



NUREG-1409, Rev. 1

Backfitting Guidelines

Office of Nuclear Reactor Regulation

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NUREG-1409, Rev. 1

1 **Backfitting Guidelines**

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4 [Comments]

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ABSTRACT

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

8
9 Backfitting occurs when the NRC imposes new or changed regulatory requirements or staff
10 interpretations of the regulations or requirements on nuclear power reactor licensees, certain
11 nuclear power reactor applicants, or select nuclear materials licensees. Backfitting is an integral
12 part of the regulatory process and may be needed when the staff addresses safety or security
13 issues. The NRC may take a backfitting action only after conducting a formal, systematic
14 review to ensure that the action is defined and justified. This process ensures discipline,
15 predictability, and optimal use of NRC, ~~and~~ licensee, ~~and~~ applicant resources. The backfitting
16 requirements are in 10 CFR 50.109, "~~Backfitting,~~" 70.76, "~~Backfitting,~~" 72.62, "~~Backfitting,~~" and
17 76.76, all titled, "Backfitting." Provisions analogous to the backfitting requirements, referred to
18 as issue finality provisions, ~~are set forth appear~~ in 10 CFR Part 52, "Licenses, ~~C~~certifications,
19 and ~~A~~approvals for ~~N~~nuclear ~~P~~power ~~P~~plants."

20
21 Forward fitting occurs when the NRC conditions its approval of a licensee-initiated request for a
22 licensing action on the licensee's compliance with a new or modified requirement or staff
23 interpretation of a requirement that the licensee did not request. ~~Generally, T~~he new or
24 modified requirement or staff interpretation must result in, ~~generally,~~ a change to the licensee's
25 systems, structures, components, design, approval, procedures, or organization. A similar
26 process to forward fitting can also apply to certain applications for initial licenses.

27
28 The NRC issued the previous version of this NUREG in 1990, but the 1990 document did not
29 address the backfitting requirements in 10 CFR Part 70, "Domestic ~~L~~icensing of ~~S~~pecial
30 ~~N~~nuclear ~~M~~aterial," 10 CFR Part 72, "Licensing ~~R~~requirements for the ~~i~~ndependent ~~S~~torage
31 of ~~S~~pent ~~N~~nuclear ~~F~~uel, ~~H~~igh-~~L~~level ~~R~~adioactive ~~W~~aste, and ~~R~~eactor-~~R~~elated ~~G~~reater
32 ~~T~~han Class C ~~W~~aste," or 10 CFR Part 76, "Certification of ~~G~~aseous ~~D~~iffusion ~~P~~plants"; the
33 issue finality provisions in 10 CFR Part 52; or the Commission's forward fitting policy in
34 Management Directive 8.4, most of which were developed after 1990. This version-update of
35 NUREG-1409 is a substantial revision of-to the 1990 version-document and addresses all
36 backfitting and issue finality provisions in the regulations listed above and the Commission's
37 backfitting, issue finality, and forward fitting policies.

