

Backfitting Guidelines

Final Report

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Backfitting Guidelines

Final 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 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, licensee, and applicant resources. The backfitting requirements are in 10 CFR 50.109, 70.76, 72.62, and 76.76, all titled, "Backfitting." Provisions analogous to the backfitting requirements, referred to as issue finality provisions, appear 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. Generally, the new or modified requirement or staff interpretation must result in a change to the licensee's systems, structures, components, design, approval, procedures, or organization. A similar process to forward fitting can also apply to certain applications for initial licenses.

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 update of NUREG-1409 is a substantial revision to the 1990 document 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 implementing 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 certain nuclear power reactor-related approvals under Title 10 of the *Code of Federal Regulations* (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. A similar process to forward fitting can also apply to certain applications for initial licenses. 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.

In the NRC's regulations, 10 CFR 50.109, "Backfitting" (the Backfit Rule), provides backfitting provisions for nuclear power reactor licensees and certain applicants. 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, 72.62, and 76.76, all titled, "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, licensee, and applicant resources.

The backfitting regulations address both generic and facility-specific backfitting actions. The backfitting provision in 10 CFR Part 50, "Domestic licensing of production and utilization facilities," defines a backfitting action as follows:

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 10 CFR 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 specifies when the NRC can impose a new or modified requirement on 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 justify 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 the 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 when one of the adequate protection exceptions applies, unless there are multiple ways of implementing the new requirements. If neither of the adequate protection exceptions applies, then the NRC should consider the compliance exception or determine through a backfit analysis whether the action would result in 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 edition 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.

ABBREVIATIONS

10 CFR	Title 10 of the <i>Code of Federal Regulations</i>
ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act of 1954, as amended
AEC	Atomic Energy Commission
ASLBP	Atomic Safety and Licensing Board Panel
ASME	American Society of Mechanical Engineers
CDF	core damage frequency
CFR	<i>Code of Federal Regulations</i>
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	<i>Federal Register</i>
GDC	general design criterion/criteria
ISFSI	independent spent fuel storage installation
LAR	license amendment request
LWR	light-water reactor
MD	management directive
ML	manufacturing license
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, ISSUE FINALITY, 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 (except for Chapter 4, which also contains guidance for use by affected entities), is not legally binding, and does not contain or imply requirements for any affected entity. For the purposes of this NUREG, the unqualified term “affected entity” comprises the entities listed in Section 2.3 of this NUREG.

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, justify, and consider the costs of potential forward fitting actions. Chapter 4 presents 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, 70.76, 72.62, and 76.76, all titled, “Backfitting.”

1.2 Backfitting and Issue Finality

The NRC refers to the provisions in 10 CFR 50.109 as “the Backfit Rule.” The rule defines the term “backfitting” to mean the following for nuclear power reactors licensed under 10 CFR Part 50, “Domestic licensing of production and utilization facilities,” and 10 CFR Part 52, “Licenses, certifications, and approvals for nuclear power plants”:

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

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

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 licensee's licensing basis,² 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 Principles of Good Regulation provided in the NRC's "Strategic Plan for Fiscal Years 2018–2022," issued February 2018 (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 agency to justify the backfitting action. It also contributes to the transparency of the NRC's decisionmaking by requiring the agency 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. In 1987, the U.S. Court of Appeals for the D.C. Circuit vacated the 1985 rule in *Union of Concerned Scientists v. NRC*. 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

² 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 the holder of a license for a fuel facility issued under 10 CFR Part 70, "Domestic licensing of special nuclear material," for which Subpart H, "Additional requirements for certain licensees authorized to possess a critical mass of special nuclear material," is applicable, the licensing basis is defined within the license. For the 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," 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 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.³

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 in 10 CFR Part 76, “Certification of gaseous diffusion plants,” for gaseous diffusion plants.⁴ 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 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

The only parts of the NRC’s regulations that contain backfitting provisions are 10 CFR Parts 50, 52, 70, 72, and 76. As discussed in Section 2.3 of this NUREG, it is the NRC’s policy that nonpower 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, and 76.76 may collectively be referred to as the “backfitting regulations” or “backfitting provisions.” Table 1-1 lists the NRC regulations that contain backfitting or issue finality provisions.

³ 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 regulated entity 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 AEA, no further explanation, including consideration of cost, is necessary. Otherwise, the Administrative Procedure Act’s reasoned decisionmaking requirement compels some consideration of cost.

⁴ Because no gaseous diffusion plants are currently operating, and the NRC does not expect to license any such plants in the foreseeable future, this NUREG does not provide specific guidance for implementing 10 CFR 76.76.

Table 1-1 NRC Backfitting and Issue Finality Requirements

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 proper 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 explained that, although 10 CFR 50.109(a)(1) refers only to regulations, backfitting can result from the imposition of a new or changed regulation or requirement through rulemaking or order or from the communication of a new or changed staff position interpreting those requirements. For backfitting, issue finality, and forward fitting⁵ purposes, the following contain the requirements that legally bind 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 additions over the life of the facility that are docketed and in effect, including any

⁵ Section 1.3 of this NUREG contains a more detailed discussion of forward fitting.

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
- orders

1.2.2.2 *Staff Positions*

The backfitting requirements in 10 CFR Parts 50, 70, and 76 define backfitting in terms of “cause” and “effect.” Backfitting is “caused” by 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 “effect” of backfitting is a modification of or addition to systems, structures, components, or (for power reactors) design of a facility; or (for power reactors) the design approval or manufacturing license for a facility; or the procedures or organization required to operate or (for power reactors) design or construct a facility. Forward fitting is also defined, in part, in this cause and effect context. Consistent with these definitions, the causes of backfitting can also affect the issue finality of a 10 CFR Part 52 approval. Recognizing that the “causal” element of backfitting, issue finality, and forward fitting can involve a regulatory staff position interpreting the Commission’s regulations is important to comprehending backfitting, issue finality, and forward fitting.

For backfitting, issue finality, and forward fitting purposes, staff positions are those documented interpretations of the Commission’s regulations applicable to an affected entity or “class” of affected entities 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 (e.g., NRC approvals), exemptions, or NRC-issued facility-specific correspondence discussing the NRC’s regulatory bases for its decisions (e.g., a safety evaluation, which may or may not be related to a requested licensing action). Inspection reports can also contain staff positions, but the staff must not use inspection reports to create staff positions on the adequacy of the licensing basis, although some exceptions may apply depending on the type of inspection. Section 5.3 of this NUREG contains additional guidance on staff positions in inspection reports. Staff positions in safety evaluations are not requirements; rather, they are the NRC’s regulatory bases for its decisions or interpretations. A safety evaluation (or safety evaluation report) provides the staff position on why an affected entity’s proposed means of implementing or complying with a governing requirement is acceptable and results in compliance with the requirement. The safety evaluation is 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 and issue finality considerations.⁶

In general, internal agency communications are not staff positions. For example, the staff’s conclusion for a technical assistance request is not a staff position. The conclusion could become a staff position if it is used as the documented basis for further staff action. Until or

⁶ NRR Office Instruction LIC-100 states that NRC staff safety evaluations are not part of a plant’s licensing basis. However, changes to staff positions established in safety evaluations (and other correspondence) are subject to the backfitting and forward fitting provisions and policy.

unless it is used for that purpose, the conclusion is an internal agency communication. Section 5.1.2.2 of this NUREG provides more information about the technical assistance request process.

Documents such as regulatory guides, standard review plans, NUREGs, interim staff guidance, branch technical positions, and NRC-endorsed industry topical reports may contain generic staff positions. 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 of meeting or complying with a governing requirement, the NRC imposes generic positions on specific licensees through orders or rulemakings, or the NRC issues licensing actions that incorporate generic positions into licensing bases. Even if a generic staff position applies to individual licensees resulting from one of the actions in the preceding sentence, subsequent revisions of these generic staff positions are not applicable to a licensee unless or until one of the actions in the preceding sentence occurs. Chapter 5 of this NUREG has additional guidance on the relationships among backfitting, issue finality, and generic communications.

If the staff proposes to develop a new or modified regulatory staff position, and the prior position would no longer be available for use or its use would be restricted in some manner for licensees having that prior staff position in their licensing basis, then that proposed action would likely involve backfitting or issue finality and possibly forward fitting. The staff would need to address the backfitting, issue finality, and forward fitting implications at the time the new or amended staff position is issued. Chapters 2 and 3 of this NUREG provide guidance on how to consider the backfitting, issue finality, and forward fitting implications. Chapter 5 of this NUREG describes the relationship of backfitting, issue finality, and forward fitting to developing or withdrawing guidance.

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 to 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 the public health and safety or 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 a 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 act as 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 nevertheless requires the NRC to take the action to address the issue. For this reason, as directed by the Commission in Staff Requirements Memorandum (SRM) COMSECY-16-0020, "Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception to Backfit Rule," dated November 29, 2016, and explained in an NRC memorandum dated December 20, 2016, from the NRC Solicitor to the Chairman 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 act as necessary to achieve adequate protection, the agency 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 the public health and safety, the NRC must prepare an imminent threat analysis that determines whether immediate action is necessary.

Only after determining that neither of the adequate protection exceptions applies to a proposed backfitting action 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 result 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 the public health and safety or the common defense and security.

The backfitting provisions in 10 CFR Part 72 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 to 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 10 CFR 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 decisionmaking 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 or would change a 10 CFR Part 52 approval but not satisfy the applicable issue finality criteria, then the Commission can exempt itself from the applicable backfitting or issue finality provisions. The Commission described this concept in SRM-SECY-93-086, “Backfit Considerations,” dated June 30, 1993, and in greater detail in the statement of considerations (SOC) for the 2009 Aircraft Impact Assessment Rule. As a practical matter, an administrative exemption should be considered only when none of the criteria for justifying the backfitting action or changing the 10 CFR Part 52 approval can be met and either the Commission or the EDO has indicated a desire to proceed with the proposed action 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 or meet the applicable issue finality criteria to change the 10 CFR Part 52 approval.

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 was for Order EA-12-051, “Order Modifying Licenses with Regard to Reliable Spent Fuel Pool Instrumentation” (77 FR 16082; 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 SRM-SECY-93-086, the Commission discussed the use of the administrative exemption in rulemaking, explaining that it 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.

As demonstrated in Order EA-12-051, the NRC uses the administrative exemption outside of rulemaking only in certain situations: (1) highly exceptional actions with extraordinary underlying circumstances, (2) extensive stakeholder engagement, (3) a need for timely action, and (4) broad endorsement from stakeholders for timely action.

1.2.5 Facility-Specific and Generic Backfitting Actions

There are two types of backfitting actions: facility-specific and generic. Facility-specific backfitting actions involve positions unique to a particular facility or docket. The NRC 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 to an affected entity of a proposed or issued backfitting action should include the backfitting assessment for the action, instructions on the use of the appeals process (Chapter 4 of this NUREG has more information on the appeals process), and a schedule for implementing the action once it becomes effective, as applicable. 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)). Section 5.1.4 of this NUREG contains guidance for NRC staff communications with the affected entity about proposed or issued backfitting actions and the options available to the NRC staff and affected entity.

Generic backfitting actions apply to more than one affected entity (typically a class of affected entities) 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 affected entities. 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 give the public an opportunity to 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 its authority to the EDO (although the Commission must review all proposed backfits invoking the adequate protection exceptions).

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 10 CFR 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, then 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 10 CFR 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 10 CFR Part 52 approval. Furthermore, 10 CFR 50.109 applies to certain 10 CFR Part 52 approvals, as shown in Table 1-1.

1.3 Forward Fitting

1.3.1 Definition

The NRC does not have a regulation on forward fitting requirements, but MD 8.4 does reflect the Commission's policy on forward fitting. Forward fitting is similar to backfitting in that the NRC imposes on an affected entity 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. Like backfitting, the definition of forward fitting has cause and effect elements. The fundamental difference between backfitting and forward fitting is that backfitting modifies NRC regulatory approvals already held by an affected entity, whereas a forward fit happens when the NRC's approval of an affected entity-initiated request for a licensing action includes a condition that the affected entity comply with a new or modified requirement or regulatory staff position that the affected entity did not request.

1.3.2 Direct Nexus, Essentiality, and Cost

Like the backfitting requirements, the forward fitting policy requires the NRC to justify and document its assessment of the forward fitting action to ensure reasoned and informed NRC decisionmaking and transparency. Under MD 8.4, the assessment must show that the proposed action meets the definition of a "forward fit" and demonstrate that (1) there is a direct nexus between the new or modified requirement or regulatory staff position and the affected entity'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 affected entity's request. The staff must adequately explain how each of these two elements is independently met. Then, to complete the forward fitting assessment, the staff must consider the costs of the proposed forward fitting action. Section 3.5 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.12 of MD 8.4, the Commission requires the NRC staff to consider risk insights, to the extent practical, for any proposed backfitting, issue finality, or forward fitting action. Because risk information forms part of the basis for any backfitting, issue finality, 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" (60 FR 42622; August 16, 1995). 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, issue finality, or forward fit assessments. 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 or change to a 10 CFR Part 52 approval, the staff must first determine the safety significance of the issue following a risk-informed approach, such as using a PRA. This determination should be made before considering whether the issue presents a backfitting, issue finality, 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 facility has operated safely for years does not, in itself, mean that a condition that has persisted for years should not be reevaluated. However, 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 warranted.

1.5 Communications with Affected Entities

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 an affected entity that a specific action is needed to comply with NRC requirements or to satisfy existing applicable staff positions may be perceived as backfitting or a change affecting issue finality. In a similar manner, if during a licensing review of a voluntary⁷ submittal, the affected entity perceives that the staff is pressuring it to adopt a specific staff position, then the affected entity can 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, a change affecting issue finality, or forward fitting.

⁷ For purposes of this NUREG, "voluntary" is considered to be any action or request to the NRC by the affected entity that was made of the affected entity's own accord, without the force of a legally binding requirement or an NRC representation of further licensing or enforcement action. For example, if the NRC issues an order to a licensee and the licensee must submit a license amendment request to effectuate part of the order, then, in general, the license amendment request would not be considered to have been submitted voluntarily because the NRC required the submittal. However, the order may have allowed the licensee some discretion in the content of its license amendment request, so those aspects of the request could be considered voluntary.

In contrast, during the conduct of normal agency regulatory functions, the staff might suggest that affected entities consider various actions (e.g., the staff might suggest various corrective actions for licensee consideration to address performance deficiencies). Discussion or comments by the staff that constitute suggestions for consideration by affected entities, whether in meetings or written reports, do not constitute backfitting actions or changes affecting issue finality if the suggestions are not presented as actions the affected entity must take beyond its current requirements. Affected entities 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 that any specific corrective actions are discussed as considerations, without the 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 imply requirements through informal communications. An affected entity is not obligated to conform to staff suggestions; however, if it chooses to do so, the affected entity should understand that it is doing this voluntarily and that the suggestion does not constitute the imposition of a requirement. If the affected entity concludes that an NRC suggestion is a backfit or a forward fit or affects the issue finality of a 10 CFR Part 52 approval, then the affected entity can clarify with the staff whether the staff intends to impose a backfitting or forward fitting action or change the approval.

If an affected entity orally raises a backfitting, issue finality, or forward fitting concern or provides the NRC staff with a written backfitting, issue finality, or forward fitting concern that the entity does not identify as an MD 8.4 appeal, including concerns about a proposed violation, then the NRC staff should discuss the concern with the affected entity to ensure mutual understanding. The staff must ensure that its division-level management is informed of an affected entity's concern and must evaluate the points raised by the affected entity before taking a proposed staff action (e.g., issuing a violation or license amendment). The staff's evaluation of the affected entity's concern is not intended to be exhaustive but should appropriately consider the affected entity's concerns within the established schedule for issuing the NRC action (e.g., an inspection report following the exit meeting). The staff should orally reply to the affected entity regarding the staff's evaluation of the affected entity's concern. The staff must ensure that communications and the bases for its decisions comply with MD 3.53, "NRC Records and Document Management Program," dated March 15, 2007, and any applicable NRC office-level implementation procedures.

Backfitting, issue finality, and forward fitting concerns may arise because the affected entity and NRC staff have different understandings about the affected entity's licensing basis. If an affected entity raises a backfitting, issue finality, or forward fitting concern, then the staff should orally discuss its understanding of the licensing basis without conveying an expectation of licensee action.

1.6 Management and Oversight of Backfitting, Issue Finality, and Forward Fitting

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

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 or change 10 CFR Part 52 approvals outside of rulemaking. The office or the region that initiated a backfitting or forward fitting⁸ action or a change affecting issue finality supports NRR or NMSS with its obligation to impose the action or change. 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. The Director of NRR is also responsible for changes affecting issue finality.

To ensure consistent implementation of the backfitting, issue finality, 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 and changes affecting issue finality. 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 and changes affecting issue finality are appropriately justified in accordance with the backfitting and issue finality provisions in 10 CFR Chapter I and the NRC's backfitting and issue finality 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, and NRR is responsible for changes affecting issue finality, the CRGR provides key oversight for backfitting, issue finality, 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 or change affecting issue finality, including the supporting analyses, findings, and justifications.⁹ If the CRGR accepts the request, then the CRGR will recommend approval, revision, or disapproval of the proposed action. 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.

⁸ For licenses that are within the scope of backfitting provisions and, therefore, the forward fitting policy, all licensing actions are processed only in the NRR and NMSS program offices. Therefore, forward fitting actions are not expected to arise in the regional offices.

⁹ The CRGR does not review immediately effective actions. The CRGR Charter contains the procedures to follow in these circumstances.

1.7 Implementation of Backfitting, Issue Finality, and Forward Fitting Process

The NRC staff is responsible for identifying potential backfitting and forward fitting actions and changes affecting issue finality 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.

As stated in the Community of Practice Charter, the purpose of the Community of Practice is to promote the sharing of backfitting, forward fitting, and issue finality issues, knowledge, and practices across the agency, and the consistent implementation of backfitting, forward fitting, and issue finality decisions and policies. The staff accomplishes this through the group's activities, including reviewing draft documents (e.g., agency guidance and office-specific procedures), advising on issues at the staff level, developing and delivering training, and making recommendations to management and the CRGR. The Charter describes the roles and responsibilities of Community of Practice members and the procedures the members will follow.

