



NUREG-1409, Rev. 1

# Backfitting Guidelines

Office of Nuclear Reactor Regulation

## AVAILABILITY OF REFERENCE MATERIALS IN NRC PUBLICATIONS

### <sup>1</sup> NRC Reference Material

As of November 1999, you may electronically access NUREG-series publications and other NRC records at the NRC's Public Electronic Reading Room at <http://www.nrc.gov/reading-rm.html>. Publicly released records include, to name a few, NUREG-series publications; *Federal Register* notices; applicant, licensee, and vendor documents and correspondence; NRC correspondence and internal memoranda; bulletins and information notices; inspection and investigative reports; licensee event reports; and Commission papers and their attachments.

NRC publications in the NUREG series, NRC regulations, and Title 10, "Energy," in the *Code of Federal Regulations* may also be purchased from one of these two sources.

#### 1. The Superintendent of Documents

U.S. Government Publishing Office  
Mail Stop SSOP  
Washington, DC 20402-0001  
Internet: <http://bookstore.gpo.gov>  
Telephone: 1-866-512-1800  
Fax: (202) 512-2104

#### 2. The National Technical Information Service

5301 Shawnee Road  
Alexandria, VA 22161-0002  
<http://www.ntis.gov>  
1-800-553-6847 or, locally, (703) 605-6000

A single copy of each NRC draft report for comment is available free, to the extent of supply, upon written request as follows:

#### U.S. Nuclear Regulatory Commission

Office of Administration  
Publications Branch  
Washington, DC 20555-0001  
E-mail: [distribution\\_resource@nrc.gov](mailto:distribution_resource@nrc.gov)  
Facsimile: (301) 415-2289

Some publications in the NUREG series that are posted at the NRC's Web site address <http://www.nrc.gov/reading-rm/doc-collections/nuregs> are updated periodically and may differ from the last printed version. Although references to material found on a Web site bear the date the material was accessed, the material available on the date cited may subsequently be removed from the site.

### Non-NRC Reference Material

Documents available from public and special technical libraries include all open literature items, such as books, journal articles, transactions, *Federal Register* notices, Federal and State legislation, and congressional reports. Such documents as theses, dissertations, foreign reports and translations, and non-NRC conference proceedings may be purchased from their sponsoring organization.

Copies of industry codes and standards used in a substantive manner in the NRC regulatory process are maintained at—

#### The NRC Technical Library

Two White Flint North  
11545 Rockville Pike  
Rockville, MD 20852-2738

These standards are available in the library for reference use by the public. Codes and standards are usually copyrighted and may be purchased from the originating organization or, if they are American National Standards, from—

#### American National Standards Institute

11 West 42nd Street  
New York, NY 10036-8002  
<http://www.ansi.org>  
(212) 642-4900

Legally binding regulatory requirements are stated only in laws; NRC regulations; licenses, including technical specifications; or orders, not in NUREG-series publications. The views expressed in contractor-prepared publications in this series are not necessarily those of the NRC.

The NUREG series comprises (1) technical and administrative reports and books prepared by the staff (NUREG-XXXX) or agency contractors (NUREG/CR-XXXX), (2) proceedings of conferences (NUREG/CP-XXXX), (3) reports resulting from international agreements (NUREG/IA-XXXX), (4) brochures (NUREG/BR-XXXX), and (5) compilations of legal decisions and orders of the Commission and Atomic and Safety Licensing Boards and of Directors' decisions under Section 2.206 of NRC's regulations (NUREG-0750).

**DISCLAIMER:** This report was prepared as an account of work sponsored by an agency of the U.S. Government. Neither the U.S. Government nor any agency thereof, nor any employee, makes any warranty, expressed or implied, or assumes any legal liability or responsibility for any third party's use, or the results of such use, of any information, apparatus, product, or process disclosed in this publication, or represents that its use by such third party would not infringe privately owned rights.



NUREG-1409, Rev. 1

# 1 Backfitting Guidelines

2

3

4[Comments]

5

6

Manuscript Completed: Month YYYY

Date Published: Month YYYY

Prepared by:

H. Benowitz

A. Klett

T. Reed

U. S. Nuclear Regulatory Commission

Washington, DC 20555



## ABSTRACT

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

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

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, T~~he new or modified requirement or staff interpretation must result in, ~~generally,~~ a change to the licensee's systems, structures, components, design, approval, procedures, or organization. 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 ~~L~~icensing of ~~S~~pecial ~~N~~uclear ~~M~~aterial," 10 CFR Part 72, "Licensing ~~R~~requirements for the ~~I~~ndependent ~~S~~torage of ~~S~~pent ~~N~~uclear ~~F~~uel, ~~H~~igh-~~L~~evel ~~R~~adioactive ~~W~~aste, and ~~R~~eactor-~~R~~elated ~~G~~reater ~~T~~han Class C ~~W~~aste," or 10 CFR Part 76, "Certification of ~~G~~aseous ~~D~~iffusion ~~P~~lants"; the issue finality provisions in 10 CFR Part 52; or the Commission's forward fitting policy in Management Directive 8.4, most of which were developed after 1990. This ~~version-update~~ of NUREG-1409 is a substantial revision ~~of to~~ the 1990 ~~version 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.



## TABLE OF CONTENTS

**Commented [AK1]:** Staff updated the TOC. The deleted version is not shown in tracked changes. The pages numbers in this document's TOC will not match those of the final version.

<b>ABSTRACT .....</b>	<b>ili</b>
<b>LIST OF FIGURES .....</b>	<b>ix</b>
<b>LIST OF TABLES .....</b>	<b>ix</b>
<b>EXECUTIVE SUMMARY .....</b>	<b>xi</b>
<b>ABBREVIATIONS AND ACRONYMS .....</b>	<b>xiii</b>
<b>1 OVERVIEW OF BACKFITTING, ISSUE FINALITY, AND FORWARD FITTING .....</b>	<b>1-1</b>
1.1 Introduction .....	1-1
1.2 Backfitting and Issue Finality .....	1-2
1.2.1 Backfitting and Issue Finality Regulations .....	1-3
1.2.2 Terminology .....	1-54
1.2.2.1 Requirements .....	1-54
1.2.2.2 Staff Positions .....	1-64
1.2.3 Backfitting Justifications .....	1-84
1.2.4 Administrative Exemption .....	1-104
1.2.5 Facility-Specific and Generic Backfitting Actions .....	1-104
1.2.6 Issue Finality Provisions .....	1-124
1.3 Forward Fitting .....	1-144
1.3.1 Definition .....	1-144
1.3.2 Direct Nexus, Essentiality, and Cost .....	1-144
1.4 Risk Considerations and Safety Significance .....	1-144
1.5 Communications with Licensees .....	1-154
1.6 Management and Oversight of Backfitting and Forward Fitting .....	1-174
1.7 Implementation of Backfitting and Forward Fitting Process .....	1-184
<b>2 SCREENING AND JUSTIFYING BACKFITTING ACTIONS AND CHANGES AFFECTING ISSUE FINALITY .....</b>	<b>2-1</b>
2.1 Introduction .....	2-1
2.2 Question 1: Is the proposed action excluded from the backfitting and issue finality provisions? .....	2-22
2.3 Question 2: Would the proposed action affect any entity that is within the scope of a backfitting or issue finality provision? .....	2-3
Power reactors licensed under Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) Part 50 .....	2-42
2.3.1 <b>Error! Bookmark not defined.</b> .....	2-3
2.3.2 Power reactors licensed and approved under 10 CFR Part 52 .....	2-52
2.3.3 Materials licensees licensed under 10 CFR Part 70 .....	2-62
2.3.4 Materials licensees licensed under 10 CFR Part 72 .....	2-62
2.3.5 Materials licensees licensed under 10 CFR Part 76 .....	2-72
2.3.6 Other materials licensees .....	2-82
2.3.7 Proposed actions affecting both licensees that are within and licensees that are not within the scope of backfitting and issue finality .....	2-82

2.4	Question 3: Would the proposed action constitute backfitting or affect issue finality?	2-112-7
2.5	Question 4: Do any of the exceptions to the requirement of preparing a backfit analysis apply to the proposed backfitting?	2-122-8
2.5.1	Question 4a: Do one or both of the adequate protection exceptions to the requirement of preparing a backfit analysis apply?	2-132-8
2.5.1.1	Background	2-132-8
2.5.1.2	Adequate Protection Determinations	2-142-10
2.5.1.3	Documenting Adequate Protection Evaluations	2-162-11
2.5.2	Question 4b: Does the compliance exception to the requirement of preparing a backfit analysis apply?	2-162-12
2.5.2.1	Background	2-162-12
2.5.2.2	Compliance Exception Determinations	2-172-13
2.5.2.3	Documenting Compliance Exception Evaluations	2-212-16
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?	2-212-17
2.6.1	Background	2-212-17
2.6.2	Cost-Justified Substantial Increase in Overall Protection Determinations	2-222-17
2.6.3	Documenting a Backfit Analysis	2-242-19
2.6.4	Issue Finality	2-252-20
<b>3</b>	<b>FORWARD FITTING</b>	<b>3-1</b>
3.1	Background	3-1
3.2	Forward Fitting Screening	3-1
3.3	Forward Fitting Justification	3-33-2
3.4	Forward Fitting Screening and Justification Scenarios	3-73-4
3.4.1	NRC Condition Meets Definitions of "Forward Fit," "Direct Nexus," and "Essential"	3-73-4
3.4.2	NRC Condition Meets Definitions of "Forward Fit" and "Essential" but not "Direct Nexus"	3-83-5
3.4.3	NRC Condition Meets Definitions of "Forward Fit" and "Direct Nexus" but not "Essential"	3-83-6
3.4.4	NRC Condition Meets Definition of "Forward Fit" but not "Direct Nexus" or "Essential"	3-93-6
3.5	Cost Considerations	3-93-7
3.6	Documenting the Forward Fit Assessment	3-103-7
<b>4</b>	<b>MANAGEMENT DIRECTIVE 8.4 APPEALS</b>	<b>4-1</b>
4.1	Introduction	4-1
4.2	Using the MD 8.4 Appeal Process	4-34-1
4.2.1	Submitting an Appeal	4-34-1
4.2.2	Stakeholder Participation	4-44-2
4.2.3	Draft or Proposed Generic Documents or Actions for Comment	4-44-2
4.2.4	Appeals of NRC Actions Subject to 10 CFR Part 2 Proceedings	4-44-3
4.2.4.1	Orders and MD 8.4 Appeals	4-44-3
4.2.4.2	Violations and MD 8.4 Appeals	4-54-3



4.2.4.2.1	MD 8.4 Appeals Submitted Before Issuing a Violation .....	<b>Error!</b>
	<b>Bookmark not defined.4-3</b>	
4.2.4.2.2	MD 8.4 Appeals Submitted After Issuance of a Violation or Communication of an Apparent Violation.....	<b>Error! Bookmark not defined.4-4</b>
4.2.5	Appeals Associated with Licensing Actions.....	4-74-5
4.2.5.1	Appeals Submitted Before Issuing a Licensing Action.....	4-74-5
4.2.5.2	Appeals Submitted After Issuing a Licensing Action.....	4-74-5
4.3	NRC Processing of Appeals.....	4-84-5
4.3.1	First-Level Appeals.....	4-84-6
4.3.1.1	Receipt of an Appeal and Initiation of the First-Level Appeal Process.....	4-84-6
4.3.1.2	Determination of Oversight Responsibility and First- Level Appeal Screening.....	4-84-6
4.3.1.3	Review of the First-Level Appeal .....	4-104-6
4.3.1.4	Response to the First-Level Appeal.....	4-114-7
4.3.2	Second-Level Appeal.....	4-124-8
4.3.2.1	Receipt of an Appeal and Initiation of the Second-Level Appeal Process.....	4-124-8
4.3.2.2	Determination of Oversight Responsibility and Second- Level Appeal Screening.....	4-134-9
4.3.2.3	Review of the Second-Level Appeal .....	4-134-9
4.3.2.4	Response to the Second-Level Appeal.....	4-144-10
<b>5</b>	<b>RELATIONSHIP OF BACKFITTING AND FORWARD FITTING TO VARIOUS PROCESSES.....</b>	<b>5-1</b>
5.1	Licensing Bases and Processes .....	5-1
5.1.1	Licensing Bases.....	5-1
5.1.1.1	Regulations.....	5-1
5.1.1.1.1	Statements of Considerations .....	5-1
5.1.1.1.2	General Design Criteria for Nuclear Power Reactors .....	5-25-1
5.1.1.2	Orders.....	5-35-2
5.1.1.2.1	Imminent Threat Analyses.....	5-3
5.1.1.2.2	Confirmatory Orders .....	5-3
5.1.1.3	Exemptions .....	5-45-3
5.1.1.4	Mandated Licensing Basis Documents.....	5-45-3
5.1.1.5	Change Control Processes.....	5-4
5.1.1.6	Commitments.....	5-55-4
5.1.2	Licensing Basis Verifications .....	5-65-5
5.1.2.1	Differing Views .....	5-65-5
5.1.2.2	Technical Assistance Requests .....	5-65-5
	Requested Licensing Actions.....	5-75-6
5.1.3	.....	5-75-6
5.1.3.1	Pre-application Meetings .....	5-75-6
5.1.3.2	Initial Licensing .....	5-85-6
5.1.3.3	Acceptance Reviews.....	5-95-7
5.1.3.4	Safety Evaluations and Safety Evaluation Reports.....	5-95-7
5.1.3.5	Section 50.55a Requests.....	5-105-8
5.1.3.5.1	Relief Requests.....	5-105-8
5.1.3.5.2	Proposed Alternatives.....	5-105-8
5.1.3.6	License Transfers .....	5-115-8

1	5.1.4	Communicating Potential Backfits or Forward Fits during	
2		Licensing .....	<del>5-115-9</del>
3	5.2	Generic Processes .....	<del>5-125-10</del>
4	5.2.1	Regulatory Analyses .....	<del>5-125-10</del>
5	5.2.2	Rulemaking .....	<del>5-135-10</del>
6	5.2.2.1	Rulemaking Process .....	<del>5-135-11</del>
7	5.2.2.2	Voluntary Consensus Standards .....	<del>5-135-11</del>
8	5.2.2.3	Voluntary Relaxations .....	<del>5-145-12</del>
9	5.2.3	Guidance Documents .....	<del>5-155-13</del>
10	5.2.3.1	Regulatory Guides .....	<del>5-165-14</del>
11	5.2.3.2	Interim Staff Guidance .....	<del>5-175-14</del>
12	5.2.3.3	Standard Review Plans .....	<del>5-175-14</del>
13	5.2.3.4	Withdrawing Guidance Documents .....	<del>5-175-14</del>
14	5.2.4	Topical Reports .....	<del>5-185-15</del>
15	5.2.5	Generic Communications .....	<del>5-195-15</del>
16	5.2.6	Clarifications .....	<del>5-195-16</del>
17	5.2.7	Information Requests .....	<del>5-195-16</del>
18	5.2.8	Policy Statements .....	<del>5-205-17</del>
19	5.3	Inspection Processes .....	<del>5-215-17</del>
20	5.3.1	Oral Communications .....	<del>5-215-17</del>
21	5.3.2	Inspection Reports .....	<del>5-215-18</del>
22	5.3.3	Licensing Basis Questions .....	<del>5-225-18</del>
23	5.4	Enforcement Processes .....	<del>5-225-19</del>
24	5.4.1	Violations .....	<del>5-235-19</del>
25	5.4.2	Enforcement Orders .....	<del>5-245-19</del>
26	5.4.3	Confirmatory Action Letters .....	<del>5-245-20</del>
27	5.4.4	Notices of Deviation .....	<del>5-245-20</del>
28	6	RECORDKEEPING AND DOCUMENTATION .....	<del>6-1</del>
29	7	REFERENCES .....	<del>7-1</del>
30		APPENDIX A - BACKFITTING FLOWCHARTS .....	<del>A-1A-1</del>
31		APPENDIX B – WORKSHEETS .....	<del>B-1B-1</del>
32		APPENDIX C - GUIDES .....	<del>C-1C-1</del>
33			
34			

1

## LIST OF FIGURES

2 Figure ~~A-1-~~ NRC Backfitting Process Flowchart ..... A-~~8~~

3 Figure ~~A-2-~~ Backfitting Appeal Process Flowchart ..... A-~~7~~

4

5

## LIST OF TABLES

6 Table 1-1: NRC Backfitting and Issue Finality Requirements ..... ~~1-51-4~~

7



## EXECUTIVE SUMMARY

This document presents guidance on the implementation of the U.S. Nuclear Regulatory Commission (NRC) regulations on backfitting and issue finality and the Commission's policies on backfitting, issue finality, and forward fitting. Backfitting occurs when the NRC imposes certain new or changed regulatory requirements or staff positions interpreting requirements on nuclear power reactor licensees, select nuclear power reactor applicants, or select nuclear materials licensees. Backfitting is an integral part of the regulatory process and may be needed when the staff addresses safety or security issues. Issue finality is a concept similar to backfitting that applies only to the holders of certain nuclear power reactor-related approvals under 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.

Title 10 of the Code of Federal Regulations (10 CFR) Section 50.109, "Backfitting" (the Backfit Rule), provides backfitting provisions for nuclear power reactor licensees 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 licensees; for commercial and industrial facilities," are not within the scope of the backfitting provisions. Backfitting provisions for select nuclear material licensees are contained in 10 CFR 70.76, "Backfitting," 72.62, "Backfitting," and 76.76, 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, and licensee, and applicant resources.

The backfitting regulations address both generic and facility-specific backfitting actions for power reactor licensees and select materials licensees. The backfitting provision in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," defines a backfitting action as 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 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

**Commented [BH2]:** The staff removed references to "holders of Part 52 approvals" because entities do not "hold" a design certification.

**Commented [BH3]:** The staff deleted these words because backfitting actions can also affect certain applicants, but it is unnecessary to list all entities that are within the scope of backfitting actions again (see lines 4-7 above).

1 ~~R~~adioactive ~~W~~aste, and ~~R~~eactor-~~R~~elated ~~G~~reater than Class C ~~W~~aste," is limited to  
2 changes to the structures, systems, or components of, or the procedures or organization  
3 required to operate, an independent spent fuel storage installation or monitored retrievable  
4 storage installation. Issue finality within 10 CFR Part 52 defines the changes specifies when the  
5 NRC can impose a new or modified requirement for an approved facility license, permit, or  
6 design.

Commented [KA4]: Comment 4.1.2

8 Although the specific backfitting provisions in the various parts of the NRC's regulations differ in  
9 detail, they are generally structured to allow backfitting actions, provided the actions are  
10 supported by a backfit analysis or meet one of the exceptions to the requirement to perform a  
11 backfit analysis. The three exceptions are: (1) actions necessary to ensure adequate  
12 protection; (2) actions defining or redefining the level of protection considered adequate; and  
13 (3) actions necessary for compliance with NRC requirements or conformance with written  
14 licensee commitments (abbreviated as "the compliance exception"). If the NRC uses one of the  
15 exceptions, then it must provide a justification for invoking the exception. Otherwise, a backfit  
16 analysis must show that (1) the action will provide a substantial increase in the overall protection  
17 of the public health and safety or the common defense and security, and (2) the direct and  
18 indirect costs of implementing the backfitting action are justified in view of the increased  
19 protection.

21 The NRC is required under the Atomic Energy Act of 1954, as amended, to impose regulatory  
22 requirements that provide for reasonable assurance of adequate protection of public health and  
23 safety and the common defense and security. Accordingly, for proposed adequate protection  
24 actions that involve backfitting, the NRC does not need to consider other reasons justifying the  
25 backfitting action. Additionally, the NRC does not consider costs for these actions or forward  
26 fitting actions when one of the that involve adequate protection exceptions applies, unless there  
27 are multiple ways of implementing the new requirements. If neither of the adequate protection  
28 exceptions applies proposed backfitting action does not involve adequate protection, then the  
29 NRC should consider the compliance exception or determine through a backfit analysis whether  
30 the action would result in is a cost-justified, substantial increase in overall protection. Backfitting  
31 and forward fitting justifications other than adequate protection must consider cost.

Commented [AK5]: Comment 4.2.19

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

Commented [BH6]: The staff separated backfitting from issue finality to avoid any confusion when, for example, references to "backfitting" in this NUREG are meant to be references to only backfitting and not issue finality.

## ABBREVIATIONS AND ACRONYMS

10 CFR	Title 10 of the <i>Code of Federal Regulations</i>
ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act of 1954, as amended
AEC	Atomic Energy Commission
ASLBP	<u>Atomic Safety and Licensing Board Panel</u>
ASME	American Society of Mechanical Engineers
CDF	core damage frequency
CFR	<i>Code of Federal Regulations</i>
CoC	<del>C</del> ertificate of <del>C</del> ompliance
COL	combined license
CRGR	Committee to Review Generic Requirements
D.C.	<u>District of Columbia</u>
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	<u>license amendment request</u>
LWR	light-water reactor
MD	<del>M</del> anagement <del>D</del> irective
ML	manufacturing license
NCV	<del>non-cited violation</del>
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	<del>S</del> taff <del>R</del> equirements <del>M</del> emorandum
SRP	<del>S</del> tandard <del>R</del> eview <del>P</del> lan
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.<sup>1</sup> 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, licensee,<sup>2</sup> any holder of a standard design approval, or any design certification applicant after the NRC issues the applicable design certification rule under 10 CFR Part 52.

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

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

Commented [BH7]: Comment 4.1.7.

Commented [BH8]: These edits clarify that the consideration of costs is used to inform, but not justify, a forward fit.

<sup>1</sup> References to MD-8.4 in this NUREG include the MD and its associated Directive Handbook.

<sup>2</sup> For the purposes of this NUREG, the unqualified term "licensee" includes the holder of a power reactor limited work authorization, construction permit, or power reactor license issued under 10 CFR Part 50; "Domestic Licensing of Production and Utilization Facilities"; the holder of a license or permit issued under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants"; holder of a license for a fuel facility issued under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material"; holder of a license for a spent fuel or radioactive waste storage facility issued under 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste"; holder of a certificate for a gaseous diffusion plant issued under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants"; and holder of one or more of these approvals while its facility is in a decommissioning phase, as applicable.

In this NUREG, the NRC uses the terms “backfit” and “backfitting” generally to mean backfitting actions as defined in 10 CFR 50.109, ~~“Backfitting,”~~ 70.76, ~~“Backfitting,”~~ 72.62, ~~“Backfitting,”~~ and 76.76, all titled, “Backfitting,” and matters involving issue finality under 10 CFR Part 52, “Licenses, certifications, and approvals for nuclear power plants.”

## 1.2 Backfitting and Issue Finality

The NRC ~~uses the term “the Backfit Rule” to refer~~s 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 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 facility’s licensing basis, ~~the~~ Backfit Rule allows a licensee to operate a facility in accordance with its licensing basis and reasonably rely on the NRC to impose only justified changes to its license or facility. This reliability is part of the basis of the NRC’s regulatory framework, as explained in the ~~NRC’s~~ Principles of Good Regulation, ~~as~~ provided in the NRC’s “Strategic Plan for Fiscal 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.

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

**Commented [KA9]:** The staff made this change for consistency with the same terminology throughout the NUREG.

**Commented [BH10]:** The staff edited footnote 3 as a result of the edits to footnote 2.

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

3  
4 The Backfit Rule also ensures reasoned and informed NRC decisionmaking, by requiring the  
5 ~~NRC agency~~ to justify the backfitting action, ~~and it also contributes to the~~ transparency of the  
6 NRC's decisionmaking, by requiring the ~~NRC agency~~ to document its analysis of the backfitting  
7 action.

8  
9 The U.S. Atomic Energy Commission issued the Backfit Rule for power reactors in 1970. The  
10 NRC revised the Backfit Rule in 1985 to provide specific standards for backfitting decisions,  
11 such as cost-justification and required documentation. ~~In 1987, The 1985 rule was vacated by~~  
12 the U.S. Court of Appeals for the D.C. Circuit ~~in 1987 vacated the 1985 rule~~ in *Union of*  
13 *Concerned Scientists v. NRC*. The court stated that the 1985 Backfit Rule conflicted with the  
14 Atomic Energy Act of 1954, as amended (AEA), by including cost considerations in adequate  
15 protection determinations. In 1988, the NRC issued an amended Backfit Rule that was again  
16 subject to court review and was upheld. The amended rule does not require a cost justification  
17 or analysis of the increase in protection to the public health and safety or the common defense  
18 and security in cases of ensuring, defining, or redefining adequate protection, or in cases of  
19 ensuring compliance with NRC requirements or conformance with written licensee  
20 commitments.<sup>4</sup>

21  
22 In subsequent years, the NRC issued backfitting rules in 10 CFR 70.76 for entities licensed to  
23 possess special nuclear material in quantities greater than a critical mass and engage in  
24 specific activities (e.g., fuel facilities), 10 CFR 72.62 for independent spent fuel storage  
25 installations (ISFSIs) and monitored retrievable storage installations, and 10 CFR 76.76 ~~in~~  
26 ~~10 CFR Part 76, "Certification of gaseous diffusion plants,"~~ for gaseous diffusion plants.<sup>5</sup> These  
27 regulations provide definitions of "backfitting" and related requirements that are similar to those  
28 in the Backfit Rule. The NRC also provided issue finality provisions in 10 CFR Part 52 (as listed  
29 in Table 1-1) that are analogous to backfitting but apply to only certain ~~holders of~~ Part 52  
30 approvals. The NRC voluntarily self-imposed these backfitting and issue finality regulations.  
31 There is no statutory requirement for the agency's backfitting and issue finality requirements.

### 32 33 1.2.1 Backfitting and Issue Finality Regulations

34 ~~The only parts of the NRC's regulations that contain backfitting provisions are 10 CFR Parts 50,~~  
35 ~~52, 70, 72, and 76 are the only parts of the NRC's regulations that contain backfitting provisions.~~  
36 As discussed in Section 2.3 of this NUREG, it is the NRC's policy that non-power production or  
37 utilization facilities licensed under 10 CFR 50.21, "Class 104 licenses; for medical therapy and  
38 research and development facilities," paragraphs (a) or (c), or 10 CFR 50.22, "Class 103  
39 licenses; for commercial and industrial facilities," are outside the scope of the Backfit Rule. For

<sup>4</sup> The Supreme Court's decision in *Michigan v. Environmental Protection Agency*, 135 S. Ct. 2699 (2015), reflects the view that, under the Administrative Procedure Act of 1946, unless Congress has indicated otherwise, an agency's decisionmaking calculus should include at least some consideration of the cost placed on a ~~licensee-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 ~~Atomic Energy Act of 1954 (AEA), as amended~~, no further explanation, including consideration of cost, is necessary. Otherwise, the Administrative Procedure Act's reasoned decisionmaking requirement compels some consideration of cost.

<sup>5</sup> 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 implementation ~~of~~ 10 CFR 76.76.

1 the purposes of this guidance, 10 CFR 50.109, 70.76, 72.62, [and](#) 76.76, ~~and the issue finality~~  
2 ~~provisions of Part 52~~ may collectively be referred to as the "backfitting regulations" or  
3 "backfitting provisions." Table 1-1 lists the NRC regulations that contain backfitting [or issue](#)  
4 [finality](#) provisions.  
5

**Table 1-1. NRC Backfitting and Issue Finality Requirements<sup>6</sup>**

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

**Commented [BH11]:** The staff deleted footnote 6 because it is now redundant with the revised footnote 2.

## 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.

**Commented [BH12]:** Comment 4.1.14

### 1.2.2.1 Requirements

In Directive Handbook Section I.A.4 of MD 8.4, the Commission ~~clarified-explained~~ that, although 10 CFR 50.109(a)(1) refers only to ~~only~~ regulations, backfitting can result from the imposition of a new or changed regulation or requirements—beyond regulations—or through rulemaking or order or from the communication of a new or changed regulatory staff positions

<sup>6</sup> Section 2.3 of this NUREG provides a more detailed list of the entities that are within the scope of backfitting or issue finality provisions.

1 interpreting those requirements. For backfitting, issue finality, and forward fitting<sup>7</sup> purposes, the  
2 following contain the ~~legally-binding~~ requirements ~~on that legally bind~~ a licensee:

- 3
- 4 • the license, which ensures compliance with and operation within applicable NRC  
5 requirements and the facility-specific design bases as well as all modifications and  
6 additions over the life of the facility that are docketed and in effect, including any  
7 NRC-approved license amendments, license renewals, license conditions, and license  
8 appendices such as technical specifications and an environmental protection plan;
- 9 • the regulations as they apply to the licensee; ~~and~~
- 10 • orders.

#### 11 1.2.2.2 Staff Positions

12 The backfitting requirements in 10 CFR Parts 50, 70, and 76 define backfitting in terms of  
13 "cause" and "effect." Backfitting is "caused" by a new or amended provision in the  
14 Commission's regulations or the imposition of a regulatory staff position interpreting the  
15 Commission's regulations that is either new or different from a previously applicable staff  
16 position. The "effect" of backfitting is a modification of or addition to systems, structures,  
17 components, or (for power reactors) design of a facility; or (for power reactors) the design  
18 approval or manufacturing license for a facility; or the procedures or organization required to  
19 operate or (for power reactors) design or construct a facility. Forward fitting is also defined, in  
20 part, in this cause and effect context. Consistent with these definitions, the causes of backfitting  
21 can also affect the issue finality of a 10 CFR Part 52 approval. Recognizing that the "causal"  
22 element of backfitting, issue finality, and forward fitting can involve a regulatory staff position  
23 interpreting the Commission's regulations is important to comprehending backfitting, issue  
24 finality, and forward fitting.

