licensee concludes an NRC suggestion is a backfit or a forward fit, then the licensee can clarify with the staff whether the staff intends to impose a backfitting or forward fitting action.

1.6 Management and Oversight of Backfitting and Forward Fitting

The NRC policy and the staff responsibilities for managing and implementing the backfitting and forward fitting provisions are contained in MD 8.4. Management responsibilities include determining if the backfitting or forward fitting action is warranted, ensuring proper implementation of the backfitting and forward fitting processes, and approving the necessary backfit documented evaluation, backfit analysis, or forward fit analysis.

The program offices (i.e., the Office of Nuclear Reactor Regulation (NRR) and the Office of Nuclear Material Safety and Safeguards (NMSS)) have the obligation to impose backfitting or

forward fitting actions. The office or the region that initiated a backfitting or forward fitting[9] action supports NRR or NMSS with its obligation to impose the backfitting or forward fitting action. The Director of NRR or NMSS is responsible for generic backfitting actions and facility-specific backfitting or forward fitting actions arising from licensing or other headquarters actions, and the office staff performs the initial screening of the backfitting action and develops the documented evaluation or backfit analysis. Generic backfitting actions may need EDO or Commission approval unless otherwise delegated. Regional administrators are responsible for facility-specific backfitting actions arising from inspection (i.e., regional staff performs the initial screening of the backfitting action and supports NRR or NMSS in the development of the documented evaluation or backfit analysis), but regional administrators do not impose backfitting or forward fitting actions.

To ensure consistent implementation of the backfitting and forward fitting processes across the program and regional offices, the Commission requires the staff to provide the CRGR with an opportunity to review proposed backfitting (generic and facility-specific) and forward fitting actions. The CRGR is an advisory committee to the EDO, composed of senior managers from multiple NRC offices and one regional office, established to ensure that proposed backfits are appropriately justified in accordance with the backfitting provisions in 10 CFR Chapter I and the NRC's backfitting policies in MD 8.4 and that forward fits are appropriately justified in accordance with the forward fitting policy in MD 8.4.

Although the primary responsibility for issuing backfitting and forward fitting actions belongs to NRR and NMSS, the CRGR provides key oversight for backfitting and forward fitting. The Director of NRR or NMSS, or designee, should request CRGR review of the documents that propose a backfitting or forward fitting action, including the supporting analyses, findings, and justifications. If the CRGR accepts the request, then the CRGR will recommend approval, revision, or disapproval of the documents. If the NRR or NMSS Office Director agrees with the CRGR recommendation, then NRR or NMSS implements the recommendation in accordance with this guidance, if applicable. If the NRR or NMSS Office Director does not agree with the CRGR recommendation, then the NRR or NMSS Office Director may refer the issue to the EDO for a decision.

1.7 Implementation of Backfitting and Forward Fitting Process

The NRC staff is responsible for identifying potential backfitting and forward fitting actions and addressing such actions in accordance with agency policy in MD 8.4 and the guidance in this NUREG. To assist the staff, the NRC created a Backfitting and Forward Fitting Community of Practice, consisting of representatives from the Office of the Chief Information Officer, Office of Enforcement, Office of the Chief Human Capital Officer, NMSS, NRR, Office of the General Counsel, Office of Nuclear Regulatory Research, Office of Nuclear Security and Incident Response, and each of the regions. When staff members in these offices and regions have a backfitting, issue finality, or forward fitting question, they should reach out to their respective Community of Practice members.

Before the staff expends significant resources justifying a proposed backfitting or forward fitting action, the staff first should screen the issues for potential backfitting or forward fitting implications. The steps for screening and justifying backfitting and forward fitting actions may

[9] For licenses that are within the scope of backfitting provisions and, therefore, the forward fitting policy, all licensing actions are processed only with the NRR and NMSS program offices. Therefore, forward fitting actions are not expected to arise in the regional offices.

need to be adjusted depending on the context of the staff's proposed action (e.g., rulemaking). Chapters 2 and 3 and Appendices B and C of this NUREG provide detailed instructions, worksheets, and guides for screening and justifying a backfitting or forward fitting action.

2 SCREENING AND JUSTIFYING BACKFITTING ACTIONS AND CHANGES AFFECTING ISSUE FINALITY

2.1 Introduction

When screening proposed staff actions for backfitting concerns or changes that could affect issue finality and justifying the staff actions identified as backfits or changes affecting issue finality, the U.S. Nuclear Regulatory Commission (NRC) staff should ask the following six questions:

1. Is the proposed action excluded from backfitting and issue finality provisions?

2. Would the proposed action affect any entity that is within the scope of a backfitting or issue finality provision?

3. Would the proposed action constitute backfitting or affect issue finality?

4. Do any of the exceptions to the requirement of preparing a backfit analysis apply to the proposed backfitting?

    4a. Do one or both of the adequate protection exceptions to the requirement of preparing a backfit analysis apply?

    4b. Does the compliance exception to the requirement of preparing a backfit analysis apply?

5. Does the proposed backfitting action constitute a cost-justified substantial increase in the overall protection of public health and safety or the common defense and security, or does the change affecting issue finality in the proposed action satisfy an issue finality criterion?

6. Should the NRC take an action to avoid the effect of the backfitting or issue finality provision on the proposed action by invoking an administrative exemption from the backfitting or issue finality provision?

Questions 1 through 3 help the staff determine whether proposed staff actions would constitute backfitting or affect issue finality. For those proposed staff actions that would constitute backfitting or affect issue finality, questions 4a, 4b, and 5 help the staff justify the backfit or change affecting issue finality. Except for question 6, Sections 2.2 through 2.6 of this chapter describe these questions in more detail. The staff will rarely reach question 6, as explained in Section 1.2.4 of this NUREG.

Appendix B to this NUREG provides a worksheet to assist the staff in screening and justifying proposed staff actions.

2.2 Question 1: Is the proposed action excluded from the backfitting and issue finality provisions?

By answering question 1, the staff determines whether the proposed action would fall outside the purview of the backfitting regulations. Certain actions are not subject to the backfitting

requirements. None of the backfitting or issue finality provisions expressly sets forth these exclusions, but the Commission recognizes them as unsuitable for backfitting purposes.[1]

Matters that are outside the purview of the backfitting regulations include NRC actions implementing mandatory statutory requirements or requirements imposed by other Federal agencies. In these situations, the NRC has no discretion in the implementation of these requirements. Because the NRC must implement these requirements, the NRC does not need to justify any potential backfitting resulting from taking these actions.

Other matters outside the scope of the backfitting provisions include those that do not have a direct link to and do not further a substantive radiological[2] public health and safety or common defense and security objective. In addition, these actions would not meet the definition of "backfitting." Such actions include information collection and reporting requirements;[3] changes to NRC administrative procedures;[4] corrections of regulatory language, including typographical mistakes, misspellings, and inadvertent omissions (when the NRC's objective is expressly reflected in the regulatory record); and NRC organization and structure changes. Nevertheless, the NRC must have legal authority to justify taking such actions. Information collection and reporting requirements facilitate the NRC's regulatory oversight responsibility. Administrative and organizational requirements enable the NRC to carry out its mission.

Requirements for appeal processes[5] are also outside the purview of backfitting provisions. An appeal process protects an individual's due process, which is guaranteed by the Fifth Amendment to the U.S. Constitution: "No person shall … be deprived of life, liberty, or property, without due process of law …." Although the Fifth Amendment requires the Federal Government to provide due process to persons, the NRC can, in implementing its own authority, ensure that its regulated entities provide adequate due process to their personnel through the entities' appeals processes that are consistent with Federal due process requirements.

Because the backfitting and issue finality provisions do not expressly identify these exclusions, the staff should consult the NRC Backfitting and Forward Fitting Community of Practice to assist with determining whether the proposed action would be excluded from backfitting considerations. For proposed actions that are outside the scope of the backfitting regulations, the staff should exit the backfitting process and proceed under an appropriate agency process. For proposed actions that are within the scope of the backfitting regulations, the staff should continue through the screening process.

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[1] For example, "Regulatory Improvements to the Nuclear Materials Management and Safeguards System; Final Rule," 73 FR 32453, 32461 (June 9, 2008) (reporting requirements did not meet the definition of "backfitting"); "Miscellaneous Corrections—Organizational Changes; Final Rule," 83 FR 58721, 58722 (November 21, 2018) (the corrections were non-substantive changes that did not meet the definition of "backfitting").

[2] For materials licensees that are the subject of the backfitting provisions in Title 10 of the *Code of Federal Regulations* (10 CFR) Section 70.76, this also includes the potential effects of hazardous chemicals produced from licensed material. For licensees that are the subject of the backfitting provisions in 10 CFR 72.62, occupational health and safety is an explicit criterion for use of the adequate protection exception (10 CFR 72.62(b)) and for backfit analysis (10 CFR 72.62(c)(1)).

[3] For example, 10 CFR 50.73, "Licensee event report system," and 70.74, "Additional reporting requirements."

[4] For example, changes to 10 CFR Part 2, "Agency Rules of Practice and Procedure."

[5] For example, 10 CFR 26.39, "Review process for fitness-for-duty policy violations," and 10 CFR 73.56(l), "Review procedures."

2.3 Question 2: Would the proposed action affect any entity that is within the scope of a backfitting or issue finality provision?

In question 2, the staff must determine whether the affected entity is within the scope of the backfitting regulations. Table 1-1 lists the regulations that contain backfitting or issue finality provisions. If the entity is not within the scope of the backfitting regulations, then the backfitting regulations do not apply, and the staff can exit the backfitting process and issue the proposed action or staff position under an appropriate agency process without further screening. If the entity is within the scope of the backfitting regulations, the staff should continue with the screening process. The following list contains the entities within the scope of the backfitting or issue finality provisions.

- power reactors licensed under 10 CFR Part 50
  - holder of a limited work authorization (10 CFR 50.10, "License required; limited work authorization")
  - holder of a construction permit (10 CFR 50.50, "Issuance of licenses and construction permits")
  - applicant for an initial operating license (10 CFR 50.50)[6]
  - holder of an initial operating license (10 CFR 50.56, "Conversion of construction permit to license; or amendment of license," and 50.57, "Issuance of operating license")
  - applicant for a renewed operating license (10 CFR Part 54) (There are no backfitting provisions in Part 54. However, the regulatory structure of Part 54 bounds what the staff can review in these applications, as described in Section 5.16 of this NUREG.)
  - holder of a renewed operating license (10 CFR Part 54)
- power reactors licensed and approved under 10 CFR Part 52[7]
  - holder of an early site permit (ESP) (10 CFR 52.39)
  - applicant for renewal of an ESP (10 CFR 52.31, "Criteria for renewal")
  - applicant for a design certification (DC), after issuance of the final DC rule (10 CFR 52.63)[8]
  - applicant for renewal of a DC during the rulemaking for renewal (10 CFR 52.59, "Criteria for renewal")
  - applicant for a combined license (COL) if referencing an ESP, standard design approval (SDA), DC, or manufacturing license (ML) (10 CFR 52.83, "Finality of referenced NRC approvals; partial initial decision on site suitability")
  - holder of a COL (10 CFR 52.98)
  - applicant for renewal of a COL (10 CFR Part 54)
  - holder of a renewed COL (10 CFR 52.98)

[6] The Part 50 backfitting provision applies to applicants for an operating license under Part 50 for the information within the scope of the construction permit.

[7] Applicants referencing an ESP, DC, or SDA have issue finality for only the information within the scope of the ESP, DC, or SDA.

[8] Each approved DC contains more specific provisions for issue finality, including changes to and departures from the approved design (e.g., 10 CFR Part 52, Appendix D, Sections VI and VIII), than 10 CFR 52.63.

  - holder of an SDA (10 CFR 52.145, “Finality of standard design approvals; information requests”)
  - holder of an ML (10 CFR 52.171, “Finality of manufacturing licenses; information requests”)
  - applicant for renewal of an ML (10 CFR 52.179, “Criteria for renewal”)

- materials licensees

  - licensees authorized to engage in specific activities and possess special nuclear material above a critical mass (10 CFR 70.76)
  - holder of a general or specific license for an independent spent fuel storage installation (10 CFR 72.62)
  - holder of a license for a monitored retrievable storage installation (10 CFR 72.62)
  - holder of a certificate of compliance for a gaseous diffusion plant (10 CFR 76.76)

The rest of this section provides more details as to how backfitting regulations apply to these entities.

The Backfit Rule applies to a holder of a power reactor construction permit or operating license issued under 10 CFR Part 50. This means that the NRC would have to meet the criteria in 10 CFR 50.109 to change the issued construction permit or operating license. The Backfit Rule does not apply to all aspects of the construction permit or operating license. As with the other backfitting provisions in Table 1-1, the scope of 10 CFR 50.109 generally includes the modification of, or addition to, structures, systems, or components (SSCs) and the procedures or organization required to operate the facility. Further, 10 CFR 50.109 applies to certain Part 52 approvals, as shown in Table 1-1 and discussed in Section 1.2.6 of this NUREG.

The Commission provided issue finality for Part 52 approvals and licenses in 1989 and amended those provisions in 2007. Each of the approvals issued under 10 CFR Part 52 has issue finality for the duration of that approval. For example, a holder of an ESP can maintain that approval for a term of up to 20 years. During that 20-year term, the NRC cannot impose a change to the ESP without meeting the criteria provided in 10 CFR 52.39. The holder can seek renewal of that ESP for another 20 years. For the NRC to impose new requirements on that ESP holder at the time the NRC issues the renewed ESP, the NRC would have to satisfy the criteria in 10 CFR 52.31. Similarly, a COL applicant can reference an NRC-approved ESP or DC in its application, and certain matters concerning that ESP or DC are considered resolved, such that changes to the ESP or DC are governed by the applicable ESP or DC issue finality provision.

Backfitting ordinarily does not apply to the renewal of an operating license under 10 CFR Part 54. However, similar to the constraints of the staff’s review of a license amendment request, if the NRC proposes to address safety or security issues outside the scope of Part 54 (i.e., other than issues related to time-limited aging analyses and aging management of long-lived, passive SSCs), then any actions necessary to address such out-of-scope safety or security issues are subject to the Backfit Rule. Once the NRC issues a renewed license, the Backfit Rule applies to the renewed license. Renewal of a COL under 10 CFR Part 54 would be similar to renewal of an operating license, except that Section VI.B of the DC appendices in 10 CFR Part 52 provides issue resolution in proceedings to renew a COL.

The NRC's policy is not to apply the backfitting provisions to non-power production and utilization facilities, including radioisotope production facilities, research reactors, and testing facilities, licensed under 10 CFR Part 50. Historically, the NRC expressed the regulatory basis for 10 CFR 50.109 solely in terms of nuclear power reactors. For example, the NRC's Advanced Notice of Proposed Rulemaking, Policy Statement, Proposed Rule, and Final Rule for the 1985 revision of 10 CFR 50.109 involved only nuclear power reactors. As a result, the NRC has not applied 10 CFR 50.109 to research reactors, testing facilities, and other non-power facilities licensed under 10 CFR Part 50.[9] In a 2012 final rule concerning non-power reactors, the NRC stated, "The NRC has determined that the backfit provisions in § 50.109 do not apply to test, research, or training reactors because the rulemaking record for § 50.109 indicates that the Commission intended to apply this provision to only power reactors, and NRC practice has been consistent with this rulemaking record."

The NRC issued backfitting provisions for independent spent fuel storage installation licensees in 1988 and gaseous diffusion plants in 1994. In SECY-95-061, "Need for a Backfit Rule for Materials Licensees," dated March 14, 1995, the NRC staff recommended to the Commission that the NRC not extend backfitting provisions to all other materials licensees. The staff determined that extending the Backfit Rule to all other materials licensees would create technical problems (e.g., the challenge of developing a consistent definition of "substantial" and the uncertainties in quantifying risk) and potentially significant resource burdens for the staff. The staff also determined that regulatory analysis requirements, already applicable to NRC actions involving materials licensees, were similar to the Backfit Rule in preventing the imposition of generic requirements having marginal overall safety benefit or costs not commensurate with the benefits. The Commission approved the staff's recommendation in the Staff Requirements Memorandum (SRM) to SECY-95-061, dated June 29, 1995, and instructed the staff to "consider the applicability of a backfit provision to particular classes of licensees." Subsequently, the NRC added a backfitting provision to Part 70. However, the backfitting provision in Part 70 is only applicable to Part 70 licensees authorized to engage in specific activities and possess greater than a critical mass of special nuclear material. The Part 72 backfitting provision applies to Part 72 licensees but not to holders of a Part 72 certificate of compliance.

In certain circumstances, a proposed action may affect entities that are within the scope of backfitting or issue finality provisions and entities that are not within the scope of backfitting or issue finality provisions. A proposed action may also affect entities authorized to conduct certain activities under multiple parts of the NRC's regulatory framework (e.g., nuclear power reactor licensees that are authorized to receive, possess, and use source, byproduct, and special nuclear material under Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," Part 40, "Domestic Licensing of Source Material," Part 50, and Part 70). The staff needs to determine whether any backfitting or issue finality provision applies and, if so, which one. For nuclear power reactor licensees and certain materials licensees, the staff can

[9] For example, "Limiting the Use of Highly Enriched Uranium in Domestically Licensed Research and Test Reactors; Final Rule" (51 FR 6514; March 27, 1986), and "Clarification of Physical Protection Requirements at Fixed Sites; Final Rule" (58 FR 13699; March 15, 1993).

typically make that determination by ascertaining how the proposed action would affect the licensee. To help make that determination, the staff should follow these steps:

1. Identify all the NRC-regulated entities affected by the proposed action.

2. Identify all the NRC-regulated entities affected by the proposed action that are within the scope of a backfitting or issue finality provision.

    a. For those NRC-regulated entities that are not within the scope of a backfitting or issue finality provision, the staff can exit the backfitting process. The NRC can still consider taking the proposed action, but the staff does not need to consider the backfitting implications of the proposed action for these entities.

    b. For those NRC-regulated entities that are within the scope of a backfitting or issue finality provision and are nuclear power reactor licensees, go to step 3.

    c. For those NRC-regulated entities that are within the scope of a backfitting or issue finality provision, are authorized to conduct activities involving NRC-regulated materials (e.g., under Part 70) but not a nuclear power reactor license, and are authorized to conduct activities under a part that does not contain a backfitting provision (e.g., Part 40):

        i. if the proposed action affects the activities under the part that does not contain a backfitting provision (e.g., Part 40), then no backfitting provision would apply to these entities. The NRC can still consider taking the proposed action, but the staff does not need to consider the backfitting implications of the proposed action for these entities.

        ii. if the proposed action affects the activities under the part that does contain a backfitting provision (e.g., Part 70), then continue to Section 2.4 of this NUREG.

        Footnote 10 in this section contains an example of this scenario.

3. For those NRC-regulated entities affected by the proposed action that are nuclear power reactor licensees, determine whether the proposed action:

    a. would apply uniformly to all applicable non-nuclear power reactor licensees, and at least one of these non-nuclear power reactor licensees (i.e., material licensees) is within the scope of an applicable backfitting provision;

    b. is directed only at nuclear power reactor licensees; or

    c. seeks a level of performance for nuclear power reactor licensees that is higher than the level of performance sought from non-nuclear power plant licensees.

4. If all the answers to the questions in step 3 are “NO,” then the staff can exit the backfitting process. In this case, the NRC would be imposing the proposed action on nuclear power reactor licensees in a manner that is equal to the manner that the NRC would impose the proposed action on non-nuclear power plant licensees. In other words, nuclear power reactor licensees would receive equal treatment as materials licensees because the proposed action would be imposed on the nuclear power reactor

licensees in their capacities as material licensees. Therefore, to ensure equal backfitting treatment, no backfitting provision should apply to the nuclear power reactor licensees in this instance because, in this case, no backfitting provision applies to the non-nuclear power plant licensees. The staff need not consider the backfitting or issue finality implications of its proposed action.[10]

5. If the answer to any of the questions in step 3 is "YES," then continue to Section 2.4 of this NUREG. When the answer to the question in step 3.a is "YES," nuclear power reactor licensees would receive equal treatment as materials licensees that are within the scope of a backfitting provision. When the answer to the question in step 3.b or 3.c is "YES," then the NRC would be treating nuclear power reactor licensees differently than other NRC-regulated entities solely because they are power reactor licensees, which are within the scope of backfitting and issue finality provisions.

2.4 Question 3: Would the proposed action constitute backfitting or affect issue finality?

In answering question 3, the staff determines whether the proposed action constitutes backfitting (or affects issue finality). To determine whether the proposed action constitutes backfitting, the answer to each of the following five questions must be "YES":

1. Is there either—

   a. a new or changed (e.g., amended, revised, or modified) NRC requirement (e.g., a regulation or order), or

   b. a new or changed staff interpretation of an NRC requirement?

2. Is the NRC imposing the new or changed requirement or interpretation on an applicable entity?

3. Will there be a modification or addition to—

   a. SSCs of the entity's facility;

   b. design (including but not limited to a DC, SDA, or ML) of the entity's facility; or

   c. procedures or organization for designing, constructing, or operating the entity's facility?

4. Is the modification or addition (third question above) the result of the new or changed requirement or interpretation (first question) that is being imposed (second question)?

[10] For example, the NRC could propose an action to amend 10 CFR Part 40 that would apply uniformly to Part 50 nuclear power reactor licensees (which also are authorized to conduct activities under Part 40), Part 70 fuel cycle facility licensees (which also are authorized to conduct activities under Part 40), and Part 40 source material licensees. Although the proposed action would apply equally to the three classes of licensees, and Part 50 and Part 70 have backfitting provisions, those provisions would not apply to the proposed action because the action affects those licensees regarding activities they are authorized to conduct under Part 40.

5. Will the imposition of the new or changed NRC requirement or interpretation occur after the point that the applicable backfitting provision begins to apply (e.g., as specified in 10 CFR 50.109(a)(1)(i) through (vii))?

If the answer to any of the five questions above is "NO," then the proposed action is not backfitting. The staff should document the conclusion, exit the backfitting process, and proceed to take the proposed action using the appropriate agency process, without further evaluating the remaining steps.

The staff should use a similar process for determining whether a proposed action affects issue finality under 10 CFR Part 52. However, the staff should also recognize that issue finality for some entities involves matters other than adequate protection, compliance, and substantial increase in overall protection. In some cases, issue finality does not specifically involve any of those three matters (e.g., for an SDA), while in other cases, issue finality includes and goes beyond these three matters (e.g., for a DC). The specific issue finality provisions define the scope of matters considered for issue finality. In general, the staff should use the same hierarchy for determining whether issue finality would be affected if the requirement is imposed by the NRC (i.e., adequate protection first, then compliance, and/or substantial increase in overall protection, as applicable). Most other changes that would involve issue finality would likely be voluntary, such as departures from a DC taken or requested by a COL holder or requests to amend a DC to reduce unnecessary regulatory burden or contribute to increased standardization. Even if the changes are voluntary, the changes must still meet the applicable issue finality criteria.