Before expending significant resources justifying a proposed backfitting or forward fitting action or a change affecting issue finality, the staff first should screen the issues for potential backfitting, issue finality, or forward fitting implications. The steps for screening and justifying backfitting and forward fitting actions or changes affecting issue finality may 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 to this NUREG provide detailed instructions, worksheets, and guides for screening and justifying a backfitting or forward fitting action or change affecting issue finality.

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?
 - (a) Do one or both of the adequate protection exceptions to the requirement of preparing a backfit analysis apply?
 - (b) 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 the 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 act 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 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. However, the applicable issue finality provisions may have additional or alternative criteria for assessing a 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 A to this NUREG provides a flowchart showing the backfitting process. 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 and issue finality regulations. Certain actions are not subject to the backfitting and issue finality requirements. None of the backfitting or issue finality provisions expressly states these exclusions, but the Commission recognizes them as unsuitable for backfitting and issue finality purposes because these proposed actions would not meet the definition of “backfitting”¹ or constitute changes affecting issue finality.

Actions that would not meet the definition of “backfitting” or constitute changes affecting issue finality include changes to NRC administrative procedures;² corrections of regulatory language, including typographical mistakes, misspellings, or inadvertent omissions (when the regulatory record expressly reflects the NRC’s objective); and NRC organization and structure changes. Nevertheless, the NRC must have legal authority to justify taking such actions. Administrative and organizational requirements enable the NRC to carry out its mission. For these proposed actions, the staff should exit the backfitting process and proceed under an appropriate agency process.

The following actions are typically outside the scope of backfitting or issue finality, but the staff must determine if they meet the definition of “backfitting” or constitute changes affecting issue finality on a case-by-case basis: NRC actions implementing mandatory statutory requirements or requirements imposed by other Federal agencies, information collection and reporting requirements,³ and appeal processes required of affected entities, which are not NRC adjudicatory processes under 10 CFR Part 2 or backfitting, issue finality, and forward fitting appeals described in Chapter 4 of this NUREG.⁴ The NRC generally has no discretion in the implementation of statutory requirements or requirements imposed by other Federal agencies. However, the NRC must ensure that any related actions not directly required by statute or other agency action do not meet the definition of “backfitting” or constitute a change affecting issue finality. Information collection and reporting requirements typically do not meet the definition of “backfitting” or constitute a change affecting issue finality because they would not be a procedure or organization required to design, construct, or operate a facility; the NRC nonetheless must ensure that any such requirements do not meet the definition of “backfitting” or constitute a change affecting issue finality. Appeal processes usually do not meet the definition of “backfitting” or constitute a change affecting issue finality because they would not be a procedure or organization required to design, construct, or operate a facility. For these proposed actions, 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 or issue finality considerations. For proposed actions that are within the scope of the backfitting or issue finality regulations, the staff should continue through the screening process.

¹ For example, “Regulatory Improvements to the Nuclear Materials Management and Safeguards System; Final Rule” (73 *Federal Register (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 nonsubstantive changes that did not meet the definition of “backfitting”).

² For example, changes to Title 10 of the *Code of Federal Regulations (CFR)* Part 2, “Agency rules of practice and procedure.”

³ For example, 10 CFR 50.73, “Licensee event report system,” and 10 CFR 70.74, “Additional reporting requirements.”

⁴ 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 a backfitting or issue finality regulation. Table 1-1 lists the regulations that contain backfitting or issue finality provisions. If the entity is not within the scope of these regulations, then these regulations do not apply, and the staff can exit the backfitting or issue finality 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 a backfitting or issue finality regulation, then the staff should continue with the screening process. The following sections describe the entities within the scope of a backfitting or issue finality provision (i.e., affected entities). Affected entities with licensed facilities remain within the scope of a backfitting or issue finality provision when the facility is in a decommissioning phase, except for a facility licensed under 10 CFR Part 70, for which Subpart H is applicable, because, under 10 CFR 70.60, "Applicability," such a facility in a decommissioning phase is not within the scope of the 10 CFR Part 70 backfitting provision.

2.3.1 Power Reactors Licensed under 10 CFR Part 50

For power reactors licensed under 10 CFR Part 50, entities within the scope of backfitting include the following:

- 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)⁵
- holder of an initial operating license (10 CFR 50.56, "Conversion of construction permit to license; or amendment of license," and 10 CFR 50.57, "Issuance of operating license")
- applicant for a renewed operating license (10 CFR Part 54, "Requirements for renewal of operating licenses for nuclear power plants")
- holder of a renewed operating license (10 CFR Part 54)

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.

Backfitting ordinarily does not apply to the renewal of an operating license under 10 CFR Part 54. 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

⁵ The 10 CFR Part 50 backfitting provision applies to applicants for an operating license under Part 50 for the information within the scope of the construction permit.

final rule (60 FR 22461; May 8, 1995) 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, 10 CFR 54.4, "Scope," and 10 CFR 54.21, "Contents of application—technical information," limit the scope of a license renewal review. In part, 10 CFR 54.30(a) states that licensed activities will be conducted in accordance with the current licensing basis. 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 should not be part of the license renewal process and could be subject to a backfitting assessment during the application review. Once the NRC issues the renewed license, 10 CFR 50.109 applies to the entire license with very limited exceptions.

The NRC does not apply the backfitting provisions to nonpower production and utilization facilities, including radioisotope production facilities, research reactors, and testing facilities, licensed under 10 CFR Part 50. The regulatory basis for the 1985 and 1988 Backfit Rule rulemakings addressed only commercial nuclear power reactors. Moreover, the NRC practice has been to apply the Backfit Rule only to commercial nuclear power reactors licensed under Sections 103 and 104b of the Atomic Energy Act of 1954, as amended (AEA). In contrast, the Commission has consistently excluded from the scope of the Backfit Rule nonpower facilities licensed under AEA Sections 103, 104a, or 104c. In the Staff Requirements Memorandum (SRM) to SECY-86-17, "Final Rule; Limitation on the Use of Highly Enriched Uranium (HEU) in Research and Test Reactors," dated February 14, 1986, the Commission declined to apply the Backfit Rule in that rulemaking, stating, "[T]he backfit rule should not be applied to this amendment of the regulations which relates only to non-power reactors."

2.3.2 Power Reactors Licensed and Approved under 10 CFR Part 52

For approvals issued under 10 CFR Part 52, entities within the scope of issue finality provisions include the following:

- holder of an early site permit (ESP) (10 CFR 52.39, "Finality of early site permit determinations")
- 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, "Finality of standard design certifications")⁶
- 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, "Finality of combined licenses; information requests")
- applicant for renewal of a COL (10 CFR Part 54)
- holder of a renewed COL (10 CFR 52.98)

⁶ Each approved DC contains more specific provisions for issue finality than are found in 10 CFR 52.63. These include provisions for changes to and departures from the approved design (e.g., 10 CFR Part 52, Appendix D, "Design Certification Rule for the AP1000 Design," Sections VI and VIII). Also, in determining whether to make a generic change to a design certification rule, the applicable issue finality criteria must be satisfied even if the design certification applicant is not directly affected by the change.

- 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”)

The Commission provided issue finality for 10 CFR Part 52 approvals and licenses in 1989 and amended those provisions in 2007. Applicants referencing an ESP, DC, SDA, or ML have issue finality for only the information within the scope of the ESP, DC, SDA, or ML. Different issue finality provisions apply to renewal of an approval than apply during the term of the approval. For example, during the 20-year term of an ESP, the NRC cannot impose a change to the ESP without meeting the criteria in 10 CFR 52.39. The holder can seek renewal of that ESP for another 20 years. To impose new requirements on that ESP holder at the time the NRC issues the renewed ESP, the agency would have to satisfy the criteria in 10 CFR 52.31. 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.

2.3.3 Materials Licensees under 10 CFR Part 70

The backfitting provision in 10 CFR 70.76 applies to licensees authorized to engage in specific activities and possess special nuclear material above a critical mass pursuant to 10 CFR Part 70, Subpart H.

2.3.4 Materials Licensees under 10 CFR Part 72

The backfitting provision in 10 CFR 72.62 applies to holders of a general or specific license for an independent spent fuel storage installation (ISFSI) or holders of a license for a monitored retrievable storage installation. 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 certificate of compliance (CoC) to the vendor of the associated spent fuel storage cask design. The 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, were not 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. However, documentation provided by a CoC holder indicating that an ISFSI licensee that may be impacted by the revision voluntarily supports the revision and will willingly comply with the revised CoC eliminates 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.

2.3.5 Materials Licensees under 10 CFR Part 76

The backfitting provision in 10 CFR 76.76 applies to a holder of a CoC for a gaseous diffusion plant.

2.3.6 Other Materials Licensees

The NRC issued backfitting provisions for ISFSI 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 agency 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 on 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 SRM-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 the backfitting provision to 10 CFR Part 70 that is applicable only to Part 70 licensees authorized to engage in specific activities and possess greater than a critical mass of special nuclear material.

2.3.7 Proposed Actions Affecting Both Entities That Are Within and Entities That Are Not Within the Scope of Backfitting and Issue Finality

In certain circumstances, a proposed action may affect entities within the scope and entities 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 10 CFR Part 30, “Rules of general applicability to domestic licensing of byproduct material”; 10 CFR Part 40, “Domestic licensing of source material”; 10 CFR Part 50; and 10 CFR 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 typically make that determination by ascertaining how the proposed action would affect the licensee. In general, a proposed NRC action that would affect an activity regulated by a 10 CFR part that does not contain a backfitting or issue finality provision is not subject to a backfitting or issue finality assessment. For an affected entity that is within the scope of a backfitting or issue finality provision, if the proposed NRC action would inextricably affect that entity’s activities regulated under the same 10 CFR part that contains the backfitting or issue finality provision, then the proposed NRC action would be subject to a backfitting or issue finality assessment (for that affected entity).

The definition of “backfitting” in the Commission’s regulations supports this approach. For example, under 10 CFR 70.76, backfitting is a modification of, or addition to, the SSCs of a facility, or the procedures or organization required to operate a facility. For a proposed NRC action to “inextricably affect” a 10 CFR Part 70 licensee’s activities, the proposed NRC action would need to affect the Part 70-related SSCs of the licensee’s facility or the Part 70-related procedures or organization required to operate its facility. The NRC’s statements in the 2013 *Federal Register* notice (78 FR 29016) for draft Regulatory Guide 7009, “Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material,” support this approach:

However, the exception to this principle is not applicable to the issuance of this regulatory guide, which addresses QA [quality assurance] for transportation of radioactive materials. Nuclear power plant licensees, for example, are protected by backfitting requirements in 10 CFR 50.109, and (depending upon the circumstance) issue finality requirements in 10 CFR part 52. Nonetheless, quality assurance governing transportation of certain radioactive materials is not an inextricable part of the licensed activity in 10 CFR parts 50 and 52, viz. the design, construction and operation of a nuclear power plant.

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 imposing⁷ the new or changed requirement or interpretation on an applicable entity?
- (3) Will there be a modification or addition to—
 - (a) SSCs or design of a facility;
 - (b) the design approval or ML for a facility; or
 - (c) the procedures or organization required for designing, constructing, or operating a 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)?

⁷ Not all backfitting actions require an imposition, as discussed in Section 5.2.3 of this NUREG.

- (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 fourth question listed above captures the cause and effect elements of backfitting described in Section 1.2.2.2 of this NUREG: would the cause (i.e., the imposition of a new or changed requirement or interpretation) result in the effect (i.e., the modification or addition)?

The staff should use a similar process for determining whether a proposed action affects issue finality under 10 CFR Part 52. For proposed actions that affect the issue finality of a 10 CFR Part 52 approval, the staff should go to Section 2.6.4 of this NUREG for guidance on determining whether that proposed action satisfies the criteria in the issue finality provision that applies to the Part 52 approval.

Under 10 CFR 50.109(d), the staff must not withhold 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 could be either backfits 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. For proposed backfits, whether the licensing action can be finalized in a proceeding separate from the backfitting assessment will be a fact-specific decision. The backfitting assessment could affect the staff’s determination of the requested licensing action. This would be consistent with the 1985 Backfit Rule statement of considerations (SOC), in which the Commission said that the staff’s review of the requested licensing action should proceed until the backfitting review is concluded: “[U]ntil a backfit analysis is complete, licensing action should continue along a course consistent with normal practice.”

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 in accordance with Section 1.6 of this NUREG.

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.⁸ Furthermore, the staff must consider whether one or both of the adequate protection exceptions applies to the backfitting action before considering justification by the compliance exception.

⁸ The issue finality provisions in 10 CFR Part 52 may have different or additional exceptions as discussed in Section 2.6.4 of this NUREG.

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 to the public health and safety or common defense and security that should be considered as adequate, then the 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 one or both of the adequate protection exceptions applies to the backfitting action, 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. If the documented evaluation is not ready before the agency needs to take an immediate adequate protection action, then the justification presented to the Commission can be transmitted through a different means (e.g., a briefing).

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 radiological⁹ releases and does not include the economic impacts that may ensue). This is 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., "Staff Requirements—COMSAJ-97-008—Discussion on Safety and Compliance," 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 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, "Issuance of Order To Modify Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events," dated March 12, 2012, to provide additional capability to address such 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 ISFSI or

⁹ 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.

monitored retrievable storage installation if the NRC finds that the backfit is necessary to ensure adequate protection to occupational or public health and safety.

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 in these circumstances, 10 CFR 50.109(a)(6) permits the staff to impose the backfitting action before documenting the justification, the staff should document the reason the adequate protection issue represents an imminent hazard and the rationale for imposing the backfit in as much detail as practicable to support developing the order. The justification can be transmitted through means other than a documented evaluation (e.g., a briefing).

2.5.1.2 Adequate Protection Determinations

A licensee's compliance with applicable NRC requirements provides a presumption of adequate protection of the public health and safety. For the NRC to impose new or changed requirements to provide for adequate protection of the public health and safety or the common defense and security, the agency must present 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 the public health and safety exists or will exist 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 an adequate protection exception can be established when new information reveals an unforeseen hazard or 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 agency would use the "defining or redefining adequate protection" exception. Notwithstanding which exception is used, in SRM-SECY-99-063, "Staff Requirements—SECY-99-063—The Use by Industry of Voluntary Initiatives in the Regulatory Process," 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 into 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 goal¹⁰ surrogates (e.g., core damage frequency (CDF) and containment failure probability) for the quantitative health objectives. The Commission issued the quantitative health objectives as part of its 1986 Safety Goal Policy Statement (51 FR 30028; August 21, 1986) 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. NUREG/BR-0058 provides guidance on safety goal screening that the NRC staff can 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 decisionmakers 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 affected entities (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. When considering any generically applicable adequate protection backfitting actions, the staff should inform the Commission so that it can decide whether it wishes to review and approve the action or otherwise direct the staff. When considering any facility-specific adequate protection backfitting actions, the NRC staff should inform the Executive Director for Operations (EDO). Such notifications should occur once the staff has determined that an adequate protection exception may apply and the staff has begun developing a documented evaluation for that 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 affected entity'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 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 CDF per reactor year or conditional containment failure probability.

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 adequate protection exceptions, the documented evaluation must include the basis for invoking the selected exception. 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. The NRC staff should send a copy of the documented evaluation to the EDO and appropriate regional administrator before transmitting the backfitting documentation to the affected entity.

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 neither adequate protection exception applies to the backfitting action, 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 commitments¹¹ 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 ISFSI 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

¹¹ 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 5.1.1.6 of this NUREG.

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.

When questions arise concerning a potential violation that will necessitate a detailed review of the licensee's licensing basis or a complex technical evaluation, the inspectors should contact the appropriate licensing project manager, use the Very Low Safety Significance Issue Resolution process in the NRC's Inspection Manual Chapter 0612, "Issue Screening," dated December 12, 2019, 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 following:

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 its own error or by licensee, applicant, 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.

For example, the NRC typically invokes the compliance exception when all of the following three statements are true:

- (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 agency would not have approved the licensee's method of compliance.

If more than one error or omission occurred, the staff needs to consider whether knowledge of only one of the errors or omissions, or a combination of errors, omissions, or both, could have resulted in a different outcome.

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 at the time it made the approval. 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 at the time the original determination was made.

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

- Provide information to the NRC (or other necessary Federal agency the NRC relies on 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).

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 licensee as having occurred—cannot be the basis for invoking 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 application and any supplements to it should explain the meaning and underlying purpose.

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 agency 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 of the implied approval must be a direct and necessary aspect of the subject of the express approval (e.g., the licensee's methodology for implementing the standard). Finally, the NRC's approval documentation must expressly discuss the subject of the implied approval (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 a 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 (e.g., more than 10 years) has passed since the staff made the decision in question determining 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 approach¹² 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 discernible 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 implementing the compliance backfit, if the NRC determines that it should not impose the compliance backfit, then the agency 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.

¹² 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.

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. The staff should send a copy of the documented evaluation to the EDO and appropriate regional administrator before transmitting the backfitting documentation to the licensee. If the staff cannot justify the proposed action using the compliance exception and 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 Determinations of Cost-Justified Substantial Increase in Overall Protection

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 the 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 that must be 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 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 their expanded use 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 to determine 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 agency has several alternatives:

- The NRC can seek 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 *Federal Register* notice for a proposed rulemaking), issuing an order or a 10 CFR 50.54(f) letter (for 10 CFR 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.

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 facility as a whole, not just the part of the facility 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 10 CFR 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), then 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 50.109(c), the NRC 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 and the level of detail supplied.

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. The staff should send a copy of the backfit analysis to the EDO and appropriate regional administrator before transmitting the backfitting documentation to the licensee.

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

2.6.4 Issue Finality

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. These 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 and 10 CFR 50.109(a)(1)(vii), different backfitting criteria may 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 would apply to the site characteristics, design parameters, and terms and conditions in the ESP, and (3) 10 CFR 52.63 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.

To address the issue finality criteria, the staff should prepare an assessment specific to the applicable issue finality provision. The staff can use a guide in Appendix C to this NUREG, revised as appropriate for the issue finality criteria, to document this issue finality assessment.

3 FORWARD FITTING

3.1 Background

Management Directive 8.4 contains the Commission's forward fitting policy. Forward fitting is similar to backfitting in that it promotes regulatory stability, reasoned decisionmaking, and transparency. Like backfitting, forward fitting occurs when the U.S. Nuclear Regulatory Commission (NRC) imposes on an affected entity (i.e., one of the entities listed in Section 2.3 of this NUREG) 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; 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 an affected entity when the imposition of the qualifying new or amended requirement or staff interpretation of a requirement is a condition¹ of approving the affected entity's requested licensing action, and the affected entity's underlying request does not propose to comply with the new or revised requirement or interpretation. To justify a forward fit, the NRC must show that the forward fit satisfies the definitions of "direct nexus" and "essential." These additional aspects of forward fitting can differentiate a proposed forward fit from a proposed backfit. A complete forward fitting assessment also considers the costs of the forward fit.