25  
26 For backfitting, issue finality, and forward fitting purposes, staff positions are those documented  
27 interpretations of the Commission's regulations applicable to an affected entity licensee or  
28 "class" of affected entities licensees at the time of the identification of the proposed backfitting or  
29 forward fitting. Staff positions can be facility-specific or generic.

30  
31 The NRC establishes facility-specific staff positions through licensing actions (~~i.e.,~~ NRC  
32 approvals), exemptions, or NRC-issued facility-specific correspondence discussing the NRC's  
33 regulatory bases for its decisions (e.g., inspection reports (see caution below) or a safety  
34 evaluation~~s~~, which may or may not be related to a requested licensing action). Inspection  
35 reports can also contain staff positions, but the staff must not use inspection reports to create  
36 staff positions on the adequacy of the licensing basis, although some exceptions may apply  
37 depending on the type of inspection. Section 5.3 of this NUREG contains additional guidance  
38 on staff positions in inspection reports. Staff positions in safety evaluations are not  
39 requirements; rather, they are the NRC's regulatory bases for its decisions or interpretations. A  
40 safety evaluation (or safety evaluation report~~s~~) provides the staff position on whether an  
41 affected entity licensee's proposed means ~~for of~~ implementing or complying with a governing  
42 requirement is acceptable and results in compliance with the requirement. The safety  
43 evaluation is generally not part of the licensing basis unless specifically incorporated by the  
44 licensee or required as a condition of approval by the staff. If the NRC subsequently decides

<sup>7</sup> ~~Forward fitting is discussed in more detail in~~ Section 1.3 of this NUREG contains a more detailed discussion  
of forward fitting.

Commented [BH13]: Comment 4.1.14

Commented [BH14]: Comment 4.1.10

Commented [KA15]: Comment 4.5.4

Commented [BH16]: The staff moved this sentence from the following paragraph as part of moving most of that paragraph to Chapter 5. The staff also removed the "e.g." parenthetical in the original sentence and added the subsequent sentence.

Commented [KA17]: The staff changed "whether" to "why" because the approval or denial of the change communicates this decision, not the safety evaluation. The safety evaluation documents the basis for the decision.

Commented [RT18]: The staff deleted "generally" because a safety evaluation is never a part of the licensing basis unless there is an additional action to make it such.

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<sup>8</sup>.

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

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 unless it is used for that purpose, the conclusion is an internal agency communication. Section 5.1.2.24 of this NUREG provides more information about the technical assistance request process.

Generic staff positions may be contained in documents such as regulatory guides, standard review plans, NUREGs, interim staff guidance, branch technical positions, and NRC-endorsed industry topical reports 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 ~~for of~~ meeting or complying with a governing requirement, the NRC imposes generic positions on specific licensees through orders or rulemakings, or the NRC approves issues licensing actions involving that incorporate the 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 between 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 and forward fitting implications. Chapter 5 of this NUREG describes the

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

**Commented [BH19]:** The staff changed "assessment" to "considerations" because a backfitting assessment is not defined until Chapter 2.

**Commented [BH20]:** The staff moved the first sentence of this paragraph into the preceding paragraph and the rest of the Caution statement to Chapter 5's discussion of inspection reports.

**Commented [BH21]:** The staff reordered the sentences in this paragraph to improve the structure of the paragraph.

**Commented [BH22]:** The staff edited this sentence to provide more specific guidance on how an NRC licensing action can turn a generic staff position into a licensee-specific staff position.

**Commented [BH23]:** The staff moved this sentence from the last paragraph of this section 1.2.2 because, like the preceding sentence in this paragraph, the sentence concerns the relationship between generic staff positions and individual licensees.

**Commented [KA24]:** Comment 4.3.8.



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

### 1.2.3 Backfitting Justifications

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

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

- The action is necessary to ensure that the facility provides adequate protection ~~of 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 ~~the~~ common defense and security that should be regarded as adequate.
- The action is necessary to bring a facility into compliance with applicable requirements or into conformance with written commitments by the licensee.

When the action is justified based on one or more of these exceptions, the NRC completes a documented evaluation in lieu of ~~the more detailed 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 ~~take an action 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 ~~nevertheless~~ 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

**Commented [AK25]:** The staff moved the first two sentences to the Chapter 5 discussion of information requests. The last sentence was moved up two paragraphs.

**Commented [KA26]:** The staff deleted these words because they could have implied that a document evaluation does not need to be detailed.

**Commented [BH27]:** The staff revised this word to be consistent with the Solicitor's memo and other references within this NUREG.



adequate protection before considering other justifications. Because the NRC is mandated to ~~take an action involving as necessary to achieve~~ adequate protection, the ~~NRC 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.

Commented [BH28]: Comment 4.2.19

Only after determining that ~~neither of the adequate protection exceptions applies to~~ a proposed backfitting action ~~does not meet the adequate protection exception~~ can the staff consider whether the compliance exception applies. If the proposed action cannot be justified by one of the adequate protection or compliance exceptions, then the staff must complete a backfit analysis showing that the proposed action represents a cost-justified substantial increase in overall protection. If the proposed backfitting action cannot be justified by any of these means, then the action cannot be pursued through backfitting, and the staff can consider other agency processes.

Commented [BH29]: Comment 4.2.19

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

The backfitting provisions in 10 CFR Part 72, ~~"Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste,"~~ contain justification concepts similar to the other backfitting regulations but apply those concepts differently. Under 10 CFR 72.62(b), the NRC will require backfitting of an ISFSI or monitored retrievable storage installation if the NRC finds that backfitting is necessary to ensure adequate protection ~~efo~~ 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 decision-making objectives of the Backfit Rule, the NRC should prepare a backfit analysis for all proposed backfitting actions under 10 CFR 72.62(c).

Commented [BH30]: The staff removed this title because it is provided in footnote 3.

## 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 ~~(codified at 10 CFR 50.150)~~. As a practical matter, an administrative exemption should be considered only when none of the criteria for justifying the backfitting action 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 backfitting 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 ~~time~~ was for Order EA-12-051, “Order Modifying Licenses with Regard to Reliable Spent Fuel Pool Instrumentation” (77 FR 16082; ~~dated~~ March 19, 2012), issued after the accident at the Fukushima nuclear reactors in Japan in 2011. As these examples show, the NRC should employ the exemption only in very significant circumstances.

In SRM-SECY-93-086 rulemaking, 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.

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

There are two types of backfitting actions: ~~generic and~~ 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

Commented [BH31]: The staff removed the reference to 10 CFR 50.150 because it is unnecessary.

Commented [KA32]: Comment 4.1.15

Commented [BH33]: Comment 4.1.18

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~~

Generic backfitting actions apply to more than one ~~licensee-affected entity~~ (typically a class of ~~licenseesaffected 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 ~~licenseesaffected 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 ~~provide-give the public~~ an opportunity ~~for public-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~~~~the Commission's~~ authority to the EDO (although the Commission must review all proposed backfits invoking the adequate protection exceptions). ~~This authority may have been redelegated to a program office director (e.g., Section III.B.8 of MD 6.3, "The Rulemaking Process," dated July 3, 2019, lists the rulemakings under 10 CFR 50.55a, "Codes and standards," as being delegated from the EDO to the NRR Office Director.).~~

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

#### ~~1.2.5.2 Facility-Specific Backfitting Actions~~

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

**Commented [BH34]:** The staff moved this sentence from the end of this section because the sentence concerns facility-specific backfitting actions, which is the topic of this paragraph.

**Commented [KA35]:** Comment 4.1.19. Also, MD 8.4 authorizes the EDO to delegate authority for facility-specific backfitting but not for generic backfitting.

**Commented [BH36]:** The staff moved this paragraph to Section 4.1.4, "Draft or Proposed Generic Documents or Actions for Comment" and revised it.

**Commented [KA37]:** Comment 4.1.18

~~staff assessments, inspection reports, and oral communications with licensees. Section 1.5 of this NUREG contains additional information on communications with licensees.~~

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

**Commented [BH38]:** The staff moved this sentence to the end of the facility-specific paragraph at the beginning of this section 1.2.5.

## 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.

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

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

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

certifications," would apply to design matters resolved in the DC, unless the DC includes specific issue finality provisions, in which case those specific provisions will govern.

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

#### 1.3.0 Independent Spent Fuel Storage Installations

Part 72 of the NRC's regulations contains requirements for, among other things, ISFSIs and Certificates of Compliance (CoCs) approving spent fuel storage cask designs. Typically, for an ISFSI associated with a nuclear power plant, the licensee for the nuclear power plant is licensed to operate the ISFSI. The NRC issues a CoC to the vendor of the associated cask design. The Part 72 backfitting provisions in 10 CFR 72.62 involve the ISFSI but do not address CoCs. This means that the user of the cask—the ISFSI licensee—is within the scope of 10 CFR 72.62 but the CoC holder—the vendor—is not.

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

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

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

Commented [BH39]: Comment 4.1.16

Commented [BH40]: Comment 4.1.17

## 4.13-1.3 Forward Fitting

### 4.13-1.3.1 Definition

The NRC does not have a regulation ~~regarding on~~ forward fitting requirements, ~~but MD 8.4 does reflect.~~ The Commission's policy on forward fitting ~~is reflected in MD 8.4.~~ Forward fitting is similar to backfitting in that the NRC imposes on an ~~affected entity licensee~~ a new or modified requirement or staff interpretation of a requirement (i.e., ~~a~~ staff position, as defined in Section 1.2.2.2 of this NUREG) that results in a modification of or addition to the systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a facility. ~~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 licensee~~, whereas a forward fit happens when the NRC's approval of an ~~affected entity licensee~~-initiated request for a licensing action includes a condition that the ~~licensee-affected entity~~ comply with a new or modified requirement or regulatory staff position that the ~~affected entity licensee~~ did not request.

**Commented [BH41]:** The staff added this sentence to help show the similarities between the backfitting and forward fitting definitions.

### 4.13-2.1.3.2 Forward Fitting Justifications ~~Direct Nexus, Essentiality, and Cost~~

Like the backfitting requirements, the forward fitting policy requires the NRC to justify and document its ~~assessment analysis~~ of the forward fitting action to ensure reasoned and informed NRC decisionmaking and transparency. ~~Under MD 8.4, states that the analysis 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 licensee's~~ request, and (2) the imposition of the new or modified requirement or regulatory staff position is essential to the NRC staff's determination of the acceptability of the ~~affected entity licensee's~~ request. The staff must adequately explain why 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 ~~unless the forward fit would be necessary for adequate protection.~~ Section 3.53 of this NUREG describes how to conduct the cost evaluation that supports a proposed forward fitting action.

**Commented [BH42]:** The staff changed the heading because forward fitting justifications do not include considerations of cost because forward fits do not need to be cost-justified.

**Commented [BH43]:** The edits in this paragraph reflect the staff's use of the term "forward fitting assessment" to be consistent with "backfitting assessment," both of which are used to describe the entire screening, justifying, and costing processes, and to prevent any confusion with a backfit analysis, which involves cost justification whereas forward fitting does not. The staff replaced "analysis" with "assessment" in the forward fitting context throughout the document.

### 4.14-1.4 Risk Considerations and Safety Significance

In Directive Handbook Section ~~I.A.124~~ 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 ~~analyses or justifications 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 ~~plant facility~~ has operated safely for a ~~period of years~~ does not ~~mean~~, in ~~and of itself~~, ~~mean~~ that a condition that has persisted for years should not be re-evaluated. ~~But~~ ~~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 ~~still~~ warranted.

**Commented [RT44]:** The staff revised this sentence to remove the implication that considering risk and safety significance are different things.

#### **4.45-1.5 Communications with Licensees 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 ~~a licensee~~ ~~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 voluntary<sup>9</sup> submittal, the ~~affected entity~~ ~~licensee~~ perceives that the staff is pressuring ~~it~~ ~~the licensee~~ to adopt a specific staff position, then the ~~affected entity~~ ~~licensee~~ would

**Commented [AK45]:** Comment 4.5.29

<sup>9</sup> 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.

1 ~~generally be expected to~~can raise this concern to the staff. If the staff desires to impose the  
2 specific staff position, then the staff should follow the guidance in this NUREG to determine  
3 whether the position would constitute backfitting, a change affecting issue finality, or forward  
4 fitting.

5  
6 In contrast, during the conduct of normal agency regulatory functions, the staff might suggest  
7 that affected entities~~licensees~~ consider various actions (e.g., the staff may suggest various  
8 corrective actions for licensee consideration to address performance deficiencies). Discussion  
9 or comments by the staff that constitute suggestions ~~and for~~ considerations ~~for by~~ affected  
10 entities~~licensees~~, whether in meetings or written reports, ~~if made in a neutral context (i.e., not~~  
11 ~~suggesting a licensee must take an action that goes beyond its current requirements)~~, do not  
12 constitute backfitting actions or changes affecting issue finality if the suggestions are not  
13 ~~presented as actions the affected entity must take beyond its current requirements.~~ Affected  
14 entities~~Suggestions for consideration do not constitute backfitting, and licensees~~ may consider  
15 the suggestions and choose whether to implement them. An example would be a discussion of  
16 an NRC information notice describing operating experience that may apply to the facility. When  
17 discussing corrective actions required by 10 CFR Part 50, Appendix B, "Quality Assurance  
18 Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," Criterion XVI, "Corrective  
19 Action," the staff should be careful to ensure that any specific corrective actions are discussed  
20 as considerations, without the implication that a particular action must be taken. However, the  
21 staff must not act in a "consulting" capacity. The staff can avoid this by cautioning the licensee  
22 that the suggestions or considerations from individual staff members have not gone through  
23 formal agency review and approval for that licensee and that the licensee is responsible for  
24 meeting its licensing basis.

25  
26 The NRC staff should not attempt to impose or ~~suggest~~imply requirements through informal  
27 communications. An affected entity~~licensee~~ is not obligated to conform to staff suggestions;  
28 however, if it chooses to do so, the ~~licensee~~affected entity should understand that it is doing  
29 this voluntarily and that the suggestion does not constitute the imposition of a requirement. If  
30 the affected entity~~licensee~~ concludes that an NRC suggestion is a backfit or a forward fit or  
31 affects the issue finality of a 10 CFR Part 52 approval, then the affected entity~~licensee~~ can  
32 clarify with the staff whether the staff intends to impose a backfitting or forward fitting action or  
33 change the approval.

34  
35 If an affected entity orally raises a backfitting, issue finality, or forward fitting concern or provides  
36 the NRC staff with a written backfitting, issue finality, or forward fitting concern that the licensee  
37 does not identify as an MD 8.4 appeal, including concerns about a proposed violation, then the  
38 NRC staff should discuss the concern with the affected entity to ensure mutual understanding.  
39 The staff must ensure that its division-level management is informed of an affected entity's  
40 concern and must evaluate the points raised by the affected entity before taking a proposed  
41 staff action (e.g., issuing a violation or license amendment). The staff's evaluation of the  
42 affected entity's concern is not intended to be exhaustive but should appropriately consider the  
43 affected entity's concerns within the established schedule for issuing the NRC action (e.g., an  
44 inspection report following the exit meeting). The staff should orally reply to the affected entity  
45 regarding the staff's evaluation of the affected entity's concern. The staff must ensure that  
46 communications and the bases for its decisions comply with MD 3.53, "NRC Records and  
47 Document Management Program," dated March 15, 2007, and any applicable NRC office-level  
48 implementation procedures.

49  
50 Backfitting, issue finality, and forward fitting concerns may arise because the licensee and NRC  
51 staff have different understandings about the affected entity's licensing basis. If an affected

Commented [BH46]: The staff edited this sentence to simplify the sentence.



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 affected entity action. The staff should subject the proposed action to a backfitting or forward fitting screening. If the staff determines that the proposed staff action would not constitute backfitting or forward fitting, then the staff may proceed with the proposed staff action. If the staff determines that the proposed staff action could constitute backfitting or forward fitting and wishes to proceed with the action, then the staff needs to complete the backfitting or forward fitting assessment.

#### 4.16.1.6 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 ~~are contained in MD 8.4~~. Management responsibilities include determining if the backfitting or forward fitting 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 analysis 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 of the region that initiated a backfitting or forward fitting<sup>10</sup> action or a change affecting issue finality supports NRR or NMSS with its obligation to impose the backfitting or forward fitting 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.

**Commented [AK47]:** Comments 4.4.1, 4.4.14. Although the comments pertained to text in Chapter 4 of the draft NUREG, the staff relocated these revised paragraphs from Chapter 4 to this section because the communications described in these paragraphs do not constitute appeals.

**Commented [AK48]:** This information is covered in Chapters 2 and 3.

<sup>10</sup> For licenses that are within the scope of backfitting provisions and, therefore, the forward fitting policy, all licensing actions are processed only in with the NRR and NMSS program offices. Therefore, forward fitting actions are not expected to arise in the regional offices.

1 Although the primary responsibility for issuing backfitting and forward fitting actions belongs to  
2 NRR and NMSS, [and NRR is responsible for changes affecting issue finality](#), the CRGR  
3 provides key oversight for backfitting, [issue finality](#), and forward fitting. The Director of NRR or  
4 NMSS, or designee, should request CRGR review of the documents that propose a backfitting  
5 or forward fitting action [or change affecting issue finality](#), including the supporting analyses,  
6 findings, and justifications.<sup>11</sup> If the CRGR accepts the request, then the CRGR will recommend  
7 approval, revision, or disapproval of the [documents proposed action](#). If the NRR or NMSS Office  
8 Director agrees with the CRGR recommendation, then NRR or NMSS implements the  
9 recommendation in accordance with this guidance, if applicable. If the NRR or NMSS Office  
10 Director does not agree with the CRGR recommendation, then the NRR or NMSS Office  
11 Director may refer the issue to the EDO for a decision.

Commented [BH49]: The staff added footnote 11 for additional guidance regarding the CRGR.

#### 13 [4.17.1.7](#) **Implementation of Backfitting, Issue Finality, and Forward Fitting** 14 **Process**

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

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

Commented [BH50]: Comment 4.1.21

34 Before ~~the staff~~ [expending](#) significant resources justifying a proposed backfitting or forward  
35 fitting action [or a change affecting issue finality](#), the staff first should screen the issues for  
36 potential backfitting, [issue finality](#), or forward fitting implications. The steps for screening and  
37 justifying backfitting and forward fitting actions [or changes affecting issue finality](#) may need to be  
38 adjusted depending on the context of the staff's proposed action (e.g., ~~rulemaking~~). Chapters 2  
39 and 3 and Appendices B and C ~~of~~ this NUREG provide detailed instructions, worksheets, and  
40 guides for screening and justifying a backfitting or forward fitting action [or a change affecting](#)  
41 [issue finality](#).

<sup>11</sup> [The CRGR does not review immediately effective actions. The CRGR Charter contains the procedures to follow in these circumstances.](#)

## 2 SCREENING AND JUSTIFYING BACKFITTING ACTIONS AND CHANGES AFFECTING ISSUE FINALITY

Commented [KA51]: Comment 4.2.2

### 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?
  - ~~4(a)-~~ Do one or both of the adequate protection exceptions to the requirement of preparing a backfit analysis apply?
  - ~~4(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 ~~take an action~~ to avoid the effect of the backfitting or issue finality provision on the proposed action by invoking an administrative exemption from the backfitting or issue finality provision?

Questions 1 through 3 help the staff determine whether proposed staff actions would constitute backfitting or affect issue finality. For those proposed ~~staff~~ actions that would constitute backfitting or affect issue finality, ~~q~~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 ~~q~~Question 6, Sections 2.2 through 2.6 of this chapter describe these questions in more detail. The staff will rarely reach ~~q~~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 ~~sets forth~~ 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;"<sup>1</sup> or constitute changes affecting issue finality.~~

~~Matters that are outside the purview of the backfitting regulations include~~

~~Other matters outside the scope of the backfitting provisions include those that do not have a direct link to and do not further a substantive radiological<sup>2</sup> public health and safety or common defense and security objective. In addition, these actions that would not meet the definition of "backfitting;" ~~Such actions or constitute changes affecting issue finality~~ include information collection and reporting requirements;<sup>3</sup> changes to NRC administrative procedures;<sup>4</sup> corrections of regulatory language, including typographical mistakes, misspellings, ~~and or~~ inadvertent omissions (when ~~the NRC's objective is expressly reflected in~~ 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. ~~Information collection and reporting requirements facilitate the NRC's regulatory oversight responsibility. 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,<sup>5</sup> 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.<sup>6</sup> In these situations, The NRC generally has no~~

<sup>1</sup> 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 non-substantive changes that did not meet the definition of "backfitting").

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

<sup>3</sup> For example, 10 CFR 50.73, "Licensee event report system," and 70.74, "Additional reporting requirements."

<sup>4</sup> For example, changes to Title 10 of the *Code of Federal Regulations* (CFR) Part 2, "Agency Rules of Practice and Procedure."

<sup>5</sup> For example, 10 CFR 50.73, "Licensee event report system," and 10 CFR 70.74, "Additional reporting requirements."

<sup>6</sup> For example, 10 CFR 26.39, "Review process for fitness-for-duty policy violations," and 10 CFR 73.56(l), "Review procedures."

discretion in the implementation of ~~these statutory~~ requirements ~~or requirements imposed by other Federal agencies~~. ~~Because~~ However, the NRC must ~~implement these requirements, the NRC does not need to justify any potential backfitting resulting from taking these actions.~~ 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. Requirements for appeal processes<sup>7</sup> are also outside the purview of backfitting provisions. An appeal process protects an individual's due process, which is guaranteed by the Fifth Amendment to the U.S. Constitution: "No person shall ... be deprived of life, liberty, or property, without due process of law ...." Although the Fifth Amendment requires the Federal Government to provide due process to persons, the NRC can, in implementing its own authority, ensure that its regulated entities provide adequate due process to their personnel through the entities' appeals processes that are consistent with Federal due process requirements. 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.

Because the backfitting and issue finality provisions do not expressly identify these exclusions, 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 outside the scope of the backfitting regulations, the staff should exit the backfitting process and proceed under an appropriate agency process. For proposed actions that are within the scope of the backfitting or issue finality regulations, the staff should continue through the screening process.

### 2.3 Question 2: Would the ~~p~~Proposed ~~a~~Action ~~a~~Affect ~~a~~Any ~~e~~Entity ~~t~~That ~~i~~s ~~w~~Within the ~~s~~Scope of a ~~b~~Backfitting or ~~i~~Issue ~~f~~Finality ~~p~~Provision?

In ~~q~~Question 2, the staff must determine whether the affected entity is within the scope of ~~the a~~ backfitting or issue finality regulations. Table 1-1 lists the regulations that contain backfitting or issue finality provisions. If the entity is not within the scope of ~~the a~~ backfitting regulations, then ~~these~~ backfitting 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 ~~the a~~ backfitting or issue finality regulations, ~~then~~ the staff should continue with the screening process. The following ~~list~~ sections ~~contains describe~~ the entities within the scope of ~~the a~~ backfitting or issue finality provisions (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,

Commented [KA52]: Comment 4.2.4

Commented [BH53]: The staff deleted these two sentences because this NUREG isn't the place to justify NRC-required appeal processes.

Commented [KA54]: Comment 4.2.6

Commented [KA55]: Comment 4.2.7

Commented [BH56]: These edits reflect the change in the organization of Section 2.3.

<sup>7</sup>For example, 10 CFR 26.39, "Review process for fitness-for-duty policy violations," and 10 CFR 73.56(l), "Review procedures."

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

##### 2.3.1

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)<sup>8</sup>
- 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")
- ~~(There are no backfitting provisions in Part 54. However, the regulatory structure of Part 54 bounds what the staff can review in these applications, as described in Section 5.16 of this NUREG.)~~
- holder of a renewed operating license (10 CFR Part 54)

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 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

**Commented [BH57]:** The staff moved this text from footnote 2 in the draft NUREG and revised the text to clarify the applicability of certain Part 70 licensees.

**Commented [BH58]:** This parenthetical is not necessary because the staff included a discussion of Part 54 and its scope after this list.

**Commented [BH59]:** The staff moved this paragraph as part of the reorganization of Section 2.3.

**Commented [BH60]:** Comment 4.5.28

<sup>8</sup> 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.

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 nonpower reactors."

### 2.3.2 pPower rReactors lLicensed and aApproved under 10 CFR Part 52<sup>9</sup>

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")<sup>10</sup>
- 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)
- 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")

<sup>9</sup> Applicants referencing an ESP, DC, or SDA have issue finality for only the information within the scope of the ESP, DC, or SDA.

<sup>10</sup> Each approved DC contains more specific provisions for issue finality than are found in 10 CFR 52.63. These include provisions for including changes to and departures from the approved design (e.g., 10 CFR Part 52, Appendix D, "Design Certifications Rule for the AP1000 Design," Sections VI and VIII), that 10 CFR 52.63. 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.

Commented [KA61]: Comment 4.1.6

Commented [BH62]: The staff made footnote 9 (footnote 7 in the draft NUREG) the new second sentence in the paragraph following the list of Part 52 entities.



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. Similarly, a COL applicant can reference an NRC-approved ESP or DC in its application, and certain matters concerning that ESP or DC are considered resolved, such that changes to the ESP or DC are governed by the applicable ESP or DC issue finality provision.

**Commented [BH63]:** The staff moved this paragraph as part of the reorganization of Section 2.3.

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.

**Commented [BH64]:** With the addition of the second sentence of this paragraph (which was footnote 7 in the draft NUREG), this sentence became redundant.

**Commented [BH65]:** The staff moved this sentence as part of the reorganization of Section 2.3.

### **2.3.3 ~~m~~Materials Licensees under 10 CFR Part 70**

**Commented [BH66]:** Comment 4.2.7

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 (10 CFR 70.76).

### **2.3.4 ~~M~~aterials Licensees under 10 CFR Part 72**

**Commented [BH67]:** Comments 4.1.17, 4.2.7

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) (10 CFR 72.62) or holders of a license for a monitored retrievable storage installation (10 CFR 72.62). 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 an ISFSI licensee has purchased a cask for which a revision is sought and the

**Commented [BH68]:** The staff added this sentence and deleted the subsequent sentence. This new sentence is based on RIS 2017-05, which is referenced in the next paragraph.



~~ISFSI licensee is made aware of the revision and voluntarily agrees to implement the change, then the NRC would not be imposing the revised technical change on the licensee, thereby eliminating the potential backfitting. If the ISFSI licensee does not agree to implement the revision, then the staff would need to perform a backfit analysis under 10 CFR 72.62 to impose the revision.~~

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

### **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 certificate of compliance for a gaseous diffusion plant. (10 CFR 76.76)~~

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

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

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

~~The NRC's policy is not to apply the backfitting provisions to non-power production and utilization facilities, including radioisotope production facilities, research reactors, and testing facilities, licensed under 10 CFR Part 50. Historically, the NRC expressed the regulatory basis for 10 CFR 50.109 solely in terms of nuclear power reactors. For example, the NRC's Advanced Notice of Proposed Rulemaking, Policy Statement, Proposed Rule, and Final Rule for the 1985 revision of 10 CFR 50.109 involved only nuclear power reactors. As a result, the NRC has not applied 10 CFR 50.109 to research reactors, testing facilities, and other non-power~~

**Commented [BH69]:** Comment 4.2.7

**Commented [BH70]:** The staff either moved these paragraphs as noted in other comment bubbles or replaced them with new text as part of the reorganization of Section 2.3

1 facilities licensed under 10 CFR Part 50.<sup>14</sup> In a 2012 final rule concerning non-power reactors,  
2 the NRC stated, "The NRC has determined that the backfit provisions in § 50.109 do not apply  
3 to test, research, or training reactors because the rulemaking record for § 50.109 indicates that  
4 the Commission intended to apply this provision to only power reactors, and NRC practice has  
5 been consistent with this rulemaking record."

### 6 7 **2.3.6 Other Materials Licensees**

Commented [BH71]: Comments 4.2.7, 4.2.8

8 The NRC issued backfitting provisions for ~~ISFSI~~ independent spent fuel storage installation  
9 licensees in 1988 and gaseous diffusion plants in 1994. In SECY-95-061, "Need for a Backfit  
10 Rule for Materials Licensees," dated March 14, 1995, the NRC staff recommended to the  
11 Commission that the ~~NRC agency~~ not extend backfitting provisions to all other materials  
12 licensees. The staff determined that extending the Backfit Rule to all other materials licensees  
13 would create technical problems (e.g., the challenge of developing a consistent definition of  
14 "substantial" and the uncertainties in quantifying risk) and potentially significant resource  
15 burdens ~~for on~~ the staff. The staff also determined that regulatory analysis requirements,  
16 already applicable to NRC actions involving materials licensees, were similar to the Backfit Rule  
17 in preventing the imposition of generic requirements having marginal overall safety benefit or  
18 costs not commensurate with the benefits. The Commission approved the staff's  
19 recommendation in the ~~Staff Requirements Memorandum (SRM)~~ to SECY-95-061, dated  
20 June 29, 1995, and instructed the staff to "consider the applicability of a backfit provision to  
21 particular classes of licensees." Subsequently, the NRC added ~~a~~the backfitting provision to  
22 10 CFR Part 70 ~~that~~. ~~However, the backfitting provision in Part 70 is only applicable only to~~  
23 Part 70 licensees authorized to engage in specific activities and possess greater than a critical  
24 mass of special nuclear material. ~~The Part 72 backfitting provision applies to Part 72 licensees~~  
25 ~~but not to holders of a Part 72 certificate of compliance.~~

### 26 27 **2.3.7 Proposed Actions Affecting Both Entities That Are Within and Entities That Are** 28 **Not Within the Scope of Backfitting and Issue Finality**

Commented [KA72]: Comment 4.2.9

29 In certain circumstances, a proposed action may affect entities ~~that are~~ within the scope of  
30 ~~backfitting or issue finality provisions~~ and entities ~~that are~~ not within the scope of backfitting or  
31 issue finality provisions. A proposed action may also affect entities authorized to conduct  
32 certain activities under multiple parts of the NRC's regulatory framework (e.g., nuclear power  
33 reactor licensees that are authorized to receive, possess, and use source, byproduct, and  
34 special nuclear material under 10 CFR Part 30, "Rules of ~~G~~eneral ~~A~~pplicability to ~~D~~omestic  
35 ~~L~~icensing of ~~B~~yproduct ~~M~~aterial," 10 CFR Part 40, "Domestic ~~L~~icensing of ~~S~~ource  
36 ~~M~~aterial," 10 CFR Part 50, and 10 CFR Part 70). The staff needs to determine whether any  
37 backfitting or issue finality provision applies and, if so, which one. For nuclear power reactor  
38 licensees and certain materials licensees, the staff can typically make that determination by  
39 ascertaining how the proposed action would affect the licensee. In general, a proposed NRC  
40 action that would affect an activity regulated by a 10 CFR part that does not contain a backfitting  
41 or issue finality provision is not subject to a backfitting or issue finality assessment. For an  
42 affected entity that is within the scope of a backfitting or issue finality provision, if the proposed  
43 NRC action would inextricably affect that entity's activities regulated under the same

<sup>14</sup> For example, "Limiting the Use of Highly Enriched Uranium in Domestically Licensed Research and Test Reactors; Final Rule" (51 FR 6514; March 27, 1986); and "Clarification of Physical Protection Requirements at Fixed Sites; Final Rule" (58 FR 13699; March 15, 1993).