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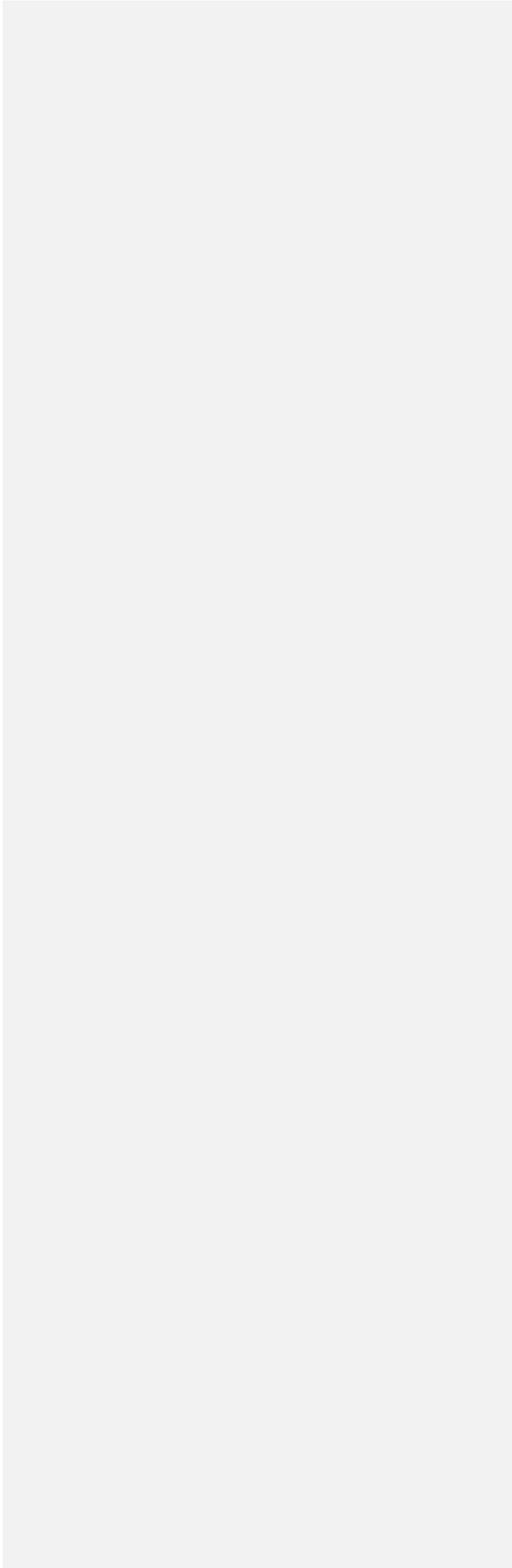
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1

EXECUTIVE SUMMARY

2 This document presents guidance on ~~the implementation of~~ the U.S. Nuclear Regulatory
 3 Commission (NRC) regulations on backfitting and issue finality and the Commission's policies
 4 on backfitting, issue finality, and forward fitting. Backfitting occurs when the NRC imposes
 5 certain new or changed regulatory requirements or staff positions interpreting requirements on
 6 nuclear power reactor licensees, select nuclear power reactor applicants, or select nuclear
 7 materials licensees. Backfitting is an integral part of the regulatory process and may be needed
 8 when the staff addresses safety or security issues. Issue finality is a concept similar to
 9 backfitting that applies only to ~~the holders of~~ certain nuclear power reactor-related approvals
 10 under ~~Title 10 of the Code of Federal Regulations (10 CFR) Part 52, "Licenses, Certifications,~~
 11 ~~and Approvals for Nuclear Power Plants."~~ Forward fitting occurs when the NRC imposes
 12 on a licensee certain new or revised requirements or staff interpretations of a requirement
 13 during its review of a licensee-initiated request for a licensing action. [A similar process to](#)
 14 [forward fitting can also apply to certain applications for initial licenses.](#) Management
 15 Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information
 16 Requests," dated September 20, 2019, describes the Commission's policies on backfitting,
 17 issue finality, and forward fitting.

18
 19 ~~Title 10 of the Code of Federal Regulations (10 CFR) Section~~ ~~In the NRC's regulations,~~
 20 ~~10 CFR 50.109, "Backfitting" (the Backfit Rule),~~ provides backfitting provisions for nuclear power
 21 reactor licensees ~~and certain applicants.~~ It is the NRC's policy that nonpower production or
 22 utilization facilities licensed under 10 CFR 50.21, "Class 104 licensees; for medical therapy and
 23 research and development facilities," paragraphs (a) or (c), or 10 CFR 50.22, "Class 103
 24 licensees; for commercial and industrial facilities," are not within the scope of the backfitting
 25 provisions. Backfitting provisions for select nuclear material licensees are contained in
 26 10 CFR 70.76, ~~"Backfitting,"~~ 72.62, ~~"Backfitting,"~~ and 76.76, ~~all titled,~~ "Backfitting." Each of
 27 these provisions, as with the issue finality provisions in 10 CFR Part 52, requires that the NRC
 28 follow a formal, systematic process before imposing new or changed regulatory requirements or
 29 staff positions interpreting requirements on entities that are the subject of these regulations.
 30 This process ensures discipline, predictability, and optimal use of NRC, ~~and~~ licensee, ~~and~~
 31 ~~applicant~~ resources.