The forward fitting policy applies only to those affected entities that are 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, as discussed in Section 5.1.3.2 of this NUREG, to impose any change from the requirements or regulatory staff positions that such applicants relied on in developing their applications, the NRC staff should follow the same reasoned decisionmaking process as it would to impose a forward fit.

3.2 Forward Fitting Screening

To determine whether an NRC proposed action constitutes forward fitting, the agency must screen the proposed action to determine if it meets the definition of a "forward fit." This definition is met when each of the following statements is true:

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

¹ The use of "condition" in forward fitting is not limited to a license condition. It is an NRC-imposed stipulation to its approval.

- (4) The imposition of the new or changed requirement or interpretation will result in a modification or addition to any of the following:
 - (a) systems, structures, or components of the affected entity's facility
 - (b) design (including but not limited to standard design approval or manufacturing license) of the affected entity's facility
 - (c) procedures or organization required for designing, constructing, or operating the affected entity's facility
- (5) The new or changed NRC requirement or interpretation being imposed on the affected entity is a condition of the NRC's approval of the affected entity-initiated licensing action.
- (6) The affected entity's underlying request does not propose to comply with the staff's proposed new or revised requirement or interpretation. This means that the affected entity's initial submittal of the requested licensing action and any written supplements do not include, as part of the licensing action, a proposal to comply with the staff's new or revised requirement or interpretation. Commitments offered in the affected entity's requested licensing action would not constitute legally binding requirements if the NRC approves the requested licensing action, so such commitments would not constitute the affected entity's proposal to comply with the staff's new or revised requirement or interpretation. Section 5.1.1.6 of this NUREG contains more information on commitments.

If one or more of the statements is not true, then the proposed action is not forward fitting. For example, the staff's proposed action cannot be a requirement or staff position that is already in the affected entity's licensing basis (statement 3). Or, if the proposed action is similar to an action described in Section 2.2 of this NUREG (i.e., would not meet the definition of backfitting and, therefore, the definition of forward fitting), then the staff should consider the guidance in Section 2.2 to determine whether the proposed action is within the scope of forward fitting. The staff should document that conclusion as described in Chapter 6 of this NUREG. If the second statement is not true, then the staff needs to assess the proposed action for backfitting. If one or more of the other statements is not true, then the staff may take the proposed action without justifying it as a forward fit or backfit. However, if all the statements are true, then the staff's proposed action meets the definition of a "forward fit," and the staff must justify the proposed action to impose it.

3.3 Forward Fitting Justification

The NRC justifies the forward fit by showing in the forward fitting assessment that the following criteria are met: (1) there is a direct nexus between the new or modified requirement or regulatory staff position and the affected entity'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 affected entity's request.

A direct nexus between the new or modified requirement or regulatory staff position and the affected entity's request occurs when both of the following statements are true:

- (1) The affected entity's requested change would create
 - (a) a safety or security issue, or
 - (b) a noncompliance with a requirement that is already in the affected entity's licensing basis or a new requirement the affected entity proposed in its requested change, that would not exist but for NRC approval of the requested change without a condition.
- (2) The NRC's proposed condition would address the issue or noncompliance.

The first element of the direct nexus definition specifies the types of issues identified during the NRC's review of the affected entity's request that could be the subject of a forward fit. If the affected entity's change would not create the issue or noncompliance if approved by the NRC without a condition, then the issue or noncompliance existed before the affected entity submitted its request. In this case, the direct nexus criterion is not met, and the NRC should take the appropriate regulatory action to address the issue or noncompliance. If an existing requirement or staff position within the affected entity's licensing basis can address the issue or noncompliance, then the NRC's condition of its approval based on an existing requirement or staff position would not meet the definition of a "forward fit" in Management Directive 8.4 (i.e., "the imposition of a new or modified requirement or regulatory staff interpretation of a requirement"). The second element of the direct nexus definition establishes the "direct" relationship between the affected entity's request and the NRC's condition.

For a forward fit to be "essential," it must be necessary for the NRC staff to make the safety or security finding to support the agency's approval of the affected entity's request. A forward fit that is "necessary to make the safety or security finding" will likely be necessary for adequate protection² or continued compliance with all applicable requirements, but the definition of "essential" is not limited only to adequate protection or compliance because the standards for the NRC findings differ depending on the licensing action. For example, Title 10 of the *Code of Federal Regulations* (10 CFR) 50.92, "Issuance of amendment," and 10 CFR 50.40, "Common standards," require that, for license amendments, the staff conclude that there is reasonable assurance that the 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

² However, as explained in Management Directive 8.4, forward fits 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) on 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 as necessary to ensure adequate protection of the public health and safety.

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 regulations and guidance for a specific requested licensing action review to determine what information, including risk insights, is essential to make a conclusion on the acceptability of the request.

The NRC's use of the term "compliance" in a forward fitting context is not the same as use of the term "compliance" in a compliance exception under the Backfit Rule. In the forward fitting context, "compliance" looks ahead to ensure that the affected entity would continue to comply with all applicable requirements following the NRC's review and approval of the request. In contrast, "compliance" when used in the context of compliance exception backfits looks back to the time of a previous NRC approval. The use of risk also differs in these two processes. When considering a compliance backfitting action, the staff should evaluate the safety or security risk if the NRC does not take the backfitting action. With forward fitting, if the staff does not impose the condition necessary to ensure compliance, then the staff would be knowingly approving a noncompliance, which is not permissible under the NRC's regulations (e.g., under 10 CFR 50.92(a) and 10 CFR 50.57, the Commission cannot issue an amendment to an operating license until finding that, among other things, the facility will operate in conformity with the Atomic Energy Act of 1954, as amended, and the rules and regulations of the Commission).

If the proposed action cannot satisfy the direct nexus or essential definition, then the proposed action is not a justified forward fit. The staff should document that conclusion as described in Chapter 6 of this NUREG. If the staff intends to pursue the imposition, then the staff must consider the action in accordance with the backfitting guidance in Chapter 2 of this NUREG.

If the proposed action satisfies the direct nexus and essential definitions, then the NRC staff may communicate the results of the forward fitting screening and justification to the requesting affected entity. Section 5.1.4 of this NUREG contains guidance for NRC staff communications with the affected entity about the safety or security issue or compliance issues preventing NRC approval and the options available to the NRC staff and affected entity. Each communication to an affected entity of a proposed or issued forward fitting action should include the forward fitting assessment for the action and instructions on the use of the appeals process (see Chapter 4 of this NUREG for more information on the appeals process). Subsequently, if the staff decides to pursue the forward fit, then it needs to consider the costs of the proposed forward fit in accordance with Section 3.5 of this NUREG and determine the appropriate action.

3.4 Forward Fitting Screening and Justification Scenarios

The following scenarios demonstrate how the definitions of a "forward fit," "direct nexus," and "essential" would be applied in a voluntarily submitted license amendment request (LAR) to change existing structures, systems, and components (SSCs) within the licensing basis of an affected entity. These scenarios do not address the forward fitting assessment's final step of considering costs.

3.4.1 NRC Condition Meets Definitions of "Forward Fit," "Direct Nexus," and "Essential"

The NRC identifies a safety or security issue or noncompliance that would result from NRC approval of the LAR without imposing a condition to address the issue or noncompliance. The

issue or noncompliance would prevent the NRC from making the findings necessary to approve the LAR. The NRC's proposed condition to address the issue or noncompliance is not already within the affected entity's licensing basis.

The NRC's proposed condition meets the definition of a "forward fit" because the condition would impose a staff position that modifies an SSC as a condition of the NRC's approval of an affected entity-initiated request for a licensing action when the underlying request did not propose to comply with the staff position, and the proposed condition is a new or changed requirement or staff position (i.e., it is not already within the affected entity's licensing basis). The definition of "direct nexus" is met because (1) the affected entity's requested change, if approved by the NRC without a condition, would create a safety or security issue, or a noncompliance with an existing requirement or new requirement proposed by the affected entity, that would not exist but for the change, and (2) the NRC condition would address that issue or noncompliance. The definition of "essential" is met because the forward fitting action would be necessary to make the safety or security finding to support the NRC's approval of the affected entity's request.

The NRC could discuss the staff's concern about the LAR with the affected entity in accordance with Section 5.1.4 of this NUREG. If the affected entity does not supplement its LAR to address the issue or withdraw the LAR, then the NRC has options, including denying the LAR or pursuing the forward fit.

3.4.2 NRC Condition Meets Definitions of "Forward Fit" and "Essential" but Not "Direct Nexus"

In its review of the LAR, the NRC identifies an error it made in a previous licensing action that results in a noncompliance with a requirement, and the LAR under review relies on the erroneous prior approval. The noncompliance existed before the LAR, so approving the LAR would not create the noncompliance. Because the affected entity is acting in accordance with an NRC approval, the NRC cannot issue a violation for the noncompliance. However, the noncompliance must be corrected before completing the review of the LAR because the noncompliance would prevent the NRC from making the findings necessary to approve the LAR. The NRC's proposed condition would correct the previous licensing error.

The NRC's proposed condition meets the definition of a "forward fit" because the condition would impose a staff position that modifies an SSC as a condition of the NRC's approval of an affected entity-initiated request for a licensing action when the underlying request does not propose to comply with the staff position. However, the NRC's proposed condition does not meet the definition of "direct nexus" because the LAR did not create the noncompliance (i.e., the noncompliance existed before submittal of the LAR). The definition of "essential" is met because the NRC's proposed condition would be necessary to make the safety or security finding to support the NRC's approval of the affected entity's request.

Because the NRC's proposed condition does not meet the definition of "direct nexus," the NRC cannot pursue forward fitting. However, the NRC's condition could constitute backfitting because the NRC would be imposing a new staff position on the affected entity. Thus, the "causal" element of backfitting would be met. The NRC could discuss the staff's concern about the LAR with the affected entity. If the affected entity does not voluntarily supplement its LAR to address the issue, then the NRC may need to perform a backfitting assessment to determine if it can pursue backfitting before completing its review of the LAR. Alternatively, the NRC could

deny the LAR and pursue backfitting to correct the previous licensing error. Sections 2.4 and 5.1.4 of this NUREG contain additional guidance on the relationship between backfitting and licensing actions.

3.4.3 NRC Condition Meets Definitions of “Forward Fit” and “Direct Nexus” but Not “Essential”

The NRC identifies a safety or security issue (but not a noncompliance) that would result from agency approval of the LAR without imposing a condition to address the issue. The issue would not prevent the NRC from making the findings necessary to approve the LAR because of the issue’s very low safety significance (e.g., NRC Regulatory Guide 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” discusses the use of probabilistic risk information in assessing an issue’s safety significance). The NRC’s proposed condition to address the issue is not already within the affected entity’s licensing basis.

The NRC’s proposed condition meets the definition of a “forward fit” because the condition would impose a staff position that modifies an SSC as a condition of the NRC’s approval of an affected entity-initiated request for a licensing action when the underlying request does not propose to comply with the staff position, and the proposed condition is a new or changed requirement or staff position (i.e., it is not already within the affected entity’s licensing basis). The definition of “direct nexus” is met because (1) the affected entity’s requested change, if approved by the NRC without a condition, would create a safety or security issue that would not exist but for the change, and (2) the NRC condition would address that issue. However, the definition of “essential” is not met because the proposed condition would not be necessary to make the safety or security finding to support the NRC’s approval of the affected entity’s request.

The NRC cannot justify a forward fitting action. The NRC could assess the proposed condition for backfitting. If backfitting can be justified, then the NRC could discuss the staff’s concern about the LAR with the affected entity in accordance with Section 5.1.4 of this NUREG.

3.4.4 NRC Condition Meets Definition of “Forward Fit” but Not “Direct Nexus” or “Essential”

The NRC can approve the LAR without a condition but proposes to condition its approval on a change to the licensing basis without identifying a safety or security issue or noncompliance that would result from NRC approval of the LAR without a condition (e.g., imposing a newer version of guidance that provides a greater safety margin). The NRC’s proposed condition meets the definition of a “forward fit” because the condition would impose a staff position that modifies an SSC as a condition of the NRC’s approval of an affected entity-initiated request for a licensing action when the underlying request does not propose to comply with the staff position, and the proposed condition is a new or changed requirement or staff position (i.e., it is not already within the affected entity’s licensing basis). The NRC’s condition of its approval would not be needed to address a safety or security issue or noncompliance, so the NRC condition would have no direct nexus to the LAR. Also, because the NRC could approve the LAR without the condition, the condition would not be essential to the NRC’s acceptance of the LAR.

Furthermore, the condition would improperly introduce a nonmaterial issue that is outside the scope of the LAR. The NRC’s regulations limit intervention in proceedings to matters within the scope of the proceeding and material to the findings the NRC must make to issue the LAR. Just

as the NRC regularly denies intervention petitions attempting to introduce matters outside the scope of the proceeding and required findings, the NRC staff cannot introduce matters outside the scope of the LAR.

However, the NRC's condition could constitute backfitting. The NRC determined that it could approve the LAR. If the NRC's approval of the LAR without the condition is considered the applicable staff position, then the NRC's condition of the approval would be imposing a staff position that is new or different from the previously applicable staff position. Thus, the "causal" element of backfitting would be met. The NRC would need to subject the condition to a backfitting assessment.

3.5 Cost Considerations

If the staff's proposed action meets the definitions of a "forward fit," "direct nexus," and "essential," then to complete the forward fit assessment, the staff informs its decision with a cost consideration. The Commission gives the staff substantial flexibility in determining how much cost consideration is appropriate based on the specific facts of each case.

The standards for considering costs are different for forward fitting and backfitting. In a backfit analysis, the NRC must show that the proposed agency action would be cost-justified. For a compliance backfit or a forward fit, the NRC must only consider costs to inform the decision whether to take the backfitting or forward fitting action. During the forward fitting process, the affected entity would still have the choice to revise its request, withdraw its request, or accept the NRC's proposed forward fit. If the affected entity has already incurred costs associated with the request, then the affected entity assumes that licensing risk. The cost estimated for the forward fit would exclude those costs.

The staff should compare the costs of all methods of implementing the forward fit and select the least costly alternative. When there is only one method to implement the forward fit, then the staff should evaluate the incremental cost of the forward fit. Because the staff has the option to deny the requested licensing action and the affected entity has the option to revise or withdraw its request, the cost consideration can inform the decisionmaking path. The staff may use a regulatory analysis to demonstrate its cost consideration. NUREG/BR-0058 provides guidance on the preparation of a regulatory analysis.

If a forward fit would impose a generic staff position on the affected entity (i.e., a staff position that is not within that affected entity's licensing basis), then the staff should inform its facility-specific regulatory analysis using the generic regulatory analysis that was performed by the staff when it issued the generic staff position. If no prior staff position exists because approval of the requested licensing action without a condition would create a safety or security issue or noncompliance that would not exist but for the requested licensing action and, thus, no applicable regulatory analysis exists, then the staff still needs to consider the costs of the forward fit.

3.6 Documenting the Forward Fit Assessment

Appendix C to this NUREG contains a guide for drafting a forward fit assessment to support a forward fitting action. Unlike a backfit analysis described in Section 2.6 of this NUREG, a forward fit assessment contains the staff's evaluation of the proposed action against the definitions of a "forward fit," "direct nexus," and "essential" and the staff's consideration of the costs of the forward fit.

4 MANAGEMENT DIRECTIVE 8.4 APPEALS

4.1 Introduction

The U.S. Nuclear Regulatory Commission (NRC) provides a process in Management Directive (MD) 8.4 by which an affected entity (i.e., one of the entities listed in Section 2.3 of this NUREG) may appeal a proposed or issued staff action when the affected entity believes the staff did not properly perform a backfitting or forward fitting assessment. This NUREG refers to a backfitting or forward fitting appeal as an “MD 8.4 appeal.”¹ Affected entities can use the MD 8.4 appeal process only in either of the following situations:

- The NRC staff imposed (or will impose) a new or revised staff position or requirement on the affected entity that the staff determined was not (or will not be) backfitting or forward fitting but that the affected entity believes is (or will be) backfitting or forward fitting.
- The NRC staff imposed (or will impose) a new staff position or requirement on the affected entity that the staff determined was (or will be) backfitting or forward fitting but that the affected entity believes was (or is) 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 claiming that a backfitting action justified by one or more of the adequate protection or compliance exceptions in fact must be justified through a backfit analysis.

Affected entities have two levels of appeal: a first-level appeal at the office director level² and a second-level appeal to the Executive Director for Operations (EDO). References to the MD 8.4 appeal process in this NUREG include the first-level appeal and second-level appeal, unless otherwise specified. If the NRC already completed the MD 8.4 appeal process for an issue (i.e., the NRC completes the first-level appeal and the second-level appeal, or the NRC completes the first-level appeal and the opportunity for the affected entity to submit a second-level backfit appeal has elapsed), then the NRC will not accept another MD 8.4 appeal for the issue throughout its processing of the agency action unless the NRC substantively changes the issue that the entity appealed.

Affected entities may raise concerns about the NRC staff’s application of the backfitting regulations and forward fitting policy during interactions with the NRC staff, as discussed in Section 1.5 of this NUREG. Raising a backfitting or forward fitting concern does not constitute submission of an MD 8.4 appeal. If an affected entity wants to appeal a proposed or issued staff action, then the affected entity may follow the process described in Section 4.2 of this NUREG. Appendix A to this NUREG provides a flowchart showing the MD 8.4 appeal process.

¹ An affected entity may appeal a change affecting issue finality using the MD 8.4 appeal process described in this chapter.

² In accordance with MD 8.4, the regional administrator is not the official decisionmaker but is expected to be involved and may be the one receiving the appeal.

4.2 Using the Management Directive 8.4 Appeal Process

4.2.1 Submitting an Appeal

The NRC accepts appeals only from those affected entities that are the subject of the staff action that is the basis of the appeal.³ The NRC does not accept MD 8.4 appeals of proposed or issued NRC actions submitted by anyone other than an affected entity, including NRC staff⁴ who disagree with an agency action.