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.

To help make that determination, the staff should follow these steps:

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

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

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

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

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

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

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

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

1  
2 For those NRC-regulated entities affected by the proposed action that are nuclear power reactor  
3 licensees, determine whether the proposed action:

4  
5 would apply uniformly to all applicable non-nuclear power reactor licensees, and at least one of  
6 these non-nuclear power reactor licensees (i.e., material licensees) is within the scope of an  
7 applicable backfitting provision;

8  
9 is directed only at nuclear power reactor licensees; or

10  
11 seeks a level of performance for nuclear power reactor licensees that is higher than the level of  
12 performance sought from non-nuclear power plant licensees.

13  
14 If all the answers to the questions in step 3 are "NO," then the staff can exit the backfitting  
15 process. In this case, the NRC would be imposing the proposed action on nuclear power  
16 reactor licensees in a manner that is equal to the manner that the NRC would impose the  
17 proposed action on non-nuclear power plant licensees. In other words, nuclear power reactor  
18 licensees would receive equal treatment as materials licensees because the proposed action  
19 would be imposed on the nuclear power reactor licensees in their capacities as material  
20 licensees. Therefore, to ensure equal backfitting treatment, no backfitting provision should  
21 apply to the nuclear power reactor licensees in this instance because, in this case, no backfitting  
22 provision applies to the non-nuclear power plant licensees. The staff need not consider the  
23 backfitting or issue finality implications of its proposed action.<sup>12</sup>

24  
25 0. If the answer to any of the questions in step 3 is "YES," then continue to Section 2.4 of  
26 this NUREG. When the answer to the question in step 3.a is "YES," nuclear power  
27 reactor licensees would receive equal treatment as materials licensees that are within  
28 the scope of a backfitting provision. When the answer to the question in step 3.b or 3.c  
29 is "YES," then the NRC would be treating nuclear power reactor licensees differently  
30 than other NRC-regulated entities solely because they are power reactor licensees,  
31 which are within the scope of backfitting and issue finality provisions.  
32

---

<sup>12</sup> For example, the NRC could propose an action to amend 10 CFR Part 40 that would apply uniformly to Part 50 nuclear power reactor licensees (which also are authorized to conduct activities under Part 40), Part 70 fuel cycle facility licensees (which also are authorized to conduct activities under Part 40), and Part 40 source material licensees. Although the proposed action would apply equally to the three classes of licensees, and Part 50 and Part 70 have backfitting provisions, those provisions would not apply to the proposed action because the action affects those licensees regarding activities they are authorized to conduct under Part 40.

**2.34.2.4 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/YES”:

- (1) Is there either—
  - (a) a new or changed (e.g., amended, revised, or modified) NRC requirement (e.g., a regulation or order), or
  - (b) a new or changed staff interpretation of an NRC requirement?
- (2) Is the NRC imposing<sup>13</sup> 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 the entity's facility;
  - (b) The design (including but not limited to a DC, SDA, approval or ML) of the entity's for a facility; or
  - (c) The procedures or organization required for designing, constructing, or operating the entity's facility?
- (4) Is the modification or addition (third question above) the result of the new or changed requirement or interpretation (first question) that is being imposed (second question)?
- (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/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. However, the staff should also recognize that issue finality for some entities involves matters other than adequate protection, compliance, and substantial

Commented [BH73]: Comment 4.2.13

Commented [AK74]: The staff revised this guidance to conform to the text of the 50.109 regulation.

Commented [BH75]: Comment 4.1.10

Commented [BH76]: Comments 4.1.16

<sup>13</sup> Not all backfitting actions require an imposition, as discussed in Section 5.2.3 of this NUREG.

1 increase in overall protection. In some cases, issue finality does not specifically involve any of  
2 those three matters (e.g., for an SDA), while in other cases, issue finality includes and goes  
3 beyond these three matters (e.g., for a DC). The specific issue finality provisions define the  
4 scope of matters considered for issue finality. In general, the staff should use the same  
5 hierarchy for determining whether issue finality would be affected if the requirement is imposed  
6 by the NRC (i.e., adequate protection first, then compliance, and/or substantial increase in  
7 overall protection, as applicable). Most other changes that would involve issue finality would  
8 likely be voluntary, such as departures from a DC taken or requested by a COL holder or  
9 requests to amend a DC to reduce unnecessary regulatory burden or contribute to increased  
10 standardization. Even if the changes are voluntary, the changes must still meet the applicable  
11 issue finality criteria.

12  
13 Under 10 CFR 50.109(d), the staff must not ~~withhold, interrupt or delay~~ licensing actions while  
14 the NRC is processing a backfit analysis. This provision was codified in 1985, when the NRC  
15 described as "backfitting" those actions that are now called "forward fitting." As implemented  
16 today, new or changed requirements or staff positions proposed by the NRC staff during a  
17 licensing action ~~are could be~~ either backfits ~~that need to be addressed through a separate~~  
18 ~~action~~ or forward fits. If the proposed action is a forward fit, then the staff must follow the  
19 forward fitting policy described in Chapter 3 of this NUREG. ~~For proposed backfits, whether the~~  
20 ~~licensing action can be finalized in a proceeding separate from the backfitting assessment will~~  
21 ~~be a fact-specific decision. The backfitting assessment could affect the staff's determination of~~  
22 ~~the requested licensing action. This would be consistent with the 1985 Backfit Rule statement~~  
23 ~~of considerations (SOC), in which the Commission said that the staff's review of the requested~~  
24 ~~licensing action should proceed until the backfitting review is concluded: "[U]ntil a backfit~~  
25 ~~analysis is complete, licensing action should continue along a course consistent with normal~~  
26 ~~practice."~~

27  
28 As soon as practical after identification of a potential backfitting issue, the staff should present  
29 the potential backfitting action to the responsible office director or regional administrator, ~~who~~  
30 ~~then reviews the issue and determines whether the action constitutes backfitting. If the office~~  
31 ~~director determines the issue constitutes backfitting, then the office director will oversee the~~  
32 ~~NRC staff's development of appropriate backfitting documentation and determine if the~~  
33 ~~proposed action is justified. If the regional administrator determines the issue constitutes~~  
34 ~~backfitting, then the regional administrator will forward the issue to the office director for~~  
35 ~~disposition and provide support as needed in accordance with Section 1.6 of this NUREG.~~

#### 36 37 **2.35-2.5 Question 4: Do ~~a~~Any of the ~~e~~Exceptions to the** 38 **~~r~~Requirement of ~~p~~Preparing a ~~b~~Backfit ~~a~~Analysis ~~a~~Apply to the** 39 **~~p~~Proposed ~~b~~Backfitting?**

40 By reaching ~~q~~Question 4, the staff has determined that its proposed action would constitute  
41 backfitting or affect issue finality. Now the staff must justify its proposed action. The default  
42 method for justifying a proposed backfitting action is a backfit analysis. However, the  
43 Commission has directed the staff to first determine whether the proposed action satisfies the  
44 criteria for one (or more) of three exceptions to the requirement to prepare a backfit analysis.<sup>14</sup>  
45 Furthermore, the staff must consider whether ~~one or both of the adequate protection exceptions~~  
46 ~~applies to the backfitting action involves the adequate protection exception~~ before considering  
47 justification by the compliance exception.

<sup>14</sup> 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.

Commented [BH77]: The staff revised these words to conform to the text of the regulations.

Commented [BH78]: Comment 4.3.7.

Commented [KA79]: The staff revised this paragraph to simplify the guidance.

Commented [BH80]: Comment 4.2.19

**2.35.4-2.5.1 Question 4a: Do ~~e~~One or ~~b~~Both of the ~~a~~Adequate ~~p~~Protection  
~~e~~Exceptions to the ~~r~~Requirement of ~~p~~Preparing a ~~b~~Backfit ~~a~~Analysis  
~~a~~Apply?**

**2.35.4-2.5.1.1 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 ~~ef~~to the public health and safety or common defense and security that should be considered as adequate, then the ~~Atomic Energy Act of 1954, as amended (AEA),~~ requires that regulatory action be implemented. The staff would prepare a documented evaluation. The responsible staff should seek advice from the Office of the General Counsel (OGC) and Office of Enforcement on imposition of all adequate protection actions. ~~If one or both of the adequate protection exceptions applies to the backfitting action involves an issue of adequate protection,~~ then the backfitting justification must either be reviewed and approved by the Commission or provided to the Commission sufficiently in advance of the issuance of the backfitting action to enable the Commission to change the proposed action if it chooses to do so. ~~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 radiological<sup>15</sup> releases and does not include the economic impacts that may ensue). ~~as 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 RequirementsSRM—COMSAJ-97-008—Discussion of 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 ~~statement of considerations (SOC)~~ that it "can still make sound judgments about what 'adequate protection' requires, by relying upon expert engineering and scientific judgment, acting in the light of all relevant and material information." For example, the Commission concluded that greater uncertainty was associated with the capability of nuclear power plants to withstand extreme external events as a result of lessons learned from the Fukushima accident, and it decided that new requirements needed to be imposed as a matter of adequate protection (i.e., ~~beyond-design-basis external events could present undue risk~~). The Commission imposed these new requirements by Order EA-12-049, ~~"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 ~~beyond design-basis 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

<sup>15</sup> 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.

Commented [BH81]: Start here

Commented [AK82]: Comment 4.2.19

Commented [KA83]: Comment 4.2.16



1 protection aspects of 10 CFR Part 70, Subpart H, as part of the overall protection of public  
2 health and safety or the common defense and security. Under 10 CFR 72.62, the provisions  
3 specifically state that the Commission will require the imposition of a backfit of an  
4 ~~ISFSI independent spent fuel storage installation~~ or monitored retrievable storage installation if  
5 the NRC finds that the backfit is necessary to ensure adequate protection to occupational or  
6 public health and safety.

7  
8 Upon determining that a backfitting action is necessary for adequate protection of the public  
9 health and safety or the common defense and security, the staff must prepare an imminent  
10 threat analysis that determines whether immediate action is necessary. An adequate protection  
11 issue does not necessarily mean that the issue is an imminent hazard. If the responsible office  
12 director determines that the adequate protection issue presents an imminent hazard, then the  
13 NRC can impose the backfitting action immediately through an order. Although in these  
14 circumstances, 10 CFR 50.109(a)(6) permits the staff ~~in these circumstances~~ to impose the  
15 backfitting action before documenting the justification, the staff should document the reason the  
16 adequate protection issue represents ~~ed~~ an imminent hazard and the rationale for imposing the  
17 backfit in as much detail as practicable to support developing the order. The justification can be  
18 transmitted through means other than a documented evaluation (e.g., a briefing).

Commented [KA84]: Comment 4.2.16

#### 20 2.35.1.2-2.5.1.2 Adequate Protection Determinations

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

Commented [BH85]: The staff inserted "or will exist" to conform to the "or will not" text earlier in the sentence.

33  
34 Typically, a clear basis for invoking ~~the an~~ adequate protection exception can be established  
35 when new information reveals ~~that an unforeseen hazard exists or that there is~~ a substantially  
36 greater potential for a known hazard to occur than previously believed, thereby creating a  
37 condition of undue risk to public health and safety. This new information may result from  
38 information such as operational experience, technical research, or issuance of new industry or  
39 government reports. In such situations, the NRC has the statutory authority to require licensee  
40 action beyond existing requirements to maintain the level of protection necessary to avoid  
41 undue risk to public health and safety. In this case, the NRC would use the "necessary to  
42 ensure adequate protection" exception. If the NRC determines that action is necessary to  
43 change the level of protection that is considered adequate, then the ~~NRC agency~~ would use the  
44 "defining or redefining adequate protection" exception. Notwithstanding which exception is  
45 used, in SRM-SECY-99-063, "Staff Requirements—SECY-99-063—The Use by Industry of  
46 Voluntary Initiatives in the Regulatory Process," dated May 27, 1999, the Commission directed  
47 that matters required for adequate protection cannot be addressed through voluntary industry or  
48 licensee actions.



1 Quantitative risk estimates serve as important measures of facility safety, but do not embody the  
2 full range of considerations that enter into the judgment for adequate protection. The judgment  
3 for adequate protection derives from a more diverse set of considerations, such as acceptable  
4 design, construction, operation, maintenance, modification, and quality assurance measures.  
5 Quantitative measures used in the consideration of adequate protection for power reactors are  
6 the safety goal<sup>16</sup> surrogates (e.g., core damage frequency (CDF) and containment failure  
7 probability) ~~to~~for the quantitative health objectives. The Commission issued the quantitative  
8 health objectives as part of ~~the~~its 1986 Safety Goal Policy Statement (51 FR 30028;  
9 August 21, 1986) to provide an acceptable level of risk to the public from the regulated use of  
10 nuclear material. The NRC staff uses the safety goal surrogates to measure conformance with  
11 the purpose of the safety goals. ~~The "Regulatory Analysis Guidelines of the U.S. Nuclear~~  
12 ~~Regulatory Commission"~~ (NUREG/BR-0058) provides guidance on safety goal screening that  
13 the NRC staff ~~can~~ould use to make a determination about adequate protection depending on  
14 the change in the CDF and the conditional containment failure probability. However, a change  
15 in the CDF cannot be applied in evaluating all potential regulatory actions (e.g., spent fuel pools,  
16 materials, security), and, in some cases, determining the change in CDF would be difficult if not  
17 impossible (e.g., safeguards and security).

18  
19 Because an adequate protection backfit would impose new requirements to address a condition  
20 that is considered to present undue risk to public health and safety or the common defense and  
21 security, it is essential to fully inform this backfit decision with available risk information and risk  
22 insights to enable decision-makers to reasonably conclude that the undue risk condition exists  
23 and warrants imposition of new requirements. The staff should consider available risk  
24 information in a manner that is consistent with the Commission's policy on the use of  
25 probabilistic risk assessment, as discussed in Section 1.4 of this NUREG.

26  
27 When considering an adequate protection backfitting action, the staff must determine whether  
28 the issue and action should be applied to one or a limited number of ~~licensees-affected entities~~  
29 (facility-specific backfitting action), or whether the issue and action should be applied generically  
30 (generic backfitting action). Next, the staff must determine, based on the safety or security risk  
31 of the issue, whether the NRC must issue an immediately effective order. ~~The staff should~~  
32 ~~inform the Commission when the staff is~~When considering any generically applicable adequate  
33 protection backfitting actions, ~~to enable the staff should inform~~ the Commission ~~so that it can~~ to  
34 decide whether it wishes to review and approve the action or otherwise direct the staff. ~~The~~  
35 ~~NRC staff should inform the Executive Director for Operations (EDO) when the staff is~~When  
36 considering any facility-specific adequate protection backfitting actions, ~~the NRC staff should~~  
37 ~~inform the Executive Director for Operations (EDO).~~ Such notifications should occur once the  
38 staff has determined that ~~the an~~ adequate protection exception may apply and the staff has  
39 begun developing a documented evaluation for ~~that~~adequate protection exception, ~~not~~  
40 when the staff first considers adequate protection. The staff should seek advice from OGC on  
41 the imposition of all adequate protection actions, including the ~~licensee's-affected entity's~~  
42 proposed implementation schedule.

43  
44 The NRC does not usually impose new adequate protection requirements in rulemakings  
45 because matters of adequate protection usually need to be addressed more quickly than the  
46 time afforded by rulemaking. In these situations, the NRC typically issues licensee-specific  
47 orders followed by a rule that makes the associated orders generically applicable. One

<sup>16</sup> 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~~core damage frequency per reactor year or conditional containment failure probability.

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.

#### 2-35.1-3-2.5.1.3 Documenting Adequate Protection Evaluations

For any backfitting action that meets the definition and requirements for adequate protection backfitting, the staff must prepare a documented evaluation of the type discussed in 10 CFR 50.109(a)(6), 70.76(a)(4), or 76.76(a)(4) in lieu of a backfit analysis. To impose the backfitting action, the staff must find that the action is necessary for adequate protection. Because there are ~~two options for invoking the~~ adequate protection exceptions, the documented evaluation must include the basis for invoking the selected exception ~~and must clearly explain which option is being used and why~~. The staff must also describe the safety or security risk if the action is not taken. No further explanation is necessary to justify the backfitting action and it should be implemented without consideration of cost, except if there are multiple ways to implement the action and the NRC prescribes one way to comply with requirements or to achieve adequate protection. In that case, cost may be a factor in selecting the action, provided that the objective of adequate protection is met.

**Commented [BH86]:** The staff edited this sentence to clarify that there are two adequate protection exceptions and not two options for invoking a single adequate protection exception.

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

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

#### 2-35.2-2.5.2 Question 4b: Does the ~~e~~CCompliance ~~e~~Exception to the ~~r~~Requirement of ~~p~~Preparing a ~~b~~Backfit ~~a~~Analysis ~~a~~Apply?

##### 2-35.2-1-2.5.2.1 Background

If, in answering ~~q~~Question 4a, the staff determines that ~~the neither adequate protection exception applies to the~~ backfitting action ~~does not represent an issue of adequate protection,~~ then the staff proceeds to ~~q~~Question 4b to determine whether the backfitting action is necessary to ensure compliance with the license or the rules and orders of the NRC, or with written licensee commitments<sup>17</sup> 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 independent spent fuel storage installation or monitored retrievable storage installation into compliance with a license or the Commission's orders or rules, or into conformance with the licensee's written commitments. NRR or NMSS staff must seek advice from OGC and the Office of Enforcement on the imposition of all compliance backfits, including the proposed implementation schedule.

**Commented [BH87]:** Comment 4.2.19

<sup>17</sup> In accordance with 10 CFR 50.109, 70.76, 72.62, and 76.76, the NRC may require backfitting, if necessary, to bring a facility into conformance with the licensee's written commitments, as discussed in Section 5.3.1.1.6 of this NUREG.

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

When questions arise concerning a potential violation that will necessitate a detailed review of the facility's licensee's licensing basis or a complex technical evaluation, the inspectors should contact the appropriate licensing project manager ~~for advice~~, use the Very Low Safety Significance Issue Resolution process in the NRC's Inspection Manual Chapter 0612, "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.

#### 2-35.2-2.2.5.2.2 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 ~~e~~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~~the staff's 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, if~~ the NRC typically invokes the compliance exception when all of the following three ~~conditions-statements~~ are ~~met~~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 ~~NRC 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 ~~in existence~~ at the time it made the approval ~~at issue~~. The understanding of what constituted proper implementation of the regulations, standards, and practices must have been widely known or understood by professionals at the time. This is not restricted to the regulatory positions of the NRC but includes any applicable industry or professional standards and practices ~~in existence~~ at the time the original determination was made.

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

- ~~Provide~~ Provide information to the NRC (or other necessary Federal agency the NRC relies upon in its approval decision) that should have been submitted in connection with obtaining the NRC approval at issue.
- ~~Consider or address~~ 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).
- ~~consider or address information that the NRC requires be addressed through a legal obligation (e.g., for nuclear power plant licensees, the change control provisions of 10 CFR 50.59, "Changes, tests, and experiments").~~

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

The applicant's, licensee's, or third party's error or omission must be relevant and material to the NRC's approval that is now regarded as incorrect. An omission or error—even those now acknowledged by the ~~applicant or~~ licensee as having occurred—cannot be the basis for

**Commented [BH88]:** The staff edited this sentence to clarify that this is just an example.

**Commented [BH89]:** Comment 4.7.2

**Commented [BH90]:** Comment 4.2.27

invoking~~ation of~~ the compliance exception if that error or omission, had it been known to the NRC at that time, would not have affected the NRC's approval.

Understanding the meaning of the governing requirement is important. If the governing requirement is in the *Code of Federal Regulations*, then the meaning and underlying purpose of that requirement should have been established when the agency issued the regulation in a final rule. The staff should first review the language of the regulation. If the meaning of the regulation is not clear, then the staff should review the supporting SOC for the final rule and any guidance that the NRC found to be an acceptable means for implementing or complying with the requirement. If the license contains the governing requirement (e.g., a license condition or technical specification), then the ~~meaning and underlying purpose should be explained in the~~ application and any supplements ~~made to it~~ 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 ~~NRC~~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 ~~matter~~ of the implied approval must be a direct and necessary aspect of the subject ~~matter~~ of the express approval (e.g., the licensee's methodology for implementing the standard). Finally the ~~NRC's approval documentation must expressly discuss the~~ subject ~~matter~~ of the implied approval ~~must be expressly discussed in the NRC's approval documentation~~ (e.g., the NRC's safety evaluation references the methodology but does not make an acceptability finding on the methodology). If the implied approval meets these three criteria, then it is considered an NRC approval for purposes of the compliance exception.

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

- The staff's error occurred while the staff was using standards and practices that, at the time of the original NRC determination, were not commonly recognized as the prevailing professional standards and practices.
- The NRC evaluated the error using professional standards and practices that were developed or accepted after the time of the NRC determination (e.g., the staff determines that the licensee's method of compliance does not meet the requirement based on a changed staff position or new standards and practices that became known after the NRC determination at issue). Such issues may constitute justifiable backfitting; however, backfitting would need to be justified through adequate protection or 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 (e.g., more than 10 years) for which the staff determin~~ing~~<sup>es</sup> that a regulation or requirement is not satisfied, then the staff should identify the benefits of compliance and compare these benefits to the cost of achieving and maintaining compliance to ensure that costs have been adequately considered. The staff should apply a graded approach<sup>18</sup> 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 discern~~ible~~<sup>able</sup> 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.

<sup>18</sup> 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.

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 NRC 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.

#### 2.35.2.3-2.5.2.3 Documenting Compliance Exception Evaluations

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

The office director responsible for issuing the backfitting action must approve any documented evaluation, and The staff should send a copy of the documented evaluation should be sent to the EDO and appropriate regional administrator before the staff transmitting the backfitting documentation to the licensee. If the staff cannot justify the proposed action using the compliance exception, and the staff cannot justify a cost-beneficial substantial safety enhancement, then the staff must document its conclusions as described in Chapter 6 of this NUREG.

**2.36.2.6 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?**

#### 2.36.1-2.6.1 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



1 be justified. If the proposed backfitting action is shown to result in a substantial increase in  
2 overall protection, but the costs cannot be justified, then the backfitting action cannot be  
3 justified. In either event, the staff should document its conclusions as described in Chapter 6 of  
4 this NUREG.

#### 5 6 2.36.2-2.6.2 Determinations of Cost-Justified Substantial Increase in Overall Protection 7 Determinations

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

15  
16 The definition of "substantial" is ultimately a regulatory and policy determination. The  
17 determination, however, that must be rational (i.e., not illogical) and supported by evidence or  
18 fact, as applicable.

19  
20 This approach is flexible enough to allow for arguments that consistency with national and  
21 international standards, or the incorporation of widespread industry practices, contributes  
22 directly or indirectly to a substantial increase in safety. Such arguments concerning consistency  
23 with other standards, or the incorporation of industry practices, may have to rest on the aspects  
24 of a given proposed action.

25  
26 In SRM-SECY-93-086, "Backfit Considerations," the Commission explained that the "substantial  
27 increase" criterion "allow[s] for qualitative consideration of factors to determine that a given  
28 proposed rule would substantially increase safety." In accordance with SRM-SECY-14-0087,  
29 "Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit  
30 Analyses," dated March 4, 2015, this consideration of qualitative factors does not authorize an  
31 expansion of such consideration their expanded use in regulatory analyses and backfit  
32 analyses. Instead, the staff should use qualitative factors in a judicious and disciplined manner  
33 to inform decisionmaking, in limited cases, when quantitative analyses are not possible or  
34 practical (e.g., due to lack of methodologies or data). NUREG/BR-0058 is intended to be a  
35 primary source of guidance on the application of the "substantial increase" standard as well as  
36 the application of the Commission's safety goals. While the staff should strive to use all  
37 available quantitative factors, the consideration of qualitative factors in regulatory  
38 decisionmaking can be important to the overall understanding and discussion of the impacts of  
39 a regulatory action. The quantitative information must meet generally accepted professional  
40 levels of quality and reliability for use in quantitative analyses. Qualitative analysis should be  
41 used in accordance with NUREG/BR-0058. The staff uses a risk-informed decisionmaking  
42 framework as input into determine whether the substantial safety enhancement criterion is met.

43  
44 If the NRC does not have access to quantitative information on benefits or costs when it is  
45 preparing the backfit analysis, then the NRC agency has several alternatives:

- 46  
47 • The NRC can seek to obtain the necessary quantitative benefit or cost information, for  
48 example, by performing a literature search, querying other Federal agencies, requesting  
49 that the information be provided voluntarily (e.g., in a proposed rule Federal Register  
50 notice for a proposed rulemaking), issuing an order or a 10 CFR 50.54(f) letter (for

**Commented [BH91]:** The staff edited this sentence to simplify it and because the original sentence could have been read to mean that regulatory and policy determinations are not rational or logical.



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 ~~or impose a change affecting issue~~ ~~finality~~.

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

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

**Commented [BH92]:** The staff deleted these words because they imply that a backfit analysis is necessary to impose a change affecting issue finality.

**Commented [KA93]:** The staff changed "plant" to "facility" in this sentence because the facility may not always be a nuclear power plant.

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.

#### ~~2.36.3~~ 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 ~~40 CFR Part 50,~~ 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 ~~supplied~~ and the level of detail provided.

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

#### 2.36.4-2.6.4 Issue Finality

Commented [BH94]: Comment 4.2.37

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. For proposed actions that affect the issue finality of a Part 52 approval, the staff must determine whether that proposed action satisfies the criteria in the issue finality provision that applies to the Part 52 approval. Because the issue finality provisions in Part 52 vary by approval, the details of the criteria will depend on the Part 52 approval.

The staff may need to prepare a backfit analysis as described in this Section 2.6 or an analysis specific to the issue finality provision, which is an "issue finality analysis." To address the issue

1 finality criteria, the staff should prepare an **assessment** specific to the applicable issue finality  
2 provision. The staff can use a guide in Appendix C to this NUREG, revised as appropriate for  
3 the issue finality criteria, to document this issue finality **assessment**.  
4  
5

**Commented [BH95]:** The staff changed from "analysis" to "assessment" to be consistent with the terminology used for backfitting and forward fitting.

### 3 FORWARD FITTING

#### 3.1 Background

Management Directive (MD)-8.4, “~~Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,~~” dated September 20, 2010, contains the Commission’s forward fitting policy. Forward fitting is similar to backfitting in that forward fitting it promotes regulatory stability, reasoned decisionmaking, and transparency. Like backfitting, forward fitting occurs when requires the U.S. Nuclear Regulatory Commission (NRC) to justify the imposition imposes on an affected entity (i.e., one of the entities listed in Section 2.3 of this NUREG) ~~licensee~~ of a new or amended requirement or staff interpretation of a requirement that results in the modification of or addition to systems, structures, components, or the design of a facility; ~~or the~~ design approval or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a facility. However, unlike backfitting, forward fitting occurs only during licensing actions that are initiated voluntarily by an affected entity licensee, when the imposition of. ~~The forward fit happens when the NRC imposes the~~ qualifying new or amended requirement or staff interpretation of a requirement is a condition<sup>1</sup> of approving the ~~licensee’s affected entity’s~~ requested licensing action, and the ~~licensee’s affected entity’s~~ underlying request ~~did 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 ~~to~~ only to those ~~licensees affected entities~~ that are ~~also~~ within the scope of backfitting provisions. Forward fits generally do not include instances when an applicant files an initial licensing action for a new facility. However, 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 upon in ~~the development of~~ their applications, the NRC staff should follow the same reasoned decisionmaking process as it would to impose a forward fit.

#### 3.2 Forward Fitting Determinations Screening

To determine whether ~~the 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 ~~must be is~~ true:

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

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

<sup>1</sup> The use of “condition” in forward fitting is not limited to a license condition. It is an NRC-imposed stipulation to its approval.

**Commented [BH96]:** The staff’s edits in Section 3.1 clarify the definition of a “forward fit” and introduce the justification and cost consideration elements of the forward fitting assessment, which Section 3.1 of the draft NUREG did not do.