Under 10 CFR 50.109(d), the staff must not interrupt or delay licensing actions while the NRC is processing a backfit analysis. This provision was codified in 1985, when the NRC described as "backfitting" those actions that are now called "forward fitting." As implemented today, new or changed requirements or staff positions proposed by the NRC staff during a licensing action are either backfits that need to be addressed through a separate action or forward fits. If the proposed action is a forward fit, then the staff must follow the forward fitting policy described in Chapter 3 of this NUREG.

As soon as practical after identification of a potential backfitting issue, the staff should present the potential backfitting action to the responsible office director or regional administrator, who then reviews the issue and determines whether the action constitutes backfitting. If the office director determines the issue constitutes backfitting, then the office director will oversee the NRC staff's development of appropriate backfitting documentation and determine if the proposed action is justified. If the regional administrator determines the issue constitutes backfitting, then the regional administrator will forward the issue to the office director for disposition and provide support as needed.

2.5 Question 4: Do any of the exceptions to the requirement of preparing a backfit analysis apply to the proposed backfitting?

By reaching question 4, the staff has determined that its proposed action would constitute backfitting or affect issue finality. Now the staff must justify its proposed action. The default method for justifying a proposed backfitting action is a backfit analysis. However, the Commission has directed the staff to first determine whether the proposed action satisfies the criteria for one (or more) of three exceptions to the requirement to prepare a backfit analysis. Furthermore, the staff must consider whether the backfitting action involves the adequate protection exception before considering justification by the compliance exception.

2.5.1 Question 4a: Do one or both of the adequate protection exceptions to the requirement of preparing a backfit analysis apply?

2.5.1.1 Background

If the staff determines that the agency must impose a backfitting action to ensure that a facility provides adequate protection to the public health and safety and is in accord with the common defense and security, or if the Commission decides that the agency needs to define or redefine the level of protection of public health and safety or common defense and security that should be considered as adequate, then the Atomic Energy Act of 1954, as amended (AEA), requires that regulatory action be implemented. The staff would prepare a documented evaluation. The responsible staff should seek advice from the Office of the General Counsel (OGC) and Office of Enforcement on imposition of all adequate protection actions. If the backfitting action involves an issue of adequate protection, then the backfitting justification must either be reviewed and approved by the Commission or provided to the Commission sufficiently in advance of the issuance of the backfitting action to enable the Commission to change the proposed action if it chooses to do so.

The concept of adequate protection is limited to considerations of radiological public health and safety and common defense and security (i.e., it is limited to human health effects from radiological[11] releases and does not include the economic impacts that may ensue) as discussed in SECY-12-0110, "Consideration of Economic Consequences within the U.S. Nuclear Regulatory Commission's Regulatory Framework," dated August 14, 2012, and confirmed by the Commission in its SRM for SECY-12-0110, dated March 20, 2013. Although the NRC discusses adequate protection in several agency guidance documents (e.g., SRM-COMSAJ-97-008, dated August 25, 1997), the AEA does not explicitly define the term "adequate protection" and the equivalent phrase "no undue risk." With respect to "adequate protection," the Commission said in the 1988 Backfit Rule statement of considerations (SOC) that it "can still make sound judgments about what 'adequate protection' requires, by relying upon expert engineering and scientific judgment, acting in the light of all relevant and material information." For example, the Commission concluded that greater uncertainty was associated with the capability of nuclear power plants to withstand extreme external events as a result of lessons learned from the Fukushima accident, and it decided that new requirements needed to be imposed as a matter of adequate protection (i.e., beyond-design-basis external events could present undue risk). The Commission imposed these new requirements by Order EA-12-049, dated March 12, 2012, to provide additional capability to address beyond-design-basis events. This backfitting action shows that adequate protection requirements can be imposed to provide greater defense-in-depth.

There is an important nuance in how the backfitting regulations view issues of adequate protection for materials licensees. The provisions within 10 CFR 70.76 consider the worker protection aspects of 10 CFR Part 70, Subpart H, as part of the overall protection of public health and safety or the common defense and security. Under 10 CFR 72.62, the provisions specifically state that the Commission will require the imposition of a backfit of an independent spent fuel storage installation or monitored retrievable storage installation if the NRC finds that the backfit is necessary to ensure adequate protection to occupational or public health and safety.

[11] For materials licensees that are the subject of the backfitting provisions in 10 CFR 70.76, this also includes the potential effects of hazardous chemicals produced from licensed material.

Upon determining that a backfitting action is necessary for adequate protection of the public health and safety or the common defense and security, the staff must prepare an imminent threat analysis that determines whether immediate action is necessary. An adequate protection issue does not necessarily mean that the issue is an imminent hazard. If the responsible office director determines that the adequate protection issue presents an imminent hazard, then the NRC can impose the backfitting action immediately through an order. Although 10 CFR 50.109(a)(6) permits the staff in these circumstances to impose the backfitting action before documenting the justification, the staff should document the reason the adequate protection issue represented an imminent hazard and the rationale for imposing the backfit in as much detail as practicable to support developing the order.

2.5.1.2 Adequate Protection Determinations

A licensee's compliance with applicable NRC requirements provides a presumption of adequate protection of public health and safety. For the NRC to impose new or changed requirements on a licensee that are intended to provide for adequate protection of the public health and safety or the common defense and security, the NRC must provide within the documented evaluation a clear basis for why compliance with the existing requirements does not or will not provide reasonable assurance of adequate protection (i.e., a condition of undue risk to public health and safety exists despite compliance with requirements) and how the backfitting action addresses the condition of undue risk. In the 1985 and 1988 Backfit Rule SOCs, the Commission stated that the presumption that compliance with the regulations ensures adequate protection of the public health and safety can be overcome only by significant new information or some showing that the regulations do not address some significant safety issue.

Typically, a clear basis for invoking the adequate protection exception can be established when new information reveals that an unforeseen hazard exists or that there is a substantially greater potential for a known hazard to occur than previously believed, thereby creating a condition of undue risk to public health and safety. This new information may result from information such as operational experience, technical research, or issuance of new industry or government reports. In such situations, the NRC has the statutory authority to require licensee action beyond existing requirements to maintain the level of protection necessary to avoid undue risk to public health and safety. In this case, the NRC would use the "necessary to ensure adequate protection" exception. If the NRC determines that action is necessary to change the level of protection that is considered adequate, then the NRC would use the "defining or redefining adequate protection" exception. Notwithstanding which exception is used, in SRM-SECY-99-063, dated May 27, 1999, the Commission directed that matters required for adequate protection cannot be addressed through voluntary industry or licensee actions.

Quantitative risk estimates serve as important measures of facility safety, but do not embody the full range of considerations that enter the judgment for adequate protection. The judgment for adequate protection derives from a more diverse set of considerations, such as acceptable design, construction, operation, maintenance, modification, and quality assurance measures. Quantitative measures used in the consideration of adequate protection for power reactors are the safety goal[12] surrogates (e.g., core damage frequency (CDF) and containment failure probability) to the quantitative health objectives. The Commission issued the quantitative health

[12] A "safety goal" evaluation determines, from a regulatory analysis perspective, whether the proposed requirement constitutes a substantial improvement in public health and safety, including a change in core damage frequency per reactor year or conditional containment failure probability.

objectives as part of the its 1986 Safety Goal Policy Statement to provide an acceptable level of risk to the public from the regulated use of nuclear material. The NRC staff uses the safety goal surrogates to measure conformance with the purpose of the safety goals. The "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" (NUREG/BR-0058) provide guidance on safety goal screening that the NRC staff could use to make a determination about adequate protection depending on the change in the CDF and the conditional containment failure probability. However, a change in the CDF cannot be applied in evaluating all potential regulatory actions (e.g., spent fuel pools, materials, security), and in some cases, determining the change in CDF would be difficult if not impossible (e.g., safeguards and security).

Because an adequate protection backfit would impose new requirements to address a condition that is considered to present undue risk to public health and safety or the common defense and security, it is essential to fully inform this backfit decision with available risk information and risk insights to enable decision makers to reasonably conclude that the undue risk condition exists and warrants imposition of new requirements. The staff should consider available risk information in a manner that is consistent with the Commission's policy on the use of probabilistic risk assessment, as discussed in Section 1.4 of this NUREG.

When considering an adequate protection backfitting action, the staff must determine whether the issue and action should be applied to one or a limited number of licensees (facility-specific backfitting action), or whether the issue and action should be applied generically (generic backfitting action). Next, the staff must determine, based on the safety or security risk of the issue, whether the NRC must issue an immediately effective order. The staff should inform the Commission when the staff is considering any generically applicable adequate protection backfitting actions to enable the Commission to decide whether it wishes to review and approve the action or otherwise direct the staff. The NRC staff should inform the Executive Director for Operations (EDO) when the staff is considering any facility-specific adequate protection backfitting actions. Such notifications should occur once the staff has determined that the adequate protection exception may apply and the staff has begun developing a documented evaluation for the adequate protection exception, not when the staff first considers adequate protection. The staff should seek advice from OGC on the imposition of all adequate protection actions, including the licensee's proposed implementation schedule.

The NRC does not usually impose new adequate protection requirements in rulemakings because matters of adequate protection usually need to be addressed more quickly than the time afforded by rulemaking. In these situations, the NRC typically issues licensee-specific orders followed by a rule that makes the associated orders generically applicable. One exception was the final rule amending 10 CFR 50.61, "Fracture toughness requirements for protection against pressurized thermal shock events," because the underlying phenomenon would not have presented an adequate protection issue for several years.

2.5.1.3 Documenting Adequate Protection Evaluations

For any backfitting action that meets the definition and requirements for adequate protection backfitting, the staff must prepare a documented evaluation of the type discussed in 10 CFR 50.109(a)(6), 70.76(a)(4), or 76.76(a)(4) in lieu of a backfit analysis. To impose the backfitting action, the staff must find that the action is necessary for adequate protection. Because there are two options for invoking the adequate protection exception, the documented evaluation must include the basis for invoking the exception and must clearly explain which option is being used and why. The staff must also describe the safety or security risk if the action is not taken. No further explanation is necessary to justify the backfitting action and it

should be implemented without consideration of cost, except if there are multiple ways to implement the action and the NRC prescribes one way to comply with requirements or to achieve adequate protection. In that case, cost may be a factor in selecting the action, provided that the objective of adequate protection is met.

The Director of the Office of Nuclear Reactor Regulation (NRR) or the Director of the Office of Nuclear Material Safety and Safeguards (NMSS) responsible for issuing the backfitting action must approve any documented evaluation and a copy should be sent to the EDO and regional administrator, if applicable, before the staff transmits the backfitting documentation to the licensee.

Appendix C to this NUREG contains a guide for drafting a documented evaluation to justify an adequate protection backfitting action.

2.5.2 Question 4b: Does the compliance exception to the requirement of preparing a backfit analysis apply?

2.5.2.1 Background

If, in answering question 4a, the staff determines that the backfitting action does not represent an issue of adequate protection, then the staff proceeds to question 4b to determine whether the backfitting action is necessary to ensure compliance with the license or the rules and orders of the NRC, or with written licensee commitments[13] that were incorporated in the license. If so, a backfit analysis is not required, although some consideration of costs is required. Instead, NRR or NMSS staff prepares a documented evaluation of the type discussed in 10 CFR 50.109(a)(6), 70.76(a)(6), and 76.76(a)(6), with a finding that the action is necessary to ensure compliance. Under 10 CFR 72.62(b), the NRC requires backfitting if it is necessary to bring an independent spent fuel storage installation or monitored retrievable storage installation into compliance with a license or the Commission's orders or rules, or into conformance with the licensee's written commitments. NRR or NMSS staff must seek advice from OGC and the Office of Enforcement on the imposition of all compliance backfits, including the proposed implementation schedule.

Understanding the difference between the NRC issuing a violation and the NRC imposing a change to the licensing basis through a backfitting action based on the compliance exception is fundamental to the use of the compliance exception. In both cases, the NRC has determined that a licensee does not comply with a requirement. If the NRC has not made this determination (i.e., there is no requirement that the licensee is not complying with), then neither a violation nor a compliance backfitting action would be appropriate. In contrast to a violation, a compliance backfitting action occurs when the licensee previously received NRC approval of a method demonstrating compliance with a requirement, but the staff has since determined that, because of an omission or mistake of fact made at the time of or before the NRC's previous approval, the licensee's conformance with that method does not constitute compliance with the requirement. In this case, the staff would need to change its previous approval (i.e., impose a new or changed staff position) to ensure the licensee complies with the requirement. This would not result in a violation.

[13] In accordance with 10 CFR 50.109, 70.76, 72.62, and 76.76, the NRC may require backfitting if necessary to bring a facility into conformance with the licensee's written commitments, as discussed in Section 5.3 of this NUREG.

When questions arise concerning a potential violation that will necessitate a detailed review of the facility's licensing basis or a complex technical evaluation, the inspectors should contact the appropriate licensing project manager for advice, use the Very Low Safety Significance Issue Resolution process in the NRC's Inspection Manual Chapter 0612, if applicable, or, if necessary, initiate the technical assistance request process for the appropriate office to consider the regulatory, licensing, and technical aspects of the issue.

2.5.2.2 Compliance Exception Determinations

In the 1985 Backfit Rule SOC, the Commission stated, "The compliance exception 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. It should be noted that new or modified interpretations of what constitutes compliance would not fall within the exception and would require a backfit analysis and application of the standard." As approved by the Commission in SRM-COMSECY-16-0020, dated November 29, 2016, and as further explained in the NRC Solicitor's 2016 memorandum to the chairman of the Committee to Review Generic Requirements, the staff should determine that an omission or mistake of fact exists within the scope of the exception under 10 CFR 50.109(a)(4)(i), 10 CFR 70.76(a)(4)(i) or (ii), 10 CFR 72.62(b), or 10 CFR 76.76(a)(4)(i) only when all of the following three conditions exist:

1. The staff, whether by the staff's own error or by licensee or third-party error or omission, at or before the time of the staff's determination that a known and established standard of the Commission was satisfied—

   - incorrectly perceived facts,
   - performed or failed to recognize flawed analyses, or
   - failed to draw inferences from those facts or analyses.

2. The staff's error is deemed an error 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.

3. The facts, analyses, or inferences have now been properly perceived, performed, or drawn.

The NRC typically invokes the compliance exception when all of the following three conditions are met:

1. The NRC approved or found acceptable a licensee's method of compliance with a requirement.

2. The staff determines that the licensee's method of compliance does not meet the requirement because of an error or omission related to the NRC's approval.

3. If the NRC had known about the error or omission at the time it issued the approval, the NRC would not have approved the licensee's method of compliance.

To justify a compliance exception, the staff must show that the error or omission, which may have been committed by any involved party, must be traced to the licensing basis in effect at the time of the approval at issue, and the NRC decision was inconsistent with prevailing professional standards and practices in existence at the time it made the approval at issue. The

understanding of 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 applicable industry or professional standards and practices in existence at the time the original determination was made.

An omission can occur when a licensee, applicant, or third party does not do one or more of the following:

- provide information to the NRC (or other necessary Federal agency the NRC relies upon in its approval decision) that should have been submitted in connection with obtaining the NRC approval at issue;

- consider or address information that the NRC requires to be considered or addressed in connection with obtaining an NRC approval (e.g., development of an application or preparation of an applicant response to an NRC request for additional information); or

- consider or address information that the NRC requires be addressed through a legal obligation (e.g., for nuclear power plant licensees, the change control provisions of 10 CFR 50.59, "Changes, tests, and experiments").

The NRC can "incorrectly perceive facts" when it receives correct information but misinterprets it or fails to recognize when the licensee or third party provides information that is incomplete, inaccurate, or both.

The applicant's, licensee's, or third party's error or omission must be relevant and material to the NRC's approval that is now regarded as incorrect. An omission or error—even those now acknowledged by the applicant or licensee as having occurred—cannot be the basis for invocation of the compliance exception if that error or omission, had it been known to the NRC at that time, would not have affected the NRC's approval.

Understanding the meaning of the governing requirement is important. If the governing requirement is in the *Code of Federal Regulations*, then the meaning and underlying purpose of that requirement should have been established when the agency issued the regulation in a final rule. The staff should first review the language of the regulation. If the meaning of the regulation is not clear, then the staff should review the supporting SOC for the final rule and any guidance that the NRC found to be an acceptable means for implementing or complying with the requirement. If the license contains the governing requirement (e.g., a license condition or technical specification), then the meaning and underlying purpose should be explained in the application and any supplements made to it.

Equally important to understanding the applicable requirement is identifying the NRC approval of the means by which the licensee has demonstrated that it would meet the requirement (e.g., the licensee's methodology for demonstrating compliance). If the license contains the governing requirement, then the governing requirement would be based on an NRC approval (e.g., a license amendment and associated basis, documented in the safety evaluation, for its conclusions underlying the approvals).

Sometimes, the NRC's conclusion may be perceived to include an implied approval (i.e., an unstated NRC approval that can be inferred from an express NRC approval). To constitute an implied approval, the approval must be part of an expressly stated NRC determination that an

NRC requirement was met (e.g., NRC approval of a licensee's use of an industry standard to demonstrate compliance with an NRC regulatory requirement). Next, the subject matter of the implied approval must be a direct and necessary aspect of the subject matter of the express approval (e.g., the licensee's methodology for implementing the standard). Finally, the subject matter of the implied approval must be expressly discussed in the NRC's approval documentation (e.g., the NRC's safety evaluation references the methodology but does not make an acceptability finding on the methodology). If the implied approval meets these three criteria, then it is considered an NRC approval for purposes of the compliance exception.

The compliance exception does not apply in either of the following situations:

- The staff's error occurred while the staff was using standards and practices that, at the time of the original NRC determination, were not commonly recognized as the prevailing professional standards and practices.

- The NRC evaluated the error using professional standards and practices that were developed or accepted after the time of the NRC determination (e.g., the staff determines that the licensee's method of compliance does not meet the requirement based on a changed staff position or new standards and practices that became known after the NRC determination at issue). Such issues may constitute justifiable backfitting; however, backfitting would need to be justified through adequate protection or cost-justified substantial increase in overall protection.

A change in the NRC's position as to whether a licensee's design conforms to a performance standard is likely to be met with the argument that the new position does not reflect consistency with a "known and established standard," but, rather, it is a new or modified interpretation of what constitutes compliance, which the Commission said in the 1985 Backfit Rule SOC would fall outside the compliance exception.

Consideration of Costs

In a 2015 decision, *Michigan v. Environmental Protection Agency*, the United States Supreme Court held that, unless Congress has indicated otherwise, a Federal agency should consider the costs imposed on a regulated entity to comply with a new regulation. This decision had direct implications for the NRC's application of the backfitting provisions, especially the compliance exception. This decision did not affect the NRC's implementation of adequate protection backfitting because the AEA requires implementation of adequate protection actions without the need to consider costs. The Court's decision also did not change the NRC's approach to any backfitting action based on a substantial increase in overall protection because this type of backfitting must be cost-justified. However, the decision revealed a need to revisit the NRC's implementation of the compliance exception to the backfit analysis requirement. Specifically, the Commission did not view, as consistent with the *Michigan v. Environmental Protection Agency* Supreme Court ruling, the practice of ensuring compliance with a requirement without consideration of cost, as allowed under prior policy and guidance on the use of the compliance exception. In SRM-COMSECY-16-0020, as further explained in the Solicitor's 2016 memorandum, the Commission directed the staff to consider costs when using the compliance exception.

Although the extent of the cost consideration will necessarily be facility specific, factors that may be relevant are (1) the amount of time that has elapsed since the approval or decision that is now at issue and (2) the safety or security risk if the NRC does not take the backfitting action.

When the compliance backfitting issue is identified shortly after the NRC issues its approval (e.g., within 2 years), a staff-prepared cost estimate of imposing the backfitting action using information developed during the original justification may be sufficient to satisfy the consideration of cost policy. But if significant time has passed since the staff made the decision in question (e.g., more than 10 years) for which the staff determines that a regulation or requirement is not satisfied, then the staff should identify the benefits of compliance and compare these benefits to the cost of achieving and maintaining compliance to ensure that costs have been adequately considered. The staff should apply a graded approach[14] to the consideration of costs when justifying a backfitting action using the compliance exception, with the level of cost consideration increasing from minimal consideration involving issues with very recent NRC approvals to a more thorough consideration of costs for issues with NRC approvals that occurred a significant time ago. The results of the cost consideration are used to inform the decision.

If a risk-informed evaluation shows that imposing the compliance backfit would result in at least a discernable safety benefit, then the staff should further inform the regulatory decision process with a consideration of the costs and benefits of the proposed compliance backfit. The staff is given substantial flexibility, in accordance with Commission direction, to determine how much cost consideration is appropriate based on the specifics of each case, the identified risk, and the elapsed time since the approval or decision at issue.

After careful consideration of the issue with respect to the risk to public health and safety or the common defense and security, the available safety margin, the time period of the noncompliance, and the staff's estimates of licensee costs for implementation of the compliance backfit, if the NRC determines that it should not impose the compliance backfit, then the NRC may initiate and issue an acceptance of the existing condition in accordance with the appropriate process. Whether the NRC issues an acceptance depends on the specific circumstances of the proposed action, and the staff should consult with OGC and the Office of Enforcement on this issue. In such cases, the NRC should consider initiating the process to grant such an exemption, relief, or license amendment.

Appendix B to this NUREG contains a compliance exception worksheet that the staff should use to determine the applicability of the compliance exception.

2.5.2.3 Documenting Compliance Exception Evaluations

To ensure the compliance exception's proper application, documented evaluations prepared to justify invoking the compliance exception should clearly and thoroughly describe each of the elements listed in Section 2.5.2.2. Appendix C to this NUREG contains a guide for drafting a documented evaluation to justify a compliance backfitting action. The staff's compliance backfitting documentation should include risk insights to give the staff sufficient information to determine an acceptable schedule for the licensee to implement the backfit.

The office director responsible for issuing the backfitting action must approve any documented evaluation and a copy should be sent to the EDO and appropriate regional administrator before the staff transmits the backfitting documentation to the licensee. If it cannot justify the proposed

[14] In this context, a graded approach means that the process of ensuring that the level of cost consideration, analysis, documentation, and actions used to comply are commensurate with (1) the relative importance to safety, safeguards, and security, and (2) the magnitude of the risk involved.

action using the compliance exception, and the staff cannot justify a cost beneficial substantial safety enhancement, then the staff must document its conclusions as described in Chapter 6 of this NUREG.

2.6 Question 5: Does the proposed backfitting action constitute a cost-justified substantial increase in the overall protection of public health and safety or the common defense and security, or does the change affecting issue finality in the proposed action satisfy an issue finality criterion?

2.6.1 Background

If the staff determines that it cannot justify its proposed action using either of the adequate protection exceptions or the compliance exception to the requirement to conduct a backfit analysis, then the staff needs to consider whether it can justify the proposed action using a backfit analysis. In a two-part test, the staff must first show that the proposed action would provide a substantial increase in the overall protection of the public health and safety or the common defense and security. If the staff can reach that conclusion, then it must determine whether the direct and indirect costs of implementing the backfitting action are justified in view of the increased protection. These standards appear in 10 CFR 50.109(a)(3), 70.76(a)(3), 72.62(c), and 76.76(a)(3), and in certain issue finality regulations under 10 CFR Part 52.