MD 8.4 appeals should be submitted in writing. For appeals to the Director of the Office of Nuclear Reactor Regulation (NRR), the affected entity should submit the appeal in accordance with 10 CFR 50.4, "Written communications," or 10 CFR 52.3, "Written communications," as applicable, with a copy to the appropriate regional administrator. For appeals to the Director of the Office of Nuclear Material Safety and Safeguards (NMSS), the affected entity should submit the appeal in accordance with 10 CFR 70.5, "Communications," or 10 CFR 72.4, "Communications," as applicable, with a copy to the appropriate regional administrator. For a second-level appeal to the EDO, the affected entity should submit the appeal in accordance with 10 CFR 50.4, 10 CFR 52.3, 10 CFR 70.5, or 10 CFR 72.4, as applicable, with a copy to the applicable office director and regional administrator. The affected entity should also specify in its written appeal whether it requests that the NRC host a public meeting with the affected entity to discuss its appeal.

The affected entity's authorized representative should sign the appeal. The appeal should state the capacity of the person signing; the signatory's address, phone number, and e-mail address; and the date of signature. The signature of a person signing an appeal is a representation that the appeal has been subscribed in the capacity specified with full authority, that the individual has read it and knows the contents, that to the best of the individual's knowledge, information, and belief the statements made in it are true, and that it is not interposed for delay.

An affected entity should submit its first-level appeal within 30 calendar days of the issuance date of the NRC's proposed or issued staff action (unless otherwise specified by the NRC in its written communication to the affected entity of the proposed or issued staff action). The first-level appeal should include sufficient documentation to justify the affected entity's basis for the appeal. The affected entity should indicate deficiencies in the staff's action or provide other information that is relevant and material to the staff's action and supports the affected entity's position for the appeal.

A second-level appeal is an appeal of the outcome of the first-level appeal. The affected entity may not request a second-level appeal until the NRC issues its decision on a first-level appeal. If an affected entity wishes to submit a second-level appeal, then the affected entity should submit the second-level appeal within 30 calendar days of the date of the NRC's response to the first-level appeal decision unless otherwise specified by the NRC.

³ If an applicant under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50 or 10 CFR Part 52 is among the entities listed in Section 2.3 of this NUREG and believes the staff has imposed a change in requirements or regulatory staff positions from the applicable version of the standard review plan but did not follow the same reasoned decisionmaking process as for a forward fit (see Section 5.1.3.2 of this NUREG), then that applicant can submit an MD 8.4 appeal of that staff action.

⁴ The NRC staff may choose to use the Differing Professional Opinion or nonconcurrency processes.

4.2.2 Stakeholder Participation

Members of the public can participate in any public meeting associated with the MD 8.4 appeal (except when MD 8.4 appeal meetings are closed because, for example, safeguards, proprietary, or other sensitive information will be discussed). There may be other opportunities to participate in proceedings related to a change to a facility's license (e.g., through the submission of a hearing or intervention request related to a license amendment; a petition via 10 CFR 2.206, "Requests for action under this subpart"; or general correspondence). Sections 4.3.1.3 and 4.3.2.3 of this NUREG provide additional information about the level of public participation in MD 8.4 appeal public meetings.

4.2.3 Draft or Proposed Generic Documents or Actions for Comment

The backfitting appeals process is not applicable to generic documents or actions (e.g., guidance, communications, and rulemakings). As discussed in Chapter 5 of this NUREG, the NRC must perform a backfitting assessment of proposed generic documents or actions. Stakeholders have opportunities to raise backfitting concerns during the development of typical generic documents or actions by submitting comments expressing their concerns. For example, in rulemaking, stakeholders can comment on a proposed rule and the agency's discussion of backfitting in the proposed rule's statement of considerations. The NRC will not process such comments as MD 8.4 appeals.

4.2.4 Appeals of NRC Actions Subject to 10 CFR Part 2 Proceedings

An affected entity may submit an MD 8.4 appeal on a proposed or issued NRC action. However, the regulations in 10 CFR Part 2 for hearings and disputing violations take precedence over the MD 8.4 appeal process. The guidance in this section describes how the NRC processes MD 8.4 appeals in relation to 10 CFR Part 2 proceedings.

4.2.4.1 *Orders and Management Directive 8.4 Appeals*

The regulation at 10 CFR 2.202(e)(1) states, in part, that if an order involves the modification of a 10 CFR Part 50 license and is a backfit, then the requirements of 10 CFR 50.109 shall be followed unless the affected entity has consented to the action required. Therefore, if the NRC proposes to issue an order that would constitute backfitting for a 10 CFR Part 50 affected entity, then the NRC must subject the proposed order to a backfitting assessment before issuing the order unless the order is needed to address an imminent threat to public health and safety or the affected entity consents to the requirements of the order. The NRC typically provides the affected entity the opportunity to submit a backfitting appeal on a proposed facility-specific safety or security order (i.e., nonenforcement order) if time permits. Section 5.1.1.2 of this NUREG defines "safety or security order" and "enforcement order" for the purposes of this NUREG.

If the affected entity chooses to request a hearing on an issued order, then the MD 8.4 appeal process does not apply. Rather, the provisions of 10 CFR Part 2, Subpart B, "Procedure for Imposing Requirements by Order, or for Modification, Suspension, or Revocation of a License, or for Imposing Civil Penalties," would apply, as specified in MD 8.4. Any backfitting issues could be raised within the 10 CFR Part 2 proceeding. The Atomic Safety and Licensing Board (ASLB) is responsible for the resolution of the hearing, including any backfitting concerns that are raised, and an MD 8.4 appeal would no longer be an option. The ASLB decision may be

appealed (under 10 CFR Part 2) to the Commission. In this instance, the ASLB and Commission replace the MD 8.4 first-level and second-level appeals, respectively.

If the affected entity does not pursue an adjudicatory hearing, then it may submit an MD 8.4 appeal in accordance with this chapter, only if the affected entity did not already submit an MD 8.4 appeal of the proposed order and the issued order is not substantively different from the proposed order.

4.2.4.2 *Violations and Management Directive 8.4 Appeals*

The NRC typically informs the affected entity at an inspection exit meeting that the inspection results are predecisional until the inspection report or violation is issued. If an inspection report documents a violation, then the report's cover letter typically states that the affected entity may contest the violation and its significance or severity within a specified time. If an inspection report documents an apparent violation, then the report's cover letter (i.e., a choice or conference letter) typically provides a timeframe for the affected entity to communicate its position on the facts and assumptions regarding the apparent violation.

An affected entity may submit an MD 8.4 appeal of a predecisional violation; however, doing so may be premature and not result in an efficient use of NRC or affected entity resources. Predecisional violations discussed at exit meetings are subject to subsequent NRC management review before the NRC issues the inspection report, violation, or choice letter or conference letter. After an exit meeting, the NRC inspector may continue to review supporting documentation and consult with other NRC staff to ensure proper disposition of the issue of concern. The affected entity may not be aware of the latest status of the proposed violation after the exit meeting until or unless the NRC communicates a change in the proposed violation's status to the affected entity, and the proposed violation may change or not be issued at all.

To optimize NRC and affected entity resources, the NRC has the following options for processing MD 8.4 appeals associated with predecisional violations, apparent violations documented in choice or conference letters, or violations issued in inspection reports or other correspondence.

1. If the affected entity submits an MD 8.4 appeal prior to issuance of the inspection report, violation, or choice or conference letter (i.e., the appeal would be based on predecisional oral communications), then the NRC may choose one of the following options:
 - a. The NRC may hold the MD 8.4 appeal in abeyance until the NRC issues the report, violation, or choice or conference letter. The NRC will document the existence of the MD 8.4 appeal in either an inspection report or separate correspondence and obtain written confirmation from the affected entity on how it wishes the NRC to proceed with the MD 8.4 appeal (e.g., the affected entity may choose to withdraw or modify its appeal based on the contents of the inspection report, violation, or choice or conference letter).
 - b. The NRC may issue the inspection report with an unresolved item to track the concern and complete the MD 8.4 appeal process before dispositioning the unresolved item. The NRC may document an unresolved item in an initial inspection report to track the concern, note the existence of the MD 8.4 appeal in the report, and complete the MD 8.4 appeal process to determine how to

disposition the unresolved item in a subsequent report. The NRC's inspection manual chapters contain additional guidance on how to treat the timing of a violation if it is upheld after the NRC completes the MD 8.4 appeal process. If the NRC completes the MD 8.4 appeal process for the issue, then the NRC will not accept another MD 8.4 appeal for that issue.

- c. The NRC may process the MD 8.4 appeal before issuing the inspection report or violation. If the MD 8.4 appeal is denied and the violation is upheld, then the NRC will not process another MD 8.4 appeal for the issue.
2. If the NRC did not already complete the MD 8.4 appeal process for the issue, and if the affected entity submits an MD 8.4 appeal after the NRC issues a choice or conference letter documenting an apparent violation, then the NRC will typically complete the MD 8.4 appeal process prior to its disposition of the violation. If the MD 8.4 appeal is denied and the violation is upheld, then the NRC will not process another MD 8.4 appeal for the issue after issuance of the violation.
3. If an affected entity chooses to deny or dispute a violation that the NRC has issued on the basis that the violation constitutes unjustified backfitting, then the affected entity should follow the instructions in the correspondence for contesting the violation under 10 CFR 2.201. The affected entity should formally submit its basis for disputing the violation, including its backfitting concerns or an MD 8.4 appeal if the NRC has not already completed the MD 8.4 appeal process for that issue. The content of the affected entity's submittal should be consistent with the NRC Enforcement Manual for disputed nonescalated or escalated actions and MD 8.4, if applicable.
 - a. MD 8.4 Appeal but no Disputed Violation. The regulations in 10 CFR Part 2 require the NRC to specify in its communication to the affected entity a due date for the affected entity to submit a response to a cited violation, including a denial of the violation. This due date also applies to submitting a first-level MD 8.4 appeal if the NRC has not already processed an MD 8.4 appeal for that issue. If the affected entity pursues an MD 8.4 appeal after the NRC issues an inspection report or violation and the affected entity submits the appeal without disputing or denying the violation in accordance with 10 CFR 2.201, then the denied or disputed violation timeline could expire before resolution of the MD 8.4 appeal. In that situation, the affected entity would not be able to deny or dispute the violation after the MD 8.4 appeal process concludes.
 - b. Disputed Violation but no MD 8.4 Appeal. If an affected entity denies or disputes a violation under 10 CFR 2.201 based, in full or in part, on a claim of unjustified backfitting but is not explicit in its communication for denying or disputing the violation that it is also submitting an MD 8.4 appeal, then the NRC will (1) inform the entity, as part of its receipt confirmation of the disputed violation, that the NRC will not accept an MD 8.4 appeal after the NRC completes the disputed or denied violation process, and (2) if the NRC has not already completed the MD 8.4 appeal process for the issue, then request that the entity confirm whether it wants the NRC to treat its disputed violation as an MD 8.4 appeal in parallel with the disputed violation process. If the entity states that it does not want to use the MD 8.4 process, then the NRC will complete the disputed violation process and will not accept an MD 8.4 appeal after the NRC completes the disputed or denied violation process. If the entity states that it does want the NRC to consider its disputed violation in the

MD 8.4 appeal process, then the NRC will follow and complete the MD 8.4 appeal process before responding to the denied or disputed violation. The NRC should not disposition the denied or disputed violation until after an MD 8.4 second-level appeal is resolved or, if the affected entity does not submit an MD 8.4 second-level appeal, then the opportunity for the affected entity to submit an MD 8.4 second-level appeal has elapsed.

- c. Disputed Violation and MD 8.4 Appeal. The most efficient use of NRC and affected entity resources would be for the affected entity to provide the MD 8.4 appeal and 10 CFR 2.201 denial or dispute in the same correspondence if the affected entity denies or disputes a violation based on a claim of unjustified backfitting. If an affected entity denies or disputes a violation under 10 CFR 2.201 and includes an MD 8.4 appeal in its correspondence, then the NRC will follow and complete the MD 8.4 appeal process before responding to the denied or disputed violation if the NRC has not already processed an MD 8.4 appeal for that issue. The NRC should not disposition the denied or disputed violation until after a second-level appeal is resolved or, if the affected entity does not submit a second-level appeal, the opportunity for the affected entity to submit a second-level backfit appeal has elapsed.

4.2.5 Appeals Associated with Licensing Actions

An affected entity may submit an MD 8.4 appeal on a proposed or issued licensing action. The most efficient appeals approach is to provide the affected entity an opportunity to submit an MD 8.4 appeal before the NRC issues the licensing action.

4.2.5.1 Appeals Submitted Before Issuing a Licensing Action

Chapter 5 of this NUREG describes how the NRC can communicate a proposed backfitting or forward fitting action during the processing of a licensing action. Upon receipt of an NRC letter containing the NRC staff's proposed backfit or forward fit and associated assessment, an affected entity may submit an MD 8.4 appeal of the proposed action within the time specified in the NRC's letter. If the affected entity submits an MD 8.4 appeal, and the NRC grants the affected entity's appeal, then the agency will continue its review of the requested licensing action. If the NRC denies the appeal, then the agency has options, including denying the requested licensing action or conditioning its approval with the backfit or forward fit. In that situation, the NRC will not process another MD 8.4 appeal of the issued action if the NRC did not substantively change the proposed backfit or forward fit in the time between the appeal decision and issuance of the action.

4.2.5.2 Appeals Submitted After Issuing a Licensing Action

An affected entity may submit an MD 8.4 appeal after the NRC issues a licensing action if it did not already appeal the specific issue before the agency issued the licensing action. Office-level implementing procedures describe the staff actions to take upon conclusion of the appeals process (e.g., establishing an implementation period if the NRC denies the MD 8.4 appeal).

4.3 NRC Processing of Appeals

If, during the MD 8.4 appeal process, the office director of NRR or NMSS for a first-level appeal, or the EDO for a second-level appeal, determines that 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 affected entity in writing. The responsible office director, EDO, or designee, as applicable, may issue a decision on an appeal at any time without completing all the process steps (e.g., holding a public meeting) in this section of the NUREG.

4.3.1 First-Level Appeals

4.3.1.1 Receipt of an Appeal and Initiation of the First-Level Appeal Process

- (a) The first-level appeal process begins when NRC receives an affected entity's written appeal of a proposed or issued staff action. If the affected entity did not provide a copy of its appeal to the applicable office director of NRR or NMSS, then the NRC staff should ensure that the applicable office director receives a copy of the appeal. First-level appeals addressed to the EDO will be redirected to the appropriate office director for the first-level appeal process.
- (b) Upon receipt of a first-level 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 through the NRR or NMSS representatives, as applicable
 - 2. the managers in charge of the offices, divisions, and branches that proposed or issued the action in question and any other organizations 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 chairperson of the Committee to Review Generic Requirements
 - 6. the regional administrator for the affected entity that submitted the appeal
 - 7. the licensing project manager for the affected entity that submitted the appeal

4.3.1.2 Determination of Oversight Responsibility and First-Level Appeal Screening

- (a) The Director of NRR or NMSS, as appropriate, oversees the first-level appeal process and issues the decision on the appeal. This office director (hereafter referred to as the responsible manager) coordinates the review of the first-level appeal with the regional administrator overseeing the affected entity and, as applicable, the director of the Office of Nuclear Security and Incident Response.
- (b) The responsible manager (or designee) determines if the submitted appeal meets the applicable criteria in Section 4.2 of this NUREG. Within 20 business days of the NRC's receipt of the appeal (i.e., the date the document is declared an Official Agency Record in the NRC's Agencywide Documents Access and Management System), the responsible manager should respond to the affected entity by acknowledging receipt of the appeal and communicating either the staff's review plans or, if the appeal does not meet at least one of the applicable criteria in Section 4.2 of this NUREG, request that the affected entity follow the Section 4.2 criteria.

4.3.1.3 *Review of the First-Level Appeal*

- (a) The responsible manager may appoint a panel to review documentation associated with the appeal and NRC action at issue. This panel, if appointed, should consist of individuals who are independent from the action at issue (i.e., the individuals did not take part in developing, reviewing, or approving the staff action). A manager at the deputy division director level or higher should chair the panel, and members should include an attorney from OGC and staff or management with the appropriate technical and regulatory expertise and experience to thoroughly evaluate the action 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) If the affected entity did not indicate in its submitted appeal that it requests a public meeting, then the panel must offer the affected entity a public meeting to discuss its appeal. The panel may also hold a public meeting with the NRC staff responsible for the appealed staff action to discuss the facts associated with the appealed action. However, this does not preclude the panel from holding nonpublic (internal) meetings with the NRC staff to discuss the facts of the appealed action or to consult with agency experts.

A public meeting with the affected entity, NRC staff, or both would be a Category 1 public meeting and should occur, to the extent practical, within 45 calendar days of the NRC's receipt of the appeal. The panel will not make any regulatory decisions at an MD 8.4 appeal public meeting; rather, the meeting discussion should focus on factfinding. The panel will give members of the public an opportunity to speak and question the panel or staff. The panel has the discretion to determine how many public meetings it will hold (e.g., whether to hold separate meetings with the staff and affected entity if the affected entity chooses to participate or to combine the meetings), the style of information exchange, and the roles of meeting attendees. The panel should clarify this information in the meeting notice.

The panel should prepare and issue summaries of all MD 8.4 appeal public meetings with the affected entity as specified in MD 3.5, "Attendance at NRC Staff-Sponsored Meetings." Discussions involving sensitive (e.g., proprietary or security-related) information with the staff and affected entity must be closed meetings in accordance with other NRC processes; however, the NRC staff would notice the meetings and issue a redacted meeting summary in accordance with MD 3.5. If the affected entity declines its opportunity for a public meeting, and if the panel decides not to meet with the NRC staff responsible for the appealed action, then the NRC will not hold a public meeting.

The responsible manager and panel members must not have substantive discussions (i.e., conversations beyond giving a simple status of the process and scheduling logistics) about the appeal with the affected entity or its representatives during any closed drop-in visits, in accordance with MD 3.5.

- (c) The panel must consider all supporting staff analyses, affected entity-submitted analyses, and any other information that is relevant and material to the appeal.