**Commented [BH97]:** These edits align forward fitting screening with the questions in backfitting screening (i.e., does the proposed action apply to an entity within the scope of forward fitting, and would the proposed action meet the definition of a forward fit).

**Commented [KA98]:** The staff switched the order of statements 1 and 2 to reflect a more efficient application of the screening questions.

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

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

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

(4) The imposition of the new or changed requirement or interpretation will result in a modification or addition to any of the following:~~the licensee's—~~

(a) systems, structures, or components of its the affected entity's facility;

(b) design (including but not limited to design certification, standard design approval, or manufacturing license) of its the affected entity's facility; ~~or~~

(c) procedures or organization required for designing, constructing, or operating its the affected entity's facility.

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

(6) The licensee's affected entity's underlying request ~~did NOT~~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 and proceed to take the proposed action. 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 constitutes meets the definition of a "forward fitting," and the staff must justify the proposed action to impose it.

Forward fitting can occur in various ways. The NRC would be forward fitting a licensee if the staff required the licensee to use a newer version of a regulatory guide to demonstrate compliance with an existing requirement than the version the licensee proposed to use in its

**Commented [AK99]:** The staff added this guidance to clarify statement #6.

**Commented [KA100]:** The staff added these examples to address actions that do not meet the definition of forward fitting.

**Commented [KA101]:** The staff revised this paragraph to clarify that, when the proposed action does not meet the definition of a forward fit, the NRC may still take the proposed action if certain conditions are met.

requested licensing action. Forward fitting could also occur when the staff uses a guidance document in its review of the licensee's request that the licensee did not use when it submitted its request, and the staff conveys the expectation that the licensee use that guidance document in preparing the request or responding to requests for additional information related to the request.

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

Other examples of forward fitting include the following:

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

escalating regulatory commitments into licensing conditions; or

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

### 3.3 Forward Fitting Justification Justifying Forward Fits and Documenting the Analyses

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.

**Commented [RT102]:** The staff deleted this paragraph because some of these examples would be backfitting under the revised forward fitting framework. Also, Section 3.4 provides more detailed scenarios.

**Commented [KA103]:** The staff moved this paragraph to Section 1.2.2.2.

**Commented [BH104]:** The staff deleted this paragraph because some of these examples would be backfitting under the revised forward fitting framework. Also, Section 3.4 provides more detailed scenarios.

**Commented [BH105]:** Comments 4.3.3, 4.3.4

**Commented [BH106]:** Comment 4.3.4

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

14 For a forward fit to be "essential," it must be necessary for the NRC staff to make the safety or  
15 security finding to support the agency's approval of the affected entity's request. A forward fit  
16 that is "necessary to make the safety or security finding" will likely be necessary for adequate  
17 protection<sup>2</sup> or continued compliance with all applicable requirements, but the definition of  
18 "essential" is not limited only to adequate protection or compliance because the standards for  
19 the NRC findings differ depending on the licensing action. For example, Title 10 of the Code of  
20 Federal Regulations (10 CFR) 50.92, "Issuance of amendment," and 10 CFR 50.40, "Common  
21 standards," require that, for license amendments, the staff conclude that there is reasonable  
22 assurance that the public health and safety will not be endangered by operation in the proposed  
23 manner, there is reasonable assurance that such activities will be conducted in compliance with  
24 the Commission's regulations, and the issuance of the amendments will not be inimical to the  
25 common defense and security or to the public health and safety. The conclusions needed for  
26 determining the acceptability of relief requests, proposed alternatives, exemptions, or other  
27 requests will differ from those for license amendments. The staff should use the applicable  
28 regulations and guidance for a specific requested licensing action review to determine what  
29 information, including risk insights, is essential to make a conclusion on the acceptability of the  
30 request.

32 The NRC's use of the term "compliance" in a forward fitting context is not the same as use of  
33 the term "compliance" in a compliance exception under the Backfit Rule. In the forward fitting  
34 context, "compliance" looks ahead to ensure that the affected entity would continue to comply  
35 with all applicable requirements following the NRC's review and approval of the request. In  
36 contrast, "compliance" when used in the context of compliance exception backfits looks back to  
37 the time of a previous NRC approval. The use of risk also differs in these two processes. When  
38 considering a compliance backfitting action, the staff should evaluate the safety or security risk if  
39 the NRC does not take the backfitting action. With forward fitting, if the staff does not impose  
40 the condition necessary to ensure compliance, then the staff would be knowingly approving a

<sup>2</sup> 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.

Commented [BH107]: Comments 4.3.4, 4.3.6

Commented [BH108]: Comment 4.3.4

Commented [BH109]: The staff added this discussion of risk in the context of forward fits necessary for compliance.



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.

Whenever the staff intends to forward fit a licensee, the staff must justify the forward fit. The NRC justifies the forward fit through an analysis that shows the following criteria are met: (1) there is a direct nexus between the new or modified requirement or regulatory staff position and the licensee's request and (2) the imposition of the new or modified requirement or regulatory staff position is essential to the NRC staff's determination of the acceptability of the licensee's request. The staff must also consider the costs of the forward fitting action unless adequate protection is involved, as discussed below. The staff should identify the benefits of the forward fit and compare these benefits to the cost of implementation. Based on a risk-informed evaluation, if the safety benefit of imposing the forward fit is determined to be very low or negligible, then the staff should no longer consider imposing the forward fit. For forward fits having greater safety benefit, the staff should further inform the regulatory decision process by considering the costs and benefits of the proposed forward fit. The Commission gives the staff substantial flexibility to determine how much cost consideration is appropriate based on the specific facts of each case and the identified risk.

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

The second criterion is that the imposition of the new or modified requirement or regulatory staff position is essential for the NRC staff to make a finding that the licensee's requested licensing action is acceptable (i.e., without the imposition, the staff could not make its safety or security finding). What is essential to make such a determination will vary depending on the type of request. For example, for license amendments, Title 10 of the Code of Federal Regulations (10 CFR) Section 50.92, "Issuance of amendment," and Section 50.40, "Common standards,"

Commented [KA110]: Comment 4.3.7

Commented [BH111]: Comments 4.3.16, 4.3.17, 4.3.18

1 ~~require that the staff conclude that there is reasonable assurance that public health and safety~~  
2 ~~will not be endangered by operation in the proposed manner, there is reasonable assurance~~  
3 ~~that such activities will be conducted in compliance with the Commission's regulations, and the~~  
4 ~~issuance of the amendments will not be inimical to the common defense and security or to the~~  
5 ~~public health and safety. The conclusions needed for determining the acceptability of relief~~  
6 ~~requests, proposed alternatives, exemptions, or other requests will differ from those for license~~  
7 ~~amendments. The staff should use the applicable office instructions or guidance for a specific~~  
8 ~~review to determine what information is essential to make a conclusion on the acceptability of~~  
9 ~~the request.~~

10  
11 ~~If the staff concludes that the two criteria are met and it cannot approve the licensee's requested~~  
12 ~~action because reasonable assurance of adequate protection would not be maintained, then the~~  
13 ~~staff can deny the request, ask for additional information, or approve the request with a forward~~  
14 ~~fit to maintain reasonable assurance of adequate protection. Requesting additional information~~  
15 ~~through carefully worded questions to the licensee is an appropriate method for obtaining the~~  
16 ~~information the staff needs to make its finding. These information requests must not tell the~~  
17 ~~licensee what it needs to do to obtain staff approval. The staff also should not provide advice or~~  
18 ~~direction to a licensee that is not appropriate given the staff's role as the regulator. To ensure~~  
19 ~~that requests for additional information are not phrased as forward fits, the staff should clearly~~  
20 ~~articulate why it cannot make its safety finding and leave responsibility for solutions to the~~  
21 ~~licensee. If the staff pursues a forward fit, the staff would not need to consider the costs of the~~  
22 ~~forward fit because it involves adequate protection.~~

23  
24 ~~If the staff determines that the two criteria are met and it cannot approve the licensee's~~  
25 ~~requested action because granting the request would not provide reasonable assurance that the~~  
26 ~~licensee's activities would be conducted in compliance with the Commission's regulations, but~~  
27 ~~the staff's determination does not involve adequate protection (because a licensee's non-~~  
28 ~~compliance with one or more applicable requirements does not necessarily mean that public~~  
29 ~~health and safety are no longer adequately protected), then the staff can deny the request, ask~~  
30 ~~for additional information, or approve the request with a cost justified forward fit to ensure~~  
31 ~~continued compliance with the Commission's regulations. The licensee can also request an~~  
32 ~~exemption from the applicable regulation. If the forward fit cannot be cost justified, then the staff~~  
33 ~~may have to deny the request. The NRC's denial of the request may allow the licensee to seek~~  
34 ~~redress of the denial through a demand for hearing.~~

35  
36 ~~If the staff concludes that the two criteria are met, but unlike in the situations in the preceding~~  
37 ~~paragraphs, the forward fit consists of the imposition of a modified regulatory staff position and~~  
38 ~~the existing regulatory staff position is available for current licensees to use and applicable to~~  
39 ~~the licensing action under the staff's review, then the Commission policy is that the staff should~~

**Commented [BH112]:** The staff replaced these paragraphs with the preceding paragraphs describing the definitions of "direct nexus" and "essential," although some text was moved to the new Section 3.5 on "cost consideration."

**Commented [BH113]:** The staff deleted this paragraph and the next one because the scenarios described therein would not be possible under the revised forward fitting framework. If the staff cannot approve the requested action even with the staff's proposed condition, then the condition does not meet the definition of "direct nexus," "essential," or both.

**Commented [BH114]:** Comment 4.3.12

**Commented [BH115]:** The staff moved the substance of this paragraph to new Section 3.5, "Cost Considerations."

perform a site-specific regulatory analysis of the forward fit unless the forward fit is necessary for adequate protection of the public health and safety.<sup>3</sup>

### 3.4 Forward Fitting Screening and Justification Scenarios

Commented [KA116]: Comment 4.3.15

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.

<sup>3</sup> However, as explained in MD-8.4, forward fits in this situation will not usually be justifiable as necessary for adequate protection because the NRC already had an opportunity to consider whether the new or changed requirement or staff position was necessary for adequate protection of the public health and safety. This occurred when the NRC established or modified the requirement or regulatory staff position and the NRC determined whether the resulting position should be imposed as a backfit on existing facilities. Under the mandatory backfitting provisions of 10 CFR 50.109(a)(5), 70.76(a)(5), and 76.76(a)(5), and the portions of 10 CFR 72.62(b) about backfitting necessary to ensure adequate protection of the public health and safety, if such a change were necessary to ensure adequate protection of the public health and safety when the new or modified requirement or regulatory staff position was made, the NRC would have been required to impose it as a backfit. Because such a backfit has not been imposed if the staff is considering a forward fit, it is unlikely that a change could be justified to be necessary to ensure adequate protection of the public health and safety.

#### **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

Commented [KA117]: Comment 4.3.30

Commented [BH118]: Comment 4.3.30

1 the NRC's proposed forward fit. If the affected entity has already incurred costs associated with  
2 the request, then the affected entity assumes that licensing risk. The cost estimated for the  
3 forward fit would exclude those costs.

4  
5 The staff should compare the costs of all methods of implementing the forward fit and the select  
6 least costly alternative. When there is only one method to implement the forward fit, then the  
7 staff should evaluate the incremental cost of the forward fit. Because the staff has the option to  
8 deny the requested licensing action and the affected entity has the option to revise or withdraw  
9 its request, the cost consideration can inform the decisionmaking path. The staff may use a  
10 regulatory analysis to demonstrate its cost consideration. NUREG/BR-0058 provides guidance  
11 on the preparation of a regulatory analysis.

12  
13 If the forward fit consists of a new or modified regulatory staff position and the prior regulatory  
14 staff position is no longer available for the applicant to use, then the staff must consider the  
15 costs of the forward fit. If the prior staff position is no longer available for use, then the staff  
16 should have performed a regulatory analysis when the staff issued the new or modified staff  
17 position that replaced the prior staff position. The staff should use that generic regulatory  
18 analysis, if available, to inform the site-specific regulatory analysis.

19  
20 If a forward fit would impose a generic staff position on the affected entity (i.e., a staff position  
21 that is not within that affected entity's licensing basis), then the staff should inform its  
22 facility-specific regulatory analysis using the generic regulatory analysis that was performed by  
23 the staff when it issued the generic staff position. If no prior staff position exists because  
24 approval of the requested licensing action without a condition would create a safety or security  
25 issue or noncompliance that would not exist but for the requested licensing action presents a  
26 case of first review and, thus, no applicable regulatory analysis exists, then the staff still needs  
27 to consider the costs of the forward fit but is not required to perform a site-specific regulatory  
28 analysis.

29  
30 If, during the staff's review of the licensing action, the staff discovers an issue of adequate  
31 protection with the current licensing basis, then the staff must address the existing issue through  
32 the backfitting process.

### 33 3.6 Documenting the Forward Fit Assessment

34  
35 Appendix C to this NUREG contains a guide for drafting a forward fit analysis-assessment to  
36 justify support a forward fitting action. Unlike a backfit analysis described in Section 2.6 of this  
37 NUREG, a forward fit analysis-assessment contains the staff's evaluation of the proposed action  
38 against the definitions of a "forward fit," and the "direct nexus" and "essential" and to the staff's  
39 finding" criteria, and the staff's consideration of the costs of the forward fit or its basis for  
40 determining that the forward fit involves adequate protection.

Commented [BH119]: Comment 4.3.9

Commented [BH120]: The staff revised this paragraph and made it the first sentence of the next paragraph.

Commented [BH121]: MD 8.4, Comment 4.3.28

Commented [BH122]: The staff deleted this text because a regulatory analysis is "site specific" if it supports a "site specific" licensing action.

Commented [BH123]: This sentence became the last sentence in Scenario 4 in Section 3.4.

## 4 BACKFITTING AND FORWARD FITTING MANAGEMENT DIRECTIVE

### 8.4 APPEALS

#### 4.1 Introduction

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

The U.S. Nuclear Regulatory Commission (NRC) provides a process in Management Directive (MD) 8.4 by which an affected entity<sup>1</sup> may appeal a proposed or issued staff action on the basis that when the licensee concludes believes the staff did not properly follow the performance a backfitting or forward fitting assessment process. This NUREG refers to a backfitting or forward fitting appeal as an "MD 8.4 appeal."<sup>1</sup> Each communication of a backfitting or forward fitting action issued to a licensee must include instructions on the use of the appeal process. If the licensee elects to file a backfitting or forward fitting appeal when it receives the written staff action, the licensee must submit the appeal in writing, in accordance with Section 50.4, "Written communications," of Title 10 of the Code of Federal Regulations (10 CFR), with a copy to the appropriate regional administrator and program office director (i.e., depending on the licensee, the Director for either the Office of Nuclear Reactor Regulation (NRR) or the Office of Nuclear Material Safety and Safeguards (NMSS)). For a second level appeal, the licensee must submit the written appeal in accordance with 10 CFR 50.4, with a copy to the Executive Director for Operations (EDO).

The NRC will not accept oral appeals of backfitting or forward fitting actions or appeals submitted by a third party. In these cases, the staff will not consider any appeal until it receives a written appeal from a licensee. If the NRC initiated a staff action using an order, the appeal process described in this section does not apply. After the NRC issues an order, appeals are governed by the provisions of 10 CFR Part 2, "Agency Rules of Practice and Procedure," Subpart B, "Procedure for Imposing Requirements by Order, or for Modification, Suspension, or Revocation of a License, or for Imposing Civil Penalties," as specified in Management Directive (MD) 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," dated September 20, 2019.

For backfitting or forward fitting appeals, licensees have two levels of appeal: a first level appeal at the office director level<sup>2</sup> and a second level appeal to the EDO. Licensees-Affected entities can use the backfitting or forward fitting MD 8.4 appeal process only in either of the following situations:

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

<sup>2</sup> In accordance with MD 8.4, the regional administrator is not the official decision maker but is expected to be involved and may be the one receiving the appeal.

**Commented [KA124]:** The staff reorganized this chapter to clarify and add new guidance on submitting and processing appeals. The staff significantly revised the chapter, so the tracked changes view may not be helpful.

**Commented [KA125]:** The staff revised and moved the information in this paragraph to Section 4.2.

**Commented [KA126]:** Comments 4.4.3, 4.4.16, 4.4.17 (Conforming changes were made throughout the NUREG to reflect that the appeal process applies to proposed and issued actions.)

**Commented [KA127]:** Revised to reflect MD 8.4 language.

**Commented [BH128]:** Comment 4.4.2

**Commented [KA129]:** The staff revised and moved this information below in this Chapter 4 introduction.

**Commented [BH130]:** The staff revised and moved the information in this paragraph to Section 4.2.

**Commented [KA131]:** The staff revised and moved information from this paragraph to Section 4.2.

**Commented [KA132]:** The staff moved this information below in this Chapter 4 introduction.



- 1
- 2
- 3
- 4
- 5
- The NRC staff imposed (or will impose) a new or revised applicable staff position or requirement on the affected entity/licensee that the staff determined was not (or will not be) backfitting or forward fitting, but that the affected entity/licensee believes is (or will be) backfitting or forward fitting.

**Commented [KA133]:** The staff believes this language reflects the intent of the Commission's policy.

- 6
- 7
- 8
- 9
- 10
- 11
- 12
- The NRC staff imposed (or will impose) a new applicable staff position or requirement on the licensee-affected entity that the staff determined was (or will be) backfitting or forward fitting, but that the affected entity/licensee 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.

**Commented [KA134]:** The staff believes this language reflects the intent of the Commission's policy.

13

14

15

16

17

18

19

20

21

22

Affected entities/licensees have two levels of appeal: a first-level appeal at the office director level<sup>3</sup> 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.

**Commented [KA135]:** The staff added this guidance to optimize agency resources pertaining to appeals involving proposed and issued agency actions.

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

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

**Commented [KA136]:** The staff revised and moved the information in this paragraph to Section 4.3.

<sup>3</sup> 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.<sup>4</sup> 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 staff<sup>5</sup> who disagree with an agency action.

Commented [KA137]: Comment 4.4.20

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 Section 50.4, "Written communications," or 10 CFR 52.3, "Written communications," as applicable, of Title 10 of the Code of Federal Regulations (10 CFR), with a copy to the appropriate regional administrator, and program office director (i.e., depending on the licensee. For appeals to the Director for either the Office of Nuclear Reactor Regulation (NRR) or 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/Executive Director for Operations (EDO). 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.

Commented [KA138]: Comment 4.4.13

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.

Commented [KA139]: The staff added this paragraph to specify who from within the licensee's organization should submit an appeal.

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 position or provide other information that is relevant and material to the staff's action or position 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 a 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.

<sup>4</sup> 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.

<sup>5</sup> The NRC staff may choose to use the Differing Professional Opinion or nonconcurrence 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 appeals 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 provide additional information about the level of public participation in MD 8.4 appeal public meetings.

Commented [KA140]: Comment 4.4.12

#### 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.

Commented [BH141]: The staff moved this paragraph from the draft NUREG Chapter 1's discussion of generic backfitting actions.

#### 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.

Commented [KA142]: The staff added the next two sections to account for proposed and issued actions and address the relationship between appeals and the Part 2 processes.

##### 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.

Commented [KA143]: Comments 4.4.4, 4.4.12, 4.4.16, and 4.4.17

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

1 be appealed (under 10 CFR Part 2) to the Commission. in this instance, the ASLB and  
2 Commission would replace the MD 8.4 first-level and second-level appeals, respectively.  
3  
4 If the affected entity does not pursue an adjudicatory hearing, then it may submit an MD 8.4  
5 appeal in accordance with this chapter only if the affected entity did not already submit an  
6 MD 8.4 appeal of the proposed order and the issued order is not substantively different from the  
7 proposed order. If the NRC initiated a staff action using an order, the appeal process described  
8 in this section does not apply. After the NRC issues an order, appeals are governed by the  
9 provisions of 10 CFR Part 2, "Agency Rules of Practice and Procedure," Subpart B, "Procedure  
10 for Imposing Requirements by Order, or for Modification, Suspension, or Revocation of a  
11 License, or for Imposing Civil Penalties," as specified in Management Directive (MD) 8.4,  
12 "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," dated  
13 September 20, 2019.

#### 14 15 4.2.4.2 Violations and Management Directive 8.4 Appeals

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

23  
24 An affected entity may submit an MD 8.4 appeal of a predecisional violation; however, doing so  
25 may be premature and not result in an efficient use of NRC or affected entity resources.  
26 Predecisional violations discussed at exit meetings are subject to subsequent NRC  
27 management review before the NRC issues the inspection report, violation, or choice letter or  
28 conference letter. After an exit meeting, the NRC inspector may continue to review supporting  
29 documentation and consult with other NRC staff to ensure proper disposition of the issue of  
30 concern. The affected entity may not be aware of the latest status of the proposed violation  
31 after the exit meeting until or unless the NRC communicates a change in the proposed  
32 violation's status to the affected entity, and the proposed violation may change or not be issued  
33 at all.

34  
35 To optimize NRC and affected entity resources, the NRC has the following options for  
36 processing MD 8.4 appeals associated with predecisional violations, apparent violations  
37 documented in choice or conference letters, or violations issued in inspection reports or other  
38 correspondence.

- 39  
40 1. If the affected entity submits an MD 8.4 appeal prior to issuance of the inspection report,  
41 violation, or choice or conference letter (i.e., the appeal would be based on predecisional  
42 oral communications), then the NRC may choose one of the following options:
  - 43  
44 a. The NRC may hold the MD 8.4 appeal in abeyance until the NRC issues the  
45 report, violation, or choice or conference letter. The NRC will document the  
46 existence of the MD 8.4 appeal in either an inspection report or separate  
47 correspondence and obtain written confirmation from the affected entity on how it  
48 wishes the NRC to proceed with the MD 8.4 appeal (e.g., the affected entity  
49 may choose to withdraw or modify its appeal based on the contents of the  
50 inspection report, violation, or choice or conference letter).

Commented [AK144]: Comments 4.4.15, 4.4.16, 4.4.17

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 after issuance of the violation (e.g., during resolution of a disputed or denied 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 lapsed.

#### 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).

Commented [AK145]: Comments 4.3.16, 4.3.17, 4.3.18, 4.4.3, 4.4.16, 4.4.21

### 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 Backfitting or Forward Fitting Appeals and Initiation of the First-Level Appeals Process

- (a) The first-level appeals process begins upon when the NRC's receipt of 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 backfitting or forward fitting appeal, the NRC staff should notify the following individuals or designees and provide them with a copy of the appeal:
1. the Backfitting and Forward Fitting Community of Practice through the NRR or NMSS representatives, as applicable members in the applicable program and regional offices;
  2. the managers in charge of the offices, divisions, and branches that proposed or issued the action in question and, if not any other organizations that issued the action in question, that are responsible for the technical, regulatory, or policy areas in question;
  3. the Deputy General Counsels;
  4. the director of the Office of Enforcement;
  5. the chairperson~~man~~ of the Committee to Review Generic Requirements;
  6. the regional administrator for the affected entity that submitted the appeal~~affected facility; and~~
  7. the licensing project manager for the affected entity~~licensee~~ that submitted the appeal.

##### 4.3.1.2 Determination of Oversight Responsibility and First-Level Appeal Screening

The NRC will accept appeals from only those licensees for which the NRC action constitutes a backfit or forward fit and only if they are subject to the backfitting provisions in 10 CFR Chapter I. The NRC will not accept appeals from NRC staff<sup>6</sup> who disagree with an agency action or position. Licensees should submit written

<sup>6</sup> NRC staff should utilize the Differing Professional Opinion or non-concurrence processes.

appeals within 90 days of receiving the NRC's written action or staff position or 30 days after the NRC issues its decision on a directly related disputed violation.

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

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

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

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

1. the Backfitting and Forward Fitting Community of Practice members in the applicable program and regional offices;
2. the managers in charge of the offices, divisions, and branches that issued the action in question and, if not the organization that issued the action in question, are responsible for the technical, regulatory, or policy areas in question;
3. the Deputy General Counsels;
4. the director of the Office of Enforcement;
5. the chairman of the Committee to Review Generic Requirements;
6. the regional administrator for the affected facility; and
7. the licensing project manager for the affected licensee

(a) The Director of NRR or NMSS, depending on the licensee as appropriate, will oversee the first-level appeal process and issue the decision on the appeal. This office director (hereafter referred to as the Responsible Manager) will coordinate the review of the first-level appeal with the regional administrator overseeing the affected licensee 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 45 business days of the date when the NRC receives 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/licensee by acknowledging receipt of the appeal and communicating either the staff's review plans for staff review 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.



#### 4.2.1.4.3.1.3 Review of the First-Level Appeal

(a) The ~~R~~responsible ~~M~~anager may appoint a panel to review documentation associated with the appeal and NRC action ~~or position~~ at issue. This panel, if ~~appointed~~, should consist of individuals who are independent from the ~~initial~~ action ~~or position~~ at issue (i.e., the individuals did not take part in ~~developing~~, reviewing, or approving the ~~initial~~ staff action). A manager at the deputy division director level or higher should chair the panel, and members ~~hip~~ should include an attorney from OGC and staff or management with the appropriate technical and regulatory expertise and experience to thoroughly evaluate the action ~~or position~~ at issue. The remaining steps assume that a panel has been appointed. If not, the ~~R~~responsible ~~M~~anager 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, this public meeting should occur within 45- calendar days of the NRC's receipt of the appeal. The panel will not make any regulatory decisions may be made at this 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 Ssummaries of all MD 8.4 appeal public meetings with the affected entity.licensee should be prepared and placed in the NRC's Agencywide Documents Access and Management System as specified in MD 3.5, "Attendance at NRC Staff-Sponsored Meetings." 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 need 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.~~

**Commented [AK146]:** The staff "action" could include the imposition of a staff position.

**Commented [AK147]:** Comment 4.4.13



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

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

#### 4.2.1-2.4.3.1.4 Response to the First-Level Appeal

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

(b) The Responsible Manager ~~will evaluate~~ the information and recommendation provided by the panel ~~and decides whether to grant or deny the appeal~~. The Responsible Manager ~~will draft/develops~~ a response letter to the affected entity/licensee 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 ~~will inform~~ the appropriate Deputy EDO before communicating the outcome in writing to the affected entity/licensee. ~~To the extent practical, the Responsible Manager should transmit the written response to the licensee within 90 calendar days of receipt of the appeal.~~

~~(c) To the extent practical, the responsible manager should transmit the written response letter to the affected entity within 90 calendar days of receipt of the appeal.~~

~~(d) If the NRC is granting 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., issuing an order or withdrawing or not issuing a violation request for additional information).~~

~~(e) If the NRC is denying 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/licensee that it may either 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).~~

~~or~~The NRC's response letter should also state that if the affected entity/licensee 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 take actions to comply into compliance with the agency's NRC's issued action/decision, 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 licensee to come into compliance with the NRC's issued action.

1 If, after the appeal decision upholding an NRC-issued action, the affected entity fails  
2 ~~to either does not submit a second-level~~ appeal ~~the decision within the timeframe~~  
3 ~~specified in the first-level appeal response letter- 30-calendar days or does not~~  
4 ~~implement the required action~~, then the NRC will resolve the issue through the  
5 ~~enforcement program~~ may take appropriate action to address the affected entity's  
6 noncompliance.

Commented [KA148]: Comment 4.4.7

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

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

#### 21 **4.3.2 Initial Review of a Second-Level Appeal**

##### 22 4.3.2.1 Receipt of an Appeal and Initiation of the Second-Level Appeal Process

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

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

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

33 ~~c.~~

34 d.b. Upon receipt of a second-level appeal, the NRC staff should notify the following  
35 individuals or designees ~~should be notified~~ and provided them with a copy of the  
36 appeal:

38 1. the responsible manager for the first-level appeal

39 4.2. the Backfitting and Forward Fitting Community of Practice through the  
40 NRR or NMSS representatives, as applicable members in the applicable program  
41 and regional offices;

42 2.3. managers in charge of the offices, divisions, and branches that proposed  
43 or issued the action in question and, if not any other organizations that issued the  
44 action in question, are responsible for the technical, regulatory, or policy areas in  
45 question;

46 3.4. the Deputy General Counsels;

47 4.5. the director of the Office of Enforcement;

48 5.6. the chairperson of the Committee to Review Generic Requirements;

7. the regional administrator for the affected entity~~licensee~~ that submitted the appeal~~affected facility~~
6. the licensing project manager for the affected licensee~~entity~~ that submitted the appeal;
7. the Responsible Manager involved in the first level appeal; and
8. the regional administrator for the affected facility

#### 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 1520 business days of agency the NRC's receipt of the appeal, the EDO (or designee) should respond to the affected entity~~licensee~~ by acknowledging receipt of the appeal and communicating either ~~high level~~ 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 ~~for staff review~~.

#### 4.2.1.3

#### 4.2.1.4

#### 4.2.1.5-4.3.2.3 Review of the Second-Level Appeal

- a. The EDO may appoint a panel to review documentation submitted by the licensee~~affected entity~~ with the second-level appeal, the results of the first-level appeal, and the initial proposed or issued action ~~or position~~ at issue. The panel should consist of managers at the deputy division director level or higher and an attorney from OGC; ~~each~~ with the appropriate technical and regulatory expertise and experience to thoroughly evaluate the action ~~or position~~ at issue. and who ~~Panel members should not have not previously participated in the initial proposed or issued action or staff position nor first-level appeal.~~ The members of the panel should collectively have expertise in both the technical issues and the regulatory issues at hand. The remaining steps assume that a panel has been appointed. If not, the EDO ~~(or their designee)~~ assumes responsibility for the actions in this section that a panel would otherwise conduct.
- b. 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 ~~The NRC must offer the affected entity~~~~licensee~~ a public meeting in which the second level appeal can be discuss ~~ed~~ with the panel reviewing the 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 ~~may be made at this 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 NRC staff panel should prepare and issue summaries of all MD 8.4 appeal public appeal meetings with the affected entity licensee within 30 calendar days of the meeting, 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.