32
 33 The backfitting regulations address both generic and facility-specific backfitting actions ~~for~~
 34 ~~power reactor licensees and select materials licensees.~~ The backfitting provision in
 35 10 CFR Part 50, "Domestic ~~L~~icensing of ~~P~~roduction and ~~U~~tilization ~~F~~acilities," defines a
 36 backfitting action as [follows](#):

37
 38 "the modification of or addition to systems, structures, components, or design of
 39 a facility; or the design approval or manufacturing license for a facility; or the
 40 procedures or organization required to design, construct or operate a facility; any
 41 of which may result from a new or amended provision in the Commission's
 42 regulations or the imposition of a regulatory staff position interpreting the
 43 Commission's regulations that is either new or different from a previously
 44 applicable staff position...."

45
 46 The definitions of "backfitting" in 10 CFR Part 70, "Domestic ~~L~~icensing of ~~S~~pecial ~~N~~nuclear
 47 ~~M~~aterial," and Part 76, "Certification of ~~G~~aseous ~~D~~iffusion ~~P~~lants," are very similar to the
 48 definition in 10 CFR Part 50. The definition of "backfitting" in 10 CFR Part 72, "Licensing
 49 ~~R~~requirements for the ~~I~~ndependent ~~S~~torage of ~~S~~pent ~~N~~nuclear ~~F~~uel, ~~H~~igh-~~L~~evel

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~~radioactive ~~W~~waste, and ~~R~~reactor-~~R~~related ~~G~~greater than Class C ~~W~~waste,” 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~~on 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.

20
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

32
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

1		
2	10 CFR	Title 10 of the <i>Code of Federal Regulations</i>
3	ADAMS	Agencywide Documents Access and Management System
4	AEA	Atomic Energy Act of 1954, as amended
5	AEC	Atomic Energy Commission
6	ASLBP	Atomic Safety and Licensing Board Panel
7	ASME	American Society of Mechanical Engineers
8	CDF	core damage frequency
9	CFR	<i>Code of Federal Regulations</i>
10	CoC	C ertificate of C ompliance
11	COL	combined license
12	CRGR	Committee to Review Generic Requirements
13	D.C.	District of Columbia
14	DC	design certification
15	EDO	Executive Director for Operations
16	ESP	early site permit
17	FR	<i>Federal Register</i>
18	GDC	general design criterion/criteria
19	ISFSI	independent spent fuel storage installation
20	LAR	license amendment request
21	LWR	light-water reactor
22	MD	M anagement D irective
23	ML	manufacturing license
24	NCV	non-cited violation
25	NEI	Nuclear Energy Institute
26	NMSS	Office of Nuclear Material Safety and Safeguards
27	NOV	notice of violation
28	NRC	U.S. Nuclear Regulatory Commission
29	NRR	Office of Nuclear Reactor Regulation
30	NTTAA	National Technology Transfer and Advancement Act of 1995
31	NUREG	NRC technical report designation
32	NUREG/BR	NUREG brochure
33	OGC	Office of the General Counsel
34	OMB	Office of Management and Budget
35	PDC	principal design criteria
36	PRA	probabilistic risk assessment
37	SDA	standard design approval
38	SOC	statement of considerations
39	SRM	S taff R equirements M emorandum
40	SRP	S tandard R eview P lan
41	SSC	structure, system, and component
42	U.S.C.	United States Code
43		
44		