If the proposed action is not shown to result in a substantial increase in overall protection, the staff should not proceed further with the backfit analysis because the backfitting action cannot be justified. If the proposed backfitting action is shown to result in a substantial increase in overall protection, but the costs cannot be justified, then the backfitting action cannot be justified. In either event, the staff should document its conclusions as described in Chapter 6 of this NUREG.

2.6.2 Cost-Justified Substantial Increase in Overall Protection Determinations

Using a cost-justified substantial increase in overall protection justification requires that the backfitting action would provide a “substantial increase” in protection. In the 1985 Backfit Rule SOC, the Commission stated that “substantial” means “important or significant in a large amount, extent, or degree.” Under such a standard, the Commission stated that it would not ordinarily expect that facility improvements that result in an insignificant or small benefit to public health and safety or the common defense and security, regardless of costs, would be required through cost-justified substantial increase in overall protection backfitting.

The definition of “substantial” is ultimately a regulatory and policy determination. The determination, however, must be rational (i.e., not illogical) and supported by evidence or fact, as applicable.

This approach is flexible enough to allow for arguments that consistency with national and international standards, or the incorporation of widespread industry practices, contributes directly or indirectly to a substantial increase in safety. Such arguments concerning consistency with other standards, or the incorporation of industry practices, may have to rest on the aspects of a given proposed action.

In SRM-SECY-93-086, "Backfit Considerations," the Commission explained that the "substantial increase" criterion "allow[s] for qualitative consideration of factors to determine that a given proposed rule would substantially increase safety." In accordance with SRM-SECY-14-0087, "Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," dated March 4, 2015, this consideration of qualitative factors does not authorize an expansion of such consideration in regulatory analyses and backfit analyses. Instead, the staff should use qualitative factors in a judicious and disciplined manner to inform decisionmaking, in limited cases, when quantitative analyses are not possible or practical (e.g., due to lack of methodologies or data). NUREG/BR-0058 is intended to be a primary source of guidance on the application of the "substantial increase" standard as well as the application of the Commission's safety goals. While the staff should strive to use all available quantitative factors, the consideration of qualitative factors in regulatory decisionmaking can be important to the overall understanding and discussion of the impacts of a regulatory action. The quantitative information must meet generally accepted professional levels of quality and reliability for use in quantitative analyses. Qualitative analysis should be used in accordance with NUREG/BR-0058. The staff uses a risk-informed decisionmaking framework as input into whether the substantial safety enhancement criterion is met.

If the NRC does not have access to quantitative information on benefits or costs when it is preparing the backfit analysis, then the NRC has several alternatives:

- The NRC can seek to obtain the necessary quantitative benefit or cost information, for example, by performing a literature search, querying other Federal agencies, requesting that the information be provided voluntarily (e.g., in a proposed rule *Federal Register* notice for a rulemaking), issuing an order or a 10 CFR 50.54(f) letter (for Part 50 licensees) for submission of information, or adopting a regulation requiring the submission of the necessary information. Any information requests to the public or affected stakeholders must meet applicable legal requirements such as those of the Paperwork Reduction Act. The staff should not communicate with the licensee about the possible backfitting until after receiving management's approval to do so.

- The NRC can explain the efforts it took to obtain the information or explain that the information is not reasonably available or known to any entity and proceed with a qualitative determination of benefits and costs.

- The NRC can withdraw or end its efforts to backfit or impose a change affecting issue finality.

Averted offsite costs that result from an estimated decrease in accident frequency or severity that are tied directly to public health and safety are considered benefits (i.e., safety enhancement). The intent of the Backfit Rule is to consider as benefits only averted offsite deaths and adverse health effects that result from an estimated decrease in accident frequency or severity attributable to the proposed backfitting. The staff should treat averted costs, such as onsite and offsite property damage as defined in NUREG/BR-0058, as an offset against other licensee costs to calculate the net backfit cost. The backfit analysis should clearly state that costs of averted onsite and offsite property damage are not counted as a benefit, and these costs are considered after the staff has determined that the proposed action will result in a substantial increase in the overall protection of the public health and safety or the common defense and security.

Notably, the substantial increase in overall protection must pertain to the "overall protection of the public health and safety or common defense and security." The Commission explained in the 1985 Backfit Rule SOC that the principal purpose of this standard was "to ensure that both [the proposed backfit's] negative and positive effects are taken into account in deciding whether the backfit is justified." The backfit's effects on protection provided by the plant as a whole, not just the part of the plant being backfitted, is the "overriding consideration."

The backfitting provisions in 10 CFR 72.62 differ from the backfitting requirements for nuclear power reactor licensees by specifically including occupational safety within the provisions of 10 CFR 72.62(b) and (c)(1). Under 10 CFR 72.62(b), the NRC must consider occupational health and safety in terms of adequate protection, and 10 CFR 72.62(c)(1) directs the NRC to consider occupational health and safety in determining whether the proposed action would result in a substantial increase in overall protection as part of a backfit analysis. In 10 CFR 50.109(c) and 70.76(b), the backfitting provisions require the NRC to consider radiological exposure (and hazardous chemicals under 10 CFR 70.76(b)) of facility employees only as part of a backfit analysis. Therefore, in addition to considering members of the public, cost-justified backfit analyses that are performed to satisfy these regulations need to also consider onsite personnel when analyzing the substantial increase in the overall protection resulting from the proposed action.

The Commission has also directed the staff to evaluate the NRC's regulatory actions that affect nuclear power plants for conformity with the NRC's policy statement on safety goals for the operation of nuclear power plants. The 1986 policy statement sets out two qualitative safety goals and two quantitative health objectives. Both the safety goals and health objectives apply only to the risks to the public from the accidental or routine release of radioactive materials from nuclear power plants. The safety goal evaluation applies only to regulatory initiatives considered to be generic safety enhancement backfits that are subject to the substantial additional protection standard at 10 CFR 50.109(a)(3). A safety goal evaluation is not necessary for new requirements within the exceptions at 10 CFR 50.109(a)(4)(i)–(iii) or for a facility-specific cost-justified substantial increase in overall protection backfitting. If the proposed safety goal screening criteria in NUREG/BR-0058 are satisfied (i.e., any decision except a no-action decision), the NRC considers that the substantial additional protection standard is met for the proposed new or revised requirement.

2.6.3 Documenting a Backfit Analysis

A backfit analysis must consider the factors listed in the applicable 10 CFR provisions and any other information relevant and material to the proposed backfitting. In 10 CFR Part 50, 10 CFR 50.109(c) lists the relevant factors that must be included in a backfit analysis:

1. statement of the specific objectives that the proposed backfit is designed to achieve;

2. general description of the activity that would be required by the licensee or applicant to complete the backfit;

3. potential change in the risk to the public from the accidental offsite release of radioactive material;

4. potential impact on the radiological exposure of facility employees;

5. installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay;

6. the potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements;

7. the estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;

8. the potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed backfit; and

9. whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

The level of detail in a backfit analysis can vary, depending on the circumstances. In general, the complexity and comprehensiveness of the analysis should be limited to that necessary to provide an adequate basis to show that the proposed regulatory action provides a cost-justified substantial increase in overall protection. The analysis should emphasize simplicity, flexibility, and logic, both in terms of the type of information supplied and the level of detail provided.

Similar to documented evaluations, the Director of NRR or NMSS, whichever is responsible for issuing the backfitting action (for facility-specific backfitting) or the Commission (for generic backfitting such as rulemakings) must approve any backfit analysis. A copy should be sent to the EDO and appropriate regional administrator before the staff transmits the backfitting documentation to the licensee.

Appendix C to this NUREG contains a guide for drafting a backfit analysis to justify a backfitting action.

Issue Finality

For proposed actions that affect the issue finality of a Part 52 approval, the staff must determine whether that proposed action satisfies the criteria in the issue finality provision that applies to the Part 52 approval. Because the issue finality provisions in Part 52 vary by approval, the details of the criteria will depend on the Part 52 approval. The staff may need to prepare a backfit analysis as described in this Section 2.6 or an analysis specific to the issue finality provision, which is an “issue finality analysis.”

3 FORWARD FITTING

3.1 Background

Management Directive (MD) 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," dated September 20, 2019, contains the Commission's forward fitting policy. Forward fitting is similar to backfitting in that forward fitting promotes regulatory stability, reasoned decisionmaking, and transparency. Like backfitting, forward fitting requires the U.S. Nuclear Regulatory Commission (NRC) to justify the imposition on a licensee of a new or amended requirement or staff interpretation of a requirement that results in the modification of or addition to systems, structures, components, or the 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. However, unlike backfitting, forward fitting occurs only during licensing actions that are initiated voluntarily by a licensee. The forward fit happens when the NRC imposes the qualifying new or amended requirement or staff interpretation of a requirement as a condition of approving the licensee's requested licensing action, and the licensee's underlying request did not propose to comply with the new or revised requirement or interpretation.

The forward fitting policy applies to only those licensees that are also within the scope of backfitting provisions. Forward fits generally do not include instances when an applicant files an initial licensing action for a new facility. However, any change from the requirements or regulatory staff positions that applicants relied upon in the development of their applications should follow the same reasoned decisionmaking process as a forward fit.

3.2 Forward Fitting Determinations

To determine whether the proposed action constitutes forward fitting, each of the following statements must be true:

1. The NRC is reviewing a request for a licensing action voluntarily initiated by a licensee (i.e., the licensee was not required to initiate the licensing action in response to an order or other new requirement).

2. The licensee is among the entities listed in Section 2.3 of this NUREG that are within the scope of the backfitting provisions listed in Table 1-1.

3. The staff's proposed action is the imposition of either—

    a. a new or changed (e.g., amended, revised, or modified) NRC requirement (e.g., a regulation or order); or

    b. a new or changed staff interpretation of an NRC requirement.

4. The imposition of the new or changed requirement or interpretation will result in a modification or addition to the licensee's—

    a. systems, structures, or components of its facility;

    b. design (including but not limited to design certification, standard design approval, or manufacturing license) of its facility; or

    c. procedures or organization required for designing, constructing, or operating its facility.

5. The new or changed NRC requirement or interpretation being imposed on a licensee is a condition of the NRC's approval of the licensee-initiated licensing action.

6. The licensee's underlying request did NOT propose to comply with the staff's proposed new or revised requirement or interpretation.

If one or more of the statements is not true, then the proposed action is not forward fitting. The staff should document that conclusion as described in Chapter 6 of this NUREG and proceed to take the proposed action. However, if all the statements are true, then the staff's proposed action constitutes forward fitting.

Forward fitting can occur in various ways. The NRC would be forward fitting a licensee if the staff required the licensee to use a newer version of a regulatory guide to demonstrate compliance with an existing requirement than the version the licensee proposed to use in its requested licensing action. Forward fitting could also occur when the staff uses a guidance document in its review of the licensee's request that the licensee did not use when it submitted its request, and the staff conveys the expectation that the licensee use that guidance document in preparing the request or responding to requests for additional information related to the request.

Forward fitting could occur if the NRC issues a guidance document that supersedes an existing guidance document. If the agency requires licensees to use the new, modified guidance document in future licensing actions, then such action could constitute forward fitting. For this reason, when the staff issues modified guidance documents, the staff should consider whether it needs to withdraw or supersede the existing guidance document. Section 5.8 of this NUREG contains a discussion of withdrawing and superseding guidance documents.

Other examples of forward fitting include the following:

- imposing a license condition that was not part of the licensee's request (e.g., requiring an approach that the staff finds more acceptable than, or preferable to, the licensee's requested action);

- escalating regulatory commitments into licensing conditions; or

- requesting additional information, asking an audit question, or engaging in a verbal discussion during a licensing action review, that suggests or implies that the licensee should meet a new standard it is not currently required or proposing to meet or should revise its request to propose a new license condition.

3.3 Justifying Forward Fits and Documenting the Analyses

Whenever the staff intends to forward fit a licensee, the staff must justify the forward fit. The NRC justifies the forward fit through an analysis that shows the following criteria are met: (1) there is a direct nexus between the new or modified requirement or regulatory staff position and 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. The staff must also consider the costs of the forward fitting action unless adequate protection is involved, as discussed below. The staff should identify the benefits of the forward fit and compare these benefits to the cost of implementation. Based on a risk-informed evaluation, if the safety benefit of imposing the forward fit is determined to be very low or negligible, then the staff should no longer consider imposing the forward fit. For forward fits having greater safety benefit, the staff should further inform the regulatory decision process by considering the costs and benefits of the proposed forward fit. The Commission gives the staff substantial flexibility to determine how much cost consideration is appropriate based on the specific facts of each case and the identified risk.

The first criterion's "direct nexus between the new or modified requirement or regulatory staff position and the licensee's request" means that the requirement or staff position must relate directly to the specific subject matter of all or part of the licensee's request for NRC approval. For example, if the licensee's license amendment request concerns the emergency diesel generators, then the new or modified requirement or regulatory staff position that the staff wants to impose on the licensee cannot involve the height of the fence surrounding the protected area. If the staff wished to impose a proposed action that does not have a direct nexus to the licensee's request, then it would have to perform a backfitting assessment.

The second criterion is that the imposition of the new or modified requirement or regulatory staff position is essential for the NRC staff to make a finding that the licensee's requested licensing action is acceptable (i.e., without the imposition, the staff could not make its safety or security finding). What is essential to make such a determination will vary depending on the type of request. For example, for license amendments, Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.92, "Issuance of amendment," and Section 50.40, "Common standards," require that the staff conclude that there is reasonable assurance that public health and safety will not be endangered by operation in the proposed manner, there is reasonable assurance that such activities will be conducted in compliance with the Commission's regulations, and the issuance of the amendments will not be inimical to the common defense and security or to the public health and safety. The conclusions needed for determining the acceptability of relief requests, proposed alternatives, exemptions, or other requests will differ from those for license amendments. The staff should use the applicable office instructions or guidance for a specific review to determine what information is essential to make a conclusion on the acceptability of the request.

If the staff concludes that the two criteria are met and it cannot approve the licensee's requested action because reasonable assurance of adequate protection would not be maintained, then the staff can deny the request, ask for additional information, or approve the request with a forward fit to maintain reasonable assurance of adequate protection. Requesting additional information through carefully worded questions to the licensee is an appropriate method for obtaining the information the staff needs to make its finding. These information requests must not tell the licensee what it needs to do to obtain staff approval. The staff also should not provide advice or direction to a licensee that is not appropriate given the staff's role as the regulator. To ensure that requests for additional information are not phrased as forward fits, the staff should clearly

articulate why it cannot make its safety finding and leave responsibility for solutions to the licensee. If the staff pursues a forward fit, the staff would not need to consider the costs of the forward fit because it involves adequate protection.

If the staff determines that the two criteria are met and it cannot approve the licensee's requested action because granting the request would not provide reasonable assurance that the licensee's activities would be conducted in compliance with the Commission's regulations, but the staff's determination does not involve adequate protection (because a licensee's non-compliance with one or more applicable requirements does not necessarily mean that public health and safety are no longer adequately protected), then the staff can deny the request, ask for additional information, or approve the request with a cost-justified forward fit to ensure continued compliance with the Commission's regulations. The licensee can also request an exemption from the applicable regulation. If the forward fit cannot be cost-justified, then the staff may have to deny the request. The NRC's denial of the request may allow the licensee to seek redress of the denial through a demand for hearing.

If the staff concludes that the two criteria are met, but unlike in the situations in the preceding paragraphs, the forward fit consists of the imposition of a modified regulatory staff position and the existing regulatory staff position is available for current licensees to use and applicable to the licensing action under the staff's review, then the Commission policy is that the staff should perform a site-specific regulatory analysis of the forward fit unless the forward fit is necessary for adequate protection of the public health and safety.[1]

If the forward fit consists of a new or modified regulatory staff position and the prior regulatory staff position is no longer available for the applicant to use, then the staff must consider the costs of the forward fit. If the prior staff position is no longer available for use, then the staff should have performed a regulatory analysis when the staff issued the new or modified staff position that replaced the prior staff position. The staff should use that generic regulatory analysis, if available, to inform the site-specific regulatory analysis.

If no prior staff position exists because the licensing action presents a case of first review and, thus, no applicable regulatory analysis exists, the staff still needs to consider the costs of the forward fit but is not required to perform a site-specific regulatory analysis.

If, during the staff's review of the licensing action, the staff discovers an issue of adequate protection with the current licensing basis, then the staff must address the existing issue through the backfitting process.

Appendix C to this NUREG contains a guide for drafting a forward fit analysis to justify a forward fitting action. Unlike a backfit analysis described in Section 2.6 of this NUREG, a forward fit

[1] However, as explained in MD 8.4, forward fits in this situation will not usually be justifiable as necessary for adequate protection because the NRC already had an opportunity to consider whether the new or changed requirement or staff position was necessary for adequate protection of the public health and safety. This occurred when the NRC established or modified the requirement or regulatory staff position and the NRC determined 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) about backfitting necessary to ensure adequate protection of the public health and safety, if such a change were necessary to ensure adequate protection of the 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 if the staff is considering a forward fit, it is unlikely that a change could be justified to be necessary to ensure adequate protection of the public health and safety.

analysis contains the staff's evaluation of the proposed action against the definition of a forward fit and the "direct nexus" and "essential to the staff's finding" criteria, and the staff's consideration of the costs of the forward fit or its basis for determining that the forward fit involves adequate protection.

4 BACKFITTING AND FORWARD FITTING APPEALS

Licensees can discuss the applicability of backfitting regulations and the forward fitting policy with the applicable U.S. Nuclear Regulatory Commission (NRC) staff whenever the licensees have a concern. The staff should ensure that its management is informed of a licensee's concern and should consider the points raised by the licensee before proceeding to issue a proposed staff action (e.g., a finding, violation, or license amendment). If the staff determines that the proposed staff action is not backfitting or forward fitting, then the staff should proceed with the proposed staff action. If the staff agrees that the proposed staff action could constitute backfitting or forward fitting, then the staff should subject the proposed action to a backfitting or forward fitting assessment.

The NRC provides a process by which licensees may appeal staff actions on the basis that the licensee concludes the staff did not properly follow the backfitting or forward fitting process. Each communication of a backfitting or forward fitting action issued to a licensee must include instructions on the use of the appeal process. If the licensee elects to file a backfitting or forward fitting appeal when it receives the written staff action, the licensee must submit the appeal in writing, in accordance with Section 50.4, "Written communications," of Title 10 of the *Code of Federal Regulations* (10 CFR), with a copy to the appropriate regional administrator and program office director (i.e., depending on the licensee, the Director for either the Office of Nuclear Reactor Regulation (NRR) or the Office of Nuclear Material Safety and Safeguards (NMSS)). For a second-level appeal, the licensee must submit the written appeal in accordance with 10 CFR 50.4, with a copy to the Executive Director for Operations (EDO).

The NRC will not accept oral appeals of backfitting or forward fitting actions or appeals submitted by a third party. In these cases, the staff will not consider any appeal until it receives a written appeal from a licensee. If the NRC initiated a staff action using an order, the appeal process described in this section does not apply. After the NRC issues an order, 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," as specified in Management Directive (MD) 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," dated September 20, 2019.

For backfitting or forward fitting appeals, licensees have two levels of appeal: a first-level appeal at the office director level[1] and a second-level appeal to the EDO. Licensees can use the backfitting or forward fitting appeal process only in either of the following situations:

- The NRC staff imposed an applicable staff position on the licensee that the staff determined was not backfitting or forward fitting, but that the licensee believes is backfitting or forward fitting.

- The NRC staff imposed an applicable staff position on the licensee that the staff determined was backfitting or forward fitting, but that the licensee believes was not properly justified. This includes an appeal to modify or withdraw a backfitting action for which the staff conducted a backfit analysis or an appeal that a backfitting action justified

[1] In accordance with MD 8.4, the regional administrator is not the official decision maker but is expected to be involved and may be the one receiving the appeal.

by the adequate protection or compliance exception in fact must be justified through a backfit analysis.

Section 5.5 of this NUREG addresses situations when the licensee raises a backfitting claim, concern, or appeal while also disputing a violation.

If, during a backfitting or forward fitting appeal process, the Director of NRR or NMSS for a first-level appeal, or the EDO for a second-level appeal, determines the appealed action constitutes unjustified backfitting or forward fitting, then the responsible office director, EDO, or designee must document the decision, request Office of the General Counsel (OGC) review of the decision, and inform the licensee in writing. The office director, EDO, or delegate, as applicable, may exit the appeal process at any time without completing all of the process steps (e.g., holding a public meeting).

4.1 Receipt of Backfitting or Forward Fitting Appeals and Initiation of the Appeals Process

a. The appeals process begins upon the NRC's receipt of a written appeal of a staff action.

b. The NRC will accept appeals from only those licensees for which the NRC action constitutes a backfit or forward fit and only if they are subject to the backfitting provisions in 10 CFR Chapter I. The NRC will not accept appeals from NRC staff[2] who disagree with an agency action or position. Licensees should submit written appeals within 90 days of receiving the NRC's written action or staff position or 30 days after the NRC issues its decision on a directly related disputed violation.

c. The first-level appeal must include sufficient documentation to justify the licensee's basis for the appeal. The licensee must indicate deficiencies in the staff's position or provide other information that is relevant and material to the staff's action or position and supports the licensee's position for the appeal.

d. The licensee may not request a second-level appeal until the NRC issues its decision on a first-level appeal.

4.2 Initial Review of a First-Level Appeal and Determination of Oversight Responsibility

a. Upon receipt of a backfitting or forward fitting appeal, the NRC staff should notify the following individuals or designees and provide them with a copy of the appeal:

   1. the Backfitting and Forward Fitting Community of Practice members in the applicable program and regional offices;

   2. the managers in charge of the offices, divisions, and branches that issued the action in question and, if not the organization that issued the action in question, are responsible for the technical, regulatory, or policy areas in question;

[2] NRC staff should utilize the Differing Professional Opinion or non-concurrence processes.

3. the Deputy General Counsels;

4. the director of the Office of Enforcement;

5. the chairman of the Committee to Review Generic Requirements;

6. the regional administrator for the affected facility; and

7. the licensing project manager for the affected licensee

b. The Director of NRR or NMSS, depending on the license, will oversee the first-level appeal process and issue the decision on the appeal. This office director (hereafter referred to as the Responsible Manager) will coordinate the review of the first-level appeal with the regional administrator overseeing the affected licensee and, as applicable, the Director of the Office of Nuclear Security and Incident Response.

c. Within 15 business days of the date when the NRC receives the appeal, the Responsible Manager should respond to the licensee acknowledging receipt of the appeal and communicating plans for staff review.

4.3 Review of the First-Level Appeal

a. The Responsible Manager may appoint a panel to review documentation associated with the appeal and NRC action or position at issue. This panel should consist of individuals who are independent from the initial action or position at issue (i.e., the individuals did not take part in reviewing or approving the initial staff action). A manager at the deputy division director level or higher should chair the panel, and membership should include an attorney from OGC and staff or management with the appropriate technical and regulatory expertise and experience to thoroughly evaluate the action or position at issue. The remaining steps assume that a panel has been appointed. If not, the Responsible Manager assumes responsibility for the actions in this section that a panel would otherwise conduct.

b. The panel must offer the licensee a public meeting to discuss its appeal. No regulatory decisions may be made at this public meeting. To the extent practical, this public meeting should occur within 45 calendar days of NRC receipt of the appeal. Summaries of all appeal meetings with the licensee should be prepared and placed in the NRC's Agencywide Documents Access and Management System as specified in MD 3.5, "Attendance at NRC Staff-Sponsored Meetings."

c. During the review process and following any public meeting with the licensee, the panel must offer a non-public internal meeting to the NRC staff who originated the contested action or position and may meet with other NRC staff who have expertise in the area.

d. The panel must consider all supporting staff analyses, licensee-submitted analyses, and any other information that is relevant and material to the appeal.