Commented [AK149]: Comment 4.4.13

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

c.

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

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

#### ~~4.2.1-6~~ 4.3.2.4 Response to the Second-Level Appeal

- a. The panel will documents its recommendation on whether to grant or deny the appeal in a memorandum from the panel chairperson to the EDO. The memorandum ~~should~~ documents the basis for the panel's recommendations.
- b. The EDO will evaluates the information and recommendation provided by the panel and ~~make a decision on whether to grant or deny~~ the appeal. The EDO will ~~draft~~ prepares a response letter to the affected entity licensee that comprehensively documents the basis for the EDO's decision and submits the draft response letter to OGC for its review.

- 1  
2  
3 c. To the extent practical, the EDO ~~should transmit~~ the response letter to the affected  
4 entity/licensee within 90 calendar days of the NRC's receipt of the second-level  
5 appeal. If applicable, this letter should also inform the licensee that the agency may  
6 issue an enforcement order if the licensee refuses to comply with the staff's position.
- 7 d. If the NRC grants the appeal, then the agency must also initiate the appropriate  
8 actions to ensure that the affected entity's licensing basis reflects the outcome of the  
9 appeal process (e.g., issuing an order or withdrawing a request for additional  
10 information or not issuing a violation).
- 11  
12 d. If the NRC denies the appeal (i.e., the EDO determines that the proposed or issued  
13 staff action is justified backfitting or forward fitting, or that the proposed or issued  
14 staff action is not backfitting or forward fitting), then the response letter ~~should~~  
15 inform the affected entity/licensee that: (1) if the NRC has already issued the action,  
16 then the NRC expects the affected entity will it must come into compliance with the  
17 agency's decision issued action, or (2) if the NRC has not yet issued the action, then  
18 the NRC will issue the proposed action with which the NRC expects the affected  
19 entity will comply. If, after issuance of the second-level appeal decision, the affected  
20 entity/licensee fails to does not implement the required action, then the NRC may take  
21 appropriate action to address the affected entity's noncompliance will resolve the  
22 issue through the enforcement program.
- 23 e. —
- 24 f. — In the case of a denied appeal of a forward fit that the NRC staff communicated to a  
25 licensee prior to the NRC staff completing a licensing action, the licensee may:  
26 (1) withdraw or modify its request for the licensing action, (2) agree to the forward fit,  
27 or (3) do nothing. If the licensee chooses option (2), then the NRC would issue the  
28 licensing action with the forward fit. If the licensee selects option (3), then the NRC  
29 could either deny the request in part or in whole or issue the licensing action with the  
30 forward fit. The NRC's denial of the request may allow the licensee to seek redress  
31 of the denial through a demand for hearing.
- 32  
33 g-e. If the NRC grants the appeal, then the agency must also initiate the appropriate  
34 actions to ensure the licensee's licensing basis reflects the outcome of the appeal  
35 process (e.g., issuing an order or withdrawing a request for additional information).  
36

Commented [KA150]: Comment 4.4.7



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

This chapter discusses the relationship of backfitting, issue finality, and forward fitting to ~~other 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 that might apply to backfitting and forward fitting.

### 5.1 Licensing Bases and Processes

~~Footnote 3 in Section 1.2 of this NUREG refers to the definition of licensing basis, as described in NRR Office Instruction LIC-100, "Control of Licensing Bases for Operating Reactors." LIC-100 provides a basic framework for making decisions about creating, revising, or deleting licensing basis information for operating power reactors. This document describes the terminology and characteristics of various documents that make up the licensing bases for an operating nuclear power plant. Not all information that constitutes Not all licensing basis information<sup>1</sup> 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 licensing basis information<sup>2</sup> is within the scope of the backfitting and forward fitting provisions (e.g., regulatory commitments that were not escalated into requirements). Likewise, some staff positions applicable to a facility may be within the scope of the backfitting and forward fitting provisions but do not constitute licensing basis information (e.g., safety evaluations) 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. Therefore, the staff should use caution when discussing licensing basis terminology.~~

#### 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

<sup>1</sup> 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.

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

**Commented [KA151]:** Comment 4.5.1 (restructuring Chapter 5)

This chapter was significantly restructured to group similar topics. Text from the draft NUREG that was relocated to its new location in this chapter of this version was "accepted" in its new location and appears as black font, and any changes to that text are shown in tracked changes.

**Commented [KA152]:** The staff added this clarification to better reflect how the guidance in Chapter 5 relates to backfitting and forward fitting.

**Commented [AK153]:** Comment 4.5.31

**Commented [KA154]:** Comment 4.5.31

are typically made through rulemaking or a notice of interpretation. Section 5.2.2 of this NUREG has additional guidance on SOC's.

#### 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 provide guidance to applicants in developing the principal design criteria (PDC) to include in applications for construction permits. The AEC stated that these GDC would not add any new requirements but were intended to describe more clearly the Commission requirements at that time to assist applicants in preparing applications. The AEC published the final rule (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 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 has published guidance on establishing PDC for these designs in 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 in those circumstances in which where the GDC is prescriptive, in nature, and the technical specifications, other licensee requirements derived from the GDC, and the PDC do not address the matter in question.

#### 5.1.1.2 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. ~~Because an order amends a license, an order issued to require a licensee to take actions to maintain or increase the protection of the public health and safety or the common defense and security generally would constitute backfitting, unless the action is an already applicable requirement, or an already applicable and imposed staff position.~~

Commented [KA155]: Comment 4.5.24 (grouping orders and confirmatory orders together).

#### 5.1.1.2.1 Imminent Threat Analyses

The NRC ~~may~~ issues an immediately effective safety or security order that requires an affected entity to implement a backfit or change affecting issue finality for taking a backfitting action before completing any of the backfitting requirements as long as the Director of NRR or NMSS, ~~as appropriate, when the NRC determines, through an imminent threat analysis,~~ that immediate regulatory action is necessary to address an imminent threat ~~or risk to the public health and safety (i.e., imminent hazard) or an imminent threat to the common defense and security (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.

Commented [KA156]: Comment 4.5.24

#### 5.1.1.2.2 Confirmatory Orders

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

Commented [KA157]: The staff made this sentence the second sentence of the paragraph.

### 5.1.1.3 Exemptions

Commented [BH158]: Comment 4.5.4

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

Commented [AK159]: Comment 4.5.3

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). Title 10 of the Code of Federal Regulations (10 CFR) Sections 50.59, 50.54(a), 50.54(p), 50.54(q), 52.98(b)–(c), 70.72, and 72.48(e). These change control requirements grant licensees the authority to make changes to their licensing bases without prior U.S. Nuclear Regulatory Commission (NRC) review and approval, provided that the change meets the specified criteria in each change control requirement that governs whether prior NRC review and approval is necessary. Licensee implementation of changes using these change control requirements is subject to NRC inspection.

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. If the change processes are used properly, then the licensee can reasonably implement the change without concern about future enforcement action and with the assurance that any future NRC-imposed modifications to the changes would be subject to backfitting considerations. This is consistent with the underlying premise of regulatory stability established within the backfitting, issue finality, and forward fitting policies-regulations and the NRC's Principles of Good Regulation. However, a licensee that improperly implements makes a change to its licensing basis under one of these change control requirements would be in violation of the requirement.

Commented [KA160]: Comment 4.5.5

#### 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, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," dated September 20, 2019, provides that, in the backfitting context, a written commitment is a commitment that has been submitted to the NRC on the docket, has been incorporated into the license, and directly relates to how the licensee complies with a requirement.

Regulatory commitments made by nuclear power reactor licensees are not legally binding requirements on licensees and, therefore, are not enforceable unless the NRC issues an order. If a regulatory commitment was/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 would/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, a commitment must be converted to 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 backfitting or forward fitting, or backfitting, or a change affecting issue finality; however, this is likely a forward fit.

Commented [AK161]: Comment 4.5.9

Commented [KA162]: Comment 4.5.8

Commented [KA163]: Comment 4.5.9

## 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 views understandings of the subject facility's licensing basis ~~for the subject facility~~. 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 staff should first identify and resolve any differing views about the licensing basis (e.g., through the technical assistance request process discussed in Section 5.21 of this NUREG) and ensure that the licensing basis is understood before beginning a backfitting or forward fitting assessment or pursuing enforcement. The NRC licensing project manager for the facility is the initial point of contact for work related to identifying and reviewing the licenseefacility's licensing basis.

Commented [AK164]: Comment 4.5.23

### 5.1.2.2 Technical Assistance Requests

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

Commented [KA165]: Comment 4.5.10, 4.5.11

Commented [BH166]: The staff revised this paragraph to clarify the interaction of the technical assistance request process and backfitting.

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

**5.1.3—**

~~5.1.4—The NRC review of applications is limited by the scope of the request and to the areas affected by the requested technical and regulatory changes. All other portions of the licensing basis that are not affected by the application are within the scope of the backfitting provisions, unless the staff can justify and document the technical or regulatory reasons for including these portions of the licensing basis into its review.~~

**5.1.5—**

~~5.1.6—The regulations in 10 CFR Part 54 delineate the scope of license renewal reviews. A license renewal review is prospective in nature, as the review is aimed at a renewed license that has not yet been issued and is a matter of future aging management. The review will address aging management or ensure an integrated approach to achieve aging management. The Commission determined in the 1995 nuclear power plant license renewal final rule that 10 CFR 50.109 does not apply to matters within the scope of the renewal of power reactor licenses under 10 CFR Part 54. In large measure, the scope of a license renewal review is limited by 10 CFR 54.4, “Scope,” and 54.21, “Contents of applications—technical information.” Section 54.30(a) states, in part, that licensed activities will be conducted in accordance with the current licensing basis.<sup>3</sup> This requirement is followed by 10 CFR 54.30(b), which states that the licensee’s compliance in this regard is NOT the subject of the license renewal review. This means that any proposed staff action on topics other than aging management taken under the current license during the application review could be subject to a backfitting assessment. Once the NRC issues the renewed license, 10 CFR 50.109 applies to the entire license with very limited exceptions.~~

**5.1.7—**

~~5.1.3 The Commission’s forward fitting policy applies to requested licensing actions and license renewal requests other than Part 54 renewals, although the imposition of a condition in a Part 54 proceeding outside the normal scope of Part 54 license renewals could constitute forward fitting.~~

**5.1.3.1 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

**Commented [KA167]:** Comments 4.5.28, 4.5.29. The staff deleted these paragraphs because the subjects are addressed in Chapters 1, 2, and 3.

**Commented [KA168]:** Comment 4.5.28. The staff moved these paragraphs to Chapter 2 and revised them.

**Commented [KA169]:** The staff added this section based on discussions with NRC staff.

<sup>3</sup>For purposes of 10 CFR Part 54 and as defined in 10 CFR 54.3, the current licensing basis “is the set of NRC requirements applicable to a specific plant and a licensee’s written commitments for ensuring compliance with and operation within applicable NRC requirements and the plant-specific design basis ... that are docketed and in effect.”

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 1989-10 CFR Part 52 final rule ~~statement of considerations~~ (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; and, 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.

**Commented [BH170]:** The staff inserted this sentence to show how the rule text effectuates the Commission's position.

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.<sup>4</sup> 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 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

<sup>4</sup> 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 ~~six~~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 six months before the date of docketing of an operating license application for either of the Bellefonte units, any change in regulation or staff position that meets the definition of "backfitting" for that unit is not backfitting.



1 applications. During initial licensing, the staff's use of acceptance criteria more stringent than  
2 those contained in the ~~s~~Standard ~~R~~Review ~~P~~lan (SRP) or taking positions more stringent than |  
3 those specified in the SRP, whether in writing or orally, is not a facility-specific backfit unless the  
4 staff's new position impacts an applicant's previously received NRC approval (e.g., a design  
5 certification referenced in a combined licensed application under 10 CFR Part 52 or a  
6 construction permit when reviewing an operating license application under 10 CFR Part 50). |  
7 However, under MD 8.4, if the staff imposes any change in requirements or regulatory staff  
8 positions from the applicable version of the SRP, then the staff should follow the same reasoned  
9 decision-making process as a forward fit to justify the change. When an SRP or other relevant  
10 guidance document does not apply to the applicant, t

11  
12 The Commission's forward fitting policy would generally ~~does not~~ apply ~~when an applicant files~~  
13 ~~an~~ to the initial licensing action for a new facility ~~for which there is no SRP.~~

#### 14 15 5.1.3.3 Acceptance Reviews

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

#### 27 28 5.1.3.4 Safety Evaluations and Safety Evaluation Reports

29 As discussed in Section 1.2.2.2 of this NUREG, the NRC can establish facility-specific staff  
30 positions through safety evaluations or safety evaluation reports, which may or may not be  
31 related to a requested licensing action. Staff positions in safety evaluations are not  
32 requirements; rather, they are the bases for the staff's decisions or interpretations (e.g., why an  
33 affected entity's proposed means for implementing or complying with a governing requirement is  
34 or is not acceptable). The safety evaluation, therefore, is not part of the licensing basis unless  
35 specifically incorporated by the affected entity or required as a condition of approval by the staff.  
36 If the NRC subsequently decides that a staff position in a safety evaluation is incorrect, then  
37 agency actions related to that decision are subject to a backfitting or issue finality  
38 assessment. Safety evaluations are useful documents when evaluating potential backfitting  
39 because they provide the bases for the staff's decisions, including the staff's decision to accept  
40 the licensee's proposed means for compliance. The staff should not attempt to establish new  
41 licensing basis information in safety evaluations to avoid backfitting through the safety  
42 evaluation. The staff can stress the importance of certain licensing basis information and can  
43 cite regulations or other established licensing basis information in its safety evaluations.

44  
45 The NRC staff cannot rely on future agency inspection activities to approve a requested  
46 licensing action. Therefore, safety evaluations should not contain staff positions based on  
47 future NRC inspection activities.  
48

Commented [AK171]: The staff added new guidance in response to NRC staff feedback.

Commented [AK172]: Comment 4.5.34

Commented [BH173]: The staff added this paragraph to provide additional guidance on staff positions in safety evaluations.

### 5.1.3.5 ~~Section 10~~ CFR 50.55a Requests

The provisions of 10 CFR 50.55a, “Codes and standards,” allow ~~affected entities~~~~licensees~~ to request relief from certain requirements in 10 CFR 50.55a and to propose alternative requirements. These provisions for requesting relief and proposing alternative requirements are found in 10 CFR 50.55a(f)(6)(i) and (g)(6)(i). The NRC calls these requests “relief requests.”<sup>5</sup> Under 10 CFR 50.55a(z), ~~affected entities~~~~licensees~~ 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.~~

Commented [AK174]: Comment 4.5.36

#### 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 upon the ~~affected entity~~~~licensee~~ 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 can be proposed by the licensee or developed by the NRC. 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~~~~licensee~~ relief (i.e., the NRC’s proposed requirements are not related to the requirements from which the ~~affected entity~~~~licensee~~ is seeking relief), then the ~~NRC 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 non-material issues that are outside the scope of the requirements from which the ~~affected entity~~ is seeking relief.

Commented [BH175]: Comment 4.5.36

#### 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~~~~licensee~~ and authorized by the NRC ~~prior to 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 permit the NRC to impose alternatives to the requirements.~~ 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. Therefore, if the NRC intends to impose an alternative to the requirement, then the NRC would need to subject its proposed alternative to a backfitting or forward fitting assessment.~~

Commented [AK176]: Comment 4.5.35

<sup>5</sup> 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.



### 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 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

**Commented [BH177]:** The staff added this section based on discussions with NRC staff.

**Commented [BH178]:** MD 8.4 Handbook Section I.B.2.(e)

**Commented [AK179]:** Comments 4.3.16, 4.3.17, 4.3.18, 4.4.3, 4.4.21

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

Commented [AK180]: Comment 4.5.27

## 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.~~ In the rulemaking process, the NRC must justify the proposed and final rules under applicable backfitting or issue finality requirements. ~~The NRC and~~ includes this justification discussion in the SOC for proposed and final rules. Lengthy backfitting and issue finality discussions can be a standalone documents summarized in the SOC. ~~Rulemaking plans contain a discussion of the potential backfitting implications of the contemplated rulemaking.~~ Many rules have an associated guidance document that provides an acceptable means for implementing the new or amended rule. The backfitting 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 SOC typically include the guidance document's backfitting and issue finality discussion. Because rulemakings are not regulatory actions associated with a licensee requests for licensing actions submitted by affected entities, it is not possible for rulemakings to do not involve forward fittings.

Commented [AK181]: Comment 4.5.32

### 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.

Commented [KA182]: Comment 4.5.33

Commented [KA183]: Comment 4.5.32

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 ~~the NRC’s~~ regulations. In the consensus process, the NRC provides its views on the codes and standards, and this communication supports a constructive consensus process. This communication, including votes, is not considered backfitting or forward fitting.

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

In the SRM to SECY-00-0011, “Evaluation of the Requirement for Licensees to Update Their Inservice Inspection and Inservice Testing Programs Every 120 Months,” dated April 13, 2000, the Commission rejected an NRC staff proposal to consider as backfits rulemakings that list updated ASME eCode editions. Therefore, such rulemakings, with or without conditions on aspects of the ASME eCodes, are not generally backfits. In addition, a new condition on a new code provision that is not present in an earlier eCode 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 eCode provision already incorporated by the NRC; (2) when the rulemaking incorporates a new provision of the ASME eCode that is substantially different from existing requirements; or (3) when the rulemaking requires that licensees-affected entities adopt provisions of the ASME eCode 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 ~~provide~~ 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

**Commented [KA184]:** The staff clarified that the codes may be incorporated with exceptions and clarifications.

1 because the licensee would not be required to follow the new requirement or staff position.<sup>6</sup>  
2 When the NRC relaxes requirements, ~~the NRC~~<sup>it</sup> must ensure that the new framework provides  
3 for the adequate protection of the public health and safety and the common defense and  
4 security. Typically, this means that the alternative approach has either results in no decrease in  
5 safety or security or, if there is a decrease, it is very small (e.g., NRC Regulatory Guide 1.174  
6 defines "very small" within the context of changes in core damage or large early release  
7 frequency).

Commented [KA185]: Comment 4.5.41

8  
9 Examples of relaxations ~~to~~<sup>of</sup> regulatory requirements include the 2004 final rule promulgating  
10 10 CFR 50.69, ~~which provided for~~<sup>"r</sup>Risk-informed categorization and treatment of structures,  
11 systems and components for nuclear power reactors, ~~SSCs,~~ and the 2010 final rule  
12 promulgating 10 CFR 50.61a, ~~"Alternate which provided alternate~~ fracture toughness  
13 requirements for protection against pressurized thermal shock events." Such changes are  
14 non-mandatory relaxations that allow the licensee to ~~continue to~~<sup>either</sup> continue to comply with  
15 the requirements of its current licensing basis or adopt the alternative requirements into its  
16 licensing basis. If a licensee decides to adopt the alternative requirements, then it must comply  
17 with those provisions, and doing so is not backfitting because it is part of the nonmandatory  
18 requirements that the licensee voluntarily chose to adopt. For example, an affected  
19 entity/licensee that chooses to adopt the risk-informed categorization and treatment of SSCs for  
20 nuclear power reactors under 10 CFR 50.69 obtains relief from the current existing special  
21 treatment requirements in 10 CFR 50.69(b), but in doing so, the affected entity/licensee must  
22 comply with all provisions of 10 CFR 50.69. Alternatively, affected entities/licensees can choose  
23 not to adopt 10 CFR 50.69, and can continue to comply with their licensed special treatment  
24 requirements.

### 25 26 **5.2.3 Guidance Documents**

Commented [AK186]: Comments 4.2.13, 4.3.8, 4.5.16

27 Generally, issuance of an NRC guidance document (e.g., regulatory guide, NUREG, interim  
28 staff guidance) does not by itself impose regulatory requirements or staff positions on licensees.  
29 The NRC would have to take a regulatory action, such as issuing an order, to impose a  
30 guidance document on a licensee. Therefore, the issuance of a new or revised guidance  
31 document that provides new or changed staff guidance on the implementation of regulations or  
32 staff positions would not normally be considered backfitting or a change affecting issue finality.<sup>7</sup>  
33 ~~One exception is the issuance of superseding guidance, as discussed in Section 5.8.4 of this~~  
34 ~~NUREG.~~

35  
36 However, there are instances when the issuance of guidance can constitute backfitting or affect  
37 issue finality even without an imposition of a staff position via a legally binding  
38 requirement. ~~Guidance documents are subject to the backfitting provisions~~

- 39  
40 • ~~if~~<sup>if</sup> The staff intends, at the time it issues the guidance, to impose the positions on an  
41 affected entity/licensee (typically through further NRC action). ~~Staff guidance is also~~  
42 ~~subject to the backfitting provisions~~

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

7 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.

- ~~when~~ The NRC expects affected entities~~licensees~~ 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 Rregulatory Gguide 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 provides states that issuance of most guidance documents, including their revisions, must include a regulatory analysis performed in accordance with NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission.”

Commented [KA187]: Comments 4.2.13 and 4.3.8

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 requirement. A licensee may incorporate, by reference, a guidance document into its licensing basis through the via 10 CFR 50.59 process or other existing change control requirements, but such action, without being incorporated into the license or without NRC review and approval, does not make the guidance document a requirement. However, the staff’s imposition of a guidance document provision on an affected entity~~licensee~~, 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~~licensee~~. Section 1.5 of this NUREG provides more information on communications with affected entity~~licensees~~.

Commented [KA188]: Comment 4.5.16

If an entity~~licensee~~ voluntarily submits an application for an initial license, an amendment, or license renewal, then the staff must should use the staff guidance applicable to that licensee 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 ~~a~~ different guidance to review the licensee’s entity’s request, then, depending on the type of application, the staff could be backfitting or forward fitting that licensee entity or affecting issue finality and would need to meet the forward fitting applicable criteria discussed in Chapters 2 and 3 of this NUREG. Draft guidance does not constitute a staff position, so the staff should must not use it in licensing decisions.

Commented [KA189]: The staff revised and moved this sentence to a new footnote on the preceding page.

Commented [KA190]: Comment 4.5.16

#### 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 NRC provides~~ the public ~~with notice~~ through the *Federal Register* of the issuance of a regulatory guide, the NRC should include in the ~~Federal Register~~ notice a discussion of the backfitting, forward fitting, and issue finality implications of the issuance of the guidance document.

#### 5.2.3.2 *Interim Staff Guidance*

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

#### 5.2.3.3 *Standard Review Plans*

SRPs delineate the scope and depth of the staff's review of ~~licensee~~ 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 ~~licensee~~ 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 ~~either forward fitting or 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~~ facility's licensing basis.

Commented [AK191]: Comment 4.5.37

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

#### 5.2.3.4 *Withdrawing Guidance Documents*

To withdraw a guidance document, the NRC typically must already have ~~located~~ the guidance ~~located~~ 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 ~~licensees~~ affected entities. However, if the NRC determines that the guidance document should be withdrawn because ~~the it contains~~ methods ~~contained 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 ~~licensees~~ 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.

#### 5.1.8 Superseding Guidance Documents

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

#### 5.2.4 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 licensees 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 restrictions on the use of the draft topical report by that licensee could be considered forward fits. 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 ~~is considering~~ determines that it may need to impose a condition of its approval that would meet the definitions of a "forward fit," "direct nexus," and "essential," then the staff needs to perform a site-specific cost consideration specific to the affected entity to complete the forward fit assessment. However, the communications with the licensee for this first-of-a-kind review should not be done in a manner that conveys expectations as to how the licensee should proceed. The staff can and should communicate to the licensee issues it identifies during the review. The staff must ensure that its communication does not limit the licensee in choosing how to resolve the issues. Section 3.3 of this NUREG contains more additional guidance on forward fitting, and these situations. 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

Commented [KA192]: Comment 4.5.17

Commented [KA193]: Comment 4.5.39

Commented [KA194]: Comment 4.5.39

Commented [AK195]: Comment 4.5.38



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

Commented [KA196]: Comment 4.5.38

3  
4 If an licensee-affected entity uses an NRC-approved topical report in an application and the  
5 NRC approves the application, any subsequent requirements imposed by the NRC that are  
6 different from those specified in the approved topical report should be considered as potential  
7 backfitting or changes affecting issue finality because the approved topical report would be a  
8 facility-specific staff position for that affected entity. If the NRC imposes requirements as part of  
9 its approval of the licensing action (e.g., conditions on the use of the approved topical report),  
10 those requirements could constitute forward backfitting, changes affecting issue finality, or  
11 forward fitting.

### 12 13 **5.2.5 Generic Communications**

14 The issuance of generic communications does not establish new requirements or impose  
15 staff positions and, therefore, cannot constitute backfitting. Therefore, the NRC must subject  
16 draft (if applicable) and final generic communications to backfitting and issue finality  
17 assessments before issuing them. Section 5.9 of this NUREG contains a discussion of generic  
18 communications that request information.

Commented [KA197]: Comment 4.5.15

### 19 20 **5.2.6 Clarifications**

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

### 37 38 **5.2.7 Information Requests**

39 When the NRC revised the Backfit Rule in 1985, it also ~~The NRC~~ revised the 10 CFR Part 50  
40 rule requiring licensee responses to both generic and facility-specific information requests  
41 (i.e., 10 CFR 50.54(f)) ~~with the Backfit Rule in 1985.~~ This information request may also be  
42 referred to as an "information collection." A request for information under 10 CFR 50.54(f) does  
43 not constitute backfitting or a change affecting issue finality, as the request imposes no change  
44 to the facility or its operation. However, because extensive information requests can impose  
45 burdens that appear similar to backfitting or a change affecting issue finality, 10 CFR 50.54(f)  
46 stipulates that, except for information sought to verify licensee compliance with the current  
47 licensing basis for its facility, the NRC must prepare the reasons for the request to ensure that  
48 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.

Commented [KA198]: Moved from Section 1.2.2.2

Letters, bulletins, and generic letters requesting information under 10 CFR 50.54(f) may promulgate new or revised staff positions and may ask licensees to state in their responses whether they have adopted or will adopt these new positions. ~~However, in~~ 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 unless the NRC has followed the backfitting or a change affecting issue finality regulations. As a matter of practice, the NRC staff should carefully consider the potential to raise backfitting and issue finality concerns issues in information requests.

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

## 5.2.8 Policy Statements

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

Commented [AK199]: Comment 4.5.26

### 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. ~~As such,~~ Thus, the inspection procedures define those items that the staff should consider in the ~~staff's determination of~~ whether the licensee is conducting the facility's activities in accordance with the ~~licensee's~~ facility's licensing basis.

In the normal course of inspections, ~~the an~~ NRC inspector may examine and identify findings or violations in specific technical or regulatory areas. Identifying findings or violations ~~usually does not~~ must not involve backfitting ~~or issue finality~~, but it may if the establishment of the NRC's position can be reasonably understood to exceed the governing requirement or a licensee's self-imposed standard that is included in the licensing basis. 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 the caution in Section 4.2.2-2-5.3.2 of this NUREG) ~~likely does not involve~~ may not constitute backfitting ~~or affect issue finality~~ because (1) most inspections use a sampling methodology, (2) circumstances surrounding the activity may have changed, (3) the focus of the inspection may be different, (4) the licensing basis may have changed, (5) maintenance that was previously committed to may not have been ~~accomplished~~ done, or (6) other factors have been considered.

#### 5.3.1 Oral Communications

~~Likewise, a~~ An inspector's discussion of ~~findings~~ proposed findings and violations with the ~~licensee-affected entity~~ is not considered backfitting ~~or a change affecting issue finality~~. During these discussions, the ~~licensee-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 as long as if~~ the inspector does not convey an expectation that the ~~licensee-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. Thus, the staff expects that if~~ Findings or violations documented as part of the NRC's inspection activities ~~would not~~ must not involve backfitting ~~or changes affecting issue finality~~. However, ~~if an licensee-affected entity concludes~~ believes that a ~~finding or violation~~ finding or violation in an ~~written~~ NRC inspection report is a new ~~or changed~~ staff position that is not part of the licensing basis, then the ~~licensee-affected entity~~ can initiate a ~~backfitting~~ an MD 8.4 appeal as described in Chapter 4 of this NUREG.

Commented [KA200]: Comment 4.5.21

Commented [AK201]: Comment 4.5.22

Commented [AK202]: Comment 4.1.12

Commented [KA203]: Comment 4.5.22

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 non-compliances but that the inspectors did not identify them in the report (e.g., because of the sampling nature of the inspection process, or because any identified 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 non-compliance 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]."