1 **1 OVERVIEW OF BACKFITTING, ISSUE FINALITY, AND FORWARD**
2 **FITTING**

3 **1.1 Introduction**

4 This document provides the U.S. Nuclear Regulatory Commission (NRC) staff with guidance to
5 ensure consistent implementation of the backfitting and issue finality provisions in Title 10 of the
6 *Code of Federal Regulations* (10 CFR) Chapter I and the backfitting, issue finality, and forward
7 fitting policies in Management Directive (MD) 8.4, "Management of Backfitting, Forward Fitting,
8 Issue Finality, and Information Requests," dated September 20, 2019.¹ This guidance is
9 intended for use by the NRC staff (except for Chapter 4, which also contains guidance for use
10 by affected entities), is not legally binding, and does not contain or imply requirements for any
11 affected entity. For the purposes of this NUREG, the unqualified term "affected entity"
12 comprises the entities listed in Section 2.3 of this NUREG, licensee,² any holder of a standard
13 design approval, or any design certification applicant after the NRC issues the applicable design
14 certification rule under 10 CFR Part 52.

15
16 In 2016, the Executive Director for Operations (EDO) tasked the Committee to Review Generic
17 Requirements (CRGR) with assessing the agency's backfitting requirements, policy, guidance,
18 criteria, training, and knowledge management. In response, the CRGR hosted two public
19 meetings to obtain stakeholder feedback on backfitting and the agency's backfitting process.
20 On June 27, 2017, the CRGR issued a report on the NRC's backfitting process and
21 recommended several actions. Subsequently, the NRC revised MD 8.4, this NUREG,
22 NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory
23 Commission," and the CRGR Charter to reflect policy updates, organizational changes, the
24 latest judicial decisions, Commission direction, and the CRGR's process for reviewing
25 backfitting activities.

26
27 This NUREG begins by describing the relevant regulations, terminology, policies, and processes
28 associated with backfitting, forward fitting, and issue finality. Chapter 2 explains how to screen
29 and justify potential backfitting actions. Chapter 3 explains how to screen, and justify, and
30 consider the costs of potential forward fitting actions. Chapter 4 presents sets forth the
31 backfitting and forward fitting appeals process. Chapter 5 describes several NRC actions and
32 processes and whether they may constitute backfitting or forward fitting. Chapter 6 provides the
33 staff's recordkeeping and documentation obligations. Chapter 7 lists the references cited in this
34 document. The appendices contain flowcharts, worksheets, and guides to assist the staff in
35 working through potential backfitting or forward fitting actions.
36

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.

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

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

1 In this NUREG, the NRC uses the terms “backfit” and “backfitting” generally to mean backfitting
2 actions as defined in 10 CFR 50.109, ~~“Backfitting,”~~ 70.76, ~~“Backfitting,”~~ 72.62, ~~“Backfitting,”~~ and
3 76.76, all titled, “Backfitting,” and matters involving issue finality under 10 CFR Part 52,
4 “Licenses, certifications, and approvals for nuclear power plants.”
5

6 **1.2 Backfitting and Issue Finality**

7 The NRC ~~uses the term “the Backfit Rule” to refer~~s to the provisions in 10 CFR 50.109 as the
8 “Backfit Rule.” The rule defines the term “backfitting” to mean the following for nuclear power
9 reactors licensed under 10 CFR Part 50, “Domestic licensing of production and utilization
10 facilities,” and 10 CFR Part 52, “Licenses, certifications, and approvals for nuclear power
11 plants”:
12

13 the modification of or addition to systems, structures, components, or design of a
14 facility; or the design approval or manufacturing license for a facility; or the
15 procedures or organization required to design, construct or operate a facility; any
16 of which may result from a new or amended provision in the Commission’s
17 regulations or the imposition of a regulatory staff position interpreting the
18 Commission’s regulations that is either new or different from a previously
19 applicable staff position....
20

21 The Backfit Rule also provides the bases on which the NRC can justify taking backfitting
22 actions. This rule is intended, in part, to provide predictability and stability to the NRC’s
23 regulatory processes. Before the NRC can impose certain requirements and positions, the staff
24 must perform a formal, systematic review to ensure that it has properly defined and justified the
25 proposed action. By limiting the changes that the NRC can make to a licensee’s facility’s
26 licensing basis, the Backfit Rule allows a licensee to operate a facility in accordance with its
27 licensing basis and reasonably rely on the NRC to impose only justified changes to its license or
28 facility. This reliability is part of the basis of the NRC’s regulatory framework, as explained in
29 the ~~NRC’s~~ Principles of Good Regulation, ~~as~~ provided in the NRC’s “Strategic Plan for Fiscal
30 Years
31 2018–2022,” issued February 2018 (NUREG–1614, Volume–7):
32