4.3.1.4 *Response to the First-Level Appeal*

- (a) The panel documents its recommendation on whether to grant or deny the appeal in a memorandum from the panel chairperson to the responsible manager. The memorandum documents the basis for the panel's recommendation.
- (b) The responsible manager evaluates the recommendation provided by the panel and decides whether to grant or deny the appeal. The responsible manager develops a response letter to the affected entity that comprehensively documents the basis for the responsible manager's decision and submits the draft response letter to OGC for its review. Subsequently, the responsible manager informs the appropriate Deputy EDO before communicating the outcome in writing to the affected entity.
- (c) To the extent practical, the responsible manager transmits the response letter to the affected entity within 90 calendar days of receipt of the appeal.
- (d) If the NRC grants the appeal, then the agency must initiate appropriate actions to ensure that the affected entity's licensing basis reflects the outcome of the appeal process (e.g., withdrawing or not issuing a violation).
- (e) If the NRC denies the appeal (i.e., the responsible manager determines that the proposed or issued staff action is justified backfitting or forward fitting, or that the proposed or issued staff action is not backfitting or forward fitting), then the NRC's response letter should inform the affected entity that it may appeal the decision to the EDO within 30 calendar days of the date of the response letter (or another duration determined by the responsible manager).

The NRC's response letter should also state that if the affected entity does not submit a second-level appeal by the date stated in the response letter, then (1) if the NRC already issued the action, then the NRC expects the affected entity will comply with the NRC's issued action, or (2) if the NRC has not issued the action yet, then the agency will issue the proposed action with which the NRC expects the affected entity will comply. The response letter must ensure that the time to file a second-level appeal is no more than the amount of time for the affected entity to come into compliance with the NRC's issued action.

If, after the appeal decision upholding an NRC-issued action, the affected entity either does not submit a second-level appeal within the timeframe specified in the first-level appeal response letter or does not implement the required action, then the NRC may take appropriate action to address the affected entity's noncompliance.

4.3.2 Second-Level Appeal

4.3.2.1 *Receipt of an Appeal and Initiation of the Second-Level Appeal Process*

- (a) The second-level appeal process begins when the NRC receives an affected entity's written appeal of the NRC's first-level appeal decision. If the affected entity did not provide a copy of its second-level appeal to the EDO, then the NRC staff should ensure that the EDO receives a copy of the appeal.

- (b) Upon receipt of a second-level appeal, the NRC staff should notify the following individuals or designees and provide them with a copy of the appeal:
1. the responsible manager for the first-level appeal
 2. the Backfitting and Forward Fitting Community of Practice through the NRR or NMSS representatives, as applicable
 3. managers in charge of the offices, divisions, and branches that proposed or issued the action in question and any other organizations responsible for the technical, regulatory, or policy areas in question
 4. the Deputy General Counsels
 5. the director of the Office of Enforcement
 6. the chairperson of the Committee to Review Generic Requirements
 7. the regional administrator for the affected entity that submitted the appeal
 8. the licensing project manager for the affected entity that submitted the appeal

4.3.2.2 *Determination of Oversight Responsibility and Second-Level Appeal Screening*

- (a) The EDO oversees the second-level appeal process and issues the decision on the appeal.
- (b) The EDO (or designee) determines if the submitted appeal meets the applicable criteria in Section 4.2 of this NUREG. Within 20 business days of the NRC's receipt of the appeal, the EDO (or designee) should respond to the affected entity by acknowledging receipt of the appeal and communicating either the staff's review plans or, if the appeal does not meet at least one of the applicable criteria in Section 4.2 of this NUREG, request that the affected entity follow the Section 4.2 criteria.

4.3.2.3 *Review of the Second-Level Appeal*

- (a) The EDO may appoint a panel to review documentation submitted by the affected entity with the second-level appeal, the results of the first-level appeal, and the proposed or issued action at issue. The panel should consist of managers at the deputy division director level or higher and an attorney from OGC with the appropriate technical and regulatory expertise and experience to thoroughly evaluate the action at issue. Panel members should not have previously participated in the proposed or issued action 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 assumes responsibility for the actions in this section that a panel would otherwise conduct.
- (b) Pursuant to Section 4.2.2 above, the affected entity should have specified in its second-level appeal whether it wants the NRC to hold a public meeting for the affected entity to discuss its appeal. If the affected entity did not indicate in its submitted appeal that it requests a public meeting, then the panel must offer the affected entity a public meeting to discuss its appeal.

The panel may also hold a public meeting to discuss the facts associated with the appealed action with the NRC staff responsible for the action. However, this does

not preclude the panel from holding nonpublic (internal) meetings with the NRC staff to discuss the facts of the appealed action or to consult with agency experts.

A public meeting with the affected entity, NRC staff, or both would be a Category 1 public meeting and should occur, to the extent practical, within 45 calendar days of the NRC's receipt of the second-level appeal. The panel will not make any regulatory decisions at an MD 8.4 appeal public meeting; rather, the meeting discussion should focus on factfinding. The panel will allow an opportunity for members of the public to speak and ask questions of the panel or staff. The panel has the discretion to determine how many public meetings it will hold (e.g., whether to hold separate meetings with the staff and affected entity if the affected entity chooses to participate or to combine the meetings), the style of information exchange, and the roles of meeting attendees. The panel should clarify this information in the meeting notice.

The panel should prepare and issue summaries of all MD 8.4 appeal public meetings with the affected entity as specified in MD 3.5. Discussions involving sensitive (e.g., proprietary or security-related) information with the staff and affected entity must be closed meetings in accordance with other NRC processes; however, the NRC staff would notice the meetings and issue a redacted meeting summary in accordance with MD 3.5. If the affected entity declines its opportunity for a public meeting, and if the panel decides not to meet with the NRC staff responsible for the appealed action, then the NRC will not hold a public meeting.

The EDO and panel members must not have substantive discussions (i.e., conversations beyond giving a simple status of the process and scheduling logistics) about the appeal with the affected entity or its representatives during any closed drop-in visits, in accordance with MD 3.5.

- (c) The panel must consider all supporting staff analyses, affected entity-submitted analyses, and any other information that is relevant and material to the appeal.

4.3.2.4 *Response to the Second-Level Appeal*

- (a) The panel documents its recommendation on whether to grant or deny the appeal in a memorandum from the panel chairperson to the EDO. The memorandum documents the basis for the panel's recommendations.
- (b) The EDO evaluates the recommendation provided by the panel and decides whether to grant or deny the appeal. The EDO prepares a response letter to the affected entity that comprehensively documents the basis for the EDO's decision and submits the draft response letter to OGC for its review.
- (c) To the extent practical, the EDO transmits the response letter to the affected entity within 90 calendar days of the NRC's receipt of the second-level appeal.
- (d) If the NRC grants the appeal, then the agency must initiate the appropriate actions to ensure that the affected entity's licensing basis reflects the outcome of the appeal process (e.g., withdrawing or not issuing a violation).

(e) If the NRC denies the appeal (i.e., the EDO determines that the proposed or issued staff action is justified backfitting or forward fitting, or that the proposed or issued staff action is not backfitting or forward fitting), then the response letter informs the affected entity that (1) if the NRC has already issued the action, then the NRC expects the affected entity will comply with the agency's issued action, or (2) if the NRC has not yet issued the action, then the NRC will issue the proposed action with which the NRC expects the affected entity will comply. If, after issuance of the second-level appeal decision, the affected entity does not implement the required action, then the NRC may take appropriate action to address the affected entity's noncompliance.

5 RELATIONSHIP OF BACKFITTING, ISSUE FINALITY, AND FORWARD FITTING TO VARIOUS PROCESSES

This chapter discusses the relationship of backfitting, issue finality, and forward fitting to various U.S. Nuclear Regulatory Commission (NRC) requirements and regulatory activities, including creating, revising, interpreting, and communicating requirements and staff positions. Additional guidance may be found in NRC office-level implementation procedures.

5.1 Licensing Bases and Processes

Not all licensing basis information¹ constitutes a requirement or a staff position for the purposes of backfitting, issue finality, and forward fitting (e.g., regulatory commitments that were not escalated into requirements). Some staff positions applicable to a facility do not constitute licensing basis information (e.g., safety evaluations) but are subject to the NRC's backfitting, issue finality, and forward fitting provisions. This section of the NUREG discusses how the backfitting, issue finality, and forward fitting provisions apply to various (but not all) licensing basis information and licensing processes.

5.1.1 Licensing Bases

5.1.1.1 *Regulations*

The establishment of a regulation through rulemaking can constitute a backfitting action or a change affecting issue finality, even though regulations are not "staff positions." Section 5.2.2 of this NUREG has additional guidance on rulemaking.

5.1.1.1.1 *Statements of Considerations*

A statement of considerations (SOC) for a final rule provides the Commission's position on the meaning and intent of a regulation and, accordingly, is very important to understanding the regulation. The staff cannot change the positions established in an SOC; rather, such changes are typically made through rulemaking or a notice of interpretation. Section 5.2.2 of this NUREG has additional guidance on SOCs.

5.1.1.1.2 *General Design Criteria for Nuclear Power Reactors*

The Atomic Energy Commission (AEC) published the proposed general design criteria (GDC) in the *Federal Register* (FR) on July 11, 1967 (32 FR 10213). The proposed rulemaking was intended to guide 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 (36 FR 3255) that added Title 10 of the *Code of Federal Regulations* (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

¹ The NRC defines the term "current licensing basis" in 10 CFR 54.3, "Definitions." This definition applies only in the license renewal process and should not be used when determining the licensing basis for backfitting or forward fitting purposes.

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 affected entities (i.e., entities listed in Section 2.3 of this NUREG) 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 the public health and safety and the common defense and security, the Commission must find that the facility has been built in accordance with the PDC and any NRC-approved changes. Thus, for 10 CFR Part 50 licensees with 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 (non-LWRs), the NRC issued 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 that are clearly meant to address the GDC at issue) and technical specifications. Therefore, for 10 CFR Part 50 licensees with construction permits issued since 1971, and for all 10 CFR Part 52 approval holders required to describe their PDC in their applications, a GDC can be regarded as a requirement where the GDC is prescriptive, and the technical specifications, other licensee requirements derived from the GDC, and the PDC do not address the matter in question.

5.1.1.2 Orders

For the purposes of this NUREG, “enforcement orders” are orders issued to ensure compliance with existing requirements and do not involve a change in staff position and, therefore, should not constitute backfitting or a change affecting issue finality. Section 5.4 of this NUREG has additional guidance on enforcement orders. For the purposes of this NUREG, “safety or security orders” are those orders that involve backfitting actions justified by adequate protection,

compliance, or cost-justified substantial increases in overall safety or security or changes to a 10 CFR Part 52 approval that satisfy the applicable issue finality criteria.

5.1.1.2.1 *Imminent Threat Analyses*

The NRC issues an immediately effective safety or security order that requires an affected entity to implement a backfit or change affecting issue finality when the NRC determines that immediate regulatory action is necessary to address an imminent threat to public health and safety or the common defense and security (i.e., imminent hazard). The Director of the Office of Nuclear Reactor Regulation (NRR) or the Office of Nuclear Material Safety and Safeguards (NMSS), as applicable, determines the need for immediate action by conducting an imminent threat analysis, which is required by MD 8.4 when a backfit is justified by one or both of the adequate protection exceptions. An imminent threat analysis is a fact-specific regulatory and technical evaluation of a potential or actual safety or security issue that defines the safety or security concern, existing regulatory requirements and licensing basis information, and, using risk insights as applicable, the consequences of taking and not taking immediate action.

5.1.1.2.2 *Confirmatory Orders*

The NRC issues a confirmatory order to ensure that a licensee complies with certain commitments it voluntarily made to the NRC by turning the commitments into legally binding requirements. A confirmatory order that confirms a licensee's commitments and imposes requirements in excess of previously applicable staff positions are not backfitting or changes affecting issue finality because the licensee agrees to the terms of the order before the NRC issues the order.

5.1.1.3 *Exemptions*

The NRC may exempt an affected entity from certain NRC regulations provided that the requirements in the pertinent exemption regulation (e.g., 10 CFR 50.12 and 10 CFR 70.17, both titled, "Specific exemptions") are met. The NRC's basis for concluding that an exemption request is acceptable is documented in its approval of the request and may create a facility-specific staff position. Any conditions of approval specified in the exemption are requirements.

5.1.1.4 *Mandated Licensing Basis Documents*

Various regulations specify the content, change control, and reporting requirements for mandated licensing basis documents, such as the updated final safety analysis report, technical specifications bases, quality assurance program, security plan, and emergency plan for operating nuclear power reactors. These regulations include 10 CFR 50.59, "Changes, tests and experiments"; 10 CFR 50.54, "Conditions of licenses"; and 10 CFR 50.71, "Maintenance of records, making of reports." Sections 1.2.2.2, 5.1.1.5, and 5.1.3.4 of this NUREG discuss the relationship among staff positions, licensee changes to its licensing basis, and NRC safety evaluations. Once the NRC issues a safety evaluation signifying staff acceptance of the programs described in (or to be added to) a mandated licensing basis document, thereby creating a staff position, a licensee should be able to conclude that the content of the mandated licensing basis document satisfies applicable NRC requirements if the licensee complies with the change control and reporting requirements for the document. 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 a backfitting or issue finality assessment.

5.1.1.5 *Change Control Processes*

Several regulations establish change control requirements, such as 10 CFR 50.59; 10 CFR 50.54(a) and (p)–(q); 10 CFR 52.98(b)–(c); 10 CFR 70.72, “Facility changes and change process”; and 10 CFR 72.48(c). These change control requirements grant licensees the authority to make changes to their licensing bases without prior NRC review and approval, provided that the change meets the specified criteria in each change control requirement that governs whether prior NRC review and approval are necessary. Licensee implementation of changes using these change control requirements is subject to NRC inspection.

Changes that licensees make to their licensing bases in accordance with change control requirements can be considered “staff positions” for purposes of backfitting, issue finality, and forward fitting because the establishment of the regulations and requirements for the change control programs provided the NRC’s position that changes made in compliance with such regulations and requirements are acceptable to the NRC staff. Any future NRC-imposed modifications to the changes would be subject to backfitting, issue finality, and forward fitting considerations. This is consistent with the underlying premise of regulatory stability established within the backfitting, issue finality, and forward fitting policies and the NRC’s Principles of Good Regulation. However, a licensee that improperly makes a change to its licensing basis under one of these change control requirements would be in violation of the requirement.

5.1.1.6 *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. Commitments are also specifically stated in the licensing basis documents for fuel facilities.

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 provides that, in the backfitting context, a written commitment is one 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. If a regulatory commitment were 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 may need to take a backfitting, issue finality, or forward fitting action to escalate a regulatory commitment into a requirement if the licensee did not voluntarily ask the NRC to do so. Similarly, if a regulatory commitment is incorporated into a mandated licensing basis document, then the commitment becomes subject to change control requirements for the mandated licensing basis document and ceases being controlled under the licensee’s commitment management program. Therefore, for nuclear power reactor licensees, the staff may need to take a backfitting, issue finality, or forward fitting action to require the

licensee to incorporate a regulatory commitment into a mandated licensing basis document if this incorporation is not already required by regulation or if the licensee did not voluntarily ask the NRC to do so. For fuel facility licensees, a commitment by a licensee is a legally binding requirement once it is referenced (i.e., “tied down”) by a license condition, which may require a backfitting or forward fitting action.

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, the staff would need to impose the commitment as a legally binding requirement (e.g., convert the commitment into a license condition) as a condition of its approval; however, the staff must screen this action for its potential to be forward fitting, backfitting, or a change affecting issue finality.

5.1.2 Licensing Basis Verifications

5.1.2.1 Differing Views

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 understandings of the subject facility’s licensing basis. The processes discussed in this NUREG assume that backfitting, issue finality, or forward fitting assessments of proposed staff actions begin with a correct understanding of the existing licensing basis. Therefore, before beginning a backfitting, issue finality, or forward fitting assessment, the NRC must verify the licensing basis using informal or formal processes internal to the NRC (e.g., routine staff interactions or technical assistance requests). The NRC licensing project manager for the facility is the initial point of contact for work related to identifying and reviewing the licensee’s licensing basis.

5.1.2.2 Technical Assistance Requests

The NRC may use its technical assistance request processes to support NRC offices and regions by addressing questions raised by NRC staff about licensing bases. The requests having the greatest relevance to backfitting and issue finality generally are those that involve determining whether a particular licensing basis requires the licensee to address a safety or security issue. However, backfitting, issue finality, and their associated activities (i.e., screening, justifying, and issuing) are outside the scope of the technical assistance request processes. As discussed in Section 1.2.2.2 of this NUREG, technical assistance request conclusions are not staff positions, nor are they intended to establish new staff positions for the purposes of backfitting. Nevertheless, a conclusion could become a staff position if it is used as the documented basis for further staff action. Until or unless a conclusion is used for that purpose, it is an internal agency communication, and such communications generally are not staff positions. If the technical assistance request process supports a conclusion that the licensee is meeting its licensing basis, then the staff should follow the technical assistance request process for communicating the results to the requesting office or region. If the staff proposes a change to the licensing basis, then it must exit the technical assistance request process and subject the proposed action to a backfit or issue finality assessment.

5.1.3 Requested Licensing Actions

5.1.3.1 *Preapplication Meetings*

An affected entity may request a preapplication or presubmittal meeting with the NRC to discuss a licensing action the affected entity plans to request. Through these meetings, which are typically public, the affected entity can improve the NRC's review efficiency by discussing the purpose and proposed contents of the planned application or submittal and helping the NRC identify information it may need to complete the review. However, the NRC staff should not make statements during the meeting or in the meeting summary that appear to be conditioning its approval of the request, if submitted, to avoid unjustified backfitting or forward fitting or changes that affect issue finality. For example, the staff should not state, "The NRC will not approve this request unless the affected entity provides the following information or takes the following actions." Rather, the NRC staff may emphasize the findings it is required to make, critical information needed to complete an acceptance review, and any concerns with the affected entity's planned application or submittal.

5.1.3.2 *Initial Licensing*

As the Commission explained in the 10 CFR Part 52 final rule SOC (54 FR 15372; April 18, 1989), 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. The backfitting and issue finality regulations include language delineating when those provisions begin; with some exceptions, they begin after the issuance of a license, permit, or approval (e.g., 10 CFR 50.109(a)(1)(iii), 10 CFR 52.98(a)). Furthermore, 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 10 CFR Part 52 applicant (e.g., a combined license applicant) references a 10 CFR 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 10 CFR Part 52 licensing processes provide regulatory stability to applicants referencing those approvals. The other exception occurs under 10 CFR Part 50. Once the NRC issues a construction permit, backfitting provisions apply to the construction permit holder.² 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 10 CFR Part 52) is not considered backfitting or a change affecting issue finality because, in this situation, the safety evaluation does not constitute the NRC's final position until the NRC issues

² The exception to this principle pertains to the Bellefonte Nuclear Plant, Units 1 and 2, because the 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. In the Backfit Rule, 10 CFR 50.109(a)(1)(ii) 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 6 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 6 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 "backfitting" for that unit is not backfitting.

the license (or other approval). The backfitting and issue finality 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 10 CFR Part 52 or a construction permit when reviewing an operating license application under 10 CFR 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 decisionmaking process as a forward fit to justify the change. When an SRP or other relevant guidance document does not apply to the applicant, the Commission's forward fitting policy would generally not apply to the initial licensing action for a new facility.