4.4 Response to the First-Level Appeal

a. The panel will document its recommendation on whether to grant or deny the appeal in a memorandum from the panel chair to the Responsible Manager. The memorandum should comprehensively document the basis for the panel's recommendation.

b. The Responsible Manager will evaluate the information and recommendation provided by the panel. The Responsible Manager will draft a response letter to the licensee that comprehensively documents the basis for the Responsible Manager's decision and submit the draft response letter to OGC for its review. Subsequently, the Responsible Manager will inform the appropriate Deputy EDO before communicating the outcome in writing to the licensee. To the extent practical, the Responsible Manager should transmit the written response to the licensee within 90 calendar days of receipt of the appeal.

c. If the NRC is denying the appeal (i.e., the Responsible Manager determines that the staff action is justified backfitting or forward fitting, or that the staff action is not backfitting or forward fitting), then the response letter should inform the licensee that it may either appeal the decision to the EDO within 30 calendar days of the date of the response letter or take actions to come into compliance with the agency's decision. If the licensee fails to appeal the decision within 30 calendar days or implement the required action by the agreed-upon date, then the NRC will resolve the issue through the enforcement program.

d. In the case of a denied appeal of a forward fit that the NRC staff communicated to a licensee prior to the NRC staff completing the licensing action, if the licensee does not appeal the decision within 30 calendar days, then the licensee may (1) withdraw or modify its request for the licensing action, (2) agree to the forward fit, or (3) do nothing. If the licensee chooses option (2), then the NRC would issue the licensing action with the forward fit. If the licensee chooses option (3), then the NRC could either deny the request in part or in whole or issue the licensing action with the forward fit. The NRC's denial of the request may allow the licensee to seek redress of the denial through a demand for hearing.

e. If the NRC is granting the appeal, then the agency must initiate appropriate actions to ensure the licensee's licensing basis reflects the outcome of the appeal process (e.g., issuing an order or withdrawing a request for additional information).

4.5 Initial Review of a Second-Level Appeal

a. Appeals addressed to the EDO that have not been processed through the first-level appeal will be redirected to the first-level appeal process. A second-level appeal is a written appeal of the outcome of the first-level appeal.

b. A second-level appeal should be dated within 30 calendar days of the date of the NRC's response to the first-level appeal.

c. Upon receipt of a second-level appeal, the following individuals or designees should be notified and provided a copy of the appeal:

1. the Backfitting and Forward Fitting Community of Practice members in the applicable program and regional offices;

2. managers in charge of the offices, divisions, and branches that issued the action in question and, if not the organization that issued the action in question, are responsible for the technical, regulatory, or policy areas in question;

3. the Deputy General Counsels;

4. the director of the Office of Enforcement;

5. the chairman of the Committee to Review Generic Requirements;

6. the licensing project manager for the affected licensee;

7. the Responsible Manager involved in the first-level appeal; and

8. the regional administrator for the affected facility

d. Within 15 business days of agency receipt of the appeal, the EDO or designee should respond to the licensee by acknowledging receipt of the appeal and communicating high-level plans for staff review.

4.6 Review of the Second-Level Appeal

a. The EDO may appoint a panel to review documentation submitted by the licensee with the second-level appeal, the results of the first-level appeal, and the initial action or position at issue. The panel should consist of managers at the deputy division director level or higher and an attorney from OGC, each with the appropriate technical and regulatory expertise and experience to thoroughly evaluate the action or position at issue and who have not previously participated in the initial action or staff position nor first-level appeal. The members of the panel should collectively have expertise in both the technical issues and the regulatory issues at hand. The remaining steps assume that a panel has been appointed. If not, the EDO (or their designee) assumes responsibility for the actions in this section that a panel would otherwise conduct.

b. The NRC must offer the licensee a public meeting in which the second-level appeal can be discussed with the panel reviewing the appeal. No regulatory decisions may be made at this public meeting. The NRC staff should prepare summaries of all appeal meetings with the licensee within 30 calendar days of the meeting, as specified in MD 3.5.

c. The panel must offer a non-public internal meeting to the originating staff of the NRC action.

d. The panel must offer a non-public internal meeting to the first-level appeal panel to discuss both the licensee's first- and second-level appeal documentation.

e. The panel should consider all supporting staff analyses, licensee-submitted analyses, and any other information that is relevant and material to the appeal.

4.7 Response to the Second-Level Appeal

a. The panel will document its recommendation on whether to grant or deny the appeal in a memorandum from the panel chair to the EDO. The memorandum should comprehensively document the basis for the panel's recommendations.

b. The EDO will evaluate the information and recommendation provided by the panel and make a decision on the appeal. The EDO will draft a response letter to the licensee that comprehensively documents the basis for the EDO's decision and submit the draft response letter to OGC for its review.

c. To the extent practical, the EDO should transmit the response letter to the licensee within 90 calendar days of receipt of the appeal. If applicable, this letter should also inform the licensee that the agency may issue an enforcement order if the licensee refuses to comply with the staff's position.

d. If the NRC denies the appeal (i.e., the EDO determines that the staff action is justified backfitting or forward fitting, or that the staff action is not backfitting or forward fitting), then the response letter should inform the licensee that it must come into compliance with the agency's decision. If the licensee fails to implement the required action, then the NRC will resolve the issue through the enforcement program.

e. In the case of a denied appeal of a forward fit that the NRC staff communicated to a licensee prior to the NRC staff completing a licensing action, the licensee may: (1) withdraw or modify its request for the licensing action, (2) agree to the forward fit, or (3) do nothing. If the licensee chooses option (2), then the NRC would issue the licensing action with the forward fit. If the licensee selects option (3), then the NRC could either deny the request in part or in whole or issue the licensing action with the forward fit. The NRC's denial of the request may allow the licensee to seek redress of the denial through a demand for hearing.

f. If the NRC grants the appeal, then the agency must also initiate the appropriate actions to ensure the licensee's licensing basis reflects the outcome of the appeal process (e.g., issuing an order or withdrawing a request for additional information).

5 RELATIONSHIP OF BACKFITTING AND FORWARD FITTING TO OTHER PROCESSES

This chapter discusses the relationship of backfitting and forward fitting to other requirements and regulatory activities that might apply to backfitting and forward fitting.

5.1 Change Control Processes

Several regulations establish change control requirements, such as Title 10 of the *Code of Federal Regulations* (10 CFR) Sections 50.59, 50.54(a), 50.54(p), 50.54(q), 52.98(b)-(c), 70.72, and 72.48(c). These change control requirements grant licensees the authority to make changes to their licensing bases without prior U.S. Nuclear Regulatory Commission (NRC) review and approval, provided the change meets the specified criteria in each change control requirement that governs whether prior NRC review and approval is necessary. Licensee implementation of changes using these change control requirements is subject to NRC inspection. If the change processes are used properly, then the licensee can reasonably implement the change without concern about future enforcement action and with the assurance that any future NRC-imposed modifications to the changes would be subject to backfitting considerations. This is consistent with the underlying premise of regulatory stability established within the backfitting regulations and the NRC's Principles of Good Regulation. However, a licensee that improperly implements a change to its licensing basis under one of these change control requirements would be in violation of the requirement.

5.2 Clarifications

A clarification, such as one communicated through the NRC's Frequently Asked Question Web site or a Regulatory Issue Summary, is a staff position that provides additional explanation of an existing requirement or staff position. Clarifications can be used for various purposes, such as addressing a requirement or staff position that may not be generally understood by licensees and may lead to multiple interpretations. They can also be used to explain a requirement or staff position that, because of issues like phrasing, grammar, and punctuation errors, may result in multiple interpretations. A clarification that does not impose a new or changed requirement or new or different staff position does not meet the definition of backfitting. However, proposed clarifications have the potential to impose new or additional requirements or staff positions (e.g., revoking previous staff positions); therefore, the staff should subject the proposed clarification to a backfitting assessment to verify that the clarification is not backfitting. If the original staff position allowed for multiple interpretations, and the staff is now trying to limit licensees to one interpretation, then that limitation would be a new staff position and, if imposed on a licensee, would require a backfitting or forward fitting justification.

5.3 Commitments

The backfitting provisions in 10 CFR 50.109(a)(4)(i), 70.76(a)(4)(i)-(ii), 72.62(b), and 76.76(a)(4)(i) provide that the NRC can impose a backfitting action to ensure a licensee's compliance with its license or NRC requirements or conformance with written licensee commitments. A nuclear power plant's licensing basis contains "commitments" that describe a method for complying with regulations or requirements; commitments that were made in docketed licensing correspondence such as licensee responses to NRC generic communications, information requests, or enforcement actions; and commitments documented in licensee event reports that detail the method or process to comply with regulations or

requirements. However, not every commitment in the licensing basis is a "written commitment" as intended by 10 CFR 50.109, 70.76, 72.62, and 76.76. Management Directive (MD) 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," dated September 20, 2019, provides that, in the backfitting context, a written commitment is a commitment that has been submitted to the NRC on the docket, has been incorporated into the license, and directly relates to how the licensee complies with a requirement.

Regulatory commitments made by nuclear power reactor licensees are not legally binding requirements on licensees and, therefore, are not enforceable unless the NRC issues an order. If a regulatory commitment was escalated into a legally binding requirement (e.g., a license condition), then that regulatory commitment would cease being a regulatory commitment upon its escalation. Therefore, for nuclear power reactor licensees, the staff would need to take a backfitting or forward fitting action to escalate a regulatory commitment into a requirement if the licensee did not voluntarily do so.

Most commitments begin as voluntary (e.g., the licensee submits through docketed correspondence regulatory commitments that the NRC did not request). The staff may determine that to approve a licensee's request, a commitment must be converted to a legally binding requirement (e.g., a license condition); however, this is likely a forward fit.

The NRC may issue a notice of deviation and request information about a licensee's failure to implement or maintain a regulatory commitment. The licensee could either reinstate or conform with its commitment. Issuance of the notice of deviation would not constitute backfitting because the NRC did not require the licensee to implement and maintain the commitment. If the NRC decides to require the licensee to implement and maintain the commitment and, therefore, removes the voluntary nature of the commitment, then the staff's proposed action would be subject to backfitting assessment.

5.4 Differing Views of a Licensing Basis

An important task in assessing potential backfitting for any facility is to identify and review NRC records and interact with licensees to understand the prevailing issue within the context of the licensing basis. In some cases, differing views (i.e., between the staff and licensee or among the staff) about the appropriateness of backfitting actions originate in differing views of the licensing basis for the subject facility. The processes discussed in this NUREG assume that backfitting or forward fitting assessments of proposed staff actions begin with a correct understanding of the existing licensing basis. Therefore, the staff should first identify and resolve any differing views about the licensing basis (e.g., through the technical assistance request process discussed in Section 5.21 of this NUREG) and ensure that the licensing basis is understood before beginning a backfitting or forward fitting assessment or pursuing enforcement. The NRC licensing project manager for the facility is the initial point of contact for work related to identifying and reviewing the facility's licensing basis.

5.5 Enforcement

The NRC issues enforcement sanctions, including orders other than "safety orders," notices of violation (NOVs) or non-cited violations (NCVs), when a licensee or non-licensee violates a legally binding requirement. The staff should take extra caution when reviewing regulatory requirements, such as an operating reactor's licensing basis, cited in an enforcement action to ensure that the enforcement action is, in fact, citing only legally binding requirements. A citation that improperly reflects a new or modified requirement or staff position constitutes backfitting.

The licensee may formally submit a backfitting appeal in accordance with Chapter 4 of this NUREG while also denying a violation in response to an enforcement action, typically an NOV or NCV. In this situation, the NRC staff will not respond to the disputed violation until the agency has reviewed the formal backfitting appeal and made a final decision on the validity of the claim. If the NRC denies the licensee's backfitting appeal, then the NRC will continue the enforcement process and ultimately either uphold or withdraw the violation. If the NRC grants the licensee's backfitting appeal, then the NRC will withdraw the violation.

By contrast, if the licensee raises a backfitting claim or concern to the NRC in conjunction with a disputed violation in reply to an NOV or NCV, but the licensee has not formally submitted a backfitting appeal, then the NRC staff should not consider the backfitting claim. Instead, the enforcement staff should direct the licensee to Chapter 4 of this NUREG. If a regional office issued the NOV or NCV and the licensee's basis for disputing the violation is that the requirement or the means by which the licensee did not meet the requirement is not in its licensing basis, then, after reaching a decision on the disputed violation, the region needs to obtain the concurrence of the appropriate program office (i.e., the Office of Nuclear Reactor Regulation (NRR) or the Office of Nuclear Material Safety and Safeguards (NMSS)) before issuing its decision on the disputed violation.

5.5.1 Confirmatory Orders and Confirmatory Action Letters

Confirmatory orders that confirm licensee commitments and impose requirements in excess of previously applicable staff positions are not backfitting. The NRC issues confirmatory orders to ensure the licensee complies with certain commitments it voluntarily made to the NRC by making them legally binding requirements. Licensees agree to the confirmatory order requirements and waive their hearing rights before issuance.

A confirmatory action letter is not a requirement and, accordingly, is not enforceable. Licensees voluntarily agree to the actions described in a confirmatory action letter. Thus, the issuance of a confirmatory action letter does not constitute backfitting. In most cases, the licensee would have taken this voluntary action in response to an enforcement action. Attempts by the NRC to require compliance with a confirmatory action letter could constitute backfitting.

5.5.2 Violations

An NOV may require a licensee to respond to the NOV by providing the corrective steps that it either has taken or will take to achieve full compliance with NRC requirements. As such, requiring a response to an NOV that includes a description of a licensee's proposed corrective action is not backfitting. The licensee's commitments in the description of a corrective action are not backfits. A statement or recommendation by the staff for the licensee to consider actions in response to an NOV is not backfitting. However, if the staff is not satisfied with the licensee's proposed corrective actions and asks the licensee to take additional actions beyond those needed to meet requirements, then those additional actions, if imposed (e.g., by order) by the NRC, may constitute backfitting. If the staff is not satisfied with a licensee's actions in response to any NOV, then subsequent discussions and considerations should remain in the enforcement process. The guidance in this section does not preclude inspectors from assessing corrective actions and issuing applicable enforcement actions.

A finding of a violation for ineffective or untimely corrective actions is not backfitting. However, NRC staff imposition of a requirement that the licensee must take a certain action may constitute backfitting, unless the action is in accordance with an existing staff position that

applies to the facility and is included in the licensing basis. If the imposed action is beyond what is required under the licensee's licensing basis, then the action would be backfitting.

Licensee actions to correct violations of the requirements in its licensing basis are not backfits. Discussions during enforcement conferences and oral responses to a licensee's questions regarding corrective actions to restore compliance with the requirements in the licensing basis are not backfitting unless the staff attempts to limit the licensee to a specific action that is not expressly required or attempts to impose some action beyond requirements.

5.6 General Design Criteria

The Atomic Energy Commission (AEC) published the proposed general design criteria (GDC) on July 11, 1967. The proposed rulemaking was intended to provide guidance to applicants in developing the principal design criteria (PDC) to include in applications for construction permits. The AEC stated that these GDC would not add any new requirements but were intended to describe more clearly the Commission requirements at that time to assist applicants in preparing applications. The AEC published the final rule that added 10 CFR Part 50, Appendix A, "General Design Criteria for Nuclear Power Plants," on February 20, 1971, with an effective date of May 21, 1971. In accordance with Staff Requirements Memorandum (SRM)-SECY-92-223, "Resolution of Deviations Identified During the Systematic Evaluation Program," dated September 18, 1992, the Commission decided not to apply the Appendix A GDC to plants with construction permits issued before May 21, 1971. The Commission stated in this SRM that the staff had evaluated these plants on a plant-specific basis and determined them to be safe, that current regulatory processes are sufficient to ensure that plants continue to be safe and comply with the intent of the GDC, and that backfitting the GDC would provide little or no safety benefit.

The GDC establish the necessary design, fabrication, construction, testing, and performance requirements for structures, systems, and components (SSCs) important to safety and the minimum requirements for development of the PDC for water-cooled nuclear power reactors. The GDC, most of which are performance-based standards, provide minimum requirements for establishing the PDC and general safety of the plant. For some design areas, many licensees have adopted the applicable GDC as the PDC for the plant. The 10 CFR Part 50 licensing process requires approval of an applicant's PDC as a condition for granting a construction permit. Before the NRC can issue an operating license and as a basis for the NRC's 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 Part 50 licensees with construction permits issued since 1971 (when the GDC were promulgated), the Commission has already concluded that the design basis of the plant, as reflected in the PDC, meets or exceeds the minimum criteria in the GDC.

Similarly, the 10 CFR Part 52 licensing processes also require certain applicants to establish the PDC for the plant. For water-cooled nuclear power plants, the NRC established the minimum requirements for PDC in Appendix A to 10 CFR Part 50. For non-light-water reactors (LWRs), the NRC has published guidance on establishing PDC for these designs in Regulatory Guide 1.232, "Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors."

In accordance with COMSECY-16-0020 and the NRC Solicitor's 2016 memorandum on the use of the GDC to justify a backfitting action and, more specifically, the compliance exception, the staff should first confirm whether other parts of a license, such as technical specifications,

incorporate the pertinent aspects of the GDC, and, if so, use those facility-specific requirements instead of the GDC. The license approval process will typically yield more specific requirements than those in the GDC. The NRC can use the GDC as the source of a requirement for purposes of invoking the compliance exception only if 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 are clearly meant to address the GDC at issue) and technical specifications. Therefore, for Part 50 licensees with construction permits issued since 1971, and for all Part 52 approval holders required to describe their PDC in their applications, a GDC can be regarded as a requirement in those circumstances in which the GDC is prescriptive in nature, and the technical specifications, other licensee requirements derived from the GDC, and the PDC do not address the matter in question.

5.7 Generic Communications

The issuance of generic communications does not establish new requirements or impose staff positions and, therefore, cannot constitute backfitting. Section 5.9 of this NUREG contains a discussion of generic communications that request information.

5.8 Guidance Documents

Generally, issuance of an NRC guidance document (e.g., regulatory guide, NUREG, interim staff guidance) does not by itself impose regulatory requirements or staff positions on licensees. The NRC would have to take a regulatory action, such as issuing an order, to impose a guidance document on a licensee. Therefore, the issuance of a new or revised guidance document that provides new or changed staff guidance on the implementation of regulations or staff positions would not normally be considered backfitting. One exception is the issuance of superseding guidance, as discussed in Section 5.8.4 of this NUREG.

Guidance documents are subject to the backfitting provisions if the staff intends, at the time it issues the guidance, to impose the positions on a licensee (typically through further NRC action). Staff guidance is also subject to the backfitting provisions when the NRC expects licensees to "voluntarily" adopt the guidance as part of the staff's basis for resolving a safety or regulatory issue. MD 8.4 provides that issuance of most guidance documents, including their revisions, must include a regulatory analysis performed in accordance with NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission."

If a license incorporates a guidance document, then that version of the guidance document becomes a requirement. A licensee may incorporate by reference a guidance document into its licensing basis through the 10 CFR 50.59 process or other existing change control requirements, but such action, without being incorporated into the license or without NRC review and approval, does not make the guidance document a requirement. However, the staff's imposition of a guidance document provision on a licensee, whether orally or in writing, could constitute backfitting, and it could constitute forward fitting if related to a requested action from the licensee. Section 1.5 of this NUREG provides more information on communications with licensees.

If a licensee voluntarily submits an application for an initial license, an amendment, or license renewal, then the staff must use the staff guidance applicable to that licensee during the review to ensure that NRC requirements are met. This would not be considered backfitting. If the staff used different guidance to review the licensee's request, then the staff could be forward fitting that licensee and would need to meet the forward fitting criteria discussed in Chapter 3 of this

NUREG. Draft guidance does not constitute a staff position, so the staff should not use it in licensing decisions.

5.8.1 Regulatory Guides

A regulatory guide includes an implementation section that explains that the NRC staff can use the regulatory guide in its regulatory processes, but the staff does not intend to use the guidance in a manner that would constitute backfitting or forward fitting or affect issue finality, as applicable. When the NRC provides the public with notice through the *Federal Register* of the issuance of a regulatory guide, the NRC should include in the *Federal Register* notice a discussion of the backfitting, forward fitting, and issue finality implications of the issuance of the guidance document.

5.8.2 Interim Staff Guidance

The NRC issues interim staff guidance as temporary guidance until the NRC issues the next revision of the applicable (permanent) guidance document that includes the staff positions from the interim guidance. The staff can use interim staff guidance in conjunction with other applicable guidance when reviewing a licensee's application. When the NRC provides the public with notice through the *Federal Register* of the issuance of interim staff guidance, the NRC should include in the *Federal Register* notice a discussion of the backfitting, forward fitting, and issue finality implications of the issuance of the interim staff guidance.

5.8.3 Withdrawing Guidance Documents

To withdraw a guidance document, the NRC typically must already have the guidance located in other documents, determine that the guidance concerns an aspect of a facility's design or operation that is no longer used as a means to meet the governing requirements, or conclude that the guidance could no longer be used to comply with applicable requirements. If the guidance can be found in other locations or is no longer needed, then withdrawing the guidance document has no substantive impact on licensees. However, if the NRC determines that the guidance document should be withdrawn because the methods contained are no longer an acceptable means of complying with the applicable requirements, then withdrawing that guidance document could constitute backfitting for those licensees using the guidance document. The backfitting would occur through another regulatory action, such as an order removing the guidance document from the license. That regulatory action would need to justify the backfitting. If the withdrawal of the guidance document requires issuance of a *Federal Register* notice, then the staff should generically address the backfitting, forward fitting, and issue finality implications of withdrawing the guidance document in the *Federal Register* notice.

5.8.4 Superseding Guidance Documents

If the NRC issues a new or modified guidance document and the prior guidance document is no longer available for licensee use, then the new version of the guidance supersedes the prior version of the guidance. Superseding prior guidance could have backfitting and forward fitting effects. To prevent backfitting, the NRC allows a licensee already using the prior version of the guidance to continue using that version as long as the licensee does not change its licensing basis relative to that guidance document. Requiring licensees to use a new or modified guidance document in future licensing actions could constitute forward fitting, and the staff would have to address the forward fitting implications of superseding the prior guidance document as part of the licensing action. When the NRC provides the public with notice through

the *Federal Register* of the issuance of superseding guidance, the NRC should include in the *Federal Register* notice a discussion of the backfitting, forward fitting, and issue finality implications of the issuance of the superseding guidance.