33 Once established, regulation should be perceived to be reliable and not
34 unjustifiably in a state of transition. Regulatory actions should always be fully
35 consistent with written regulations and should be promptly, fairly, and decisively
36 administered so as to lend stability to the nuclear operational and planning
37 processes.
38

3 ³ ~~The~~ Office of Nuclear Reactor Regulation (NRR) Office Instruction LIC-100, “Control of Licensing Bases for
Operating Reactors,” dated January–7,–2004, states that the licensing basis for a nuclear power reactor
consists of three categories of information: (1) obligations (also referred to as regulatory requirements),
which include regulations, orders, and the license; (2) mandated licensing basis documents (e.g., the
updated final safety analysis report, quality assurance program); and (3) regulatory commitments. For 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.⁴

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.⁵ 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

⁴ _____ The Supreme Court's decision in *Michigan v. Environmental Protection Agency*, 135 S. Ct. 2699 (2015),
reflects the view that, under the Administrative Procedure Act of 1946, unless Congress has indicated
otherwise, an agency's decisionmaking calculus should include at least some consideration of the cost
placed on a ~~licensee-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.

⁵ _____ 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 implement~~ing~~
~~ation~~ 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

1 **Table 1-1. NRC Backfitting and Issue Finality Requirements⁶**

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.

2
3 **1.2.2 Terminology**

4 Under the backfitting regulations, backfitting can “result from a new or amended provision in the
5 Commission’s regulations or the imposition of a regulatory staff position interpreting the
6 Commission’s regulations that is either new or different from a previously applicable staff
7 position.” To ensure the proper consistent implementation of the backfitting regulations, the
8 following discussion describes the fundamental backfitting terms.

Commented [BH12]: Comment 4.1.14

9
10 **1.2.2.1 Requirements**

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

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

1 interpreting those requirements. For backfitting, issue finality, and forward fitting⁷ 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.e.g.~~, 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~~s~~ (or safety evaluation report~~s~~) provide~~s~~ 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

⁷ ~~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.

1 that a staff position in a safety evaluation is incorrect, then agency actions related to that
2 decision are subject to backfitting and issue finality considerations⁸.

3
4 ~~Caution: Inspection reports can contain staff positions, but the staff must not use
5 inspection reports to create staff positions about the adequacy of the licensing
6 basis (e.g., "the licensee is in compliance"), although some exceptions may apply
7 depending on the type of inspection. If an inspector does not identify any
8 findings, the current practice of stating, "The NRC inspectors did not identify any
9 findings or violations of more than minor significance," in the inspection report
10 does not create a staff position. This language acknowledges the possibility that
11 there were non-compliances but that the inspectors did not identify them in the
12 report (e.g., because of the sampling nature of the inspection process, or
13 because any identified non-compliances were found to be minor). However, if
14 the inspection report states, "The licensee complied with [Requirement X]," then
15 that language would constitute a staff position. If the NRC subsequently
16 determines there is a non-compliance with "Requirement X" related to the
17 inspected sample, then the NRC may need to consider that discovery a change
18 in staff position subject to the backfitting provisions.~~

19
20 In general, internal agency communications are not staff positions. For example, the staff's
21 conclusion for a technical assistance request is not a staff position. The conclusion could
22 become a staff position if it is used as the documented basis for further staff action. Until or
23 unless it is used for that purpose, the conclusion is an internal agency communication.
24 Section 5.1.2.24 of this NUREG provides more information about the technical assistance
25 request process.