5.1.3.3 Acceptance Reviews

The regulation in 10 CFR 2.101, "Filing of application," allows the NRC staff to determine whether a request for a licensing action is complete and acceptable for docketing. When an application lacks critical information necessary for the NRC staff to complete its review, the staff may inform the affected entity of the insufficiencies and that the application is not acceptable for review. The NRC staff must ensure that its communication of the insufficiencies does not meet the definition of "backfitting" or "forward fitting" or constitute a change affecting issue finality. For example, if the insufficiency is based on a regulation or staff position that is neither within the affected entity's licensing basis nor a requirement or staff position that the affected entity has chosen to adopt as part of its application or submittal, then the communication of this insufficiency may meet the definition of "backfitting" or "forward fitting" or constitute a change affecting issue finality.

5.1.3.4 Safety Evaluations and Safety Evaluation Reports

As discussed in Section 1.2.2.2 of this NUREG, the NRC can establish facility-specific staff positions through safety evaluations or safety evaluation reports, which may or may not be related to a requested licensing action. Staff positions in safety evaluations are not requirements; rather, they are the bases for the staff's decisions or interpretations (e.g., why an affected entity's proposed means for implementing or complying with a governing requirement is or is not acceptable). The safety evaluation, therefore, is not part of the licensing basis unless specifically incorporated by the affected entity 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 a backfitting or issue finality assessment.

The NRC staff cannot rely on future agency inspection activities to approve a requested licensing action. Therefore, safety evaluations should not contain staff positions based on future NRC inspection activities.

5.1.3.5 *10 CFR 50.55a Requests*

The provisions of 10 CFR 50.55a, “Codes and standards,” allow affected entities 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.”³ Under 10 CFR 50.55a(z), affected entities can propose alternatives to certain requirements in 10 CFR 50.55a. The NRC calls these requests “proposed alternatives.” Granted relief requests and authorized alternatives can establish facility-specific staff positions.

5.1.3.5.1 *Relief Requests*

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 on the affected entity that could result if the NRC imposed the requirements on the facility. The affected entity can propose these alternative requirements, or the NRC can develop them. NRC-imposed alternative requirements do not constitute backfitting or forward fitting or a change affecting issue finality because 10 CFR 50.55a(f)(6)(i) and (g)(6)(i) allow such impositions. If the NRC intends to impose requirements that are not alternatives to the requirements from which the NRC granted the affected entity relief (i.e., the NRC’s proposed requirements are not related to the requirements from which the affected entity is seeking relief), then the agency would need to subject those proposed requirements to a backfitting, issue finality, or forward fitting assessment before it imposes the requirements. However, the NRC should not improperly introduce nonmaterial issues that are outside the scope of the requirements from which the affected entity is seeking relief.

5.1.3.5.2 *Proposed Alternatives*

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 affected entity and authorized by the NRC before the affected entity implements the alternative. In contrast to 10 CFR 50.55a(f)(6)(i) and (g)(6)(i), which permit the NRC, on its own initiative, to impose alternative requirements in certain circumstances, 10 CFR 50.55a(z) does not have such a provision. Furthermore, even when the NRC authorizes an alternative under 10 CFR 50.55a(z), the affected entity can continue to comply with current requirements; therefore, it is not possible for the NRC to impose an alternative under 10 CFR 50.55a(z). The NRC also cannot modify or add to the affected entity’s proposed alternative; otherwise, the requirement in 10 CFR 50.55a(z) for an alternative to be submitted and authorized would no longer be met. An affected entity can supplement its submittal of its own volition if the NRC or affected entity identifies issues with the proposed alternative.

5.1.3.6 *License Transfers*

A license transferee that is not an existing licensee for the license being transferred is treated as an initial license applicant for a new facility. Because, with few exceptions, backfitting cannot apply to the NRC’s actions on an application for an initial license, a license transferee is

³ NRR Office Instruction LIC-102, Revision 2, “Relief Request Reviews,” dated August 24, 2009, describes the NRC’s processing of requests submitted under 10 CFR 50.55a.

generally outside the scope of backfitting. The forward fitting policy generally applies to situations involving an existing licensee. When a license transferee is not an existing licensee for the license being transferred, any conditions imposed on the license transferee would not be subject to forward fitting considerations unless the NRC requires the license transferee to address a change in requirements or staff positions from those in the version of the SRP or other relevant guidance documents applicable to the license being transferred.

5.1.4 Communicating Potential Backfits, Changes Affecting Issue Finality, or Forward Fits during Licensing

MD 8.4 states that any change to an NRC staff position that the NRC intends to communicate by any means (e.g., via interactions with licensee personnel) to an affected entity as being applicable to its facility may be identified as backfitting. The staff should also be aware that communicating any change to a licensee's 10 CFR Part 52 approval could affect that approval's issue finality. The definition of a "forward fit" in MD 8.4 provides that the affected entity's underlying request did not propose to comply with the NRC staff's proposed new or revised requirement or interpretation (that would be a condition of the staff's approval of the request).

If the NRC identifies a safety or security concern or noncompliance that could result from its approval of the requested licensing action, then the agency may initiate a discussion (e.g., via a public meeting) with an affected entity about this concern. If the NRC staff determines that it could condition its approval with a new or changed requirement or staff position and has not yet decided to deny the application, then, after obtaining licensing and technical division director approval, the NRC may discuss with the affected entity (e.g., via a public meeting) the staff's proposed new or changed requirement or staff position as one suggested option that the affected entity may consider to address the staff's concern about the application. The NRC staff must not communicate such information using the request for additional information process. The staff should explain how the staff's proposed option would address the safety or security issue. The NRC must explicitly inform the affected entity that it is not obligated to follow the staff's proposed option. Because the NRC is not conveying to the affected entity that it must supplement its application to incorporate the staff's proposed option into its request, the staff's proposed option is not an imposition (i.e., the affected entity can propose its own solution to address the staff's concern) and, thus, not backfitting or forward fitting. In this case, the staff does not have to perform a documented evaluation or backfit analysis or consider the costs of a proposed forward fit at this point.

The affected entity can choose the path forward that suits its needs (e.g., not respond to the staff's communication or respond to it by incorporating the NRC's proposed option into a supplement to its application, proposing a different solution, providing additional justification for the affected entity's application, or withdrawing the application). If the affected entity agrees with the staff's suggestion and voluntarily supplements its application to include the staff's proposed option as part of the requested licensing action, then the affected entity's supplement is considered affected entity-proposed, and the staff's communication would not constitute backfitting, a change affecting issue finality, or forward fitting. However, if the NRC communicates in a manner that conveys that the "staff's proposal" is not optional (i.e., it is a condition of the staff's approval), then the staff's communication could constitute backfitting, a change affecting issue finality, or forward fitting and, therefore, should have been subjected to the appropriate screening and justification before its communication to the affected entity.

If, after these communications with the affected entity, the NRC determines that it cannot approve a requested licensing action without imposing a new or changed requirement or staff

position as a condition of its approval, then the NRC staff can either (1) pursue a backfit, change affecting issue finality, or forward fit, as applicable, or (2) deny the application. If the staff pursues the backfit, change affecting issue finality, or forward fit, then it will need to obtain Office Director approval to complete the applicable cost considerations for the backfit, change affecting issue finality, or forward fit. If the proposed requirement or staff position would be a cost-justified substantial increase in overall protection backfit, then the staff should consider whether to pursue that backfit separately from the licensing action. The staff must prepare the backfit, issue finality, or forward fit assessment and submit it to the Office Director for approval and offer the Committee to Review Generic Requirements the opportunity to review the package, as described in Section 1.6 of this NUREG.

If, after obtaining Office Director approval, the NRC staff intends to condition its approval of the licensing action on a proposed backfit, change affecting issue finality, or forward fit, then it must send the affected entity a letter containing the staff's proposed backfit, change affecting issue finality, or forward fit and associated assessment and offering an opportunity to submit an MD 8.4 appeal of the proposed action by a specified date. The affected entity could then either not respond to the NRC's letter (in which case the NRC staff may either issue the approval with the condition or deny the application) or respond by supplementing its application to address the safety or security issue or noncompliance, submitting an MD 8.4 appeal of the proposed backfitting, change affecting issue finality, or forward fitting, or withdrawing the application. Chapter 4 of this NUREG provides additional guidance on the MD 8.4 appeal process.

5.2 Generic Processes

5.2.1 Regulatory Analyses

Regulatory analyses are different from backfit analyses and are required for almost all regulatory actions. The NRC uses regulatory analyses to evaluate the costs and benefits of proposed regulatory actions. A regulatory analysis typically compares alternative approaches to the proposed regulatory action to support informed decisionmaking. In contrast, a backfit analysis supports one type of regulatory approach (i.e., an imposition of new requirements or new staff positions interpreting existing requirements on entities listed in Section 2.3 of this NUREG that are within the scope of the backfitting provisions listed in Table 1-1). A backfit analysis considers whether a particular proposed backfit would result in a substantial increase in the overall protection of the public health and safety or the common defense and security and, if so, whether the direct and indirect costs of implementation for that affected entity are justified in view of this increased protection. The costs identified in the regulatory analyses can be used, therefore, in determining whether a backfit can be justified. Regulatory analyses help the staff provide adequate justification for the proposed action and document a clear explanation of why the staff recommends the action. The staff provides instructions for performing regulatory analyses in NUREG/BR-0058.

5.2.2 Rulemaking

The NRC staff typically begins its rulemaking process by requesting Commission approval of a rulemaking plan. Rulemaking plans contain a discussion of the potential backfitting and issue finality implications of the contemplated rulemaking. The NRC must justify the proposed and final rules under applicable backfitting or issue finality requirements and include this justification in the SOCs for proposed and final rules. Lengthy backfitting and issue finality discussions can be standalone documents summarized in the SOCs. Many rules have an associated guidance document that provides an acceptable means for implementing the new or amended rule. The

backfitting and issue finality implications of the guidance document need to be considered within the backfitting and issue finality assessment supporting issuance of the rule. The SOCs typically include the guidance document's backfitting and issue finality discussion. Because rulemakings are not requests for licensing actions submitted by affected entities, rulemakings do not involve forward fitting.

5.2.2.1 Rulemaking Process

The NRC's 2020 template for rulemaking plans contains a placeholder for a preliminary backfit and issue finality analysis and a description of the information to be provided. The development of a regulatory basis often follows Commission approval of a rulemaking plan. For each alternative approach described in the regulatory basis, the NRC must state whether the alternative approach would constitute backfitting or affect the issue finality of a 10 CFR Part 52 approval and the basis for these preliminary conclusions. If the staff can determine at this stage that an alternative would constitute backfitting or affect the issue finality of a 10 CFR Part 52 approval, then the staff needs to discuss whether one or more of the exceptions to preparing a backfit analysis are likely to apply and be relied on by the staff or whether the applicable issue finality criteria can be satisfied.

A proposed rule would explain the Commission's intention to establish new requirements, change existing requirements, or both. Any one of these proposed new or changed requirements could constitute backfitting or affect the issue finality of a 10 CFR Part 52 approval. As part of a proposed rulemaking issued for public comment, the NRC provides its supporting backfitting and issue finality assessment for any proposed new or changed requirements that could impact an affected entity. The public is invited to comment on this backfitting and issue finality assessment, and the NRC considers those comments and all other public comments in drafting the final rule and the supporting backfitting and issue finality assessment.

The final rule published by the NRC reflects the Commission's consideration of public comments on the proposed rule, including any comments on the backfitting and issue finality assessment. The NRC must revise the final rule's backfitting and issue finality assessment to the extent that comments on the proposed rule warrant such revision.

5.2.2.2 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 its 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, as incorporated into NRC regulations at 10 CFR 50.55a with any applicable exceptions and clarifications, provide requirements for power reactor applicants and licensees. The agency periodically updates these regulations to incorporate by reference later editions of the two ASME codes. The NRC describes its approach to these rulemakings in NUREG/BR-0058, Appendix D.

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 affected entities adopt provisions of the ASME Code on an expedited schedule (i.e., sooner than the 120-month updating interval in 10 CFR 50.55a).

5.2.2.3 *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 give licensees the option of continuing as previously licensed (that is, maintaining the status quo) or following the new, relaxed regulatory requirement or staff position. With one exception, such a voluntary relaxation would not be considered backfitting or a change affecting issue finality because the licensee would not be required to follow the new requirement or staff position.⁴ When the NRC relaxes requirements, it must ensure that 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 results in no decrease in safety or security or, if there is a decrease, it is very small (e.g., NRC Regulatory Guide 1.174 defines "very small" within the context of changes in core damage or large early release frequency).

Examples of relaxations of regulatory requirements include the 2004 final rule promulgating 10 CFR 50.69, "Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors," and the 2010 final rule promulgating 10 CFR 50.61a, "Alternate fracture toughness requirements for protection against pressurized thermal shock events." Such changes are nonmandatory relaxations that allow the licensee to either continue to comply with the requirements of its current licensing basis or adopt the alternative

⁴ The exception is 10 CFR 52.63(a)(1), which includes changes that "[r]educe[] unnecessary regulatory burden...."

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, an affected entity 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 affected entity must comply with all provisions of 10 CFR 50.69. Alternatively, affected entities can choose not to adopt 10 CFR 50.69 and can continue to comply with their licensed special treatment requirements.

5.2.3 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 or a change affecting issue finality.⁵

However, there are instances when the issuance of guidance can constitute backfitting or affect issue finality even without an imposition of a staff position via a legally binding requirement:

- The staff intends, at the time it issues the guidance, to impose the positions on an affected entity (typically through further NRC action).
- The NRC expects affected entities to “voluntarily” adopt the guidance as part of the staff’s basis for resolving a safety or regulatory issue independent of a requested licensing action.
- The issuance of new guidance is associated with a restriction on the use of the previous guidance (e.g., the NRC issues a new version of a regulatory guide but makes the earlier version of the same regulatory guide no longer available for use or limits its use).
- Independent of a requested licensing action, the NRC staff conveys an expectation that affected entities change programs, processes, procedures, or the physical plant by using or committing to use guidance (e.g., regulatory guides or NRC-endorsed industry topical reports) that is not already within the licensing basis for the identified purpose.

In these circumstances, the guidance document needs to be subject to a backfitting and issue finality assessment. MD 8.4 states that issuance of most guidance documents, including their revisions, must include a regulatory analysis performed in accordance with NUREG/BR-0058.

As discussed in Section 1.2.2.2 of this NUREG, although generic staff positions may be contained in documents such as regulatory guides, SRPs, NUREGs, interim staff guidance, and branch technical positions, they 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. If a licensee incorporates a guidance document, then that version of the guidance document becomes a

⁵ Draft guidance does not constitute a staff position because the guidance is only in draft form. If the NRC issues that guidance in a final version, then the guidance can constitute a generic staff position.

requirement. A licensee may incorporate, by reference, a guidance document into its licensing basis via 10 CFR 50.59 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 an affected entity, whether orally or in writing, could constitute backfitting or a change affecting issue finality, and it could constitute forward fitting if related to a requested action from the affected entity. Section 1.5 of this NUREG provides more information on communications with affected entities.

If an entity voluntarily submits an application for an initial license, an amendment, or license renewal, then the staff should use the staff guidance applicable to the type of application during the review to ensure that NRC requirements are met. This would not be considered backfitting or a change affecting issue finality. If the staff uses different guidance to review the entity's request, then, depending on the type of application, the staff could be backfitting or forward fitting that entity or affecting issue finality and would need to meet the applicable criteria discussed in Chapters 2 and 3 of this NUREG.

5.2.3.1 Regulatory Guides

Regulatory guides describe methods that the staff considers acceptable for use in implementing specific parts of the agency's regulations, explain techniques that the staff uses in evaluating specific problems or postulated events, and provide guidance to applicants. 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 notifying the public through the *Federal Register* of the issuance of a regulatory guide, the NRC should include in the notice a discussion of the backfitting, forward fitting, and issue finality implications of the issuance of the guidance document.

5.2.3.2 Interim Staff Guidance

The NRC issues interim staff guidance as temporary guidance until the agency 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 an affected entity's application. When notifying the public through the *Federal Register* of the issuance of interim staff guidance, the NRC should include in the notice a discussion of the backfitting, forward fitting, and issue finality implications of the issuance of the interim staff guidance.

5.2.3.3 Standard Review Plans

SRPs delineate the scope and depth of the staff's review of submittals associated with various licensing activities and can be considered staff positions for purposes of backfitting, issue finality, or forward fitting. If the staff uses acceptance criteria that are more stringent than those stated in the applicable SRPs, or if it proposes actions that the affected entity take that are more stringent than or in addition to those specified in the applicable SRPs, then these criteria and actions may be considered backfitting, a change affecting issue finality, or forward fitting, 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 or a change affecting issue finality unless that version of the SRP is part of the licensee's licensing basis.

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

5.2.3.4 *Withdrawing Guidance Documents*

To withdraw a guidance document, the NRC typically must already have located the guidance in other documents, determined 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 concluded that the guidance can 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 affected entities. However, if the NRC determines that the guidance document should be withdrawn because it contains methods that are no longer an acceptable means of complying with the applicable requirements, then withdrawing that guidance document could constitute backfitting or a change affecting issue finality for those affected entities using the guidance document. The backfitting or a change affecting issue finality 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 or satisfy the applicable issue finality criteria. 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.

5.2.4 **Topical Reports**

A topical report submitted by a vendor is not subject to backfitting, issue finality, or forward fitting considerations because the vendor is not a holder of, or an applicant for, an approval under 10 CFR Part 50, 52, 70, 72, or 76. Therefore, the NRC can impose the constraints needed for the agency to conclude that affected entities' use of the topical report (within the constraints) will be acceptable without having to perform a backfitting, issue finality, or forward fitting assessment. The NRC's acceptance of a topical report must not refer to or rely on inspection reports or activities because such activities should not be used to establish staff positions on the licensing basis, as discussed in Sections 1.2.2.2 and 5.3 of this NUREG.