5.9 Information Requests

The NRC revised the 10 CFR Part 50 rule requiring licensee responses to both generic and facility-specific information requests (i.e., 10 CFR 50.54(f)) with the Backfit Rule in 1985. This information request may also be referred to as an "information collection." A request for information under 10 CFR 50.54(f) does not constitute backfitting, as the request imposes no change to the facility or its operation. However, because extensive information requests can impose burdens that appear similar to backfitting, 10 CFR 50.54(f) stipulates that, except for information sought to verify licensee compliance with the current licensing basis, the NRC must prepare the reasons for the request to ensure that the burden imposed on licensees is justified in view of the potential safety or security significance of the issue to be addressed.

Letters, bulletins, and generic letters requesting information under 10 CFR 50.54(f) may promulgate new or revised staff positions and may ask licensees to state in their responses whether they have adopted or will adopt these new positions. However, in issuing these information requests, the NRC cannot require a licensee to adopt the new staff position unless the NRC has followed the backfitting regulations. As a matter of practice, the NRC staff should carefully consider the potential to raise backfitting issues in information requests.

The staff may use a bulletin or generic letter to justify a staff recommended action or schedule. If a bulletin or generic letter requests a response, and the staff is not satisfied with that response, then subsequent staff action to direct further action by a licensee (e.g., an order) may be backfitting and should be assessed as such. The only obligation on the part of the licensee is to respond to the bulletin or generic letter. A licensee's response to the generic letter may contain licensing basis information. If the licensee adopts a recommendation from the generic letter, and the NRC does not respond to that correspondence, then the licensee's response likely constitutes a regulatory commitment, which the licensee may be able to remove in accordance with its commitment management program. If the NRC does respond to the licensee and accepts the response as addressing the issue in the generic letter, then how that information is considered in the licensing basis will depend on the manner of the licensee's and the NRC's correspondence (e.g., whether the licensee responded through a license amendment request, incorporated the information into a mandated licensing basis document, or made regulatory commitments; or whether the NRC ordered the licensee to modify its license, took enforcement action, or took another approach). The generic letter itself does not constitute the requirement or licensing basis information.

5.10 Initial Licensing

As the Commission explained in the 1989 10 CFR Part 52 final rule statement of considerations (SOC), applicants (for licenses, permits, and regulatory approvals such as design certifications) are not, with certain exceptions, within the scope of either the backfitting provisions or any issue finality provisions. Neither the backfitting provisions nor the issue finality provisions, with certain exceptions, are intended to apply to NRC actions that substantially change the expectations of current and future applicants. Applicants cannot reasonably expect that future requirements will not change.

One of the exceptions to this general principle occurs when a Part 52 applicant (e.g., a combined license applicant) references a Part 52 license or approval (e.g., an early site permit, a design certification rule, or a standard design approval) with specified issue finality provisions. The Part 52 licensing processes provide regulatory stability to applicants referencing those approvals. The other exception occurs under Part 50. Once the NRC issues a construction permit, backfitting provisions apply to the construction permit holder.[1] For an operating license applicant relying on a construction permit, matters described in the construction permit cannot be changed without meeting the backfitting provisions.

A change in a staff position before issuance of any license (or other approval under Part 52) is not considered backfitting because, in this situation, the safety evaluation does not constitute the NRC's final position until the NRC issues the license (or other approval). The backfitting provisions do not become effective until the NRC issues the license (or other approval).

For LWR facilities, 10 CFR 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 for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," that the staff should anticipate applicants for new LWR facilities to reasonably rely upon in the development of their applications. During initial licensing, the staff's use of acceptance criteria more stringent than those contained in the standard review plan (SRP) or taking positions more stringent than those specified in the SRP, whether in writing or orally, is not a facility-specific backfit unless the staff's new position impacts an applicant's previously received NRC approval (e.g., a design certification referenced in a combined licensed application under Part 52 or a construction permit when reviewing an operating license application under Part 50). However, under MD 8.4, if the staff imposes any change in requirements or regulatory staff positions from the applicable version of the SRP, then the staff should follow the same reasoned decision-making process as a forward fit to justify the change.

The Commission's forward fitting policy generally does not apply when an applicant files an initial licensing action for a new facility for which there is no SRP.

5.11 Inspections

The NRC's inspection processes and procedures govern the scope and depth of the staff inspections associated with licensee activities, such as design, construction, and operation. As such, the inspection procedures define those items that the staff should consider in the staff's determination of whether the licensee is conducting the facility's activities in accordance with the facility's licensing basis.

In the normal course of inspections, the inspector may examine and identify findings or violations in specific technical or regulatory areas. Identifying findings or violations usually does not involve backfitting, but it may if the establishment of the NRC's position can be reasonably

[1] The only exception to this principle pertains to the Bellefonte Nuclear Plant, Units 1 and 2 because Tennessee Valley Authority obtained the construction permits for these units in 1974. As of the publication date of this NUREG, the NRC has not received an application for operating licenses for those units. Section 50.109(a)(1)(ii) of the Backfit Rule states that a backfit is a change in regulation or staff position that meets the 10 CFR 50.109(a)(1) definition of "backfitting" and occurs after the date that is six months before the date of docketing of the operating license application for a facility with a construction permit issued before October 21, 1985. Therefore, until six months before the date of docketing of an operating license application for either of the Bellefonte units, any change in regulation or staff position that meets the definition of a backfit for that unit is not backfitting.

understood to exceed the governing requirement or a licensee's self-imposed standard that is included in the licensing basis.

Inspections may include the review of activities that were previously inspected. Many inspections are done on a sampling basis and the focus areas may differ from one inspector to another. A different inspection conclusion (e.g., one resulting in identified findings versus one that does not—refer to the caution in Section 1.2.2.2 of this NUREG) may not constitute backfitting because (1) most inspections use a sampling methodology, (2) circumstances surrounding the activity may have changed, (3) the focus of the inspection may be different, (4) the licensing basis may have changed, (5) maintenance that was previously committed to may not have been accomplished, or (6) other factors have been considered.

Likewise, an inspector's discussion of findings with the licensee is not considered backfitting. During these discussions, the licensee may agree that certain changes are appropriate in response to the inspector's findings. This would not constitute backfitting if the inspector does not indicate that specific actions are the only way to satisfy the staff when the licensing basis does not require the specific action. An inspector's suggestions to consider an applicable guidance document or NRC-endorsed topical report to resolve the findings are not backfitting as long as the inspector does not convey an expectation that the licensee must use the guidance document or topical report. Thus, the staff expects that findings or violations documented as part of the NRC's inspection activities would not involve backfitting. However, if a licensee concludes that a finding or violation in a written NRC inspection report is a new staff position that is not part of the licensing basis, then the licensee can initiate a backfitting appeal as described in Chapter 4 of this NUREG.

If an inspection identifies a potential safety or security issue that is beyond the requirements in the licensing basis, then the staff must follow the backfitting process to define the backfitting action, determine whether backfitting actions should be pursued, and develop the necessary justification.

If licensing bases questions arise during inspection, and the inspectors determine that the significance of the issue does not immediately screen as having very low safety significance, then the inspectors should contact the appropriate licensing project manager for advice and, if necessary, initiate the technical assistance request process for the appropriate office to consider the regulatory, licensing, and technical aspects of the issue. The outcome of this process may need to be assessed for backfitting implications. Section 5.21 of this NUREG contains additional guidance on this matter.

5.12 Licensing Basis

Footnote 3 in Section 1.2 of this NUREG refers to the definition of licensing basis, as described in NRR Office Instruction LIC-100, "Control of Licensing Bases for Operating Reactors." LIC-100 provides a basic framework for making decisions about creating, revising, or deleting licensing bases information for operating power reactors. This document describes the terminology and characteristics of various documents that make up the licensing bases for an operating nuclear power plant. Not all information that constitutes licensing basis information is within the scope of the backfitting and forward fitting provisions (e.g., regulatory commitments that were not escalated into requirements). Likewise, some staff positions applicable to a facility may be within the scope of the backfitting and forward fitting provisions but do not constitute

licensing basis information (e.g., safety evaluations). Therefore, the staff should use caution when discussing licensing basis terminology.[2]

5.13 Orders

Because an order amends a license, an order issued to require a licensee to take actions to maintain or increase the protection of the public health and safety or the common defense and security generally would constitute backfitting, unless the action is an already applicable requirement, or an already applicable and imposed staff position. The NRC may issue an immediately effective safety or security order for taking a backfitting action before completing any of the backfitting requirements as long as the Director of NRR or NMSS, as appropriate, determines, through an imminent threat analysis, that immediate regulatory action is necessary to address an imminent threat or risk to the public health and safety (i.e., imminent hazard) or an imminent threat to the common defense and security.

5.14 Policy Statements

As compared to an NRC regulation, an NRC policy statement does not establish a legally binding requirement. Thus, a policy statement, unlike an NRC regulation, is not directly enforceable. Any action to enforce the Commission's interpretation or policy in a specific case must be done through a subsequent rule or order subject to the applicable backfitting regulations or forward fitting policy.

5.15 Regulatory Analysis

Regulatory analyses are different from backfit analyses and are required for almost all regulatory actions. A regulatory analysis measures all the benefits and costs of a proposed action (whereas a backfit analysis considers only certain factors as discussed in Section 2.6 of this NUREG). Regulatory analyses help the staff provide adequate justification for the proposed action and document a clear explanation of why the staff recommends the proposed action. The staff provides instructions for performing regulatory analyses in NUREG/BR-0058.

5.16 Requested Licensing Actions

The backfitting provisions do not apply to voluntary licensee requests for changes to its licensing basis. "Voluntary" is considered to be any action or request to the NRC by the licensee that was made of the licensee's own accord, without the force of a legally binding requirement or an NRC representation of further licensing or enforcement action. Unless required by the NRC, initial license applications, license amendment requests, and license renewal applications are considered voluntary; NRC review and approval of any of these actions is not backfitting.

The NRC review of applications is limited by the scope of the request and to the areas affected by the requested technical and regulatory changes. All other portions of the licensing basis that are not affected by the application are within the scope of the backfitting provisions, unless the staff can justify and document the technical or regulatory reasons for including those portions of the licensing basis into its review.

[2] The NRC defines the term "current licensing basis" in 10 CFR 54.3, "Definitions." This definition is only applicable for use in the license renewal process and should not be used when determining the licensing basis for backfitting or forward fitting purposes.

The regulations in 10 CFR Part 54 delineate the scope of license renewal reviews. A license renewal review is prospective in nature, as the review is aimed at a renewed license that has not yet been issued and is a matter of future aging management. The review will address aging management or ensure an integrated approach to achieve aging management. The Commission determined in the 1995 nuclear power plant license renewal final rule that 10 CFR 50.109 does not apply to matters within the scope of the renewal of power reactor licenses under 10 CFR Part 54. In large measure, the scope of a license renewal review is limited by 10 CFR 54.4, "Scope," and 54.21, "Contents of applications—technical information." Section 54.30(a) states, in part, that licensed activities will be conducted in accordance with the current licensing basis.[3] This requirement is followed by 10 CFR 54.30(b), which states that the licensee's compliance in this regard is NOT the subject of the license renewal review. This means that any proposed staff action on topics other than aging management taken under the current license during the application review could be subject to a backfitting assessment. Once the NRC issues the renewed license, 10 CFR 50.109 applies to the entire license with very limited exceptions.

The Commission's forward fitting policy applies to requested licensing actions and license renewal requests other than Part 54 renewals, although the imposition of a condition in a Part 54 proceeding outside the normal scope of Part 54 license renewals could constitute forward fitting.

5.17 Rulemakings and Guidance

In the rulemaking process, the NRC must justify the proposed and final rules under applicable backfitting requirements. The NRC includes this justification discussion in the SOCs for proposed and final rules. Lengthy backfitting discussions can be a standalone document summarized in the SOCs. Rulemaking plans contain a discussion of the potential backfitting implications of the contemplated rulemaking. Many rules have an associated guidance document that provides an acceptable means for implementing the new or amended rule. The backfitting implications of the guidance document need to be considered within the backfitting evaluation supporting issuance of the rule. The SOCs typically include the guidance document's backfitting discussion. Because rulemakings are not regulatory actions associated with a licensee request, it is not possible for rulemakings to involve forward fits.

5.18 Safety Evaluations (or Safety Evaluation Reports)

Safety evaluations are useful documents when evaluating potential backfitting because they provide the bases for the staff's decisions, including the staff's decision to accept the licensee's proposed means for compliance. The staff should not attempt to establish new licensing basis information in safety evaluations to avoid backfitting through the safety evaluation. The staff can stress the importance of certain licensing basis information and can cite regulations or other established licensing basis information in its safety evaluations.

[3] For purposes of 10 CFR Part 54 and as defined in 10 CFR 54.3, the current licensing basis "is the set of NRC requirements applicable to a specific plant and a licensee's written commitments for ensuring compliance with and operation within applicable NRC requirements and the plant-specific design basis … that are docketed and in effect."

5.19 Section 50.55a Requests

The provisions of 10 CFR 50.55a allow licensees to request relief from certain requirements in 10 CFR 50.55a and to propose alternative requirements. These provisions for requesting relief and proposing alternative requirements are found in 10 CFR 50.55a(f)(6)(i) and (g)(6)(i). The NRC calls these requests "relief requests."[4] Under 10 CFR 50.55a(z), licensees can propose alternatives to certain requirements in 10 CFR 50.55a. The NRC calls these requests "proposed alternatives."

Under 10 CFR 50.55a(f)(6)(i) and (g)(6)(i), the NRC may grant relief from certain requirements that are impractical at a particular facility and impose alternative requirements if the Commission determines that the alternative requirements are authorized by law, will not endanger life or property or the common defense and security, and are otherwise in the public interest giving due consideration to the burden upon the licensee that could result if the NRC imposed the requirements on the facility. These alternative requirements can be proposed by the licensee or developed by the NRC. If the NRC intends to impose requirements that are not alternatives to the requirements from which the NRC granted the licensee relief (i.e., the NRC's proposed requirements are not related to the requirements from which the licensee is seeking relief), then the NRC would need to subject those proposed requirements to a backfitting or forward fitting assessment.

Under 10 CFR 50.55a(z), the NRR Office Director may authorize the use of alternatives to the requirements of 10 CFR 50.55a(b) through (h) or portions thereof. A proposed alternative must be submitted by the licensee and authorized by the NRC prior to implementation. In contrast to 10 CFR 50.55a(f)(6)(i) and (g)(6)(i), 10 CFR 50.55a(z) does not permit the NRC to impose alternatives to the requirements. Therefore, if the NRC intends to impose an alternative to the requirement, then the NRC would need to subject its proposed alternative to a backfitting or forward fitting assessment.

5.20 Standard Review Plans

SRPs delineate the scope and depth of the staff's review of licensee submittals associated with various licensing activities. If the staff uses acceptance criteria that are more stringent than those stated in the applicable SRPs, or if it proposes licensee actions that are more stringent than or in addition to those specified in the applicable SRPs, then these criteria and actions may be considered either forward fitting or backfitting, depending on whether the actions are associated with a licensing request or with an existing condition at the facility, and the facility has a license. Application of an SRP to an operating facility after the NRC issues the license is generally considered backfitting unless that version of the SRP is part of the facility's licensing basis.

When the NRC provides the public with notice through the *Federal Register* of the issuance of a new or revised SRP the NRC should include in the *Federal Register* notice a discussion of the backfitting, forward fitting, and issue finality implications of the issuance of the SRP.

[4] NRR Office Instruction LIC-102, Revision 2, "Relief Request Reviews," dated August 24, 2009, describes NRC's processing of requests submitted under 10 CFR 50.55a.

5.21 Technical Assistance Requests

The technical assistance request process is designed to support NRC offices and regions in answering questions that arise from regulatory activities. In terms of backfitting, the requests having the greatest relevance are those that involve determining whether a licensee is meeting its licensing basis. The response to a technical assistance request may determine that a licensee is meeting its licensing basis, but the requesting staff's concern could be whether the licensing basis is adequate. In that case, the technical assistance request process will redirect the staff to the backfitting process for consideration of further NRC action. Backfitting and its associated activities (i.e., screening, justifying, and issuing) are outside the scope of the technical assistance request process.

5.22 Topical Reports

If a licensee uses an NRC-approved topical report in an application and the NRC approves the application, any subsequent requirements imposed by the NRC that are different from those specified in the approved topical report should be considered as potential backfitting. If the NRC imposes requirements as part of its approval of the licensing action (e.g., conditions on the use of the approved topical report), those requirements could constitute forward fitting.

If a licensee submits a "draft" topical report (e.g., one that the NRC has not approved) with an application, NRC restrictions on the use of the draft topical report by that licensee could be considered forward fits. If the licensee submits information that the NRC is reviewing for the first time, the NRC has no existing staff position applicable to the licensing action under review, and the staff is considering a forward fit, then the staff needs to perform a site-specific cost consideration. However, the communications with the licensee for this first-of-a-kind review should not be done in a manner that conveys expectations as to how the licensee should proceed. The staff can and should communicate to the licensee issues it identifies during the review. The staff must ensure that its communication does not limit the licensee in choosing how to resolve the issues. Section 3.3 of this NUREG contains more guidance on these situations.

5.23 Voluntary Consensus Standards

Voluntary consensus standards document a consensus reached by the sponsoring organization that the code or standard provides an acceptable process or criteria to accomplish the task addressed by the code or standard. Congress requires consideration of voluntary consensus standards under the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Pub. L. 104-113, 110 Stat. 775), which is codified in various sections of Title 15 of the U.S. Code. In accordance with the note in 15 U.S.C. § 272, the NRC may decline to use a voluntary consensus standard if its use would be "inconsistent with applicable law or otherwise impractical." The Office of Management and Budget (OMB) established policies on the implementation of the NTTAA in OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities," revised in 2016. Both the NTTAA and OMB Circular A-119 require that "agencies must consult with voluntary consensus standards bodies and must participate with such bodies in the development of standards when consultation and participation is in the public interest and is compatible with their missions, authorities, priorities, and budgetary resources."

The NRC participates in the consensus process for codes and standards that are later adopted into the NRC's regulations. In the consensus process, the NRC provides its views on the codes

and standards, and this communication supports a constructive consensus process. This communication, including votes, is not considered backfitting or forward fitting.

Two prominent consensus standards the NRC uses are the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code and the ASME Code for Operation and Maintenance of Nuclear Power Plants. These codes are requirements for power reactor licensees because the codes are incorporated into NRC regulations at 10 CFR 50.55a. These regulations are periodically updated to incorporate by reference later editions of the ASME Boiler and Pressure Vessel Code and the ASME Code for Operation and Maintenance of Nuclear Power Plants Code. The NRC describes its approach to these rulemakings in NUREG/BR-0058, Appendix D, "Guidance on Regulatory Analysis Related to ASME Code Changes."

In the SRM to SECY-00-0011, "Evaluation of the Requirement for Licensees to Update Their Inservice Inspection and Inservice Testing Programs Every 120 Months," dated April 13, 2000, the Commission rejected an NRC staff proposal to consider as backfits rulemakings that list updated ASME code editions. Therefore, such rulemakings, with or without conditions on aspects of the ASME codes, are not generally backfits. In addition, a new condition on a new code provision that is not present in an earlier code edition would not be backfitting.

However, the general rule that these rulemakings are not backfits has three exceptions: (1) when the rulemaking imposes substantially different (i.e., more than incremental changes for technical or safety reasons) conditions or exceptions on the use of an ASME code provision already incorporated by the NRC; (2) when the rulemaking incorporates a new provision of the ASME code that is substantially different from existing requirements; or (3) when the rulemaking requires that licensees adopt provisions of the ASME code on an expedited schedule (i.e., sooner than the 120-month updating interval in 10 CFR 50.55a).

5.24 Voluntary Relaxations

A relaxation is the modification of a regulatory requirement that reduces the obligations of a licensee or class of licensees. In almost every case, a relaxation is structured to provide licensees the option of continuing as previously licensed (that is, maintaining the status quo) or following the new, relaxed regulatory requirement or staff position. When the NRC relaxes requirements, the NRC must ensure the new framework provides for the adequate protection of the public health and safety and the common defense and security. Typically, this means that the alternative approach has either no decrease in safety or security or, if there is a decrease, it is very small.

Examples of relaxations to regulatory requirements include the 2004 final rule promulgating 10 CFR 50.69, which provided for risk-informed categorization and treatment of SSCs, and the 2010 final rule promulgating 10 CFR 50.61a, which provided alternate fracture toughness requirements for protection against pressurized thermal shock events. Such changes are non-mandatory relaxations that allow the licensee to continue to either comply with the requirements of its current licensing basis or adopt the alternative requirements into its licensing basis. If a licensee decides to adopt the alternative requirements, then it must comply with those provisions, and doing so is not backfitting because it is part of the nonmandatory requirements that the licensee voluntarily chose to adopt. For example, a licensee that chooses to adopt the risk-informed categorization and treatment of SSCs for nuclear power reactors under 10 CFR 50.69 obtains relief from the current existing special treatment requirements in 10 CFR 50.69(b), but in doing so, the licensee must comply with all provisions of 10 CFR 50.69.

Alternatively, licensees can choose not to adopt 10 CFR 50.69, and can continue to comply with their licensed special treatment requirements.

6 RECORDKEEPING AND DOCUMENTATION

Offices and regions directly involved in backfitting or forward fitting are responsible for tracking and maintaining associated records originating in that office or region. In Title 10 of the *Code of Federal Regulations* (10 CFR), Sections 50.109, 70.76, 72.62, and 76.76, the NRC requires documentation of the justification for backfitting or forward fitting. Consistent with these requirements and the transparency and accountability bases underlying them, the U.S. Nuclear Regulatory Commission (NRC) staff must document its findings on issue finality under 10 CFR Part 52.

Management Directive (MD) 3.53, "NRC Records and Document Management Program," dated March 15, 2007, describes how the NRC complies with the regulations governing Federal records management. The guidance in MD 3.53 ensures that the NRC staff consider documents related to backfitting and forward fitting as possible official agency records and are preserved in the Agencywide Documents Access and Management System (ADAMS).

The office or region that proposes a backfitting or forward fitting action must administratively manage each action by maintaining all related records. Records must be maintained in accordance with NUREG-0910, "NRC Comprehensive Records Disposition Schedule," Revision 4. Backfitting or forward fitting records placed in ADAMS must be accessible to all stakeholders and profiled as publicly available consistent with agency guidance on the release of information to the public.

Internal NRC reviewers may include technical and regulatory staff and managers; formal groups such as the Committee to Review Generic Requirements (CRGR); and, in some cases, the Advisory Committee on Reactor Safeguards. Reviewers typically focus on the appropriateness of assumptions, the selection and elimination of alternatives, estimation techniques, evaluation methods, any limitations in the data used, and the decision rationale. The staff should post the analyses, with supporting documents, as publicly available documents in ADAMS or incorporate the conclusions of the analysis in the public document that implements the agency's decision, such as a letter to the licensee.

Certain regulatory actions are subject to the backfitting provisions or issue finality provisions and to the CRGR's requirements for the staff's analysis and information submittals. The NRC intends that, for these actions, the analysis performed in accordance with this guidance will satisfy the documentation requirements of the backfitting provisions and the provisions of the CRGR's requirements without a need to prepare separate submissions.