26
27 ~~Generic staff positions may be contained in documents such as regulatory guides, standard
28 review plans, NUREGs, interim staff guidance, branch technical positions, and NRC-endorsed
29 industry topical reports may contain generic staff positions. However, these generic staff
30 positions do not apply to individual licensees until or unless the licensee incorporates them into
31 its licensing basis as a means for meeting or complying with a governing requirement, the
32 NRC imposes generic positions on specific licensees through orders or rulemakings, or the
33 NRC approves issues licensing actions involving that incorporate the generic positions into
34 licensing bases. Even if a generic staff position applies to individual licensees resulting from
35 one of the actions in the preceding sentence, subsequent revisions of these generic staff
36 positions are not applicable to a licensee unless or until one of the actions in the preceding
37 sentence occurs. Chapter 5 of this NUREG has additional guidance on the relationships
38 between among backfitting, issue finality, and generic communications.~~

39
40 If the staff proposes to develop a new or modified regulatory staff position, and the prior position
41 would no longer be available for use or its use would be restricted in some manner for licensees
42 having that prior staff position in their licensing basis, then that proposed action would likely
43 involve backfitting or issue finality and possibly forward fitting. The staff would need to address
44 the backfitting, issue finality, and forward fitting implications at the time the new or amended
45 staff position is issued. Chapters 2 and 3 of this NUREG provide guidance on how to consider
46 the backfitting and forward fitting implications. Chapter 5 of this NUREG describes the

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

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.

1 relationship of backfitting, issue finality, and forward fitting to developing or withdrawing
2 guidance.

3 ~~The NRC's acknowledgment of a licensee's response to a 10 CFR 50.54(f) request for~~
4 ~~information does not establish a staff position. If the NRC subsequently sends the licensee~~
5 ~~written correspondence about the acceptability of the information for some regulatory purpose,~~
6 ~~then that correspondence would constitute an NRC position for that regulatory purpose.~~

7 ~~Subsequent revisions of a generic staff position are not applicable to a licensee unless or until~~
8 ~~that licensee specifically incorporates it into its licensing basis or the NRC imposes it through a~~
9 ~~backfitting or forward fitting action.~~

11 1.2.3 Backfitting Justifications

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

18
19 The other justifications do not require a backfit analysis. These exceptions to the requirement to
20 perform a backfit analysis can be invoked if the proposed action meets one or more of the
21 following criteria:

- 22
23 • The action is necessary to ensure that the facility provides adequate protection ~~of to~~ the
24 public health and safety and is in accord with the common defense and security.
- 25
26 • The action involves defining or redefining the level of protection to the public health and
27 safety or ~~the~~ common defense and security that should be regarded as adequate.
- 28
29 • The action is necessary to bring a facility into compliance with applicable requirements
30 or into conformance with written commitments by the licensee.

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

35
36 The AEA requires the NRC to approve, among other things, the possession and use of
37 radioactive materials only when the NRC has reasonable assurance that such possession and
38 use will provide adequate protection of the public health and safety and the common defense
39 and security (i.e., no undue risk). Thus, when an issue exists such that the NRC no longer has
40 reasonable assurance of adequate protection, the AEA requires the NRC to ~~take an action as~~
41 necessary to provide reasonable assurance of adequate protection of the public health and
42 safety and the common defense and security. If that action would constitute backfitting, then
43 the AEA ~~nevertheless~~ requires the NRC to ~~nevertheless~~ take the action to address the issue.
44 For this reason, as directed by the Commission in Staff Requirements Memorandum (SRM)
45 COMSECY-16-0020, "Revision of Guidance Concerning Consideration of Cost and Applicability
46 of Compliance Exception to Backfit Rule," dated November 29, 2016, and explained in an NRC
47 memorandum dated December 20, 2016, from the NRC Solicitor to the Chairman of the CRGR,
48 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.