**Commented [AK204]:** The staff relocated this information from Section 1.2.2.2.

**Commented [AK205]:** Comment 4.1.12

### 5.3.3 Licensing Basis Questions

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

**Commented [AK206]:** The staff relocated this information to the Section 5.3 introduction and modified it.

If licensing basis questions arise during an inspection, and the inspectors determine that the significance of the issue does not immediately screen as having very low safety significance, then the inspectors should contact the applicable appropriate licensing project manager to resolve the issue through routine staff interactions. If applicable, the staff may also for advice and, if necessary, initiate the technical assistance request process for the appropriate office to consider the regulatory, licensing, and technical aspects of the issue. ~~The outcome of this process may need to be assessed for backfitting implications.~~ Section 5.21.2 of this NUREG contains additional guidance on this matter 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 nonconcurrence 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 nonconcurrence 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 non-cited violations (NCVs), when a licensee or non-licensee

violates a legally binding requirement. The staff should take extra caution when reviewing regulatory requirements, ~~such as an operating reactor's 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 ~~constitutes~~ ~~meets the definition of "backfitting,"~~ ~~and could constitute a change affecting issue finality.~~

#### 5.4.1 Violations

An NOV may require an ~~affected entity~~licensee to respond ~~to the NOV~~ by providing the corrective steps that it either has taken or will take to ~~achieve fully compliance~~ with NRC requirements. As such, requiring a response to an NOV that ~~includes a description of an affected entity~~licensee'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~~licensee 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 ~~is not satisfied with the licensee's proposed corrective actions and asks the affected entity~~licensee to take additional actions beyond those needed to meet requirements, then those additional actions, if imposed (e.g., by order) by the NRC, may constitute backfitting ~~or changes affecting issue finality because the staff may be imposing new requirements on the licensee~~affected entity. If the staff ~~is not satisfied with a licensee's actions in response to any NOV, then subsequent discussions and considerations should remain in the enforcement process.~~ The guidance in this section does not preclude inspectors from assessing corrective actions and issuing applicable enforcement actions.

A ~~finding of a violation~~ for ineffective or untimely corrective actions is not backfitting ~~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~~licensee must take a certain action may ~~constitute 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~~licensee's licensing basis, then the action would be backfitting ~~or a change affecting issue finality.~~

~~Licensee a~~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~~licensee's questions ~~regarding 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~~licensee 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 licensee concerns of unjustified backfitting or changes affecting issue finality associated with proposed and issued violations. The licensee may formally submit a backfitting appeal in accordance with Chapter 4 of this NUREG while also denying a violation in response to an enforcement action.~~

Commented [AK207]: Comments 4.5.12, 4.5.21

Commented [BH208]: The staff revised the information in this and the following paragraph and moved it to Chapter 4.

1 typically an NOV or NCV. In this situation, the NRC staff will not respond to the disputed  
2 violation until the agency has reviewed the formal backfitting appeal and made a final decision  
3 on the validity of the claim. If the NRC denies the licensee's backfitting appeal, then the NRC  
4 will continue the enforcement process and ultimately either uphold or withdraw the violation. If  
5 the NRC grants the licensee's backfitting appeal, then the NRC will withdraw the violation.

6  
7 By contrast, if the licensee raises a backfitting claim or concern to the NRC in conjunction with a  
8 disputed violation in reply to an NOV or NCV, but the licensee has not formally submitted a  
9 backfitting appeal, then the NRC staff should not consider the backfitting claim. Instead, the  
10 enforcement staff should direct the licensee to Chapter 4 of this NUREG. If a regional office  
11 issued the NOV or NCV and the licensee's basis for disputing the violation is that the  
12 requirement or the means by which the licensee did not meet the requirement is not in its  
13 licensing basis, then, after reaching a decision on the disputed violation, the region needs to  
14 obtain the concurrence of the appropriate program office (i.e., the Office of Nuclear Reactor  
15 Regulation (NRR) or the Office of Nuclear Material Safety and Safeguards (NMSS)) before  
16 issuing its decision on the disputed violation.

#### 17 18 **5.4.2 Enforcement Orders**

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

#### 23 24 **5.4.3 Confirmatory Action Letters**

25 A confirmatory action letter is not a requirement and, accordingly, is not enforceable. Licensees  
26 voluntarily agree to the actions described in a confirmatory action letter. Thus, the issuance of a  
27 confirmatory action letter does not constitute backfitting or a change affecting issue finality. In  
28 most cases, the licensee would have taken this voluntary action in response to an enforcement  
29 action. Attempts by the NRC to require compliance with a confirmatory action letter could  
30 constitute backfitting or a change affecting issue finality. The NRC should avoid creating staff  
31 positions in confirmatory action letters by (1) stating that the staff understands that the affected  
32 entity intends to take certain actions and (2) not using language suggesting that the affected  
33 entity's actions are acceptable or would restore compliance. Furthermore, if the NRC requires  
34 the affected entity to do something more or different from the actions described in the  
35 confirmatory action letter that the affected entity is not already required to do under its licensing  
36 basis, then the imposition of the new requirement would constitute backfitting or a change  
37 affecting issue finality because the causal aspect of the backfit or change affecting issue finality  
38 would be a change to the licensing basis, not a change to the commitments or requirements in  
39 the confirmatory action letter.

#### 40 41 **5.4.4 Notices of Deviation**

42 The NRC may issue a notice of deviation and request information about a licensee's failure to  
43 implement or maintain a regulatory commitment. The licensee could either reinstate or conform  
44 with or change its commitment in accordance with its commitment management program.  
45 Issuance of the notice of deviation would not constitute backfitting or a change affecting issue  
46 finality because the NRC did not require the licensee to implement and maintain the  
47 commitment. If the NRC decides to require the licensee to implement and maintain the

Commented [AK209]: Comment 4.5.13

1 commitment and, therefore, removes the voluntary nature of the commitment, then the staff's  
2 proposed action would be subject to [a](#) backfitting [or issue finality](#) assessment. |

3  
4  
5





## 6 RECORDKEEPING AND DOCUMENTATION

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

Management Directive (MD) 3.53, "NRC Records and Document Management Program," dated March 15, 2007, describes how the NRC complies with the regulations governing Federal records management. The guidance in MD 3.53 ensures that the NRC staff considers documents related to backfitting and forward fitting as possible official agency records and ~~are~~ preserves ~~and 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 ~~licensee~~ [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 ~~needs to~~ [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 external stakeholders, and whether the documentation should be made available to external stakeholders.~~ ~~If the proposed action arose from an inspection finding, the staff could use an inspection report. For example, if the NRC staff performs a backfitting assessment to support resolution of an unresolved item, and the staff could not justify a backfitting action, then the backfitting assessment documentation should be referenced in the closure documentation of the unresolved item. An alternative could be~~ For example, the staff may provide a memorandum

**Commented [AK210]:** Comment 4.6.2

**Commented [KA211]:** Staff deleted this because inspection reports should not be used for backfitting or other licensing basis decisions.

1 to a supervisor with an attached analysis based on a guide from Appendix C to this NUREG.  
2 ~~No matter the form used by the staff, the~~ staff's document must describe the safety or security  
3 issue, the staff's proposed action to address the issue, and why the proposed action cannot be  
4 justified under the appropriate backfitting, forward fitting, or issue finality provision. The  
5 document should be placed in ADAMS.  
6

## 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."

1 10 CFR 50.56. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.56,  
2 "Conversion of construction permit to license; or amendment of license."

3 10 CFR 50.57. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.57, "Issuance  
4 of operating license."

5 10 CFR 50.59. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.59, "Changes,  
6 tests, and experiments."

7 10 CFR 50.61. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.61, "Fracture  
8 toughness requirements for protection against pressurized thermal shock events."

9 10 CFR 50.61a. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.61a,  
10 "Alternate fracture toughness requirements for protection against pressurized thermal  
11 shock events."

12 10 CFR 50.69. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.69,  
13 "Risk-informed categorization and treatment of structures, systems and components for  
14 nuclear power reactors."

15 10 CFR 50.71. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.71,  
16 "Maintenance of records, making of reports."

17 10 CFR 50.73. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.73, "Licensee  
18 event reporting system."

19 10 CFR 50.92. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.92, "Issuance  
20 of amendment."

21 10 CFR 50.109. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 50.109,  
22 "Backfitting."

23 10 CFR Part 50, Appendix A. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 50,  
24 Appendix A, "General Design Criteria for Nuclear Power Plants."

25 10 CFR Part 50, Appendix B. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 50,  
26 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel  
27 Reprocessing Plants."

28 10 CFR Part 52. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 52, "Licenses,  
29 Ccertifications, and Aapprovals for Nnuclear Ppower Pplants."

30 10 CFR 52.3. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.3, "Written  
31 communications."

32 10 CFR 52.17. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.17, "Contents  
33 of applications; technical information."

34 10 CFR 52.31. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.31, "Criteria for  
35 renewal."

1 10 CFR 52.39. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.39, "Finality of  
2 early site permit determinations."

3 10 CFR 52.47. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.47, "Contents  
4 of applications; technical information."

5 10 CFR 52.59. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.59, "Criteria for  
6 renewal."

7 10 CFR 52.63. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.63, "Finality of  
8 standard design certifications."

9 10 CFR 52.79. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.79, "Contents  
10 of applications; technical information in final safety analysis report."

11 10 CFR 52.83. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.83, "Finality of  
12 referenced NRC approvals; partial initial decision on site suitability."

13 10 CFR 52.98. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.98, "Finality of  
14 combined licenses; information requests."

15 10 CFR 52.137. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.137,  
16 "Contents of applications; technical information."

17 10 CFR 52.145. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.145, "Finality  
18 of standard design approvals; information requests."

19 10 CFR 52.157. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.157,  
20 "Contents of applications; technical information in final safety analysis report."

21 10 CFR 52.171. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.171, "Finality  
22 of manufacturing licenses; information requests."

23 10 CFR 52.179. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 52.179, "Criteria  
24 for renewal."

25 10 CFR Part 52, Appendix D. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 52,  
26 Appendix D, "Design Certification Rule for the AP1000 Design."

27 10 CFR Part 54. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 54, "Requirements  
28 for ~~R~~renewal of ~~O~~perating ~~L~~licenses for ~~N~~nuclear ~~P~~power ~~P~~plants."

29 10 CFR 54.~~43~~. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 54.~~43~~,  
30 "~~Definitions~~~~Scope~~."

31 10 CFR 54.~~34~~. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 54.~~34~~,  
32 "~~Scope~~~~Definitions~~."

33 10 CFR 54.21. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 54.21, "Contents  
34 of application—technical information."

1 10 CFR Part 70. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 70, "Domestic  
2 ~~L~~icensing of ~~S~~pecial ~~N~~nuclear ~~M~~material."  
3 10 CFR 70.60. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 70.60,  
4 "Applicability."  
5 10 CFR 70.72. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 70.72, "Facility  
6 changes and change process."  
7 10 CFR 70.74. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 70.74, "Additional  
8 reporting requirements."  
9 10 CFR 70.76. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 70.76,  
10 "Backfitting."  
11 10 CFR Part 72. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 72, "Licensing  
12 ~~R~~Requirements for the ~~I~~ndependent ~~S~~storage of ~~S~~pent ~~N~~nuclear ~~F~~uel, ~~H~~igh-~~L~~evel  
13 ~~R~~adioactive ~~W~~aste, and ~~R~~eactor-~~R~~elated ~~G~~reater ~~T~~han Class-~~C~~ ~~W~~aste."  
14 10 CFR 72.62. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 72.62,  
15 "Backfitting."  
16 10 CFR 73.56. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 73.56, "Personnel  
17 access authorization requirements for nuclear power plants."  
18 10 CFR Part 76. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 76, "Certification of  
19 ~~G~~aseous ~~D~~iffusion ~~P~~lants."  
20 10 CFR 76.76. *U.S. Code of Federal Regulations*, Title 10, "Energy," Section 76.76,  
21 "Backfitting."

22

## 23 **U.S. Nuclear Regulatory Commission Documents**

24 Staff Requirements Memorandum, "SECY-86-17—Final Rule, 'Limitation on the Use of Highly  
25 Enriched Uranium (HEU) in Research and Test Reactors,'" February 14, 1986.  
26 Agencywide Documents Access and Management System (ADAMS) Accession  
27 No. ML12248A518 (not publicly available).  
28 NUREG-1409, "Backfitting Guidelines," July 1990. ADAMS Accession No. ML032230247.  
29 Staff Requirements Memorandum, "SECY-92-223—Resolution of Deviations Identified During  
30 the Systematic Evaluation Program," ~~dated~~ September 18, 1992. ADAMS Accession  
31 No. ML003763736.  
32 SECY-93-086, "Backfit Considerations," ~~dated~~ April 1, 1993. ADAMS Accession  
33 No. ML18128A031.  
34 Staff Requirements Memorandum, "SECY-93-086—Backfit Considerations," ~~dated~~  
35 June 30, 1993. ADAMS Accession No. ML18214A193.

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

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

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

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

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

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

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

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

21 SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," ~~dated~~  
22 March 2, 1999. ADAMS Accession No. ML992810068. |

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

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

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

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

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



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

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

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

12 Merschhoff, E. W., NRC, letter to Craig Anderson, Entergy Operations, Inc., "Response to Backfit  
13 Claim Regarding NRC Inspection Report 50-313/01-06; 50-368/01-06," ~~dated~~ April 15,  
14 2002. ADAMS Accession No. ML021090419.

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

17 Office of Nuclear Reactor Regulation Office Instruction LIC-100, "Control of Licensing Bases for  
18 Operating Reactors," ~~dated~~ January 7, 2004. ADAMS Accession  
19 No. [ML072000067](#)~~ML033530249 (not publicly available)~~.

20 NUREG-0910, [Revision 4](#), "NRC Comprehensive Records Disposition Schedule-," [March 2005](#).  
21 [ADAMS Accession No. ML051390495](#).

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

25 [NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear](#)  
26 [Power Plants: LWR Edition," March 2007. ADAMS Accession No. 070660036.](#)

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

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

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

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

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

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

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

8 Order EA-12-049: "Order Modifying Licenses With Regard to Requirements for Mitigation  
9 Strategies for Beyond-Design-Basis External Events (Effective Immediately),"  
10 March 12, 2012. ADAMS Accession No. ML12056A044.

11 Order EA-12-051: "Order Modifying Licenses With Regard to Reliable Spent Fuel Pool  
12 Instrumentation (Effective Immediately)," March 12, 2012. ADAMS Accession  
13 No. ML12054A735.

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

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

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

21 Draft Regulatory Guide 7009, "Establishing Quality Assurance Programs for Packaging Used in  
22 Transport of Radioactive Material," April, 2013. ADAMS Accession No. ML13079A004.

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

26 Staff Requirements Memorandum, "Staff Requirements—SECY-14-0087—Qualitative  
27 Consideration of Factors in the Development of Regulatory Analyses and Backfit  
28 Analyses," ~~dated~~ March 4, 2015. ADAMS Accession No. ML15063A568.

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

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

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

36 Averbach, Andrew P., Office of the General Counsel, memorandum to E.M. Hackett, Committee  
37 to Review Generic Requirements, "Summary of COMSECY-16-0020 Recommendation

on Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception to Backfit Rule," ~~dated~~ December 20, 2016. ADAMS Accession No. ML16355A258.

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

NUREG/BR-0058, Revision 5, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission: Draft Report for Comment," April 2017. ADAMS Accession No. ML17101A355.

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

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

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

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

Regulatory Guide 1.232, "Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors," April 2018. ADAMS Accession No. ML17325A611.

Staff Requirements Memorandum, "Staff Requirements—SECY-18-0049—Management Directive and Handbook 8.4, 'Management of Backfitting, Issue Finality, and Information Collection,'" ~~dated~~ May 29, 2019. ADAMS Accession No. ML19149A294.

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

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

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

Management Directive 3.5, "Attendance at NRC Staff-Sponsored Meetings," December 4, 2019. ADAMS Accession No. ML19350A643.

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

1 [NRC Enforcement Policy, January 15, 2020. ADAMS Accession No. 19352E921.](#)

2 [Rulemaking Plan Template, updated May 22, 2020. ADAMS Accession No. ML19032A609 \(not](#)  
3 [publicly available\).](#)

4 [Charter for the Nuclear Regulatory Commission Backfitting and Forward Fitting Community of](#)  
5 [Practice, dated August 21, 2020. ADAMS Accession No. ML20234A443.](#)

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

8 NRC Enforcement Policy, available at [https://www.nrc.gov/about-](https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html)  
9 [nrc/regulatory/enforcement/enforce-pol.html](https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html).

10 Committee to Review Generic Requirements, Charter, available at  
11 <https://www.nrc.gov/about-nrc/regulatory/cgr/charte.html>.

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

15

## 16 **United States Code**

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

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

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

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

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

23

## 24 **Federal Register Notices**

25 32 FR 10213, "General Design Criteria for Nuclear Power Plant Construction Permits; Proposed  
26 Rule," July 11, 1967.

27 35 FR 5317, "Backfitting of Production and Utilization Facilities; Construction Permits and  
28 Operating Licenses; Final Rule," March 31, 1970.

29 36 FR 3255, "General Design Criteria for Nuclear Power Plants; Final Rule,"  
30 February 20, 1971.

31 48 FR 44173, "Revision of Backfitting Process for Power Reactors; Policy Statement,"  
32 September 28, 1983.

1 48 FR 44217, "Revision of Backfitting Process for Power Reactors; Advance Notice of Proposed  
2 Rulemaking," September 28, 1983.

3 49 FR 47034, "Revision of Backfitting Process for Power Reactors; Notice of Proposed  
4 Rulemaking," November 30, 1984.

5 50 FR 38097, "Revision of Backfitting Process for Power Reactors; Final Rule,"  
6 September 20, 1985.

7 51 FR 6514, "Limiting the Use of Highly Enriched Uranium in Domestically Licensed Research  
8 and Test Reactors; Final Rule," March 27, 1986.

9 51 FR 30028, "Safety Goals for the Operation of Nuclear Power Plants; Policy Statement;  
10 Correction and Republication," August 21, 1986.

11 53 FR 20603, "Revision of Backfitting Process for Power Reactors; Final Rule," June 6, 1988.

12 53 FR 31651, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and  
13 High-Level Radioactive Waste; Final Rule," August 19, 1988.

14 54 FR 15372, "Early Site Permits; Standard Design Certifications; and Combined Licenses for  
15 Nuclear Power Reactors; Final Rule," April 18, 1989.

16 56 FR 22300, "Fracture Toughness Requirements for Protection Against Pressurized Thermal  
17 Shock Events; Final Rule," May 15, 1991.

18 58 FR 13699, "Clarification of Physical Protection Requirements at Fixed Sites; Final Rule,"  
19 March 15, 1993.

20 59 FR 48944, "Certification of Gaseous Diffusion Plants; Final Rule," September 23, 1994.

21 60 FR 22461, "Nuclear Power Plant License Renewal; Revisions; Final Rule," May 8, 1995.

22 60 FR 42622, "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities;  
23 Final Policy Statement," August 16, 1995.

24 65 FR 56211, "Domestic Licensing of Special Nuclear Material; Possession of a Critical Mass of  
25 Special Nuclear Material; Final Rule," September 18, 2000.

26 67 FR 61695, "NRC Information Quality Guidelines," October 1, 2002.

27 69 FR 68008, "Risk-Informed Categorization and Treatment of Structures, Systems, and  
28 Components for Nuclear Power Reactors; Final Rule," November 22, 2004.

29 72 FR 49352, "Licenses, Certifications, and Approvals for Nuclear Power Plants; Final Rule,"  
30 August 28, 2007.

31 73 FR 32453, "Regulatory Improvements to the Nuclear Materials Management and Safeguards  
32 System; Final Rule," June 9, 2008.

33 74 FR 28112, "Consideration of Aircraft Impacts for New Nuclear Power Reactors; Final Rule,"  
34 June 12, 2009.

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

78 FR 29016, "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material; Draft Regulatory Guide," May 16, 2013.

~~77 FR 16082, "EA-12-051; In the Matter of All Power Reactor Licensees and Holders of Construction Permits in Active or Deferred Status: Order Modifying Licenses With Regard To Reliable Spent Fuel Pool Instrumentation (Effective Immediately)," March 19, 2012.~~

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

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

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

#### Other Documents

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

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

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

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

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

#### Court Decisions

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

2

| 3 *Michigan v. Environmental Protection Agency*, 135 S.Ct. 2699 (2015).

4

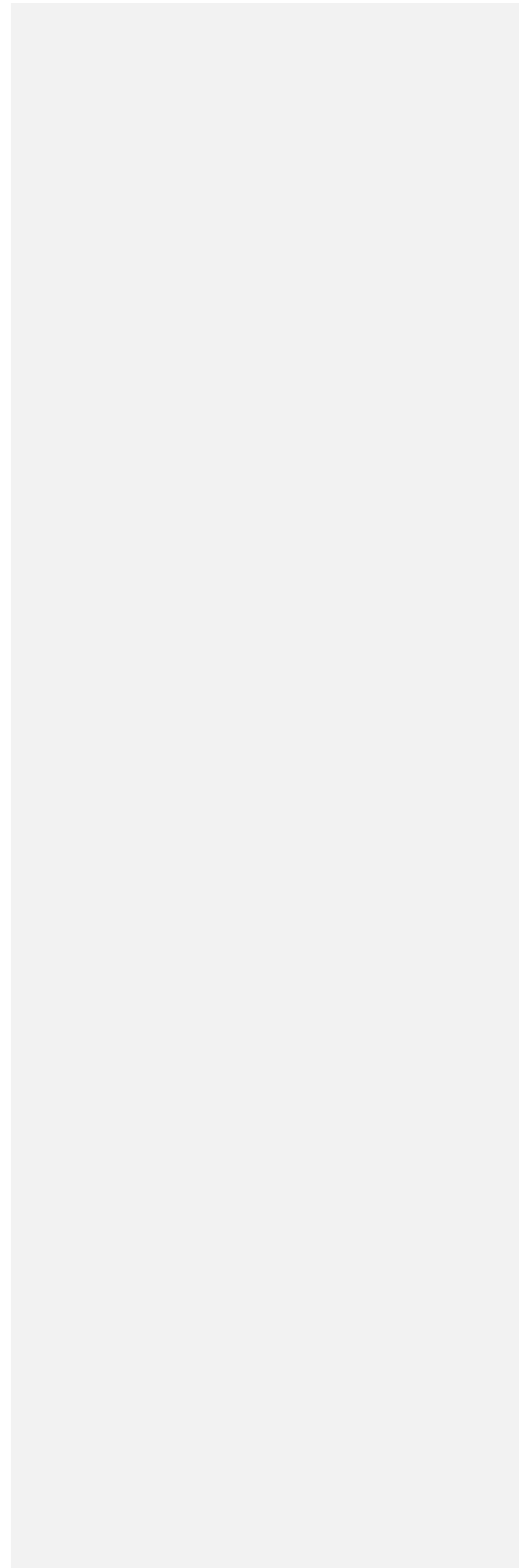
1

## **APPENDIX A - BACKFITTING FLOWCHARTS**

2

3





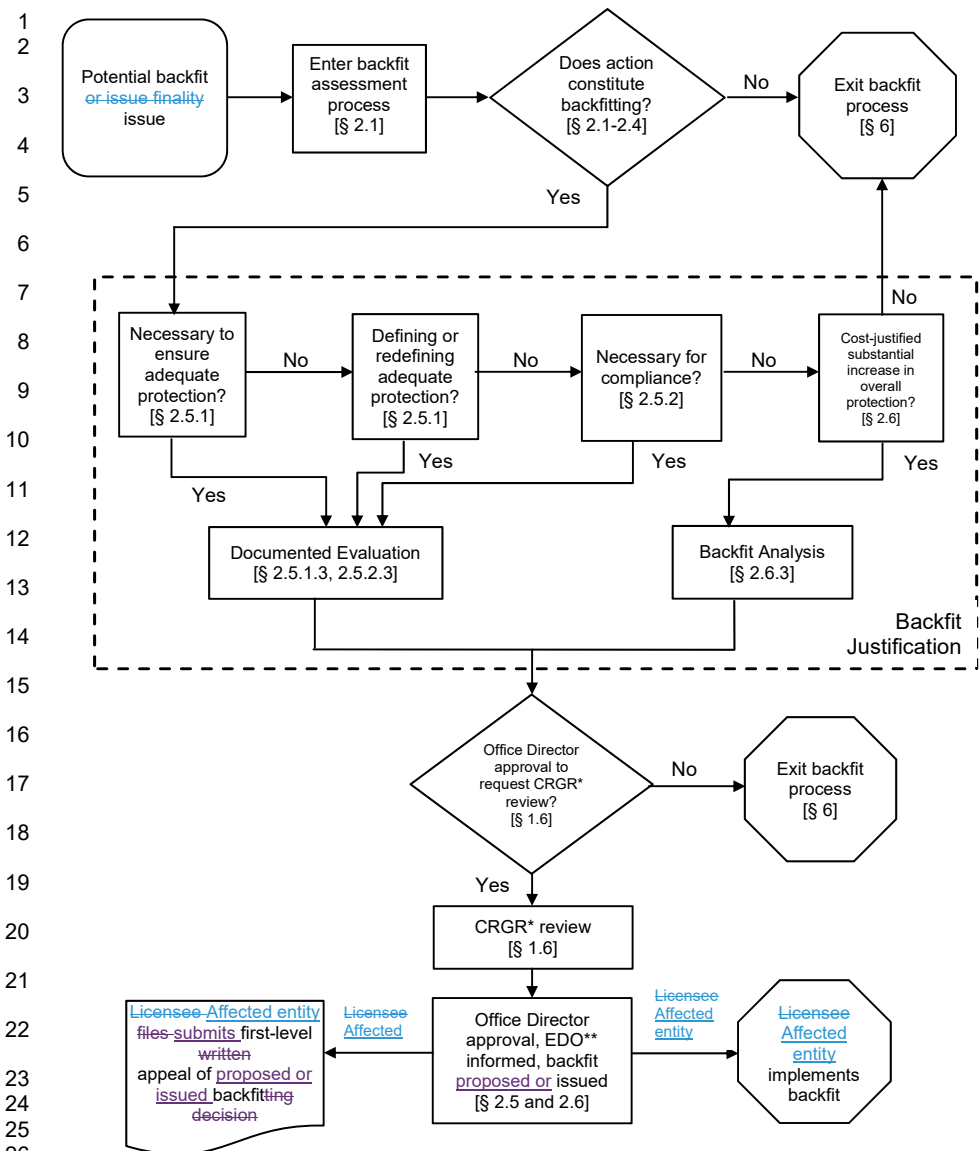
1  
2  
3  
4  
5  
6  
7

FLOWCHART 1

**NRC** BACKFITTING PROCESS FLOWCHART

|



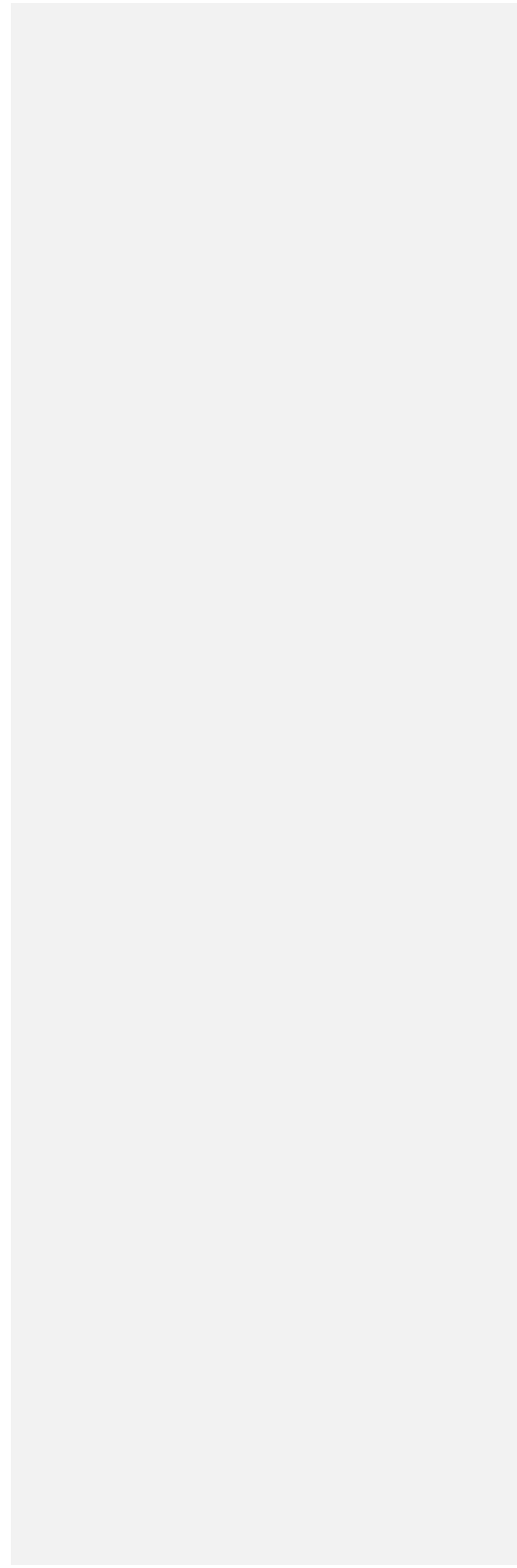


\*Committee to Review Generic Requirements

\*\*Executive Director for Operations

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

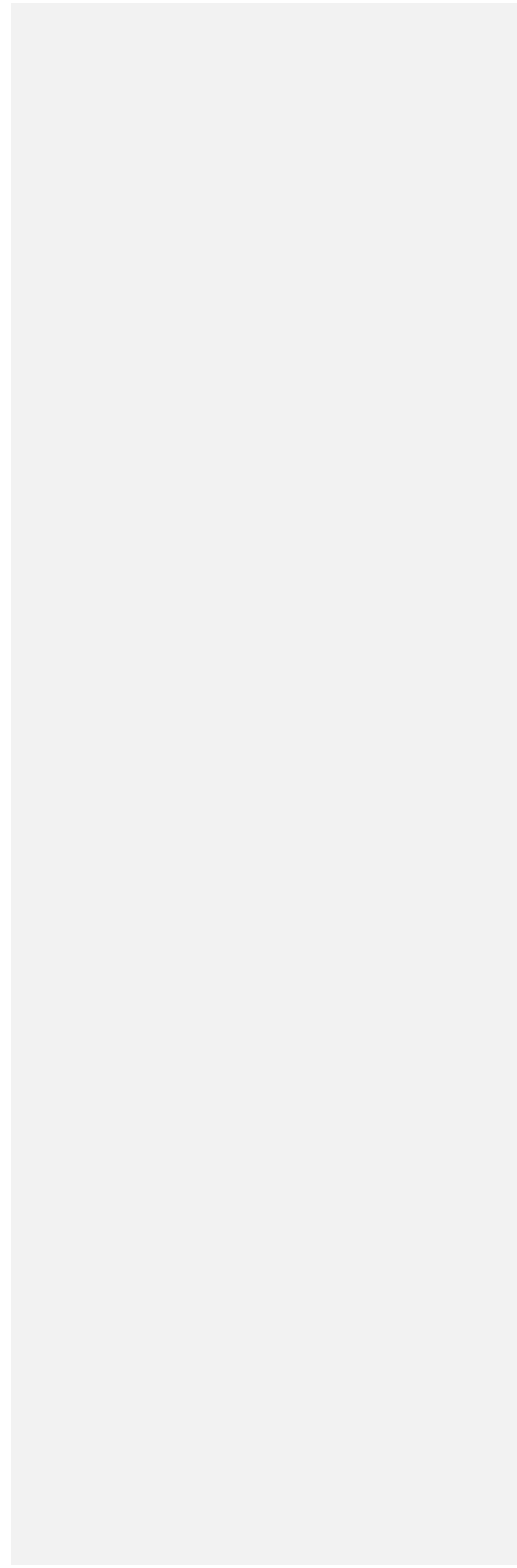
Figure A-1: NRC Backfitting Process Flowchart