If the NRC concludes that it cannot proceed with its proposed backfitting or forward fitting because the staff cannot justify the proposed action, then the staff must stop the backfitting or forward fitting process. Nevertheless, the staff needs to document its efforts. The NRC staff office responsible for the proposed backfitting or forward fitting should determine how the decision to reject the action should be documented, whether the existence of this documentation should be disclosed to external stakeholders, and whether the documentation should be made available to external stakeholders. If the proposed action arose from an inspection finding, the staff could use an inspection report. For example, if the NRC staff performs a backfitting assessment to support resolution of an unresolved item, and the staff could not justify a backfitting action, then the backfitting assessment documentation should be referenced in the closure documentation of the unresolved item. An alternative could be a memorandum to a supervisor with an attached analysis based on a guide from Appendix C to

this NUREG. No matter the form used by the staff, the document must describe the safety or security issue, the staff's proposed action to address the issue, and why the proposed action cannot be justified under the appropriate backfitting, forward fitting, or issue finality provision. The document should be placed in ADAMS.

7 REFERENCES

Code of Federal Regulations

10 CFR Part 2. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 2, "Agency Rules of Practice and Procedure."

10 CFR 26.39. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 26.39, "Review process for fitness-for-duty policy violations."

10 CFR Part 30. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material."

10 CFR Part 40. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 40, "Domestic Licensing of Source Material."

10 CFR Part 50. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 50, "Domestic Licensing of Production and Utilization Facilities."

10 CFR 50.4. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.4, "Written communications."

10 CFR 50.10. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.10, "License required; limited work authorization."

10 CFR 50.21. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.21, "Class 104 licenses; for medical therapy and research and development facilities."

10 CFR 50.22. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.22, "Class 103 licenses; for commercial and industrial facilities."

10 CFR 50.34(h). *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.34(h), "Conformance with the Standard Review Plan (SRP)."

10 CFR 50.40. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.40, "Common standards."

10 CFR 50.50. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.50, "Issuance of licenses and construction permits."

10 CFR 50.54. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.54, "Conditions of licenses."

10 CFR 50.55a. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.55a, "Codes and standards."

10 CFR 50.56. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.56, "Conversion of construction permit to license; or amendment of license."

10 CFR 50.57. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.57, "Issuance of operating license."

10 CFR 50.59. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.59, "Changes, tests, and experiments."

10 CFR 50.61. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.61, "Fracture toughness requirements for protection against pressurized thermal shock events."

10 CFR 50.61a. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.61a, "Alternate fracture toughness requirements for protection against pressurized thermal shock events."

10 CFR 50.69. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.69, "Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors."

10 CFR 50.73. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.73, "Licensee event reporting system."

10 CFR 50.92. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.92, "Issuance of amendment."

10 CFR 50.109. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.109, "Backfitting."

10 CFR Part 50, Appendix A. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 50, Appendix A, "General Design Criteria for Nuclear Power Plants."

10 CFR Part 50, Appendix B. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

10 CFR Part 52. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

10 CFR 52.17. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.17, "Contents of applications; technical information."

10 CFR 52.31. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.31, "Criteria for renewal."

10 CFR 52.39. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.39, "Finality of early site permit determinations."

10 CFR 52.47. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.47, "Contents of applications; technical information."

10 CFR 52.59. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.59, "Criteria for renewal."

10 CFR 52.63. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.63, "Finality of standard design certifications."

10 CFR 52.79. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.79, "Contents of applications; technical information in final safety analysis report."

10 CFR 52.83. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.83, "Finality of referenced NRC approvals; partial initial decision on site suitability."

10 CFR 52.98. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.98, "Finality of combined licenses; information requests."

10 CFR 52.137. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.137, "Contents of applications; technical information."

10 CFR 52.145. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.145, "Finality of standard design approvals; information requests."

10 CFR 52.157. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.157, "Contents of applications; technical information in final safety analysis report."

10 CFR 52.171. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.171, "Finality of manufacturing licenses; information requests."

10 CFR 52.179. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.179, "Criteria for renewal."

10 CFR Part 52, Appendix D. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 52, Appendix D, "Design Certification Rule for the AP1000 Design."

10 CFR Part 54. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants."

10 CFR 54.4. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 54.4, "Scope."

10 CFR 54.3. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 54.3, "Definitions."

10 CFR 54.21. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 54.21, "Contents of application—technical information."

10 CFR Part 70. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 70, "Domestic Licensing of Special Nuclear Material."

10 CFR 70.60. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 70.60, "Applicability."

10 CFR 70.74. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 70.74, "Additional reporting requirements."

10 CFR 70.76. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 70.76, "Backfitting."

10 CFR Part 72. *U.S. Code of Federal Regulations*, Title 10, "Energy," 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 72.62. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 72.62, "Backfitting."

10 CFR 73.56. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 73.56, "Personnel access authorization requirements for nuclear power plants."

10 CFR Part 76. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 76, "Certification of Gaseous Diffusion Plants."

10 CFR 76.76. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 76.76, "Backfitting."

U.S. Nuclear Regulatory Commission Documents

NUREG-1409, "Backfitting Guidelines," July 1990. ADAMS Accession No. ML032230247.

Staff Requirements Memorandum, "SECY-92-223—Resolution of Deviations Identified During the Systematic Evaluation Program," dated September 18, 1992. ADAMS Accession No. ML003763736.

SECY-93-086, "Backfit Considerations," dated April 1, 1993. ADAMS Accession No. ML18128A031.

Staff Requirements Memorandum, "SECY-93-086—Backfit Considerations," dated June 30, 1993. ADAMS Accession No. ML18214A193.

SECY-95-061, "Need for a Backfit Rule for Materials Licensees," dated March 14, 1995. ADAMS Accession No. ML12261A553.

Staff Requirements Memorandum, "SECY-95-061—Need for a Backfit Rule for Materials Licensees," dated June 29, 1995. ADAMS Accession No. ML12299A717.

SECY-95-300, "Nuclear Energy Institute's Guidance Document, 'Guideline for Managing NRC Commitments,'" dated December 20, 1995. ADAMS Accession No. ML12300A004.

Staff Requirements Memorandum, "Staff Requirements—COMSAJ-97-008—Discussion on Safety and Compliance," dated August 25, 1997. ADAMS Accession No. ML18211A524.

SECY-98-224, "Staff and Industry Activities Pertaining to the Management of Commitments Made by Power Reactor Licensees to the NRC," dated September 28, 1998. ADAMS Accession No. ML992870043.

SECY-98-253, "Applicability of Plant-Specific Backfit Requirements to Plants Undergoing Decommissioning," dated November 4, 1998. ADAMS Accession No. ML992870107.

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

Staff Requirements Memorandum, "Staff Requirements—SECY-98-253—Applicability of Plant-Specific Backfit Requirements to Plants Undergoing Decommissioning," dated February 12, 1999. ADAMS Accession No. ML003753746.

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, "Staff Requirements—SECY-99-063—The Use by Industry of Voluntary Initiatives in the Regulatory Process," dated May 27, 1999. ADAMS Accession No. ML003752062.

Regulatory Guide 1.181, "Content of the Updated Final Safety Analysis Report in Accordance with 10 CFR 50.71(e)," September 1999. ADAMS Accession No. ML003740112.

SECY-00-045, "Acceptance of NEI 99-04, 'Guidelines for Managing NRC Commitments,'" dated February 22, 2000. ADAMS Accession No. ML003679799.

Regulatory Issue Summary 2000-06, "Consolidated Line Item Improvement Process for Adopting Standard Technical Specifications Changes for Power Reactors," dated March 20, 2000. ADAMS Accession No. ML003693442.

Staff Requirements Memorandum, "Staff Requirements—SECY-00-0011—Evaluation of the Requirement for Licensees to Update Their Inservice Inspection and Inservice Testing Programs Every 120 Months," dated April 13, 2000. ADAMS Accession No. ML003702722.

Regulatory Issue Summary 2000-17, "Managing Regulatory Commitments Made by Power Reactor Licensees to the NRC Staff," dated September 21, 2000. ADAMS Accession No. ML003741774.

Committee to Review Generic Requirements, letter to Mr. Alex Marion, Nuclear Energy Institute, "CRGR Response to Industry Comments Made During NRC/NEI Licensing Forum 'CRGR Backfit Breakout Sessions,'" dated March 8, 2001. ADAMS Accession No. ML010430139.

Committee to Review Generic Requirements, letter to Mr. Daniel F. Stenger, Hopkins & Sutter, "CRGR Response to Industry Comments Made During NRC/NEI Licensing Forum 'CRGR Backfit Breakout Sessions,'" dated March 8, 2001. ADAMS Accession No. ML010430148.

Merschoff, E. W., NRC, letter to Craig Anderson, Entergy Operations, Inc., "Response to Backfit Claim Regarding NRC Inspection Report 50-313/01-06; 50-368/01-06," dated April 15, 2002. ADAMS Accession No. ML021090419.

Eltawila, F., NRC, memorandum to John A. Zwolinski, NRC, "Plant-Specific Backfit Audit Report," dated April 25, 2002. ADAMS Accession No. ML021270268.

Office of Nuclear Reactor Regulation Office Instruction LIC-100, "Control of Licensing Bases for Operating Reactors," dated January 7, 2004. ADAMS Accession No. ML033530249 (not publicly available).

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

Reyes, L. A., NRC, memorandum, "Implementation of an ADAMS-Based Record Access System for Facility-Specific Backfits," dated February 22, 2006. ADAMS Accession No. ML052720147.

Management Directive 3.53, "NRC Records and Document Management Program," dated March 15, 2007. ADAMS Accession No. ML071160026.

Office of Nuclear Regulatory Research, "Risk-Informed Decisionmaking for Nuclear Material and Waste Applications," Revision 1, dated February 2008. ADAMS Accession No. ML080720238.

Office of Nuclear Reactor Regulation Office Instruction LIC-102, "Relief Request Reviews," Revision 2, dated August 24, 2009. ADAMS Accession No. ML091380595.

SECY-10-0016, "Redelegation of Authority by the Executive Director for Operations to the Director, Office of Nuclear Reactor Regulation, to Approve Title 10 of the *Code of Federal Regulations* 50.55a Rulemakings," dated January 28, 2010. ADAMS Accession No. ML092730272.

Burns, S., NRC, letter to Ellen Ginsburg, Nuclear Energy Institute, Regarding Applicability of the Backfit Rule, dated July 14, 2010. ADAMS Accession No. ML101960180.

SECY-11-0032, "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process," dated March 2, 2011. ADAMS Accession No. ML110190027.

Staff Requirements Memorandum, "Staff Requirements—SECY-11-0032—Consideration of the Cumulative Effects of Regulation in the Rulemaking Process," dated October 11, 2011. ADAMS Accession No. ML112840466.

Management Directive 3.5, "Attendance at NRC Staff-Sponsored Meetings."

SECY-12-0110, "Consideration of Economic Consequences Within the U.S. Nuclear Regulatory Commission's Regulatory Framework," Enclosure 5, "Regulatory and Backfit Analysis," dated August 14, 2012. ADAMS Accession No. ML12173A493.

Staff Requirements Memorandum, "Staff Requirements—SECY-12-0110—Consideration of Economic Consequences Within the U.S. Nuclear Regulatory Commission's Regulatory Framework," dated March 20, 2013. ADAMS Accession No. ML13079A055.

SECY-14-0087, "Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," dated August 14, 2014. ADAMS Accession No. ML14127A458.

Staff Requirements Memorandum, "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.

Management Directive 3.54, "NRC Information Collections Program," dated March 29, 2016. ADAMS Accession No. ML15239A370.

Management Directive 6.6, "Regulatory Guides," dated May 2, 2016. ADAMS Accession No. ML16083A122.

Staff Requirements Memorandum, "Staff Requirements—COMSECY-16-0020—Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception to Backfit Rule," dated November 29, 2016. ADAMS Accession No. ML16334A462.

Averbach, Andrew P., Office of the General Counsel, memorandum to E.M. Hackett, Committee to Review Generic Requirements, "Summary of COMSECY-16-0020 Recommendation on Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception to Backfit Rule," dated December 20, 2016. ADAMS Accession No. ML16355A258.

Management Directive 9.27, "Organization and Functions, Office of Nuclear Reactor Regulation," dated January 24, 2017. ADAMS Accession No. ML16319A215.

Committee to Review Generic Requirements, "Report of the Committee to Review Generic Requirements on its Assessment of the U.S. Nuclear Regulatory Commission's Implementation of Backfitting and Issue Finality Requirements and Guidance," dated June 27, 2017. ADAMS Accession No. ML17174B161.

Regulatory Issue Summary 2017-05, "Administration of 10 CFR Part 72 Certificate of Compliance Corrections and Revisions," dated September 13, 2017. ADAMS Accession No. ML17165A183.

Regulatory Guide 1.174, Revision 3, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," January 2018. ADAMS Accession No. ML17317A256.

NUREG-1614, Vol. 7, "Strategic Plan: Fiscal Years 2018–2022," February 2018. ADAMS Accession No. ML18032A561.

Regulatory Guide 1.232, "Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors."

Staff Requirements Memorandum, "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.

Management Directive 6.3, "The Rulemaking Process," dated July 3, 2019. ADAMS Accession No. ML19211D136.

Staff Requirements Memorandum, "Staff Requirements—SECY-18-0042—Draft Final NUREG/BR-0058, Revision 5, 'Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,'" dated July 26, 2019. ADAMS Accession No. ML19207A042.

Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," dated September 20, 2019. ADAMS Accession No. ML18093B087.

Inspection Manual Chapter 0612, "Issue Screening," dated December 12, 2019. ADAMS Accession No. ML19214A243.

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

NRC Enforcement Policy, available at https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

Committee to Review Generic Requirements, Charter, available at https://www.nrc.gov/about-nrc/regulatory/crgr/charter.html.

NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," available at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/.

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.).

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).

National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, 110 Stat. 775 (codified in scattered sections of 15 U.S.C.).

Federal Register Notices

32 FR 10213, "General Design Criteria for Nuclear Power Plant Construction Permits; Proposed Rule," July 11, 1967.

35 FR 5317, "Backfitting of Production and Utilization Facilities; Construction Permits and Operating Licenses; Final Rule," March 31, 1970.

36 FR 3255, "General Design Criteria for Nuclear Power Plants; Final Rule," February 20, 1971.

48 FR 44173, "Revision of Backfitting Process for Power Reactors; Policy Statement," September 28, 1983.

48 FR 44217, "Revision of Backfitting Process for Power Reactors; Advance Notice of Proposed Rulemaking," September 28, 1983.

49 FR 47034, "Revision of Backfitting Process for Power Reactors; Notice of Proposed Rulemaking," November 30, 1984.

50 FR 38097, “Revision of Backfitting Process for Power Reactors; Final Rule,” September 20, 1985.

51 FR 6514, “Limiting the Use of Highly Enriched Uranium in Domestically Licensed Research and Test Reactors; Final Rule,” March 27, 1986.

51 FR 30028, “Safety Goals for the Operation of Nuclear Power Plants; Policy Statement; Correction and Republication,” August 21, 1986.

53 FR 20603, “Revision of Backfitting Process for Power Reactors; Final Rule,” June 6, 1988.

53 FR 31651, “Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste; Final Rule,” August 19, 1988.

54 FR 15372, “Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Reactors; Final Rule,” April 18, 1989.

56 FR 22300, “Fracture Toughness Requirements for Protection Against Pressurized Thermal Shock Events; Final Rule,” May 15, 1991.

58 FR 13699, “Clarification of Physical Protection Requirements at Fixed Sites; Final Rule,” March 15, 1993.

59 FR 48944, “Certification of Gaseous Diffusion Plants; Final Rule,” September 23, 1994.

60 FR 22461, “Nuclear Power Plant License Renewal; Revisions; Final Rule,” May 8, 1995.

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

65 FR 56211, “Domestic Licensing of Special Nuclear Material; Possession of a Critical Mass of Special Nuclear Material; Final Rule,” September 18, 2000.

67 FR 61695, “NRC Information Quality Guidelines,” October 1, 2002.

69 FR 68008, “Risk-Informed Categorization and Treatment of Structures, Systems, and Components for Nuclear Power Reactors; Final Rule,” November 22, 2004.

72 FR 49352, “Licenses, Certifications, and Approvals for Nuclear Power Plants; Final Rule,” August 28, 2007.

73 FR 32453, “Regulatory Improvements to the Nuclear Materials Management and Safeguards System; Final Rule,” June 9, 2008.

74 FR 28112, “Consideration of Aircraft Impacts for New Nuclear Power Reactors; Final Rule,” June 12, 2009.

75 FR 13, “Alternate Fracture Toughness Requirements for Protection Against Pressurized Thermal Shock Events; Final Rule,” January 4, 2010.

77 FR 16082, “EA-12-051; In the Matter of All Power Reactor Licensees and Holders of Construction Permits in Active or Deferred Status: Order Modifying Licenses With

Regard To Reliable Spent Fuel Pool Instrumentation (Effective Immediately)," March 19, 2012.

77 FR 16091, "EA-12-049; In the Matter of All Power Reactor Licensees and Holders of Construction Permits in Active or Deferred Status: Order Modifying Licenses With Regard To Requirements for Mitigation Strategies for Beyond-Design-Basis External Events (Effective Immediately)," March 19, 2012.

77 FR 27561, "Requirements for Fingerprint-Based Criminal History Records Checks for Individuals Seeking Unescorted Access to Non-Power Reactors (Research or Test Reactors); Final Rule," May 11, 2012.

83 FR 58721, "Miscellaneous Corrections—Organizational Changes; Final Rule," November 21, 2018.

Other Documents

Fertel, M., letter to Dr. Carl A. Paperiello, U.S. Nuclear Regulatory Commission, "Backfit Provision for 10 CFR 70," dated February 12, 1999. ADAMS Accession No. ML991900027.

Nuclear Energy Institute (NEI) 98-03, "Guidelines for Updating Final Safety Analysis Reports," Revision 1, June 1999. ADAMS Accession No. ML003779028.

NEI-99-04, "Guidelines for Managing NRC Commitment Changes," July 1999. ADAMS Accession No. ML003680088.

Marion, A., NEI, e-mail to J. A. Murphy, Committee to Review Generic Requirements, "Licensing Information Forum—Follow Up," dated November 7, 2000. ADAMS Accession No. ML003768615.

Office of Management and Budget, Executive Office of the President, OMB Circular No. A-119 Revised, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities," dated January 27, 2016, available at https://www.govinfo.gov/content/pkg/FR-2016-01-27/pdf/2016-01606.pdf.

Court Decisions

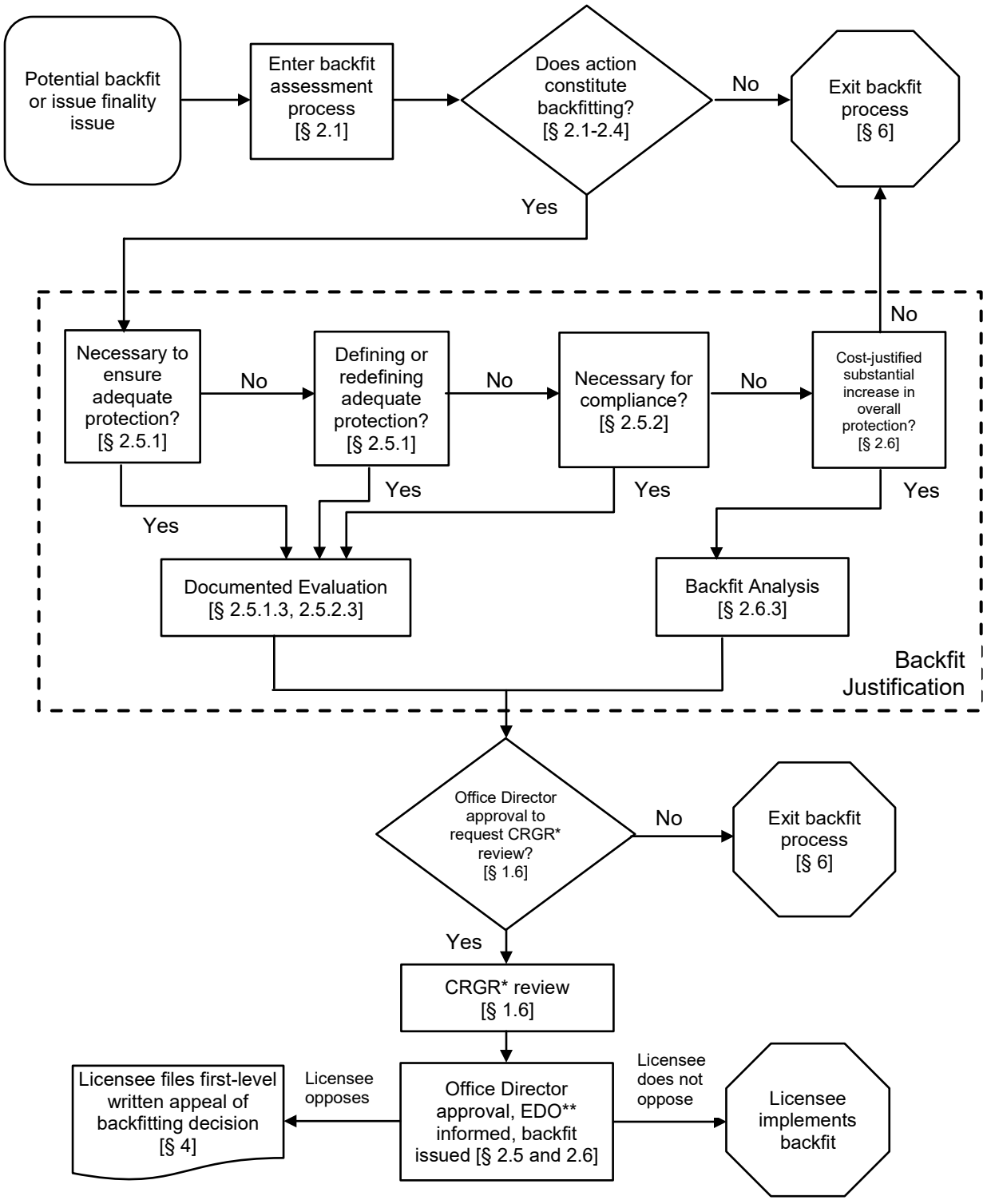
Union of Concerned Scientists v. NRC, 824 F.2d 103 (D.C. Circuit 1987).