1 adequate protection before considering other justifications. Because the NRC is mandated to
2 ~~take an action involving as necessary to achieve~~ adequate protection, the ~~NRC agency~~ does not
3 need to consider the costs of the action unless the NRC has identified more than one method of
4 achieving adequate protection and prescribes one of those methods. In that situation, the NRC
5 may consider the costs of each method when selecting the method. If the NRC does not
6 prescribe the method of achieving adequate protection, then the NRC does not consider the
7 costs of the method(s). Also, upon determining that a backfit is necessary for adequate
8 protection to the public health and safety, the NRC must prepare an imminent threat analysis
9 that determines whether immediate action is necessary.

Commented [BH28]: Comment 4.2.19

10
11 Only after determining that ~~neither of the adequate protection exceptions applies to~~ a proposed
12 backfitting action ~~does not meet the adequate protection exception~~ can the staff consider
13 whether the compliance exception applies. If the proposed action cannot be justified by one of
14 the adequate protection or compliance exceptions, then the staff must complete a backfit
15 analysis showing that the proposed action represents a cost-justified substantial increase in
16 overall protection. If the proposed backfitting action cannot be justified by any of these means,
17 then the action cannot be pursued through backfitting, and the staff can consider other agency
18 processes.

Commented [BH29]: Comment 4.2.19

19
20 The provisions of 10 CFR Part 70, Subpart H, including the backfitting provisions in
21 10 CFR 70.76, apply to certain licensees that are engaged in specific operations and are
22 authorized to possess an amount of special nuclear material greater than a critical mass
23 (e.g., nuclear fuel cycle facilities). Subpart H also includes specific requirements for adequate
24 protection of workers. These requirements include protection from nuclear-related hazards
25 (e.g., criticality, radiation) and chemical hazards that are comingled or resultant from nuclear
26 processes or events. The backfitting provisions for these licensees in 10 CFR 70.76 consider
27 these worker protection aspects as part of the overall protection of the public health and safety
28 or the common defense and security.

29
30 The backfitting provisions in 10 CFR Part 72, ~~"Licensing Requirements for the Independent
31 Storage of Spent Nuclear Fuel, High Level Radioactive Waste, and Reactor-Related Greater
32 Than Class C Waste,"~~ contain justification concepts similar to the other backfitting regulations
33 but apply those concepts differently. Under 10 CFR 72.62(b), the NRC will require backfitting of
34 an ISFSI or monitored retrievable storage installation if the NRC finds that backfitting is
35 necessary to ensure adequate protection ~~efo~~ occupational or public health and safety. Also,
36 under 10 CFR 72.62(b), the NRC will require backfitting to bring the ISFSI or monitored
37 retrievable storage installation into compliance with applicable requirements or into
38 conformance with written commitments by the licensee. Under 10 CFR 72.62(c), if the staff
39 cannot justify the backfitting action as necessary for adequate protection or compliance, but the
40 staff can justify the backfitting as a cost-justified, substantial increase in overall protection, then
41 the NRC may require backfitting. The "substantial increase" test of the 10 CFR Part 72 backfit
42 analysis also considers occupational health and safety derived from the backfitting action.
43 Commission policy in MD 8.4 requires backfitting actions under 10 CFR 72.62 that are justified
44 under an adequate protection or compliance exception to be supported by a documented
45 evaluation similar to those under 10 CFR 70.76 and 10 CFR 76.76. Consistent with
46 10 CFR 50.109(a), 70.76(a), and 76.76(a) and the transparency and reasoned decision-making
47 objectives of the Backfit Rule, the NRC should prepare a backfit analysis for all proposed
48 backfitting actions under 10 CFR 72.62(c).

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

1 **1.2.4 Administrative Exemption**

2 If the Commission needs to impose an action that meets the definition of “backfitting” but cannot
3 meet the backfitting requirements, or would change a 10 CFR Part 52 approval but not satisfy
4 the applicable issue finality criteria, then the Commission can exempt itself from the applicable
5 backfitting or issue finality provisions. The Commission described this concept in
6 SRM-SECY-93-086, “Backfit Considerations,” dated June 30, 1993, and in greater detail in the
7 statement of considerations (SOC) for the 2009 Aircraft Impact Assessment Rule ~~(codified at~~
8 ~~10 CFR 50.150)~~. As a practical matter, an administrative exemption should be considered only
9 when none of the criteria for justifying the backfitting action or changing the 10 CFR Part 52
10 approval can be met and either the Commission or the EDO has indicated a desire to proceed
11 with the proposed backfitting action after being informed by the NRC staff that it was unable to
12 justify the proposed backfitting in accordance with any of the applicable backfitting provisions or
13 meet the applicable issue finality criteria to change the 10 CFR Part 52 approval.