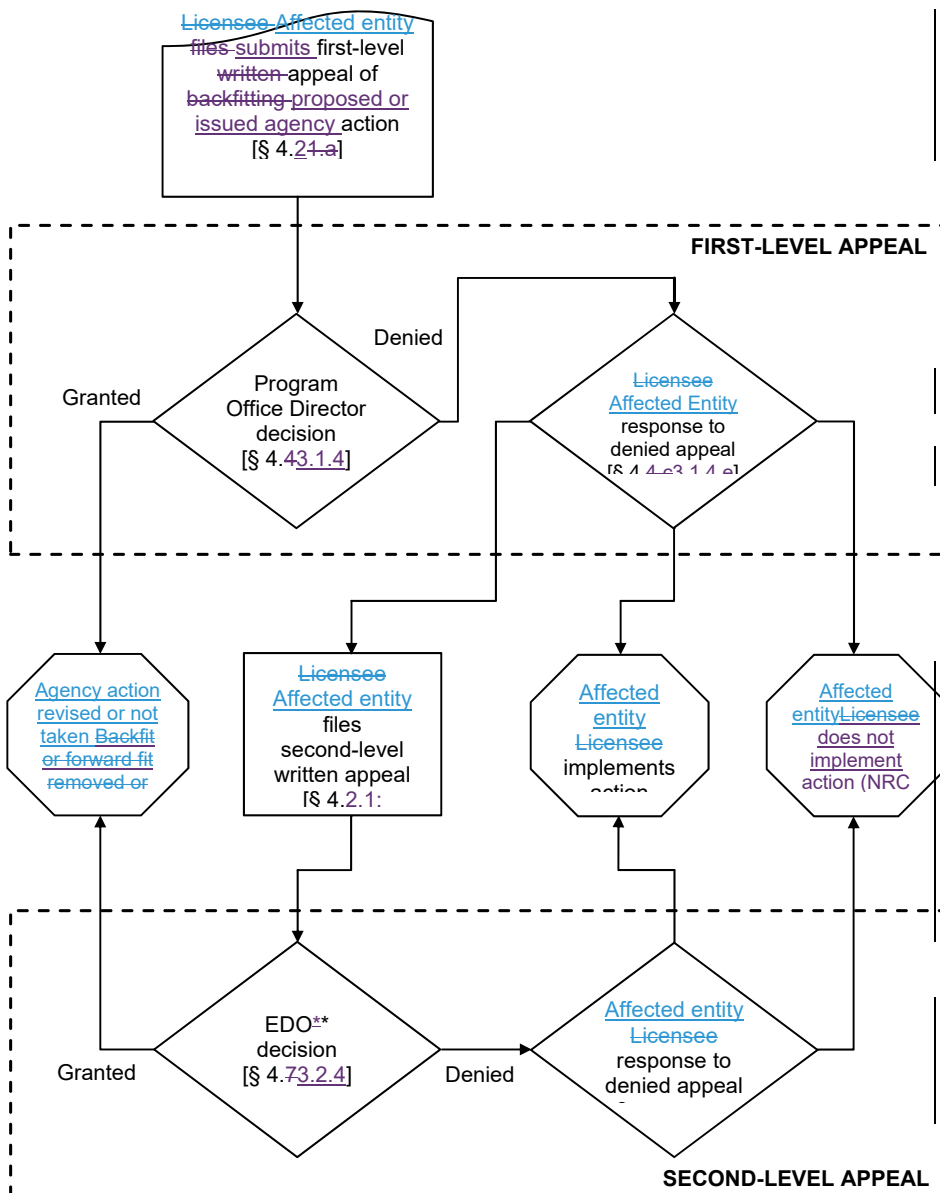


1  
2  
3  
4  
5  
6  
7

FLOWCHART 2

BACKFITTING MANAGEMENT DIRECTIVE 8.4 APPEAL PROCESS FLOWCHART |





\* U.S. Nuclear Regulatory Commission; \*\* Executive Director for Operations  
 Note: This flowchart may not capture all scenarios involving appeals.

Figure A-2. Backfitting Appeal Process Flowchart

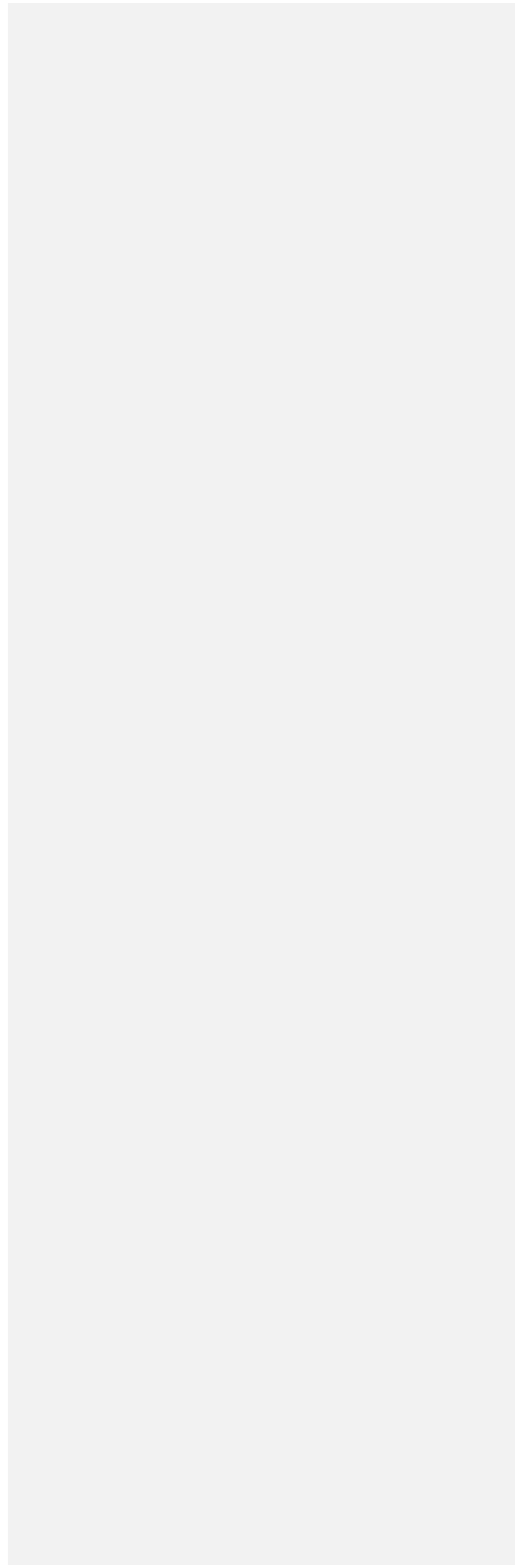




1

## **APPENDIX B – WORKSHEETS**

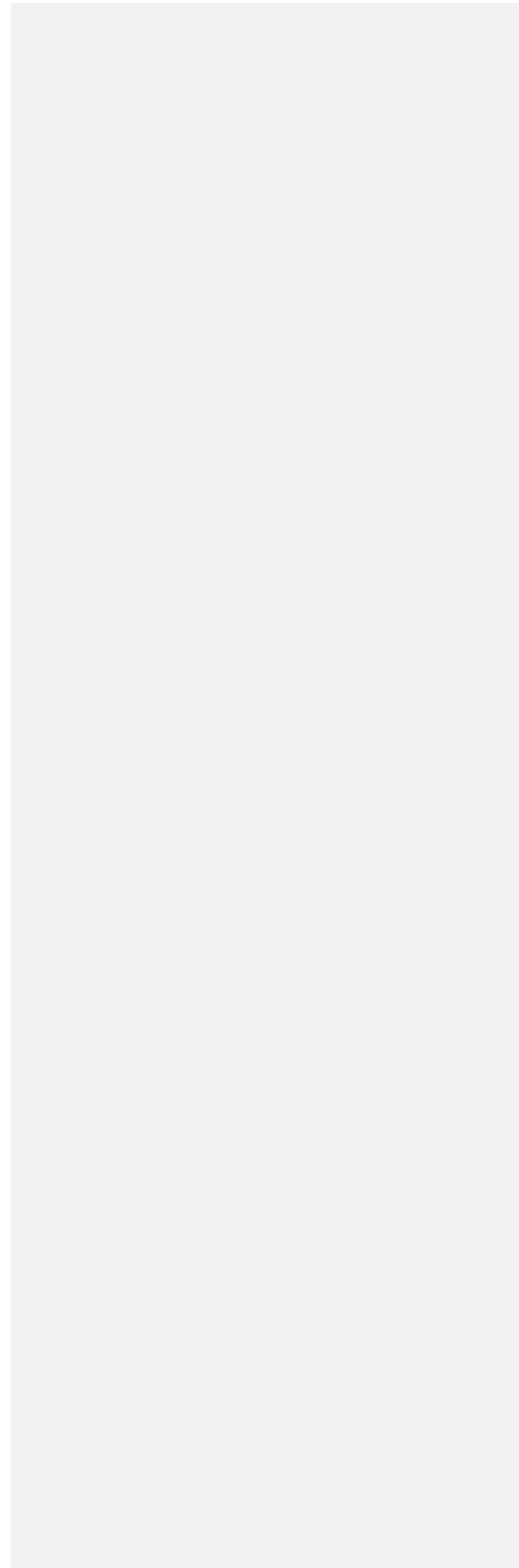
2



1  
2  
3  
4  
5  
6  
7

**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 <a href="#">or issue finality</a> 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 <a href="#">or issue finality</a> 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 <del>licensee or applicant</del> 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 <a href="#">or issue finality</a> process.</p> <p>If the <del>licensee or applicant</del> 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 <a href="#">or issue finality</a> process.</p>

BACKFITTING AND ISSUE FINALITY WORKSHEET <u>(continued)</u>		
Justification		
Step	Action	Notes
5	Obtain <u>Office of Nuclear Reactor Regulation (NRR)</u> or <u>Office of Nuclear Material Safety or Safeguards (NMSS)</u> NRR or 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"> <li>• <u>D</u>escription of the answers to the backfitting Screening questions.</li> <li>• <u>I</u>f 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 <u>n</u>ot, whether the proposed action could be justified using the compliance exception or a backfit analysis.</li> </ul> <p>If approved, proceed to the next step. <u>i</u>f 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 <u>s</u>tep 9.</p> <p>If not approved, then address the <u>NRR or NMSS O</u>ffice <u>D</u>irector's concerns and re-seek approval. If not approved, then document the basis for the <u>O</u>ffice <u>D</u>irector's decision and exit the backfitting <u>or issue finality</u> 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"> <li>• Perform an imminent threat analysis.</li> <li>• Refer to NUREG-1409, Section 2.5.1.</li> <li>• 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.</li> <li>• 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.</li> <li>• Proceed to <u>s</u>tep 10.</li> </ul> <p>If the issue is not one of adequate protection, then proceed to the next step.</p>

BACKFITTING AND ISSUE FINALITY WORKSHEET <u>(continued)</u>		
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 <a href="#">Step 10</a>.</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 <a href="#">Step 10</a>.</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 <del>NRR or NMSS Office</del> <a href="#">Office Director's</a> concerns and re-seek approval. If not approved, then document the basis for the <del>Office</del> <a href="#">Office Director's</a> decision and exit the backfitting <a href="#">or issue finality</a> process.</p>
11	Meet with the <a href="#">Committee to Review Generic Requirements (CRGR)</a> .	<p>Prepare the materials for meeting with the CRGR. See <a href="#">CRGR Charter and Procedures</a>. Afterwards, address any issues identified by the CRGR.</p> <p>Proceed to the next step.</p>



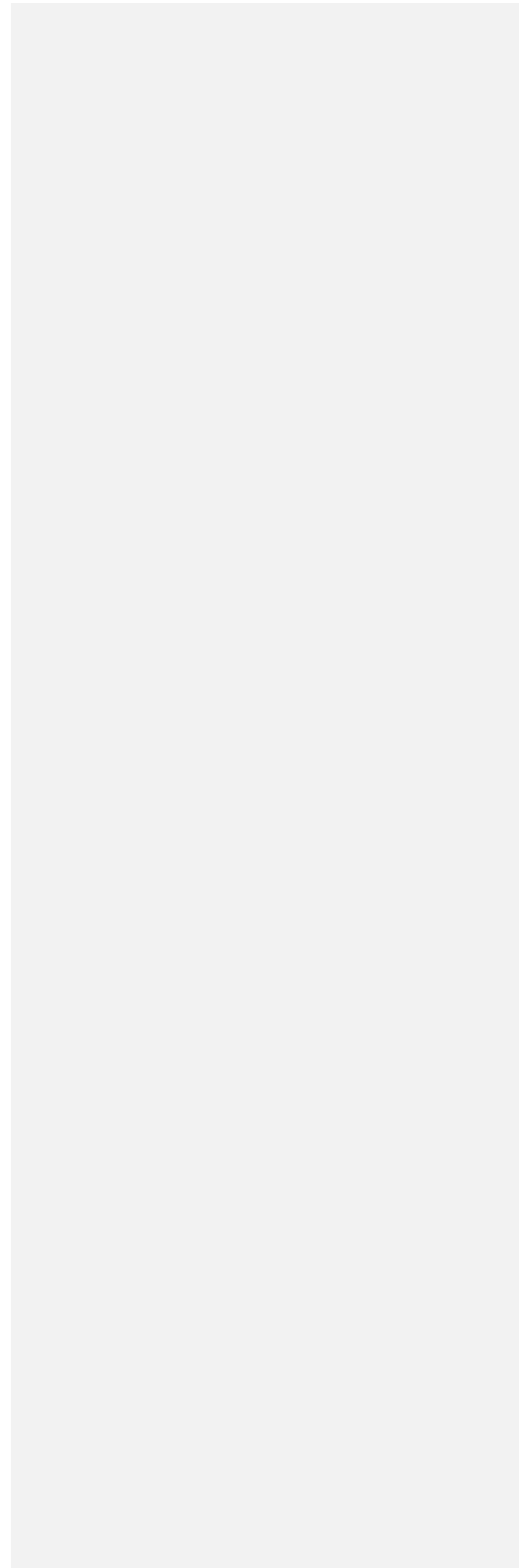
BACKFITTING AND ISSUE FINALITY WORKSHEET <u>(continued)</u>		
Justification		
Step	Action	Notes
12	Submit the final documented evaluation or backfit analysis to the NRR or NMSS Office Director (and/or OEDO or Commission) for approval.	<p>If approved, then proceed <del>with the proposed action</del> <u>to the next step</u>.</p> <p>If not approved, then address the <del>NRR or NMSS Office Director's</del> concerns and re-seek approval. If <del>still</del> not approved, then document the basis for the decision and exit the backfitting <u>or issue finality</u> process. <u>Do not proceed to the next step</u>.</p>
13	<u>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.</u>	<p><u>If the effected entity does not submit an MD 8.4 appeal, then proceed with the backfit or change affecting issue finality.</u></p> <p><u>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.</u></p>

**Commented [KA212]:** Staff added this step to show where the appeal process could be offered for proposed backfits.

1  
2  
3  
4  
5  
6  
7

**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 <del>there were inconsistent</del> interpretation and application <del>were inconsistent</del> , then it is much less likely that an error or omission can be shown to have occurred. Note that conclusion with a supporting basis.
4	The NRC approved the licensee's method of compliance with the requirement.	Note the approval type and date and describe supporting information that indicates the NRC's interpretation and application of the requirement in its approval.
The Error or Omission		
Step	Action	Notes
5	The NRC has identified <del>at least one an</del> error or omission—either the NRC's own error, or the omission or error of the licensee, <del>applicant,</del> or a third party (e.g., a vendor or another government agency), through <del>any of the following</del> : <ul style="list-style-type: none"> <li><del>i</del>ncorrect perception or understanding of the facts</li> <li><del>f</del>ailure to recognize flawed analyses</li> <li><del>f</del>ailure to draw direct inferences from those facts or analyses</li> </ul>	Describe the error(s) or omission(s).

Commented [BH213]: Comment 4.7.2

**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 <del>an</del> 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 <del>an</del> 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.

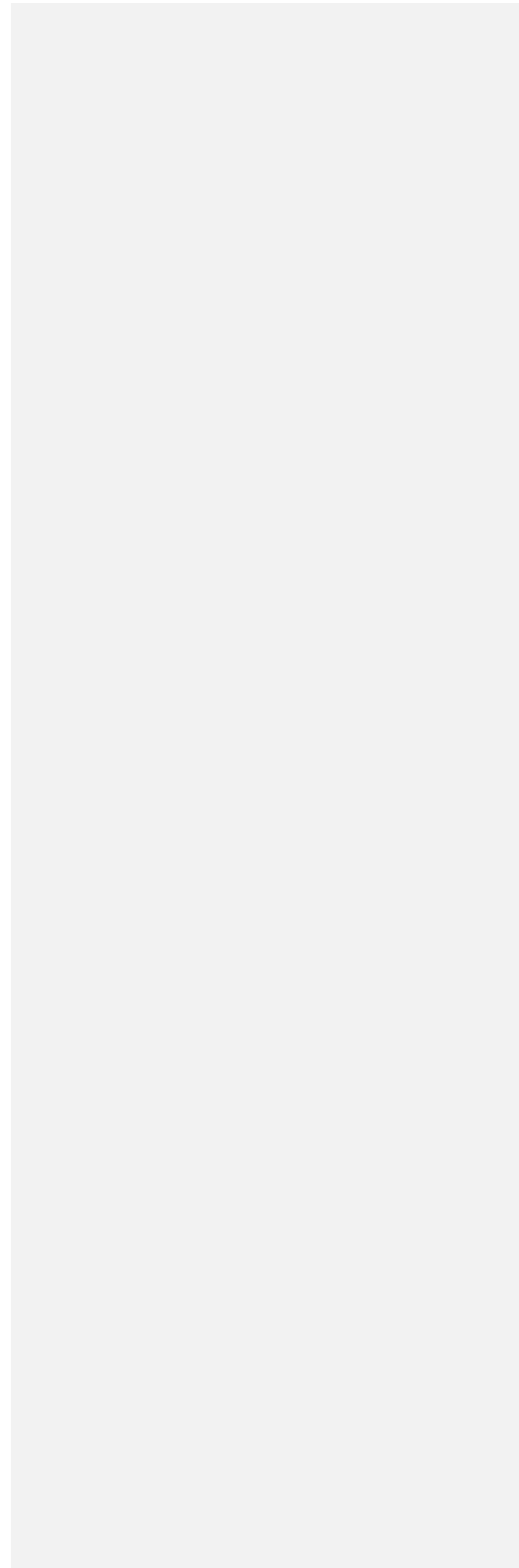
**The Costs**

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.

1  
2  
3  
4  
5  
6  
7

**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 <del>Does the issue involve an licensee-affected entity</del> or applicant that is within the scope of the forward fitting policy?	If the <del>request is not from an affected entity (i.e., an entity licensee or applicant is not</del> 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.  If the <del>request is from an affected entity licensee or applicant is within the scope of the forward fitting policy,</del> then proceed to the next step.
2	Ask: Is the NRC reviewing an <del>affected entity</del> licensee-initiated request?	If the answer is "no," then document this and exit the forward fitting process because the proposed action is not a forward fit.  If the answer is "yes," then proceed to the next step.
3	Ask: Is the <del>staff's</del> NRC's proposed action either a new or changed requirement or staff position interpreting a requirement?	If the answer is "no," then document this and exit the forward fitting process because the proposed action is not a forward fit.  If the answer is "yes," then proceed to the next step.
4	Ask: Is the new or changed NRC requirement or interpretation being imposed on an <del>affected entity</del> licensee as a condition of the NRC's approval of the <del>affected entity</del> licensee-initiated licensing action (i.e., the <del>affected entity</del> licensee's request did not propose this requirement or interpretation)?	If the answer is "no," then document this and exit the forward fitting process because the proposed action is not a forward fit.  If the answer is "yes," then proceed to the next step.

**Commented [KA214]:** The staff updated the worksheet to reflect the elements of a forward fitting assessment, reflect the revised definitions of "direct nexus" and "essential," and to incorporate guidance on communicating forward fits.

**Commented [KA215]:** The staff switched the order of Steps 1 and 2 to conform with Section 3.2.



FORWARD FITTING WORKSHEET		
Screening		
Step	Action	Notes
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>

**Commented [KA214]:** The staff updated the worksheet to reflect the elements of a forward fitting assessment, reflect the revised definitions of "direct nexus" and "essential," and to incorporate guidance on communicating forward fits.

FORWARD FITTING WORKSHEET <u>(continued)</u>		
Justification		
Step	Action	Notes
6	<p>Ask: Is there a direct nexus between the proposed action and the <a href="#">affected entity</a>'s request?</p> <p><u>1. The affected entity's requested change would create a safety or security issue or a non-compliance 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</u></p> <p><u>2. The NRC's proposed action would address the issue or non-compliance.</u></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. <u>However, the staff could consider taking the proposed action in accordance with the backfitting guidance in Chapter 2 of NUREG-1409.</u></p> <p>If the answer is "yes," then proceed to the next step.</p>

7	Ask: Is the proposed action essential to the <del>staff</del> NRC's approval of the request (i.e., <u>is it necessary to make the NRC's safety or security finding would the staff deny the request if the action is not taken</u> )?	<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. <u>However, the staff could consider taking the proposed action in accordance with the backfitting and issue finality guidance in Chapter 2 of NUREG-1409.</u></p> <p>If the answer is "yes," then proceed to the next step.</p>
8	<u>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).</u>	<p><u>If approved, then proceed to the next step.</u></p> <p>If not approved, then address the division directors' concerns and reseek 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>
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 <u>affected entity</u> .	<p><u>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.</u></p> <p>If the <u>affected entity</u> 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><u>If the staff decides to pursue the forward fit, then proceed to the next step.</u></p>

1  
2

1

<u>FORWARD FITTING WORKSHEET (continued)</u>		
<u>Cost Consideration</u>		
<u>Step</u>	<u>Action</u>	<u>Notes</u>
<u>810</u>	Obtain <u>Office of Nuclear Reactor Regulation (NRR) or Office of Nuclear Material Safety or Safeguards (NMSS) NRR or NMSS</u> Office Director approval to expend resources on <u>developing and documenting the full justification cost considerations</u> for the proposed action (i.e., <u>- completing the forward fit analysis assessment</u> ).	<p>Using Guide 4 in NUREG-1409, Appendix C, prepare the following for the <u>NRR or NMSS Ooffice Ddirector</u>:</p> <ul style="list-style-type: none"> <li>• <del>The</del> responses to the first <del>seven nine</del> steps of this <del>W</del>worksheet.</li> <li>• <del>If</del> readily available, descriptions of any safety, risk, or cost <del>benefit</del> insights.</li> </ul> <p>If approved, then proceed to the next step.</p> <p>If not approved, then address the <u>NRR or NMSS Ooffice Ddirector's</u> concerns and re-seek approval. If <u>still</u> not approved, then document the basis for the <u>Ooffice Ddirector's</u> decision, place a note to file in ADAMS, exit the forward fitting process, and do not take the proposed action.</p>
<u>11</u>	Using Section 3.5 of this <u>NUREG</u> , perform a cost consideration.	<p><u>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.</u></p> <p><u>Describe any impacts of the cost considerations on the decision to take the proposed forward fit.</u></p>

2

3

<b>FORWARD FITTING WORKSHEET (continued)</b>		
<b>Completing the Forward Fitting Assessment</b>		
<u>Step</u>	<u>Action</u>	<u>Notes</u>
<u>912</u>	Prepare the forward fit <del>analysis assessment</del> and submit it to the <del>NRR or NMSS</del> Office Director for approval to offer the <del>Committee to Review Generic Requirements (CRGR)</del> the opportunity to review the package.	<p><del>Refer to NUREG-1409, Section 3.3, and u</del>Use Guide 4 in NUREG-1409, Appendix C, to fully <del>develop the responses in steps 6 and 7, including</del> describe the following: <del>h</del></p> <p><del>ow the forward fit definition is met, how the direct nexus definition is met, how the essential definition is met, r</del>Develop risk insights associated with the staff's proposed forward fitting action-, <del>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.</del></p> <ul style="list-style-type: none"> <li><del>Is the proposed action necessary to maintain adequate protection? If yes, then do not consider the costs of the proposed action.</del></li> <li><del>Is the proposed action necessary to ensure compliance with governing requirements? If yes, then document that determination, how the proposed action ensures compliance, and consideration of the costs of the proposed action.</del></li> <li><del>If the proposed action consists of a new or modified regulatory staff position and the prior regulatory staff position is available for use by the applicant and applicable to the licensing action under review, then perform a regulatory analysis of the proposed action.</del></li> <li><del>If the proposed action consists of a new or modified regulatory staff position and the prior regulatory staff position is no longer available for use by the applicant, or if no prior staff position existed, then consider the costs of the proposed action.</del></li> </ul> <p>If approved, then proceed to the next step.</p> <p>If not approved, then address the <del>NRR or NMSS O</del>office <del>D</del>irector's concerns and re-seek approval. If <del>still</del> not approved, then document the basis for the <del>O</del>office <del>D</del>irector's decision, place a note to file in ADAMS, exit the forward fitting process, and do not take the proposed action.</p>

<del>40</del> 13	If the CRGR agrees to review the package, then follow the procedures for submitting documents to the CRGR.	Prepare the materials for the CRGR as specified in the <a href="#">CRGR Charter and Procedures</a> . Afterwards, address any issues identified by the CRGR.  Proceed to the next step.
<del>44</del> 14	Submit the final forward fit <del>analysis-assessment</del> to the NRR or NMSS Office Director for approval.	If approved, then proceed with the <del>proposed action</del> <a href="#">next step</a> .  If not approved, then address the <del>NRR or NMSS Office</del> <a href="#">Director's</a> concerns and re-seek approval. If <del>still</del> <a href="#">not</a> 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. <a href="#">Do not proceed to the next step.</a>
15	Provide the proposed forward fit to the <a href="#">affected entity</a> for an opportunity to submit an MD 8.4 appeal.	<a href="#">If the affected entity does not submit an MD 8.4 appeal, then proceed with the forward fit.</a>  <a href="#">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.</a>

## APPENDIX C – GUIDES

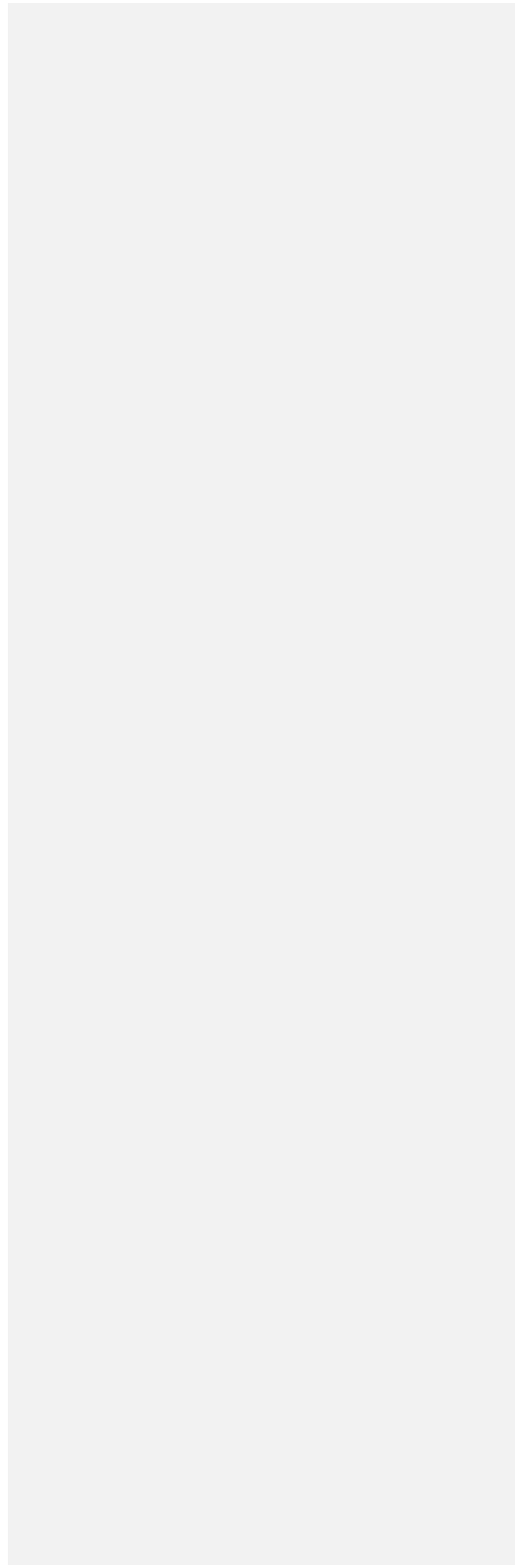
### INSTRUCTIONS FOR USING GUIDES

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

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

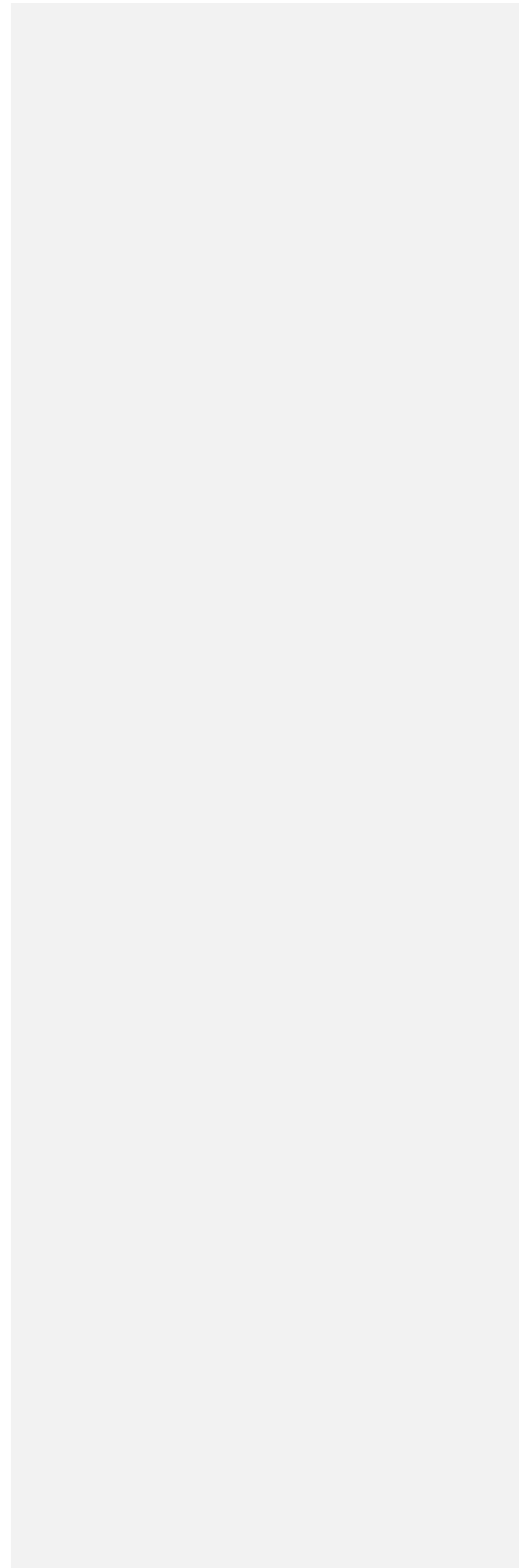


1  
2  
3  
4  
5  
6  
7  
8

**GUIDE 1**

**DOCUMENTED EVALUATION FOR USING  
THE ADEQUATE PROTECTION EXCEPTIONS**





DOCUMENTED EVALUATION

TITLE OF PROPOSED BACKFITTING

AFFECTED ENTITY/LICENSEE NAME

FACILITY NAME

DOCKET NOS.