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

APPENDIX A - BACKFITTING FLOWCHARTS

FLOWCHART 1

NRC BACKFITTING PROCESS FLOWCHART

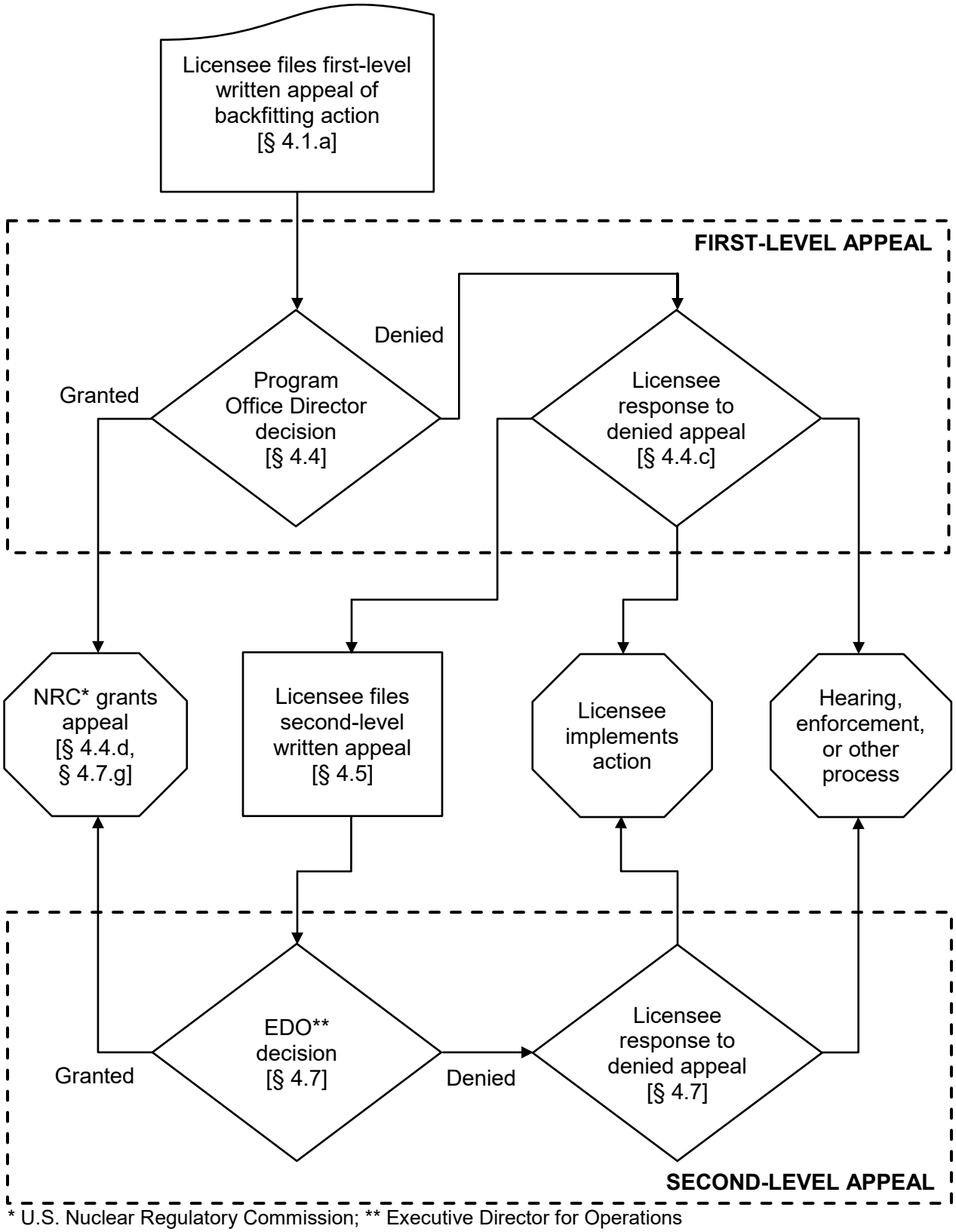


*Committee to Review Generic Requirements
**Executive Director for Operations

Figure A-1: NRC Backfitting Process Flowchart

FLOWCHART 2

BACKFITTING APPEAL PROCESS FLOWCHART



* U.S. Nuclear Regulatory Commission; ** Executive Director for Operations

Figure A-2: Backfitting Appeal Process Flowchart

APPENDIX B – WORKSHEETS

WORKSHEET 1

BACKFITTING AND ISSUE FINALITY WORKSHEET

BACKFITTING AND ISSUE FINALITY WORKSHEET		
Screening		
Step	Action	Notes
1	Document the issue, the proposed agency action, and their relationship to safety/security. Include any available risk insights.	Are new requirements or interpretations of requirements needed to address the issue fully? If no, then document the applicable enforceable requirement and exit the backfitting process. If yes, or if it appears that the NRC's approval against the requirements may be the result of an error or omission (i.e., a new interpretation is needed), then proceed to the next step.
2	Ask: Is the proposed action of the type excluded from backfitting and issue finality provisions?	If the proposed action is excluded from backfitting and issue finality provisions (see NUREG-1409, Section 2.2), then document this and exit the backfitting process. If the proposed action is not excluded, then proceed to the next step.
3	Ask: Would the proposed action affect any entity that is within the scope of a backfitting or issue finality provision?	If the licensee or applicant is not within the scope of any backfitting or issue finality provisions (see NUREG-1409, Section 2.3), then document this and exit the backfitting process. If the licensee or applicant is within the scope of a backfitting or issue finality requirement, then proceed to the next step.
4	Ask: Would the proposed action constitute backfitting or affect issue finality?	Consider the applicable definition of backfitting or issue finality provisions (see NUREG-1409, Table 1-1 and Section 2.4). The staff may need to use the technical assistance request process to determine whether a configuration is consistent with the licensing basis (but not to perform a backfit justification). If the proposed action meets the applicable definition of backfitting or satisfies an issue finality provision in 10 CFR Part 52, then notify the Backfitting and Forward Fitting Community of Practice and proceed to the next step. If not, then document that determination and exit the backfitting process.

BACKFITTING AND ISSUE FINALITY WORKSHEET		
Justification		
Step	Action	Notes
5	Obtain NRR or NMSS Office Director approval to expend resources on evaluating the issue.	Prepare the following for the office director: • Description of the answers to the backfitting Screening questions. • If readily available, descriptions of any safety, risk, and/or cost-benefit insights, including whether the issue is one of adequate protection and, if it isn't, whether the proposed action could be justified using the compliance exception or a backfit analysis. If approved, proceed to the next step if the proposed action meets a definition of backfitting. If the proposed action satisfies an issue finality provision in 10 CFR Part 52, then proceed to step 9. If not approved, then address the NRR or NMSS Office Director's concerns and re-seek approval. If not approved, then document the basis for the Office Director's decision and exit the backfitting process.
6	Ask: Is the proposed action necessary to ensure adequate protection or to define or redefine the level of protection considered adequate?	If the issue appears to be a matter of adequate protection, then take the following steps: • Perform an imminent threat analysis. • Refer to NUREG-1409, Section 2.5.1. • If the proposed action is necessary to ensure adequate protection, then, depending on timing, draft a documented evaluation to invoke the "necessary to ensure adequate protection" exception using Guide 1 in NUREG-1409, Appendix C. • If the proposed action is necessary to define or redefine the level of protection considered adequate, then depending on timing, draft a documented evaluation to invoke the "necessary to define or redefine the level of protection considered adequate" exception using Guide 1 in NUREG-1409, Appendix C. • Proceed to step 10. If the issue is not one of adequate protection, then proceed to the next step.

BACKFITTING AND ISSUE FINALITY WORKSHEET		
Justification		
Step	Action	Notes
7	Ask: Is the proposed action necessary to ensure compliance with NRC requirements or conformance with written licensee commitments?	To assess whether the compliance exception can be used, refer to NUREG-1409, Section 2.5.2 and use the Compliance Exception Worksheet in NUREG-1409, Appendix B. If the compliance exception can be used, then draft a documented evaluation to invoke the exception using Guide 2 in NUREG-1409, Appendix C and proceed to step 10. If not, then proceed to the next step.
8	Ask: Could the proposed action provide a cost-justified substantial increase in overall protection?	Prepare a backfit analysis using Guide 3 in NUREG-1409, Appendix C. Refer to NUREG-1409, Section 2.6. If the increase in overall protection is not judged to be substantial, or it is substantial but the costs would not be justified by the increase in overall protection, then document this and exit the backfitting process. If the proposed action would be a cost-justified substantial increase in overall protection, then proceed to step 10.
9	If the proposed action satisfies an issue finality provision in 10 CFR Part 52, then follow the direction provided in the issue finality provision.	The issue finality provision may direct you to one of the preceding steps in this justification process. Otherwise, proceed to the next step.
10	Provide the NRR or NMSS Office Director the documented evaluation or backfit analysis and obtain approval to request CRGR review.	If approved, then proceed to the next step. If not approved, then address the NRR or NMSS Office Director's concerns and re-seek approval. If not approved, then document the basis for the Office Director's decision and exit the backfitting process.
11	Meet with the CRGR.	Prepare the materials for meeting with the CRGR. See CRGR Charter and Procedures. Afterwards, address any issues identified by the CRGR. Proceed to the next step.

BACKFITTING AND ISSUE FINALITY WORKSHEET		
Justification		
Step	Action	Notes
12	Submit the final documented evaluation or backfit analysis to the NRR or NMSS Office Director (and/or OEDO or Commission) for approval.	If approved, then proceed with the proposed action. If not approved, then address the NRR or NMSS Office Director's concerns and re-seek approval. If not approved, then document the basis for the decision and exit the backfitting process.

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WORKSHEET 2

COMPLIANCE EXCEPTION CHECKLIST

COMPLIANCE EXCEPTION CHECKLIST		
The Requirement		
Step	Action	Notes
1	The NRC has identified an NRC requirement for which it seeks compliance.	A compliance backfit requires that an applicable requirement be in place, and the NRC's proposed backfitting action is not changing this requirement.
2	The identified requirement must have been "known and established" (i.e., the requirement cannot be implied or subjective) at the time of the NRC's approval.	Confirm timing of requirement. If not contemporaneous with the NRC's approval, then the compliance exception cannot be used.
3	The NRC consistently interpreted and applied the identified requirement.	If the NRC's interpretation was consistently applied at the time of approval, then state that finding with a supporting basis. If there were inconsistent interpretation and application, then it is much less likely that an error or omission can be shown to have occurred. Note that conclusion with a supporting basis.
4	The NRC approved the licensee's method of compliance with the requirement.	Note the approval type and date and describe supporting information that indicates the NRC's interpretation and application of the requirement in its approval.
The Error or Omission		
Step	Action	Notes
5	The NRC has identified an error or omission—either the NRC's own error, or the omission or error of the licensee/applicant or a third party (e.g., a vendor or another government agency), through: • Incorrect perception or understanding of the facts • Failure to recognize flawed analyses • Failure to draw direct inferences from those facts or analyses	Describe the error or omission.

6	The error or omission must have occurred at or before the time that the NRC found that the NRC requirement was satisfied and a regulatory approval was issued.	Note the time of the error or omission (e.g., approval date).
7	The existence of an error or omission must be determined by standards and practices that were prevailing among professionals or experts in the relevant area at the time of the NRC determination that the NRC requirement or commitment was satisfied and a regulatory approval was issued.	Refer to the requirement noted above and describe why the NRC now concludes that there was an error or omission at the time of approval.
8	The facts, analyses, or inferences that are claimed to be an error are now properly perceived, performed, or drawn (determined).	Describe how fixing the error or considering the omitted information changes the conclusion previously drawn by the licensee/applicant or the NRC.
9	The NRC would likely not have issued its approval had it known of the error or omission.	Describe how fixing the error or considering the omitted information might have caused the NRC to not grant approval at that time.
The Costs		
Step	Action	Notes
10	Costs of the compliance backfitting are considered in the NRC's documented evaluation of the backfitting action.	Discuss briefly what the corrective action would cost, and how long the facility has been in the current situation.

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2

WORKSHEET 3

FORWARD FITTING WORKSHEET

FORWARD FITTING WORKSHEET		
Screening		
Step	Action	Notes
1	Ask: Does the issue involve a licensee or applicant that is within the scope of the forward fitting policy?	If the licensee or applicant is not within the scope of the forward fitting policy (see NUREG-1409, Section 2.3), then document this and exit the forward fitting process because the proposed action is not a forward fit. If the licensee or applicant is within the scope of the forward fitting policy, then proceed to the next step.
2	Ask: Is the NRC reviewing a licensee-initiated request?	If the answer is “no,” then document this and exit the forward fitting process because the proposed action is not a forward fit. If the answer is “yes,” then proceed to the next step.
3	Ask: Is the staff’s proposed action either a new or changed requirement or staff position interpreting a requirement?	If the answer is “no,” then document this and exit the forward fitting process because the proposed action is not a forward fit. If the answer is “yes,” then proceed to the next step.
4	Ask: Is the new or changed NRC requirement or interpretation being imposed on a licensee as a condition of the NRC’s approval of the licensee-initiated licensing action (i.e., the licensee’s request did not propose this requirement or interpretation)?	If the answer is “no,” then document this and exit the forward fitting process because the proposed action is not a forward fit. If the answer is “yes,” then proceed to the next step.
5	Ask: Will the imposition of the new or changed requirement or interpretation result in a modification or addition to (1) systems, structures, components or design of a facility, (2) design approval or manufacturing license for a facility, or (3) procedures or organization for designing, constructing, or operating the facility?	If the answer is “no,” then document this and exit the forward fitting process because the proposed action is not a forward fit. If the answer is “yes,” then proceed to the next step.

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FORWARD FITTING WORKSHEET		
Justification		
Step	Action	Notes
6	Ask: Is there a direct nexus between the proposed action and the licensee's request?	If the answer is "no," then document this, exit the forward fitting process, and do not take the proposed action because the proposed action would be an unjustified forward fit. If the answer is "yes," then proceed to the next step.
7	Ask: Is the proposed action essential to the staff's approval of the request (i.e., would the staff deny the request if the action is not taken)?	If the answer is "no," then document this, exit the forward fitting process, and do not take the proposed action because the proposed action would be an unjustified forward fit. If the answer is "yes," then proceed to the next step.
8	Obtain NRR or NMSS Office Director approval to expend resources on developing and documenting the full justification for the proposed action (i.e., forward fit analysis).	Using Guide 4 in NUREG-1409, Appendix C, prepare the following for the NRR or NMSS Office Director: • The responses to the first seven steps of this Worksheet. • If readily available, descriptions of any safety, risk, or cost-benefit insights. If approved, then proceed to the next step. If not approved, then address the NRR or NMSS Office Director's concerns and re-seek approval. If not approved, then document the basis for the Office Director's decision, place a note to file in ADAMS, exit the forward fitting process, and do not take the proposed action.

FORWARD FITTING WORKSHEET		
Justification		
Step	Action	Notes
9	Prepare the forward fit analysis and submit it to the Office Director for approval to offer the CRGR the opportunity to review the package.	Refer to NUREG-1409, Section 3.3, and use Guide 4 in NUREG-1409, Appendix C, to fully develop the responses in steps 6 and 7, including the following: • Develop risk insights associated with the staff's proposed forward fitting action. • Is the proposed action necessary to maintain adequate protection? If yes, then do not consider the costs of the proposed action. • Is the proposed action necessary to ensure compliance with governing requirements? If yes, then document that determination, how the proposed action ensures compliance, and consideration of the costs of the proposed action. • If the proposed action consists of a new or modified regulatory staff position and the prior regulatory staff position is available for use by the applicant and applicable to the licensing action under review, then perform a regulatory analysis of the proposed action. • If the proposed action consists of a new or modified regulatory staff position and the prior regulatory staff position is no longer available for use by the applicant, or if no prior staff position existed, then consider the costs of the proposed action. If approved, then proceed to the next step. If not approved, then address the NRR or NMSS Office Director's concerns and re-seek approval. If not approved, then document the basis for the Office Director's decision, place a note to file in ADAMS, exit the forward fitting process, and do not take the proposed action.
10	If the CRGR agrees to review the package, then follow the procedures for submitting documents to the CRGR.	Prepare the materials for the CRGR as specified in the CRGR Charter and Procedures. Afterwards, address any issues identified by the CRGR. Proceed to the next step.

FORWARD FITTING WORKSHEET		
Justification		
Step	Action	Notes
11	Submit the final forward fit analysis to the NRR or NMSS Office Director for approval.	If approved, then proceed with the proposed action. If not approved, then address the NRR or NMSS Office Director's concerns and re-seek approval. If not approved, then document the basis for the decision, place a note to file in ADAMS, exit the forward fitting process, and do not take the proposed action.

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APPENDIX C - GUIDES

INSTRUCTIONS FOR USING GUIDES

These guides provide instructions to the U.S. Nuclear Regulatory Commission (NRC) staff on how to develop a documented evaluation, backfit analysis, or forward fit analysis. Each guide's organization of topics can be used in individual licensing and enforcement actions, as well as the issuance of regulations and guidance. NOTE: The guidance text provided under each topic should **not** be included in the document evaluation, backfit analysis, or forward fit analysis.

Although the NRC's various backfitting provisions in Title 10 of the *Code of Federal Regulations* (10 CFR) Chapter I refer to a "documented evaluation" to support an NRC decision to use the adequate protection or compliance exceptions, the NRC may also use these guides to develop a documented evaluation that states the bases for a staff recommendation or NRC decision that the exceptions may *not* be used. Similarly, although a documented evaluation and backfit analysis can be used to justify a proposed backfitting action, they can also establish the basis for not taking the proposed backfitting action. Documentation of a decision not to proceed with the use of an exception or the backfitting action itself may be as important as documenting the basis for a determination that an exception may be used or the backfitting action can be taken.

In these guides, the terms "backfit" and "backfitting action" may also mean a change affecting issue finality under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," if the proposed NRC action involves regulatory approvals under that part. Depending on the nature of the proposed NRC action, the language of these guides may have to be modified to refer to a "change affecting issue finality" in addition to or instead of "backfit" and "backfitting."

In a rulemaking, the format of the documented evaluation or backfit analysis should conform to the format of the rulemaking's supporting documents. If the documented evaluation or backfit analysis can be included in the proposed or final rule *Federal Register* notice, then the staff should revise the documented evaluation or backfit analysis format to reflect the Office of the Federal Register's notice format.

GUIDE 1

DOCUMENTED EVALUATION FOR USING THE ADEQUATE PROTECTION EXCEPTIONS

DOCUMENTED EVALUATION

TITLE OF PROPOSED BACKFITTING

LICENSEE NAME

FACILITY NAME

DOCKET NOS.

CONTENTS

A table of contents is recommended when the documented evaluation is longer than 3 pages.

I. INTRODUCTION [NUREG-1409, Revision 1, "Backfitting Guidelines," Section 2.5.1.3]

Summarize the proposed backfitting action (a more detailed description will be provided later) and the staff's conclusion. Describe the enforcement, licensing, or rulemaking context.

II. BACKGROUND

Concisely describe the historical and procedural facts that led to the proposed NRC backfitting. Summarize the entity's or entities' licensing bases and the safety or security context for the proposed backfitting action.

III. PROPOSED BACKFITTING [NUREG-1409, Revision 1, Sections 2.3, 2.4]

Describe the proposed backfitting. The description should include the following:

- the key substantive elements of the proposed backfitting and its purpose;
- the entities upon whom the proposed backfitting would be imposed;
- risk insights;
- the regulatory method (e.g., order, adoption of final regulation) by which the backfitting would be imposed; and
- the expected time, event, or occurrence by which implementation of the proposed backfitting must be completed.

IV. ADEQUATE PROTECTION EXCEPTION APPLICABILITY [NUREG-1409, Revision 1, Section 2.5.1]

Describe the basis for invoking one or both of the adequate protection exceptions from the requirement to perform a backfit analysis, including why compliance with existing applicable requirements does not or will not provide reasonable assurance of adequate protection (i.e., a condition of undue risk to public health and safety[1] exists despite compliance with requirements) and how the backfitting action addresses the condition of undue risk. If the staff determines that it cannot invoke one or both of the adequate protection exceptions, describe the basis for that determination and skip to Section VII.

V. IMMINENT THREAT ANALYSIS

If there is a basis for invoking one or both of the adequate protection exceptions, then describe the basis for determining whether an imminent threat exists that warrants an immediate agency action.

[1] For materials licensees that are the subject of 10 CFR 70.76, this also includes the potential effects of hazardous chemicals produced from licensed material. For licensees that are the subject of 10 CFR 72.62, occupational health and safety is an explicit criterion for use of the adequate protection exception (10 CFR 72.62(b)).

VI. ALTERNATIVE METHODS FOR ACHIEVING ADEQUATE PROTECTION

A. Alternatives [NUREG-1409, Revision 1, Section 2.5.1.3]

Describe the NRC's method (including selection criteria) for identifying reasonable alternatives to the proposed backfitting for achieving adequate protection. If a regulatory analysis was prepared to identify such alternatives, then—

- State that a regulatory analysis was prepared to identify alternatives.
- Provide the title, date, and the applicable Agencywide Documents Access and Management System (ADAMS) accession number of the regulatory analysis.
- Summarize the regulatory analysis's approach (including selection criteria) for identifying reasonable alternatives to the proposed backfitting for providing adequate protection.

Describe the reasonable alternative backfitting actions to the proposed backfitting action that were considered, irrespective of costs. Also describe the alternatives to the proposed backfitting that were determined not to be reasonable or feasible, irrespective of costs, and provide a basis for this determination.

B. Cost Considerations [NUREG-1409, Revision 1, Section 2.6.2]

If there are multiple ways to implement the action and the NRC prescribes one to comply with requirements or to achieve adequate protection, then the documented evaluation should describe the overall approach for considering costs, including how the staff determined the level of detail provided, categories of entities for which costs were estimated or determined, and whether quantitative information was used (and if not, why not). If only one method of achieving adequate protection is identified, then discuss the reason for this and truncate the documented evaluation by removing Section C.

The cost considerations section must describe the following:

- the costs for the proposed backfitting and each identified reasonable alternative, identifying each cost input or element that was integrated to develop the overall cost estimate;
- uncertainties in each cost input or element;
- sensitivity of results to changes to cost inputs or elements; and
- overall conclusion on cost considerations, limited to a determination that the proposed backfitting is either—
    - the least costly of the identified alternatives for achieving reasonable assurance of adequate protection; or
    - comparable in cost to the identified alternatives for achieving reasonable assurance of adequate protection.

Include a table organizing the cost results for each identified alternative and showing major categories or elements of costs if it will help the reader to understand the NRC's consideration of costs.

Proposed Backfitting Alternatives for Achieving Adequate Protection	Present Value of Costs		
	<description of first class of affected entities>	<description of second class of affected entities>	Aggregate Cost for Entire Population of Affected Entities
Alternative A (TOTAL)	$<MEAN VALUE> <90% confidence interval>	$<MEAN VALUE> <90% confidence interval>	$<MEAN VALUE> <90% confidence interval>
<cost activity 1>	$	$	$
<cost activity 2>	$	$	$
Alternative B (TOTAL)	$	$	$
<cost activity 1>	$	$	$
<cost activity 2>	$	$	$

C. Summary

Document the basis for the NRC's determination that the proposed backfitting is the most cost-effective method of achieving this protection. If one of the alternatives is the most cost-effective, then explain why that alternative is not being pursued.

VII. CONCLUSION

If the NRC determines that the proposed or final backfitting involves adequate protection in accordance with the applicable regulations and provisions, then document this decision, a summary of its basis, and that the NRC has not prepared a backfit analysis to support the proposed backfitting.

When multiple methods of achieving adequate protection are available, document the basis for the NRC's determination that the proposed backfitting is the most cost-effective method of achieving this protection.

If the NRC has determined that the proposed backfitting does not involve adequate protection under the applicable backfitting provisions, then document this decision and its basis.

VIII. REFERENCES

List the sources referenced in the documented evaluation.