If an affected entity submits its own topical report or a vendor's "draft" topical report (e.g., one that the NRC has not approved) as the affected entity's topical report with an application as justification for its requested licensing action, then NRC conditions of approval should be assessed for backfitting, issue finality, or forward fitting implications. If the affected entity 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 determines that it may need to impose a condition of its approval that would meet the definitions of "forward fit," "direct nexus," and "essential," then the staff needs to perform a cost consideration specific to the affected entity to complete the forward fit assessment. Section 3.3 of this NUREG contains additional guidance on forward fitting, and Section 5.1.4 of this NUREG has guidance on how to communicate staff proposals, backfits, changes affecting issue finality, and forward fits during licensing activities.

As described in Section 1.2.2.2 of this NUREG, NRC approval of a licensing action involving an NRC-approved topical report can establish a facility-specific staff position. However, the NRC approval can be a generic position if the safety evaluation specifically provides for other affected

entities to adopt the topical report or approved method consistent with the conditions and limitations specified in the safety evaluation.

If an affected entity 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 or changes affecting issue finality because the approved topical report would be a facility-specific staff position for that affected entity. 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 backfitting, forward fitting, or a change affecting issue finality.

5.2.5 Generic Communications

The issuance of generic communications must not establish new requirements or impose staff positions. Therefore, the NRC must subject draft (if applicable) and final generic communications to backfitting and issue finality assessments before issuing them.

5.2.6 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 have various purposes, such as addressing a requirement or staff position that may not be generally understood and, therefore, may be subject to multiple interpretations. They can also explain a requirement or staff position that, because of phrasing, grammar, or punctuation issues, 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" or a change affecting issue finality. 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 and issue finality assessment to verify that the clarification is not backfitting or a change affecting issue finality. If the original staff position allowed for multiple interpretations, and the staff seeks to limit affected entities to one interpretation, then that limitation would be a new staff position and, if imposed on an affected entity, would require a backfitting, issue finality, or forward fitting assessment.

5.2.7 Information Requests

When the NRC revised the Backfit Rule in 1985, it also 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)). 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 or a change affecting issue finality, 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 or a change affecting issue finality, 10 CFR 50.54(f) stipulates that, except for information sought to verify licensee compliance with the current licensing basis for its facility, 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. 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.

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. When issuing these information requests, the NRC cannot require a licensee to adopt the new staff position. Conveying an expectation that the licensee will adopt the new staff position would be considered backfitting or a change affecting issue finality. As a matter of practice, the NRC staff should carefully consider the potential to raise backfitting and issue finality concerns 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 or a change affecting issue finality and should be assessed as such. The licensee's only obligation 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 a requirement or licensing basis information.

5.2.8 Policy Statements

Under the Administrative Procedure Act, a policy statement does not establish a legally binding requirement. An NRC policy statement is the policy of the Commission; therefore, a Commission policy statement cannot be a regulatory staff position interpreting the Commission's regulations. To make a policy statement a requirement for a licensee, the NRC staff would issue a facility-specific licensing action (e.g., a safety or security order) involving a policy statement to create a facility-specific staff position. Such an action would be subject to a backfitting, issue finality, or forward fitting assessment. The NRC can also make a policy statement generically applicable by conducting a rulemaking that creates or amends regulations that implement the principles described in the policy statement.

5.3 Inspection Processes

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. Thus, the inspection procedures define those items that the staff should consider in determining whether the licensee is conducting the facility's activities in accordance with the licensee's licensing basis.

In the normal course of inspections, an NRC inspector may examine and identify findings or violations in specific technical or regulatory areas. Identifying findings or violations must not involve backfitting or issue finality. If an NRC inspector identifies a concern with the adequacy

of the current licensing basis, then that concern must be dispositioned in accordance with the backfitting and issue finality process discussed in this NUREG. NRR or NMSS, as appropriate, will coordinate any backfitting actions or changes affecting issue finality resulting from such concerns.

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 Section 5.3.2 of this NUREG) likely does not involve backfitting or affect issue finality because (1) most inspections use sampling, (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 done, or (6) other factors have been considered.

5.3.1 Oral Communications

An inspector's discussion of proposed findings and violations with the affected entity is not considered backfitting or a change affecting issue finality. During these discussions, the affected entity may agree that certain changes are appropriate in response to the inspector's findings. This would not constitute backfitting or a change affecting issue finality 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 or changes affecting issue finality if the inspector does not convey an expectation that the affected entity must use the guidance document or topical report.

5.3.2 Inspection Reports

The NRC staff must not document backfitting actions or changes affecting issue finality in an inspection report. Findings or violations documented as part of the NRC's inspection activities must not involve backfitting or changes affecting issue finality. If an affected entity believes that a finding or violation in an NRC inspection report is a new or changed staff position that is not part of the licensing basis, then the affected entity can initiate an MD 8.4 appeal as described in Chapter 4 of this NUREG.

As discussed in Section 1.2.2.2 of this NUREG, the NRC establishes facility-specific staff positions through its facility-specific correspondence discussing the regulatory bases for its decisions (e.g., inspection reports). 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"). An inspection report that states, "The NRC inspectors did not identify any findings or violations of more than minor significance," does not create a staff position. This statement acknowledges the possibility that there were noncompliances 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 noncompliances were minor). However, if the inspection report states, "The licensee complied with [Requirement X]," then that language would constitute a staff position on the adequacy of how the licensee complied with that requirement. If the NRC subsequently determines there is a noncompliance with "Requirement X" related to the inspected sample, then the NRC may need to treat that determination as a change in staff position subject to the backfitting provisions because of the

staff position created by the prior statement in the inspection report. Therefore, in inspection reports, the NRC staff should avoid making statements such as, “The licensee complied with [Requirement X].”

5.3.3 Licensing Basis Questions

If licensing basis questions arise during an inspection, and the inspectors determine that the issue does not immediately screen as having very low safety significance, then the inspectors should contact the applicable licensing project manager to resolve the issue through routine staff interactions. If applicable, the staff may also initiate the technical assistance request process for the appropriate office to consider the regulatory, licensing, and technical aspects of the issue. Section 5.1.2 of this NUREG contains additional guidance on licensing basis interpretations and using the technical assistance request process. The process may conclude with the region pursuing a violation (e.g., the issue of concern is a violation of a requirement in the licensing basis). However, if the process conclusion does not support a violation (e.g., the issue of concern is based on a position that is not in the affected entity’s licensing basis), then the staff should exit the technical assistance request process and consider whether to propose a change to the affected entity’s licensing basis, which would be subject to a backfitting or issue finality assessment.

The resolution of an NRC staff nonconcurrency on an inspection report that documents a licensing basis interpretation must have concurrence from the NRR or NMSS licensing division director (or designee) and the NRR or NMSS Office Director (or designee), as applicable, who are responsible for licensing actions associated with the affected entity or facility because the nonconcurrency resolution would constitute an NRC staff position on the licensing basis.

5.4 Enforcement Processes

The NRC issues enforcement sanctions, including orders other than safety or security orders, notices of violation (NOVs) or noncited violations, when a licensee or nonlicensee violates a legally binding requirement. The staff should take extra caution when reviewing regulatory requirements and licensing basis information 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 meets the definition of “backfitting” and could constitute a change affecting issue finality.

5.4.1 Violations

An NOV may require an affected entity to respond by providing the corrective steps that it either has taken or will take to fully comply with NRC requirements. As such, requiring a response to an NOV that describes an affected entity’s proposed corrective action is not backfitting or a change affecting issue finality because such a response is already a requirement for the affected entity. The affected entity’s commitments in the description of a corrective action are not backfits or changes affecting issue finality because they are the affected entity’s means for restoring compliance with an already applicable requirement. A statement or recommendation by the staff for the affected entity to consider actions in response to an NOV is not backfitting or a change affecting issue finality because such communications are not impositions, provided that the affected entity recognizes that it is not obligated to follow the staff recommendations. However, if the staff asks the affected entity 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 or changes affecting issue finality because the staff may be imposing new

requirements on the affected entity. The guidance in this section does not preclude inspectors from assessing corrective actions and issuing applicable enforcement actions.

A violation for ineffective or untimely corrective actions is not backfitting or a change affecting issue finality if the affected entity is required to take effective and timely corrective actions (i.e., there is no new requirement or staff position). However, the NRC staff imposition of a requirement that the affected entity must take a certain action may meet the definition of “backfitting” or constitute a change affecting issue finality 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 affected entity’s licensing basis, then the action would be backfitting or a change affecting issue finality.

Actions taken by an affected entity to correct violations of the requirements in its licensing basis are not backfits or changes affecting issue finality because there is no imposition of a new or changed requirement or staff position. Discussions during enforcement conferences and oral responses to an affected entity’s questions on corrective actions to restore compliance with the requirements in the licensing basis are not backfitting or changes affecting issue finality unless the staff attempts to limit the affected entity to a specific action that is not expressly required or attempts to impose some action beyond requirements.

Chapter 4 of this NUREG describes how the NRC would respond to an affected entity’s concerns of unjustified backfitting or changes affecting issue finality associated with proposed and issued violations.

5.4.2 Enforcement Orders

The NRC may issue an enforcement order when it determines that doing so is necessary to ensure compliance with existing regulations following a violation or non-compliance. As such, enforcement orders do not constitute backfitting or changes affecting issue finality because they only enforce existing requirements.

5.4.3 Confirmatory Action Letters

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 or a change affecting issue finality. 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 or a change affecting issue finality. The NRC should avoid creating staff positions in confirmatory action letters by (1) stating that the staff understands that the affected entity intends to take certain actions and (2) not using language suggesting that the affected entity’s actions are acceptable or would restore compliance. Furthermore, if the NRC requires the affected entity to do something more or different from the actions described in the confirmatory action letter that the affected entity is not already required to do under its licensing basis, then the imposition of the new requirement would constitute backfitting or a change affecting issue finality because the causal aspect of the backfit or change affecting issue finality would be a change to the licensing basis, not a change to the commitments or requirements in the confirmatory action letter.

5.4.4 Notices of Deviation

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, conform with, or change its commitment in accordance with its commitment management program. Issuance of the notice of deviation would not constitute backfitting or a change affecting issue finality 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 a backfitting or issue finality assessment.

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) 50.109, 70.76, 72.62, and 76.76, the U.S. Nuclear Regulatory Commission (NRC) requires documentation of the justification for backfitting or forward fitting. Consistent with these requirements and the transparency and accountability bases underlying them, the 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 considers documents related to backfitting and forward fitting as possible official agency records and preserves them 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, issued March 2005. 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 affected entity.

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 must 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 and whether the existence of this documentation should be disclosed and made available to the affected entity, the public, or both. For example, the staff may provide a memorandum to a supervisor with an attached analysis based on a guide from Appendix C to this NUREG. The staff's 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 2.101. *U.S. Code of Federal Regulations*, Title 10, “Energy,” Section 2.101, “Filing of application.”
- 10 CFR 2.206. *U.S. Code of Federal Regulations*, Title 10, “Energy,” Section 2.206, “Requests for action under this subpart.”
- 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 50.71. *U.S. Code of Federal Regulations*, Title 10, “Energy,” Section 50.71, “Maintenance of records, making of reports.”
- 10 CFR 50.73. *U.S. Code of Federal Regulations*, Title 10, “Energy,” Section 50.73, “Licensee event report 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 52.3. *U.S. Code of Federal Regulations*, Title 10, “Energy,” Section 52.3, “Written communications.”
- 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.”
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- 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.”
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- 10 CFR 54.21. *U.S. Code of Federal Regulations*, Title 10, “Energy,” Section 54.21, “Contents of application—technical information.”
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- 10 CFR 70.74. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 70.74, "Additional reporting requirements."
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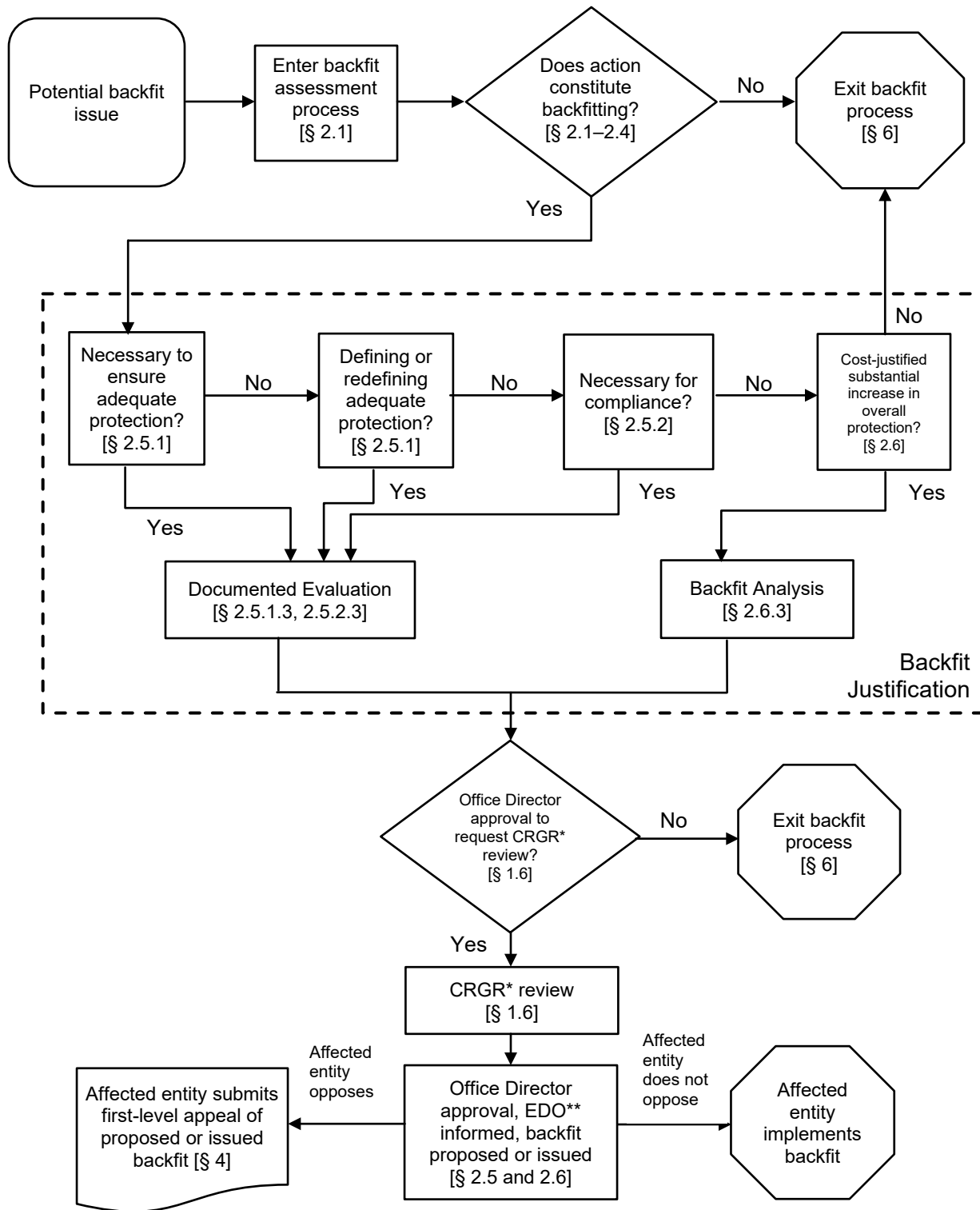
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APPENDIX A – BACKFITTING FLOWCHARTS

FLOWCHART 1

BACKFITTING PROCESS FLOWCHART



*Committee to Review Generic Requirements

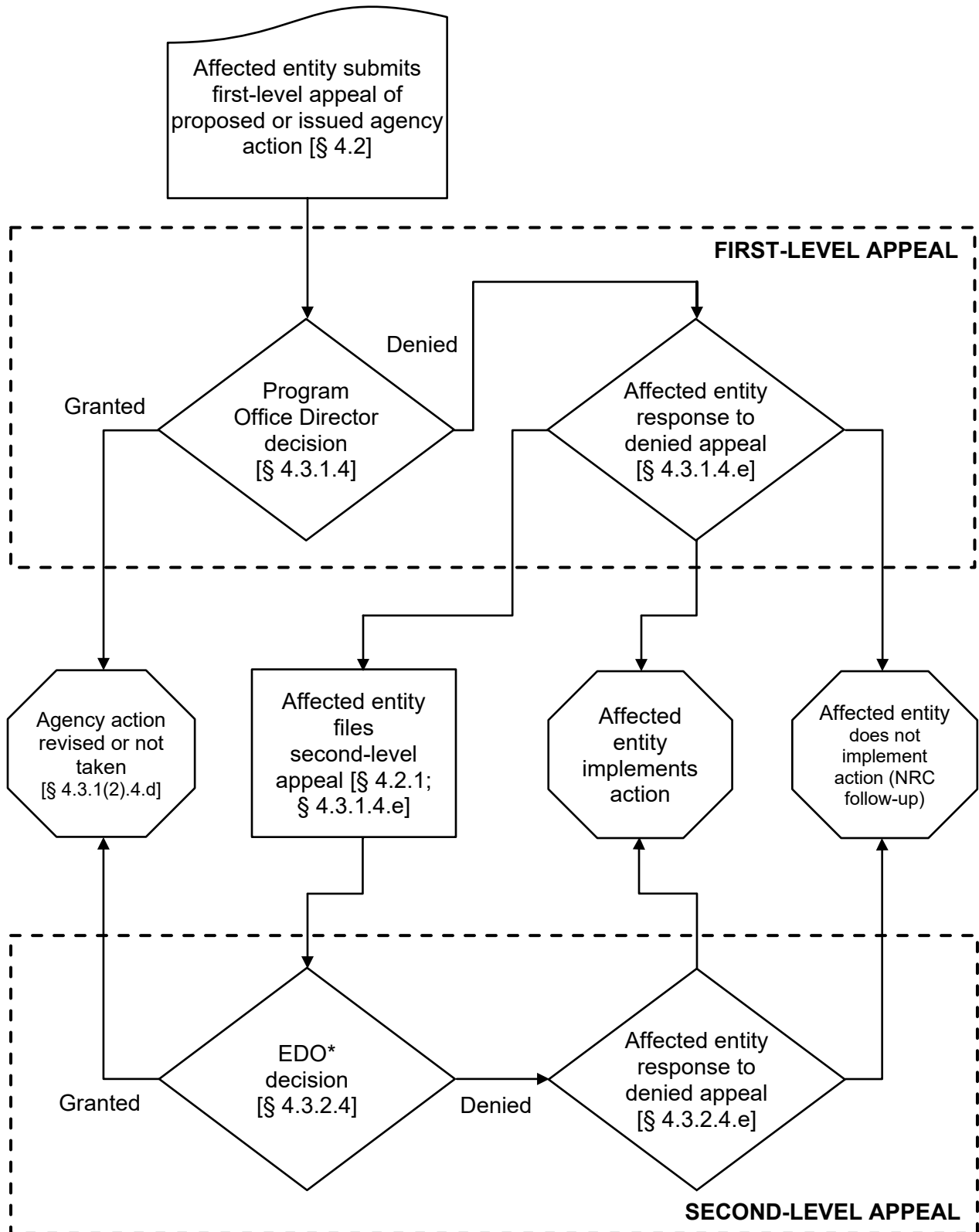
**Executive Director for Operations

Note: This flowchart may not capture all scenarios involving backfitting.