CONTENTS

A table of contents is recommended when the documented evaluation is longer than 3-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; and
- the expected time, event, or occurrence by which implementation of the proposed backfitting must be completed.

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

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

V. IMMINENT THREAT ANALYSIS [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 imminent threat exists that warrants an immediate agency action.

<sup>1</sup> 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)).

1 VI. ALTERNATIVE METHODS FOR ACHIEVING ADEQUATE PROTECTION

2  
3 A. Alternatives [NUREG-1409, Revision 1, Section 2.5.1.3]

4  
5 Describe the NRC's method (including selection criteria) for identifying reasonable alternatives  
6 to the proposed backfitting for achieving adequate protection. If a regulatory analysis was  
7 prepared to identify such alternatives, then—

- 8  
9
  - State that a regulatory analysis was prepared to identify alternatives.
  - Provide the title, date, and the applicable Agencywide Documents Access and Management System (ADAMS) accession number of the regulatory analysis.
  - Summarize the regulatory analysis's approach (including selection criteria) ~~for to~~ identifying reasonable alternatives to the proposed backfitting for providing adequate protection.

10  
11  
12 Describe the reasonable alternative backfitting actions ~~to the proposed backfitting action~~ that  
13 were considered, irrespective of costs. Also describe the alternatives to the proposed  
14 backfitting that were determined not to be reasonable or feasible, irrespective of costs, and  
15 provide a basis for this determination.  
16  
17

18  
19 B. Cost Considerations [NUREG-1409, Revision 1, Section 2.6.2]

20  
21 If there are multiple ways to implement the action and the NRC prescribes one to comply with  
22 requirements or to achieve adequate protection, then the documented evaluation should  
23 describe the overall approach for considering costs. ~~This description should include~~ This description should include how the  
24 staff determined the level of detail provided, categories of entities for which costs were  
25 estimated or determined, and whether quantitative information was used (and if not, why not). If  
26 only one method of achieving adequate protection is identified, then discuss the reason for this  
27 and truncate the documented evaluation by removing Section C.  
28  
29

30  
31 The cost considerations section must describe the following:

- 32  
33
  - the costs for the proposed backfitting and each identified reasonable alternative, identifying each cost input or element that was integrated to develop the overall cost estimate;
  - uncertainties in each cost input or element;
  - sensitivity of results to changes to cost inputs or elements; ~~and~~
  - overall conclusion on cost considerations, limited to a determination that the proposed backfitting is either—
    - of the following:
      - the least costly of the identified alternatives for achieving reasonable assurance of adequate protection; ~~or~~
      - comparable in cost to the identified alternatives for achieving reasonable assurance of adequate protection.

1 Include a table organizing the cost results for each identified alternative and showing major  
 2 categories or elements of costs if it will help the reader to understand the NRC's consideration  
 3 of costs.  
 4  
 5

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>	\$	\$	\$

#### 6 C. Summary

7 Document the basis for the NRC's determination that the proposed backfitting is the most  
 8 cost-effective method of achieving this protection. If one of the alternatives is the most  
 9 cost-effective, then explain why that alternative is not being pursued.  
 10  
 11

#### 12 VII. CONCLUSION

13 If the NRC determines that ~~one or both of the proposed or final backfitting involves adequate~~  
 14 ~~protection exceptions applies to the proposed backfitting action in accordance with the~~  
 15 ~~applicable regulations and provisions~~, then document this decision, and a summary of its basis,  
 16 and state that the NRC has not prepared a backfit analysis to support the proposed backfitting.  
 17  
 18

19 When multiple methods of achieving adequate protection are available, document the basis for  
 20 the NRC's determination that the proposed backfitting is the most cost-effective method of  
 21 achieving this protection.  
 22  
 23

24 If the NRC has determined that the ~~adequate protection exceptions do not apply to the~~  
 25 ~~proposed backfitting action does not involve adequate protection under the applicable backfitting~~  
 26 ~~provisions~~, then document this decision and its basis.  
 27

#### 28 VIII. REFERENCES

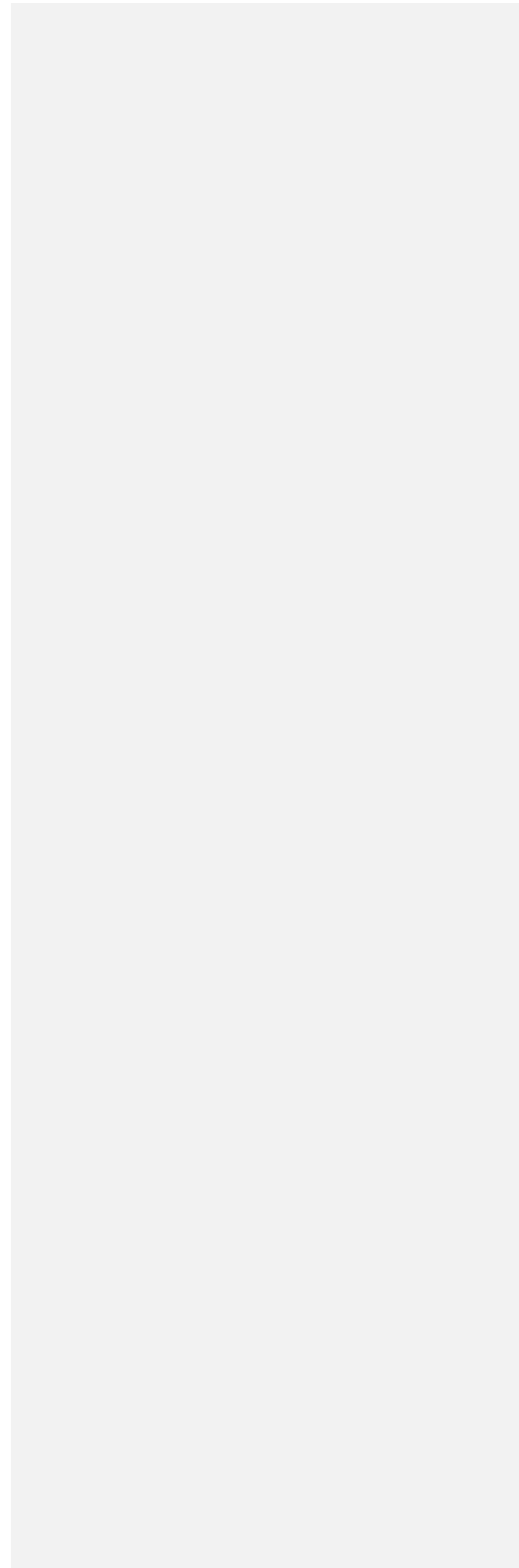
29 List the sources referenced in the documented evaluation.  
 30  
 31

Commented [KA216]: Comment 4.2.19

1  
2  
3  
4  
5  
6  
7  
8  
9

**GUIDE 2**

**DOCUMENTED EVALUATION FOR USING  
THE COMPLIANCE EXCEPTION**



DOCUMENTED EVALUATION

TITLE OF PROPOSED BACKFITTING

AFFECTED ENTITY/LICENSEE NAME

FACILITY NAME

DOCKET NOS.

CONTENTS

A table of contents is recommended when the documented evaluation is longer than 3-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; and
- the expected time, event, or occurrence by which implementation of the proposed backfitting must be completed.

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

Describe why the adequate protection exceptions do not apply to the proposed backfitting action does not involve adequate protection.

Commented [KA217]: Comment 4.2.19

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

A. Requirement

1. Applicable Requirement

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

2. Timing of Requirement

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

3. Application and Interpretation of the Requirement

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

4. Approval

Describe the NRC's approval of the licensee's method of compliance with the requirement. Describe when and in which NRC documents the ~~NRC~~ 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 ~~NRC's~~ original approval, then document those with the explanation for the limitations or caveats.

B. Error or Omission

1. Description of Error or Omission

Describe the NRC's error and, if applicable, the licensee's or third party's error or omission leading to the NRC's error. 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; ~~or~~
- the NRC's failure to draw direct inferences from those facts or analyses.

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

2. Applicability of Standards and Practices

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

3. Relationship of Error to Approval

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

Commented [BH218]: Comment 4.7.2.

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

C. Benefits of the Proposed Backfitting

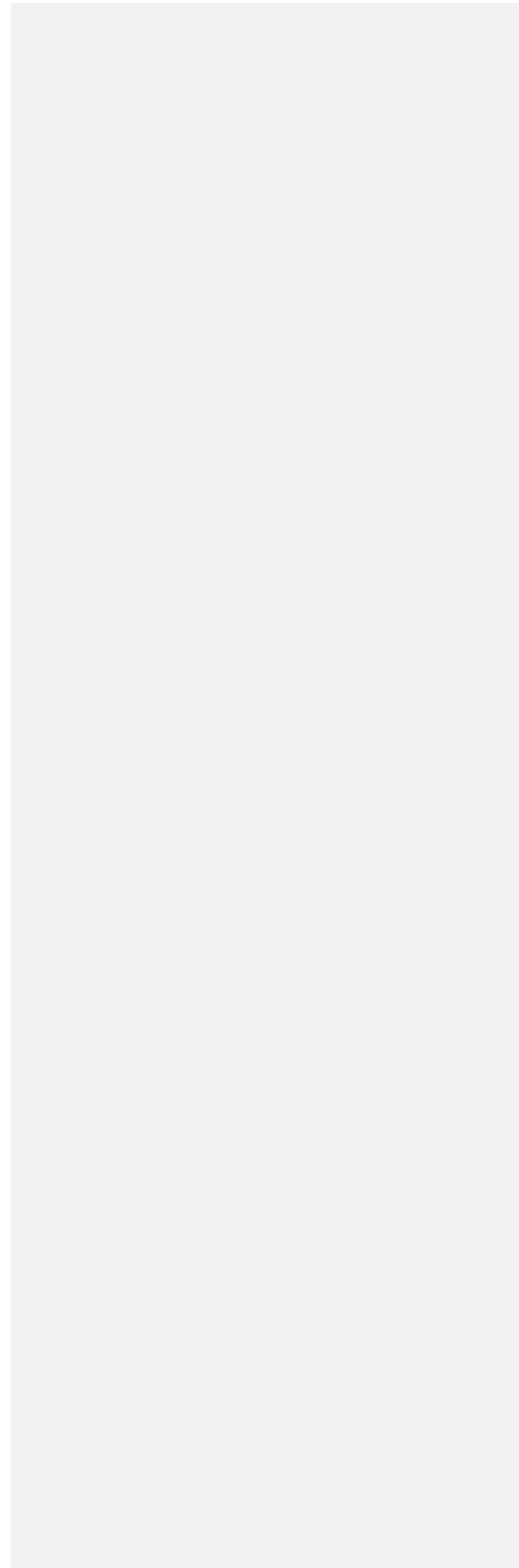
Discuss the quantitative and qualitative information in Section ~~IV~~V.B of this guide as it relates to the benefits of the proposed action.

VII. CONCLUSION

If the NRC determines that the proposed ~~or final~~ backfitting is needed to ensure compliance with the applicable regulations or provisions, then document this decision, 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.

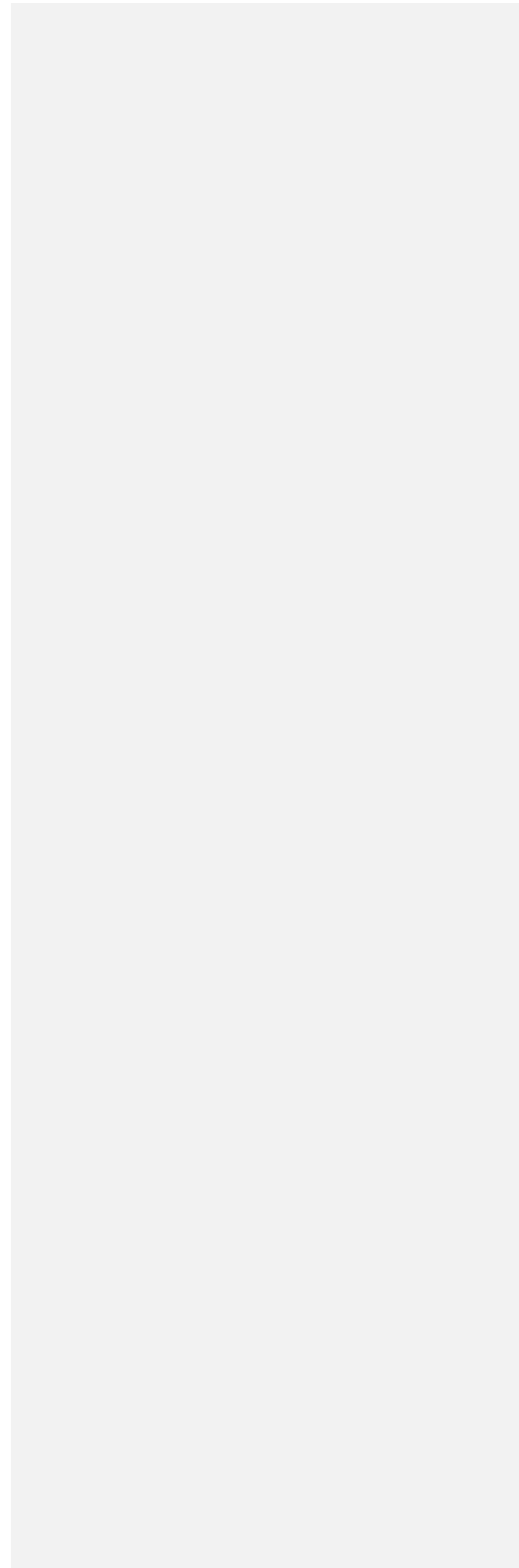
- 1 VIII. REFERENCES  
2  
3 List the sources referenced in the documented evaluation.  
4



1  
2  
3  
4  
5  
6  
7  
8

**GUIDE 3**

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



- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28
- 29
- 30
- 31
- 32
- 33
- 34
- 35
- 36
- 37
- 38
- 39
- 40
- 41
- 42

AFFECTED ENTITY~~LICENSEE~~ NAME

## CONTENTS

- 42



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

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

II. BACKGROUND

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

If the NRC is issuing a proposed rule, then describe ~~its~~ 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), ~~etc.~~). The description will include the following:

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

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

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

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

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

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

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

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

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

If the backfit analysis does not show a substantial increase in benefits, 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 safety<sup>2</sup> 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.

<sup>2</sup> 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 ~~were assessed~~ using the methods described in Appendix A to NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission." Describe the qualitative benefits to public health and safety<sup>3</sup> 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.

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

**Table 2. Qualitative Benefits of the Proposed Backfitting**

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

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

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

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

##### A. Quantitative Costs

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

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

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

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

**Table 3. Quantitative Costs of the Proposed Backfitting**

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

B. Qualitative Costs

Mention that the NRC assessed the qualitative costs ~~were assessed~~ using the methods described in Appendix A to NUREG/BR-0058. Describe the qualitative costs to public health and safety<sup>4</sup> 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.

<sup>4</sup> 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 safety<sup>5</sup> 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>

<sup>5</sup> 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)).

1 VIII. CONCLUSION

2  
3 If the backfit analysis determines that there is a cost-justified substantial increase in the overall  
4 protection of the public health and safety or the common defense and security for the proposed  
5 backfitting, then document this conclusion and summarize the basis for it, using the analysis  
6 above. Cite the applicable backfitting provision.  
7

8 If the backfit analysis determines that there is no substantial increase in the overall protection of  
9 the public health and safety or the common defense and security for the proposed backfitting,  
10 then document this conclusion and summarize the basis for it, using the analysis above, and  
11 state that, accordingly, the NRC concludes that the proposed backfitting is not justified.  
12

13 If the backfit analysis determines that there is a substantial increase in the overall protection of  
14 the public health and safety or the common defense and security for the proposed backfitting,  
15 but that the costs are not justified, then document this conclusion and summarize the basis for  
16 it, using the analysis above. Document that the NRC concludes that the proposed backfitting is  
17 not justified.  
18

19 IX. REFERENCES

20  
21 List the documents referenced in the backfit analysis.  
22

23 X. ATTACHMENT

24  
25 Consider including an attachment containing the evaluation of factors in 10 CFR 50.109(c)(1)  
26 through (9), 10 CFR 70.76(b)(1) through (9), and 10 CFR 76.76(b)(1) through (9), as applicable.  
27 This optional attachment ~~is optional and~~ may be included at the discretion of the staff. The staff  
28 may instead choose to integrate the information required to be addressed by these provisions  
29 into the applicable discussion in the backfit analysis.  
30  
31  
32

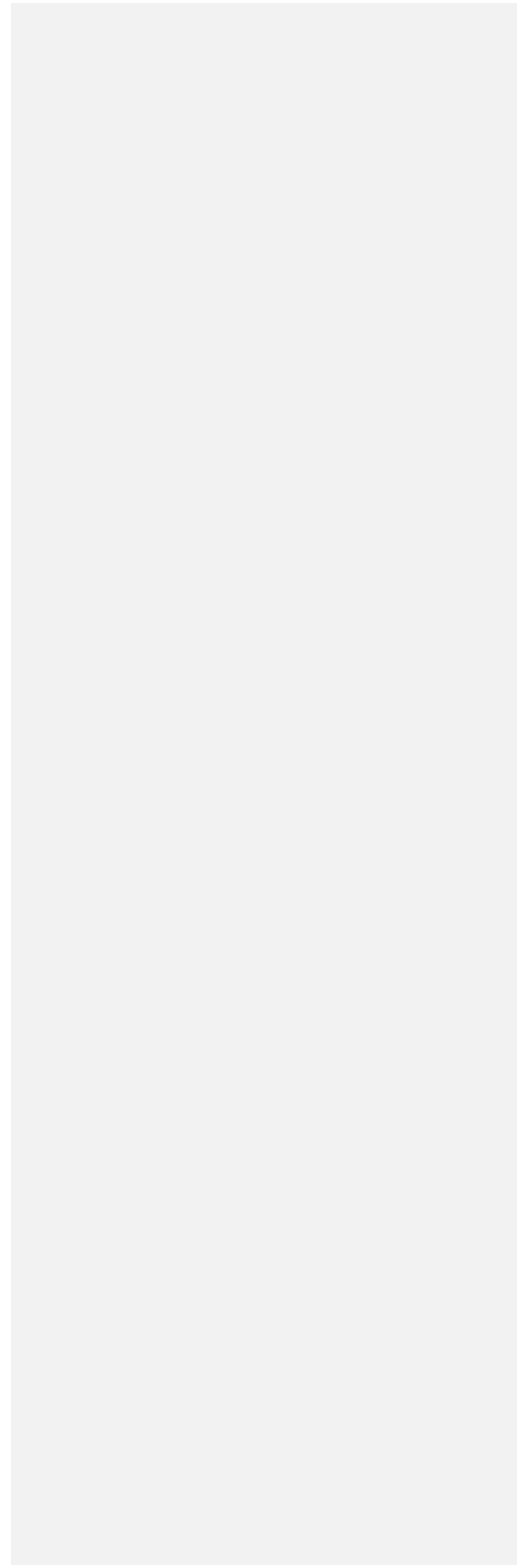
1  
2  
3  
4  
5  
6  
7  
8

GUIDE 4

FORWARD FIT ~~ANALYSIS~~ASSESSMENT

|





FORWARD FIT ~~ASSESSMENT~~ ANALYSIS

TITLE OF PROPOSED FORWARD FITTING

~~AFFECTED ENTITY~~ LICENSEE NAME

FACILITY NAME

DOCKET NOS.

#### CONTENTS

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

#### I. INTRODUCTION

#### II. BACKGROUND

#### III. PROPOSED FORWARD FITTING

##### A. ~~Forward Fitting Definition~~ Screening

##### B. Justification

##### 1. Direct Nexus

##### 2. Essential to the NRC's Determination

##### ~~3C.~~ 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 applicable aspects of the requested licensing action ~~with which the staff took issue.~~

III. PROPOSED FORWARD FITTING

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

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

1. Direct Nexus

Describe how the proposed staff action meets the definition of "direct nexus." ~~is directly related to the licensee's licensing action request.~~

2. Essential to the NRC's Determination

Describe how the proposed staff action meets the definition of "is essential." ~~to the NRC's determination of the acceptability of the licensee's request.~~

~~3C.~~ Cost Consideration [NUREG-1409, Revision 1, Section 3.35]

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

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

**Commented [BH219]:** Edits in Section III.B of this guide reflect changes to Section 3.3 of this NUREG.

**Commented [BH220]:** Edits in Section III.C of this guide reflect changes to Section 3.5 of this NUREG.

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

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

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

#### IV. CONCLUSION

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

#### V. REFERENCES

List the documents referenced in this analysis assessment.



<div><div><div>NRC FORM 335</div><div>(12-2010)</div><div>NRCMD 3.7</div></div><div><div>U.S. NUCLEAR REGULATORY COMMISSION</div><div></div></div></div> <div><div>BIBLIOGRAPHIC DATA SHEET</div><div>(See instructions on the reverse)</div></div>		<div>1. REPORT NUMBER</div> <div>(Assigned by NRC, Add Vol., Supp., Rev., and Addendum Numbers, if any.)</div> <div>NUREG-1409, Rev. 1</div>					
<div>2. TITLE AND SUBTITLE</div> <div>Backfitting Guidelines</div>		<div>3. DATE REPORT PUBLISHED</div> <table><tr><td>MONTH</td><td>YEAR</td></tr><tr><td>March</td><td>2020</td></tr></table>		MONTH	YEAR	March	2020
		MONTH	YEAR				
March	2020						
<div>5. AUTHOR(S)</div> <div>H. Benowitz A. Klett T. Reed</div>		<div>4. FIN OR GRANT NUMBER</div>					
		<div>6. TYPE OF REPORT</div> <div>Technical</div>					
<div>8. PERFORMING ORGANIZATION - NAME AND ADDRESS (If NRC, provide Division, Office or Region, U. S. Nuclear Regulatory Commission, and mailing address; if contractor, provide name and mailing address.)</div> <div>U.S. Nuclear Regulatory Commission Office of Nuclear Reactor Regulation Division of Operating Reactor Licensing Washington, DC 20555-0001</div>		<div>7. PERIOD COVERED (Inclusive Dates)</div>					
		<div>9. SPONSORING ORGANIZATION - NAME AND ADDRESS (If NRC, type "Same as above", if contractor, provide NRC Division, Office or Region, U. S. Nuclear Regulatory Commission, and mailing address.)</div> <div>Same as above</div>					
<div>10. SUPPLEMENTARY NOTES</div>							
<div>11. ABSTRACT (200 words or less)</div> <div>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."</div>							
<div>12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.)</div> <div>Backfit, backfitting, forward fit, issue finality, backfit analysis.</div>		<div>13. AVAILABILITY STATEMENT</div> <div>unlimited</div>					
		<div>14. SECURITY CLASSIFICATION</div> <div>(This Page)</div> <div>unclassified</div>					
		<div>(This Report)</div> <div>unclassified</div>					
		<div>15. NUMBER OF PAGES</div>					
		<div>16. PRICE</div>					





Federal Recycling Program







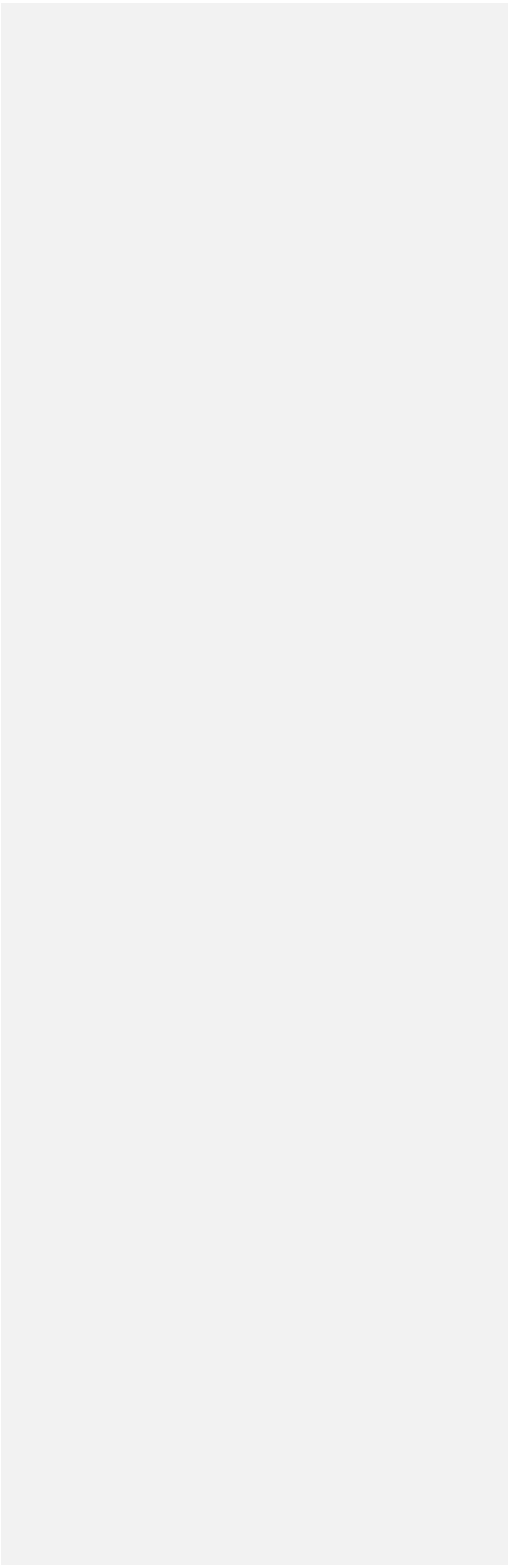
UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555-0001  
OFFICIAL BUSINESS



@NRCgov







**NUREG-1409, Rev. 1**

**Backfitting Guidelines**

**Month YYYY**