GUIDE 2

DOCUMENTED EVALUATION FOR USING THE COMPLIANCE EXCEPTION

DOCUMENTED EVALUATION

TITLE OF PROPOSED BACKFITTING

LICENSEE NAME

FACILITY NAME

DOCKET NOS.

CONTENTS

A table of contents is recommended when the documented evaluation is longer than 3 pages.

I. INTRODUCTION [NUREG-1409, Revision 1, "Backfitting Guidelines," Section 2.5.2.3]

Summarize the proposed backfitting action (a more detailed description will be provided later), the requirement with which NRC seeks licensee compliance, and the staff's conclusion. Briefly describe the enforcement, licensing, or rulemaking context.

II. BACKGROUND

Concisely describe the historical and procedural facts that led to the proposed NRC backfitting. Summarize the entity's or entities' licensing bases and the safety or security context for the proposed backfitting action.

III. PROPOSED BACKFITTING [NUREG-1409, Revision 1, Sections 2.3, 2.4]

Describe the proposed backfitting, and why this is considered backfitting. The description will include the following:

- the key substantive elements of the proposed backfitting and its purpose;
- the entities upon whom the proposed backfitting would be imposed;
- risk insights;
- the regulatory method (e.g., order, adoption of final regulation) by which the backfitting would be imposed; and
- the expected time, event, or occurrence by which implementation of the proposed backfitting must be completed.

IV. ADEQUATE PROTECTION EXCEPTION APPLICABILITY [NUREG-1409, Revision 1, Sections 2.5.1.2 and 2.5.1.3]

Describe why the proposed backfitting action does <u>not</u> involve adequate protection.

V. COMPLIANCE EXCEPTION APPLICABILITY [NUREG-1409, Revision 1, Sections 2.5.2.1 and 2.5.2.2]

A. Requirement

1. Applicable Requirement

Describe the NRC requirement with which the NRC seeks the licensee's compliance. Cite the source of the requirement.

2. Timing of Requirement

Document whether the requirement existed and was known by the NRC and licensee and established at the time of the NRC's approval.

3. Application and Interpretation of the Requirement

Document whether the NRC consistently interpreted and applied the identified requirement at the time of the NRC's approval. Provide a concise and clear history of the NRC's interpretation and application of the NRC requirement.

4. Approval

Describe the NRC's approval of the licensee's method of compliance with the requirement. Describe when and in which NRC documents the NRC approved the licensee's compliance. If there were any limitations or caveats to the NRC's approval that are relevant and necessary to understand the nature and scope of the NRC's original approval, then document those with the explanation for the limitations or caveats.

B. Error or Omission

1. Description of Error or Omission

Describe the NRC's error and, if applicable, the licensee's or third party's error or omission leading to the NRC's error. Also describe when the error occurred. The description of the NRC's error must document the following:

- the NRC's incorrect perception or understanding of the facts;
- the NRC's flawed analyses or failure to recognize flawed analyses; or
- the NRC's failure to draw direct inferences from those facts or analyses.

Document the basis showing that the omission or error occurred either at the time of the NRC's approval or before the NRC's approval (e.g., the licensee or third party made the error while preparing its flawed analyses).

2. Applicability of Standards and Practices

Document the basis showing that the staff's error would have been deemed an error as judged by the methodologies, standards, and practices that were prevailing among professionals or experts in the relevant area at the time of the NRC's approval. Also note whether the staff's error occurred while the staff was using standards and practices that, at the time of the original NRC determination, were not commonly recognized as the prevailing professional standards and practices. In that case, the staff cannot invoke the compliance exception.

3. Relationship of Error to Approval

Explain why the NRC would not have issued its approval if it had known of the error or omission. Demonstrate that the facts, analyses, or inferences that are claimed to be an error are now properly perceived, performed, or drawn, and the error or omission is directly and substantially responsible for the NRC approval that the NRC now regards as incorrect.

C. Summary

Document whether it is appropriate to invoke the compliance exception to performing a backfit analysis based on the discussion above.

VI. COST CONSIDERATIONS [NUREG-1409, Revision 1, Sections 2.5.2.2 and 2.6.2]

A. Description of the Cost Consideration Approach

Summarize the NRC's overall approach to considering cost as part of this documented evaluation. If costs are not quantified, explain why they are not, and indicate any additional factors and considerations that will be addressed to put the cost consideration in an appropriate perspective.

B. Cost of the Proposed Backfitting

Document the methodology for considering costs with respect to the timing of the NRC's approval (e.g., the level of cost consideration increases from minimal consideration involving issues with very recent NRC approvals to a more thorough consideration of costs for issues with NRC approvals that occurred a significant time ago). Discuss the quantitative data and information for costs, then provide a qualitative consideration of costs of the proposed action and the factors affecting the costs, such as the following:

- the overall magnitude of costs imposed on the regulated entities;
- the availability of cost information and the costs of obtaining information if the NRC does not have the information,
- the time between the original NRC decision and the imposition of the backfitting and the NRC and regulated entities' experience with the costs of current compliance (if applicable); and
- stakeholder feedback associated with the proposed compliance backfitting.

C. Benefits of the Proposed Backfitting

Discuss the quantitative and qualitative information in Section IV.B of this guide as it relates to the benefits of the proposed action.

VII. CONCLUSION

If the NRC determines that the proposed or final backfitting is needed to ensure compliance with the applicable regulations or provisions, then document this decision, a summary of its basis, and that the NRC has not prepared a backfit analysis to support the proposed backfitting.

If the NRC has determined that the proposed backfitting is not necessary for compliance under the applicable backfitting provisions, then document this decision and its basis.

VIII. REFERENCES

List the sources referenced in the documented evaluation.

GUIDE 3

BACKFIT ANALYSIS FOR COST-JUSTIFIED SUBSTANTIAL INCREASE IN OVERALL PROTECTION BACKFITTING

BACKFIT ANALYSIS

TITLE OF PROPOSED BACKFITTING

LICENSEE NAME

FACILITY NAME

DOCKET NOS.

CONTENTS

A table of contents is recommended when the documented evaluation is longer than 3 pages.

I. INTRODUCTION [NUREG-1409, Revision 1, "Backfitting Guidelines," Section 2.6.3]

Summarize the proposed backfitting action (a more detailed description will be provided later) and the staff's conclusion. Briefly describe the enforcement, licensing, or rulemaking context.

II. BACKGROUND

Concisely describe the historical and procedural facts that led to the proposed NRC backfitting. Summarize the entity's or entities' licensing bases and the safety or security context for the proposed backfitting action.

If the NRC is issuing a proposed rule, then describe its purpose.

III. PROPOSED BACKFITTING [NUREG-1409, Revision 1, Sections 2.3, 2.4]

Describe the proposed backfitting, why this is considered backfitting, and the applicable backfitting regulation (e.g., 10 CFR 50.109(a)(1), 10 CFR 70.76(a)(1), etc.). The description will include the following:

- the key substantive elements of the proposed backfitting and its purpose;
- the entities upon whom the proposed backfitting would be imposed;
- risk insights;
- the regulatory method (e.g., order, adoption of final regulation) by which the backfitting would be imposed; and
- the expected time, event, or occurrence by which implementation of the proposed backfitting must be completed.

For rulemaking involving the adoption of new regulations or revisions to existing regulations, describe the specific provisions in the proposed regulation(s) falling within the definition of backfitting and the action or prohibition in the identified regulatory provision(s). Also explain why the provisions constitute backfitting under the applicable backfitting definition.

For generic actions such as imposition of positions given in a guidance document, identify the specific provision(s) of the proposed guidance falling within the definition of backfitting, and describe the recommended action or prohibition in that provision of the guidance. Explain why the provisions constitute backfitting under the applicable backfitting definition. For a guidance document, explain the manner in which the "guidance" is to be imposed on the relevant entities.

For facility-specific action such as an order, identify the specific provisions of the order falling within the definition of backfitting, and describe the required action or prohibition in that provision of the order. Then, explain why the order's provisions constitute backfitting under the applicable backfitting definition.

IV. BASIS FOR NOT PERFORMING A DOCUMENTED EVALUATION [NUREG-1409, Revision 1, Section 2.5]

Describe why the proposed backfitting action does not involve the adequate protection or the compliance exceptions to the requirement to perform a backfit analysis.

V. BENEFITS [NUREG-1409, Revision 1, Section 2.6.2]

Describe the benefits of the proposed backfitting action. Document that the NRC identified quantitative and qualitative benefits of the proposed backfitting action, if applicable.

The benefits discussion should reflect a consideration of the nine factors in 10 CFR 50.109(c)(1) through (9); 10 CFR 70.76(b)(1) through (9); and 10 CFR 76.76(b)(1) through (9), as applicable. If the staff prepared a separate discussion of each of the nine factors as an attachment to the backfit analysis, then the attachment should be referenced at each appropriate point in the benefits discussion to demonstrate how the information developed in response to those nine factors was ultimately reflected in the discussion of benefits.

If the backfit analysis does not show a substantial increase in benefits, document the basis for this finding, and do not include the guide's sections on cost and the cost-justification in the backfit analysis.

A. Quantitative Benefits

Describe the present value of the quantified benefits to public health and safety[2] or the common defense and security that would be realized if the proposed backfitting is implemented. List and describe each of the quantitative benefits. Section VII of this guide describes the characterization of the quantitative benefits as a substantial increase. If the backfit analysis does not include a quantitative evaluation of benefits, then this section of the backfit analysis must explain why such a quantitative evaluation was not performed.

To the extent that the backfitting will achieve markedly different benefits for different kinds or classes of affected entities, the quantitative discussion of benefits should reflect those differences, including an explanation of why the benefit differs between the different classes of entities.

Summarize the limitations of whatever quantitative information is used. Discuss the uncertainty of quantitative benefits. Usually, this will be a summary of the uncertainty discussion in the regulatory analysis and a presentation of the numerical range of uncertainty in the cost figures if the backfitting is in the context of a rulemaking.

Quantitative benefits should be presented in a table to facilitate the reader's understanding of each benefit element and the overall integration of benefits for the proposed backfitting. Table 1 is an example of such a table, although other formats may be more appropriate.

[2] For materials licensees that are the subject of 10 CFR 70.76, this also includes the potential effects of hazardous chemicals produced from licensed material. For licensees that are the subject of 10 CFR 72.62, occupational health and safety is an explicit criterion for a backfit analysis (10 CFR 72.62(c)).

Table 1. Quantitative Benefits of the Proposed Backfitting

Safety or Security Benefits <by individual or groups of related elements or sections of the proposed backfitting, if possible>	Present Value of Benefits		
	<description of first class of affected entities>	<description of second class of affected entities>	Aggregate Benefits for Entire Population of Affected Entities
<description of benefit for Backfit Element A>	$<MEAN VALUE> <90% confidence interval>	$	$
<description of benefit for Element B>	$	$	$
<description of benefit for Element C>	$	$	$
TOTAL (MEAN) AND 90% confidence interval	$<MEAN VALUE> <90% confidence interval>	$<MEAN VALUE> <90% confidence interval>	$<MEAN VALUE> <90% confidence interval>

B. Qualitative Benefits

Mention that the qualitative benefits were assessed using the methods described in Appendix A to NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission." Describe the qualitative benefits to public health and safety[3] or the common defense and security that would be realized if the proposed backfitting is implemented. List and describe each of the qualitative benefits. Section VII of this guide describes the characterization of the qualitative benefits as a substantial increase.

Qualitative benefits should be presented in a table to facilitate the reader's understanding of each benefit element and the overall integration of benefits for the proposed backfitting. Table 2, below, is an example of such a table, although other formats may be more appropriate.

[3] For materials licensees that are the subject of 10 CFR 70.76, this also includes the potential effects of hazardous chemicals produced from licensed material. For licensees that are the subject of 10 CFR 72.62, occupational health and safety is an explicit criterion for a backfit analysis (10 CFR 72.62(c)).

Table 2. Qualitative Benefits of the Proposed Backfitting

Safety or Security Benefits <by individual or groups of related elements or sections of the proposed backfitting, if possible>	Description of Qualitative Benefits	
	<description of first class of affected entities>	<description of second class of affected entities>
<description of benefit for Backfit Element A>		
<description of benefit for Element B>		
<description of benefit for Element C>		

VI. COSTS [NUREG-1409, Revision 1, Section 2.6.2]

Document that the NRC identified quantitative costs (i.e., costs that are amenable to quantitative evaluation) and qualitative (i.e., non-quantifiable) costs, if applicable, that would be incurred if the proposed backfitting were implemented.

The cost discussion should reflect a consideration of the nine factors in 10 CFR 50.109(c)(1) through (9); 10 CFR 70.76(b)(1) through (9); and 10 CFR 76.76(b)(1) through (9), as applicable. If the staff prepared a separate discussion of each of the nine factors as an attachment to the backfit analysis, then the attachment should be referenced at each appropriate point in the cost discussion to demonstrate how the information developed in response to those nine factors was ultimately reflected in the discussion of costs.

A. Quantitative Costs

Document the NRC's estimates for the costs of implementing the proposed backfitting (e.g., document a range in dollars and any discount rate percentages). If the backfit analysis does not include a quantitative evaluation of costs, then this section of the backfit analysis must explain why a quantitative evaluation was not performed. List and describe the costs, which may be organized according to the nature of the costs or their relative magnitude.

To the extent that the backfitting will impose markedly different costs for different kinds or classes of affected entities, the quantitative discussion of costs should reflect those differences, including an explanation of why the cost differs between the different classes of entities.

Summarize the limitations of whatever quantitative information is used, including a discussion of the uncertainty of quantitative costs. Usually, this will be a summary of the uncertainty discussion in the regulatory analysis and a presentation of the numerical range of uncertainty in the cost figures if the backfitting is in the context of a rulemaking.

Quantitative costs should be presented in a table to facilitate the reader's understanding of each cost element and the overall integration of costs. Table 3, below, is an example of such a table, although other formats may be more appropriate.

Table 3. Quantitative Costs of the Proposed Backfitting

Individual Elements of the Proposed Backfitting, and Cost Activities for Each Element	Present Value of Costs		
	<description of first class of affected entities>	<description of second class of affected entities>	Aggregate Cost for Entire Population of Affected Entities
Backfit Element A (TOTAL)	$<MEAN VALUE> <90% confidence interval>	$	$
<cost activity 1>	$	$	$
<cost activity 2>	$	$	$
<cost activity 3>	$	$	$
Backfit Element B (TOTAL)	$	$	$
<cost activity 4>	$	$	$
<cost activity 5>	$	$	$
Backfit Element C (TOTAL)	$	$	$
<cost activity 6>	$	$	$
TOTALS	$<MEAN VALUE> <90% confidence interval>	$<MEAN VALUE> <90% confidence interval>	$<MEAN VALUE> <90% confidence interval>

B. Qualitative Costs

Mention that the qualitative costs were assessed using the methods described in Appendix A to NUREG/BR-0058. Describe the qualitative costs to public health and safety[4] or the common defense and security that would be realized if the proposed backfitting is implemented. List and describe each of the qualitative costs.

Qualitative costs should be presented in a table to facilitate the reader's understanding of each qualitative cost element and the overall consideration of qualitative costs for the proposed backfitting. Table 4, below, is an example of such a table, although other formats may be more appropriate.

[4] For materials licensees that are the subject of 10 CFR 70.76, this also includes the potential effects of hazardous chemicals produced from licensed material. For licensees that are the subject of 10 CFR 72.62, occupational health and safety is an explicit criterion for a backfit analysis (10 CFR 72.62(c)).

Table 4. Qualitative Costs of the Proposed Backfitting

Safety or Security Costs <by individual or groups of related elements or sections of the proposed backfitting, if possible>	Description of Qualitative Benefits	
	<description of first class of affected entities>	<description of second class of affected entities>
<description of qualitative cost for Backfit Element A>		
<description of qualitative cost for Element B>		
<description of qualitative cost for Element C>		

VII. COST-JUSTIFICATION DETERMINATION

Document whether the NRC finds that the proposed backfitting provides a cost-justified substantial increase in overall protection. Describe the rationale for the conclusion, which must reference and discuss the quantitative and qualitative benefit and cost information presented above.

Document whether the quantitative and qualitative benefits constitute a substantial increase in overall protection, and whether the costs of implementing the proposed backfitting are justified given the substantial increase in overall protection to public health and safety[5] or the common defense and security attributable to the proposed backfitting. Describe the rationale for the conclusion that the costs of the backfitting are justified, which refers to Table 5 below, a comparison of costs and benefits.

Table 5. Overall Integration of Quantitative Costs and Benefits

Costs and Benefits	<description of first class of affected entities>	<description of second class of affected entities>	Net, Aggregated for Entire Population of Affected Entities
BENEFITS (range)	$<MEAN VALUE> <90% confidence interval>	$<MEAN VALUE> <90% confidence interval>	$<MEAN VALUE> <90% confidence interval>
COSTS (range)	$<MEAN VALUE> <90% confidence interval>	$<MEAN VALUE> <90% confidence interval>	$<MEAN VALUE> <90% confidence interval>
NET	$<MEAN VALUE> <90% confidence interval>	$<MEAN VALUE> <90% confidence interval>	$<MEAN VALUE> <90% confidence interval>

[5] For materials licensees that are the subject of 10 CFR 70.76, this also includes the potential effects of hazardous chemicals produced from licensed material. For licensees that are the subject of 10 CFR 72.62, occupational health and safety is an explicit criterion for a backfit analysis (10 CFR 72.62(c)).

VIII. CONCLUSION

If the backfit analysis determines that there is a cost-justified substantial increase in the overall protection of the public health and safety or the common defense and security for the proposed backfitting, then document this conclusion and summarize the basis for it, using the analysis above. Cite the applicable backfitting provision.

If the backfit analysis determines that there is no substantial increase in the overall protection of the public health and safety or the common defense and security for the proposed backfitting, then document this conclusion and summarize the basis for it, using the analysis above, and state that, accordingly, the NRC concludes that the proposed backfitting is not justified.

If the backfit analysis determines that there is a substantial increase in the overall protection of the public health and safety or the common defense and security for the proposed backfitting, but that the costs are not justified, then document this conclusion and summarize the basis for it, using the analysis above. Document that the NRC concludes that the proposed backfitting is not justified.

IX. REFERENCES

List the documents referenced in the backfit analysis.

X. ATTACHMENT

Consider including an attachment containing the evaluation of factors in 10 CFR 50.109(c)(1) through (9), 10 CFR 70.76(b)(1) through (9), and 10 CFR 76.76(b)(1) through (9), as applicable. This attachment is optional and may be included at the discretion of the staff. The staff may instead choose to integrate the information required to be addressed by these provisions into the applicable discussion in the backfit analysis.

GUIDE 4

FORWARD FIT ANALYSIS

FORWARD FIT ANALYSIS

TITLE OF PROPOSED FORWARD FITTING

LICENSEE NAME

FACILITY NAME

DOCKET NOS.

CONTENTS

A table of contents is recommended when the documented evaluation is longer than 3 pages.

I. INTRODUCTION [NUREG-1409, Revision 1, “Backfitting Guidelines,” Section 3.1]

In the first paragraph, reference the licensing action, summarize its subject, and list related correspondence.

In the next paragraph, concisely describe the proposed forward fitting action (a more detailed description will be provided later) and the staff’s conclusion.

II. BACKGROUND

Concisely summarize the historical and procedural facts that led to the proposed forward fitting. Include a more detailed discussion (than in the introduction) of the applicable aspects of the licensing action with which the staff took issue.

III. PROPOSED FORWARD FITTING

A. Forward Fitting Definition [NUREG-1409, Revision 1, Section 3.2]

Describe in detail the key elements of the proposed staff action meeting the definition of forward fitting, explained in a manner that makes it clear why the proposed staff action, if adopted and imposed, meets the definition of forward fitting. The definition must be identified by citation of Management Directive 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,” Directive Handbook Section I.B.1, dated September 20, 2019.

B. Justification [NUREG-1409, Revision 1, Section 3.3]

1. Direct Nexus

Describe how the proposed staff action is directly related to the licensee’s licensing action request.

2. Essential to the NRC’s Determination

Describe how the proposed staff action is essential to the NRC’s determination of the acceptability of the licensee’s request.

3. Cost Consideration [NUREG-1409, Revision 1, Section 3.3]

Would approval of the requested licensing action require the forward fit to maintain adequate protection of public health and safety? If so, then document that conclusion and how the proposed action enables this to occur, and do not consider the costs of the proposed action. If not, would approval of the requested licensing action require the forward fit to ensure compliance with governing requirements? If so, then document that determination, how the proposed action enables this to occur, and the staff’s consideration of the costs of the proposed action.

If the proposed action consists of a new or modified regulatory staff position and the prior regulatory staff position is available for use by the applicant and applicable to the licensing action under review, then perform a site-specific regulatory analysis of the proposed action. Describe the conclusion of that analysis.

If the proposed action consists of a new or modified regulatory staff position and the prior regulatory staff position is no longer available for use by the applicant, then the staff should have performed a regulatory analysis when the staff issued the new or modified staff position that replaced the prior staff position. The staff should use that generic regulatory analysis, if available, to inform the site-specific regulatory analysis. If no prior staff position existed, then document the costs of the proposed action.

If more than one forward fit was considered, describe the alternatives and the costs and benefits associated with them.

IV. CONCLUSION

Document whether the analysis above justifies a forward fit and the basis for that conclusion.

V. REFERENCES

List the documents referenced in this analysis.

NRC FORM 335
(12-2010)
NRCMD 3.7

U.S. NUCLEAR REGULATORY COMMISSION

BIBLIOGRAPHIC DATA SHEET

(See instructions on the reverse)

1. REPORT NUMBER
(Assigned by NRC, Add Vol., Supp., Rev., and Addendum Numbers, if any.)

NUREG-1409, Revision 1
Draft

2. TITLE AND SUBTITLE

Backfitting Guidelines

Draft Report for Comment

3. DATE REPORT PUBLISHED

MONTH	YEAR
March	**2020**

4. FIN OR GRANT NUMBER

5. AUTHOR(S)

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6. TYPE OF REPORT

Technical

7. PERIOD COVERED (Inclusive Dates)

8. PERFORMING ORGANIZATION - NAME AND ADDRESS (If NRC, provide Division, Office or Region, U. S. Nuclear Regulatory Commission, and mailing address; if contractor, provide name and mailing address.)

U.S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation
Division of Operating Reactor Licensing
Washington, DC 20555-0001

9. SPONSORING ORGANIZATION - NAME AND ADDRESS (If NRC, type "Same as above", if contractor, provide NRC Division, Office or Region, U. S. Nuclear Regulatory Commission, and mailing address.)

Same as above

10. SUPPLEMENTARY NOTES

11. ABSTRACT (200 words or less)

This revision to NUREG-1409 is based on Commission direction in Management Directive 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests.”

12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.)

Backfit, backfitting, forward fit, issue finality, backfit analysis.

13. AVAILABILITY STATEMENT

unlimited

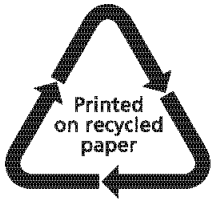
14. SECURITY CLASSIFICATION

(This Page)
unclassified

(This Report)
unclassified

15. NUMBER OF PAGES

16. PRICE



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