Figure A-1 Backfitting Process Flowchart

FLOWCHART 2

MANAGEMENT DIRECTIVE 8.4 APPEAL PROCESS FLOWCHART



* Executive Director for Operations

Note: This flowchart may not capture all scenarios involving appeals.

Figure A-2 Management Directive 8.4 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.	<p>Are new requirements or interpretations of requirements needed to address the issue fully?</p> <p>If no, then document the applicable enforceable requirement and exit the backfitting or issue finality process.</p> <p>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.</p>
2	Ask: Is the proposed action of the type excluded from backfitting and issue finality provisions?	<p>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 or issue finality process.</p> <p>If the proposed action is not excluded, then proceed to the next step.</p>
3	Ask: Would the proposed action affect any entity that is within the scope of a backfitting or issue finality provision?	<p>If the entity 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 or issue finality process.</p> <p>If the entity is within the scope of a backfitting or issue finality requirement, then proceed to the next step.</p>
4	Ask: Would the proposed action constitute backfitting or affect issue finality?	<p>Consider the applicable definition of "backfitting" or issue finality provisions (see NUREG-1409, Table 1-1 and Section 2.4).</p> <p>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).</p> <p>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 or issue finality process.</p>

BACKFITTING AND ISSUE FINALITY WORKSHEET (continued)

Justification		
Step	Action	Notes
5	Obtain Office of Nuclear Reactor Regulation (NRR) or Office of Nuclear Material Safety or Safeguards (NMSS) Office Director approval to expend resources on evaluating the issue.	<p>Prepare the following for the office director:</p> <ul style="list-style-type: none"> • 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 is not, whether the proposed action could be justified using the compliance exception or a backfit analysis. <p>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.</p> <p>If not approved, then address the 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 or issue finality process.</p>
6	Ask: Is the proposed action necessary to ensure adequate protection or to define or redefine the level of protection considered adequate?	<p>If the issue appears to be a matter of adequate protection, then take the following steps:</p> <ul style="list-style-type: none"> • 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. <p>If the issue is not one of adequate protection, then proceed to the next step.</p>

BACKFITTING AND ISSUE FINALITY WORKSHEET (continued)

Justification		
Step	Action	Notes
7	Ask: Is the proposed action necessary to ensure compliance with NRC requirements or conformance with written licensee commitments?	<p>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.</p> <p>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.</p> <p>If not, then proceed to the next step.</p>
8	Ask: Could the proposed action provide a cost-justified substantial increase in overall protection?	<p>Prepare a backfit analysis using Guide 3 in NUREG-1409, Appendix C. Refer to NUREG-1409, Section 2.6.</p> <p>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.</p> <p>If the proposed action would be a cost-justified substantial increase in overall protection, then proceed to Step 10.</p>
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.	<p>If approved, then proceed to the next step.</p> <p>If not approved, then address the office director's concerns and re-seek approval. If still not approved, then document the basis for the office director's decision and exit the backfitting or issue finality process.</p>
11	Meet with the Committee to Review Generic Requirements (CRGR).	<p>Prepare the materials for meeting with the CRGR. See CRGR Charter and Procedures. Afterwards, address any issues identified by the CRGR.</p> <p>Proceed to the next step.</p>

BACKFITTING AND ISSUE FINALITY WORKSHEET (continued)

Justification

Step	Action	Notes
12	Submit the final documented evaluation or backfit analysis to the NRR or NMSS Office Director (and Executive Director of Operations and Commission, if applicable) for approval.	If approved, then proceed to the next step. If not approved, then address the office director's concerns and re-seek approval. If still not approved, then document the basis for the decision and exit the backfitting or issue finality process. Do not proceed to the next step.
13	If time permits, provide the proposed backfit or change affecting issue finality to the affected entity for an opportunity to submit an MD 8.4 appeal.	If the affected entity does not submit an MD 8.4 appeal, then proceed with the backfit or change affecting issue finality. If the affected entity submits an MD 8.4 appeal, then complete the appeal process before or in lieu of issuing the backfit or change affecting issue finality, consistent with Chapter 4 and Section 5.1.4 of NUREG-1409.

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 interpretation and application were inconsistent, 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	<p>The NRC has identified at least one 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 any of the following:</p> <ul style="list-style-type: none"> • 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(s) or omission(s).

COMPLIANCE EXCEPTION CHECKLIST (continued)		
The Error or Omission		
6	The error(s) or omission(s) 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(s) or omission(s) (e.g., approval date).
7	The existence of the error(s) or omission(s) 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 at least one 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(s) 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(s) or omission(s).	Describe how fixing the error(s) 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.

WORKSHEET 3

FORWARD FITTING WORKSHEET

FORWARD FITTING WORKSHEET		
Screening		
Step	Action	Notes
1	Ask: Is the NRC reviewing a request for a licensing action from an affected entity?	<p>If the request is not from an affected entity (i.e., an entity within the scope of the forward fitting policy (see NUREG-1409, Sections 2.3 and 3.1)), then document this and exit the forward fitting process because the proposed action is not a forward fit.</p> <p>If the request is from an affected entity, then proceed to the next step.</p>
2	Ask: Is the NRC reviewing an affected entity-initiated request?	<p>If the answer is “no,” then document this and exit the forward fitting process because the proposed action is not a forward fit.</p> <p>If the answer is “yes,” then proceed to the next step.</p>
3	Ask: Is the NRC’s proposed action either a new or changed requirement or staff position interpreting a requirement?	<p>If the answer is “no,” then document this and exit the forward fitting process because the proposed action is not a forward fit.</p> <p>If the answer is “yes,” then proceed to the next step.</p>
4	Ask: Is the new or changed NRC requirement or interpretation being imposed on an affected entity as a condition of the NRC’s approval of the affected entity-initiated licensing action (i.e., the affected entity’s request did not propose this requirement or interpretation)?	<p>If the answer is “no,” then document this and exit the forward fitting process because the proposed action is not a forward fit.</p> <p>If the answer is “yes,” then proceed to the next step.</p>
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?	<p>If the answer is “no,” then document this and exit the forward fitting process because the proposed action is not a forward fit.</p> <p>If the answer is “yes,” then proceed to the next step.</p>

FORWARD FITTING WORKSHEET (continued)		
Justification		
Step	Action	Notes
6	<p>Ask: Is there a direct nexus between the proposed action and the affected entity's request?</p> <p>1. The affected entity's requested change would create a safety or security issue or a noncompliance with a requirement that is already in the affected entity's licensing basis or a new requirement the affected entity proposed in its requested change that would not exist but for NRC approval of the requested change without a condition, and</p> <p>2. The NRC's proposed action would address the issue or noncompliance.</p>	<p>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. However, the staff could consider taking the proposed action in accordance with the backfitting guidance in Chapter 2 of NUREG-1409.</p> <p>If the answer is "yes," then proceed to the next step.</p>
7	<p>Ask: Is the proposed action essential to the NRC's approval of the request (i.e., is it necessary to make the NRC's safety or security finding)?</p>	<p>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. However, the staff could consider taking the proposed action in accordance with the backfitting and issue finality guidance in Chapter 2 of NUREG-1409.</p> <p>If the answer is "yes," then proceed to the next step.</p>
8	<p>Obtain licensing and technical division director approval to discuss with the affected entity the NRC's issue with the application and the NRC's proposed action (i.e., the NRC's proposed option for addressing the issue).</p>	<p>If approved, then proceed to the next step.</p> <p>If not approved, then address the division directors' concerns and re-seek approval. If still not approved, then document the basis for the division directors' decision, place a note to file in ADAMS, exit the forward fitting process, and do not take the proposed action.</p>

FORWARD FITTING WORKSHEET (continued)

Justification

Step	Action	Notes
9	Using the guidance in Section 5.1.4 of this NUREG, communicate the NRC's issue with the application and the NRC's proposed option for addressing the issue with the affected entity.	<p>If the affected entity voluntarily supplements its application to address the NRC's issue, and the supplement is acceptable, then exit the forward fitting process.</p> <p>If the affected entity either does not respond or does not respond in a manner that addresses the staff's concerns, then the staff must decide if it wishes to deny the application or pursue the forward fit.</p> <p>If the staff decides to pursue the forward fit, then proceed to the next step.</p>

FORWARD FITTING WORKSHEET (continued)		
Cost Consideration		
Step	Action	Notes
10	Obtain Office of Nuclear Reactor Regulation (NRR) or Office of Nuclear Material Safety or Safeguards (NMSS) Office Director approval to expend resources on cost considerations for the proposed action (i.e., completing the forward fit assessment).	<p>Using Guide 4 in NUREG-1409, Appendix C, prepare the following for the office director:</p> <ul style="list-style-type: none"> the responses to the first nine steps of this worksheet if readily available, descriptions of any safety, risk, or cost insights <p>If approved, then proceed to the next step.</p> <p>If not approved, then address the office director's concerns and re-seek approval. If still 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.</p>
11	Using Section 3.5 of this NUREG, perform a cost consideration.	<p>Compare the costs of all methods of implementing the forward fit. The least costly alternative should be selected. When there is only one method to implement the forward fit, evaluate the incremental cost of the forward fit.</p> <p>Describe any impacts of the cost considerations on the decision to take the proposed forward fit.</p>

FORWARD FITTING WORKSHEET (continued)		
Completing the Forward Fitting Assessment		
Step	Action	Notes
12	Prepare the forward fit assessment and submit it to the NRR or NMSS Office Director for approval to offer the Committee to Review Generic Requirements (CRGR) the opportunity to review the package.	<p>Use Guide 4 in NUREG-1409, Appendix C, to fully describe how the forward fit definition is met, how the direct nexus definition is met, how the essential definition is met, risk insights associated with the staff's proposed forward fitting action, costs associated with the proposed forward fit, and the staff's consideration of those costs in its decision on whether to proceed with the forward fit.</p> <p>If approved, then proceed to the next step.</p> <p>If not approved, then address the office director's concerns and re-seek approval. If still 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.</p>
13	If the CRGR agrees to review the package, then follow the procedures for submitting documents to the CRGR.	<p>Prepare the materials for the CRGR as specified in the CRGR Charter and Procedures. Afterwards, address any issues identified by the CRGR.</p> <p>Proceed to the next step.</p>
14	Submit the final forward fit assessment to the NRR or NMSS Office Director for approval.	<p>If approved, then proceed with the next step.</p> <p>If not approved, then address the office director's concerns and re-seek approval. If still 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. Do not proceed to the next step.</p>
15	Provide the proposed forward fit to the affected entity for an opportunity to submit an MD 8.4 appeal.	<p>If the affected entity does not submit an MD 8.4 appeal, then proceed with the forward fit.</p> <p>If the affected entity submits an MD 8.4 appeal, then complete the appeal process before or in lieu of issuing the forward fit, consistent with Chapter 4 and Section 5.1.4 of NUREG-1409.</p>

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 assessment. The staff can use each guide's organization of topics 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 assessment.

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.

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" if the proposed NRC action involves regulatory approvals under 10 CFR Part 52, "Licenses, certifications, and approvals for nuclear power plants." For the purposes of this appendix, "affected entity" comprises the entities listed in Section 2.3 of this NUREG.

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

AFFECTED ENTITY NAME

FACILITY NAME

DOCKET NOS.

CONTENTS

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

- I. INTRODUCTION
- II. BACKGROUND
- III. PROPOSED BACKFITTING
- IV. ADEQUATE PROTECTION EXCEPTION APPLICABILITY
- V. IMMINENT THREAT ANALYSIS
- VI. ALTERNATIVE METHODS FOR ACHIEVING ADEQUATE PROTECTION
 - A. Alternatives
 - B. Cost Considerations
 - C. Summary
- VII. CONCLUSION
- VIII. REFERENCES

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 and 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 which 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
- 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 safety¹ 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. IMMEDIATE THREAT ANALYSIS [NUREG-1409, Revision 1, Section 5.1.1.2.1]

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

¹ For materials licensees that are the subject of 10 CFR 70.76, “Backfitting,” this also includes the potential effects of hazardous chemicals produced from licensed material. For licensees that are the subject of 10 CFR 72.62, “Backfitting,” 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) to identifying reasonable alternatives to the proposed backfitting for providing adequate protection.

Describe the reasonable alternative backfitting actions 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. This description should include 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
- overall conclusion on cost considerations, limited to a determination that the proposed backfitting is either of the following:
 - the least costly of the identified alternatives for achieving reasonable assurance of adequate protection
 - 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 one or both of the adequate protection exceptions applies to the proposed backfitting action, then document this decision and a summary of its basis and state 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 adequate protection exceptions do not apply to the proposed backfitting action, 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

AFFECTED ENTITY NAME

FACILITY NAME

DOCKET NOS.

CONTENTS

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

- I. INTRODUCTION
- II. BACKGROUND
- III. PROPOSED BACKFITTING
- IV. ADEQUATE PROTECTION EXCEPTION APPLICABILITY
- V. COMPLIANCE EXCEPTION APPLICABILITY
 - A. Requirement
 - 1. Applicable Requirement
 - 2. Timing of Requirement
 - 3. Application and Interpretation of the Requirement
 - 4. Approval
 - B. Error or Omission
 - 1. Description of Error or Omission
 - 2. Applicability of Standards and Practices
 - 3. Relationship of Error to Approval
 - C. Summary
- VI. COST CONSIDERATIONS
 - A. Description of the Cost Consideration Approach
 - B. Cost of the Proposed Backfitting
 - C. Benefits of the Proposed Backfitting
- VII. CONCLUSION
- VIII. REFERENCES

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 which 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
- 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 adequate protection exceptions do not apply to the proposed backfitting action.

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 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 agency 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 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. More than one error or omission may have occurred. 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
- 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 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 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 licensee
- 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 licensee's experience with the costs of current compliance (if applicable)
- stakeholder feedback associated with the proposed compliance backfitting

C. Benefits of the Proposed Backfitting

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

VII. CONCLUSION

If the NRC determines that the proposed backfitting is needed to ensure compliance with the applicable regulations or provisions, then document this decision and a summary of its basis, and state 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

AFFECTED ENTITY NAME

FACILITY NAME

DOCKET NOS.

CONTENTS

A table of contents is recommended when the backfit analysis is longer than three pages.

- I. INTRODUCTION
- II. BACKGROUND
- III. PROPOSED BACKFITTING
- IV. BASIS FOR NOT PERFORMING A DOCUMENTED EVALUATION
- V. BENEFITS
 - A. Quantitative Benefits
 - B. Qualitative Benefits
- VI. COSTS
 - A. Quantitative Costs
 - B. Qualitative Costs
- VII. COST-JUSTIFICATION DETERMINATION
- VIII. CONCLUSION
- IX. REFERENCES
- X. ATTACHMENT

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 the proposed rule’s 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)). The description will include the following:

- the key substantive elements of the proposed backfitting and its purpose
- the entities upon which 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
- 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, then 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 safety² 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 NRC assessed the qualitative benefits 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 safety³ 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., nonquantifiable) 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 their nature or 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 NRC assessed the qualitative costs using the methods described in Appendix A to NUREG/BR-0058. Describe the qualitative costs to public health and safety⁴ 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 the public health and safety⁵ 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 optional attachment 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 ASSESSMENT

FORWARD FIT ASSESSMENT

TITLE OF PROPOSED FORWARD FITTING

AFFECTED ENTITY NAME

FACILITY NAME

DOCKET NOS.

CONTENTS

A table of contents is recommended when the assessment is longer than three pages.

- I. INTRODUCTION
- II. BACKGROUND
- III. PROPOSED FORWARD FITTING
 - A. Screening
 - B. Justification
 - 1. Direct Nexus
 - 2. Essential to the NRC's Determination
 - C. Cost Consideration
- IV. CONCLUSION
- V. REFERENCES

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 staff’s concerns about the requested licensing action.

III. PROPOSED FORWARD FITTING

A. Screening [NUREG-1409, Revision 1, Section 3.2]

Describe in detail the key elements of the proposed staff action meeting the definition of a “forward fit,” explained in a manner that makes it clear why the proposed staff action, if adopted and imposed, meets the definition of a “forward fit.” 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 meets the definition of “direct nexus.”

2. Essential to the NRC’s Determination

Describe how the proposed staff action meets the definition of “essential.”

C. Cost Consideration [NUREG-1409, Revision 1, Section 3.5]

Costs are considered only for purposes of informing the decision whether to take the forward fitting action. Compare the costs of all methods of implementing the forward fit. The least costly alternative should be selected. When there is only one method to implement the forward fit, then evaluate the incremental cost of the forward fit. If the affected entity has already incurred costs associated with its request, then exclude those costs from the cost estimate for the forward fit.

A regulatory analysis may be used to demonstrate the staff’s cost consideration. NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” provides guidance on the preparation of a regulatory analysis.

If the forward fit would impose a generic staff position on the affected entity (i.e., a staff position that is not within that affected entity’s licensing basis), then perform the facility-specific regulatory analysis using the generic regulatory analysis done by the staff when it issued the

generic staff position. If no prior staff position exists and, thus, no applicable regulatory analysis exists, then document the costs of the proposed action.

IV. CONCLUSION

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

V. REFERENCES

List the documents referenced in this assessment.

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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.

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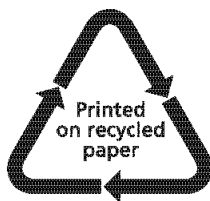
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