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

14
15 The agency has used the administrative exemption only twice since the Commission first
16 articulated the concept in 1993. The first use of this exemption was for the Aircraft Impact
17 Assessment Rule, which followed the events of September 11, 2001. The second ~~time~~ was for
18 Order EA-12-051, “Order Modifying Licenses with Regard to Reliable Spent Fuel Pool
19 Instrumentation” (77 FR 16082; ~~dated~~ March 19, 2012), issued after the accident at the
20 Fukushima nuclear reactors in Japan in 2011. As these examples show, the NRC should
21 employ the exemption only in very significant circumstances.

22
23 In SRM-SECY-93-086 rulemaking, the Commission discussed the use of the administrative
24 exemption in rulemaking, explaining that it may implement the administrative exemption by
25 making a finding in a proposed rule’s SOC, thereby providing the public with notice and an
26 opportunity to comment. Although not an administrative exemption, the Commission can also
27 change the applicable backfitting or issue finality provision through a rulemaking, which would
28 also provide the public with notice and an opportunity to comment.

29
30 In other circumstances (e.g., the issuance of orders), to implement the administrative
31 exemption, the Commission should, unless immediate action is necessary, provide the public
32 with an opportunity to comment on the proposed action. As demonstrated in Order EA-12-051,
33 the NRC uses the administrative exemption outside of rulemaking only in certain situations:
34 (1) highly exceptional actions with extraordinary underlying circumstances, (2) extensive
35 stakeholder engagement, (3) a need for timely action, and (4) broad endorsement from
36 stakeholders for timely action.

Commented [KA32]: Comment 4.1.15

37
38 **1.2.5 ~~Generic and Facility-Specific~~ and Generic Backfitting Actions**

Commented [BH33]: Comment 4.1.18

39 There are two types of backfitting actions: ~~generic and~~ facility-specific and generic.
40 Facility-specific backfitting actions involve positions unique to a particular facility or docket.
41 The NRC imposes a backfitting action on a specific facility through a letter communicating a
42 change in staff position or an order imposing a new or changed requirement. Each
43 communication to an affected entity of a proposed or issued backfitting action should include the
44 backfitting assessment for the action, instructions on the use of the appeals process (Chapter 4
45 of this NUREG has more information on the appeals process), and a schedule for implementing
46 the action once it becomes effective, as applicable. To determine an acceptable schedule for a
47 licensee to implement a facility-specific backfitting action, the staff must consider the
48 significance of the safety or security concern and the timing of other ongoing regulatory
49 activities at the facility, such as planned construction, outages, or other maintenance, in

1 ~~accordance with the applicable backfitting regulations (e.g., 10 CFR 50.109(c)). Section 5.1.4 of~~
2 ~~this NUREG contains guidance for NRC staff communications with the affected entity about~~
3 ~~proposed or issued backfitting actions and the options available to the NRC staff and affected~~
4 ~~entity.~~

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.

6 ~~—Generic Backfitting Actions~~

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

14
15 Regardless of whether a generic backfitting action is the result of an order, rulemaking, or a new
16 or changed staff interpretation, the staff must document its justification. Stakeholders must
17 generally have had an opportunity to review and provide comments in response to a *Federal*
18 *Register* notice. Because the NRC does not typically notice draft orders for public comment in
19 the *Federal Register*, the staff should hold a public meeting to ~~provide~~ **give the public** an
20 opportunity ~~for public to~~ comment when the generic backfitting action is the result of an order.
21 However, significant safety or security generic backfitting actions requiring timely action may not
22 allow for prior public notice and opportunity to comment.

23
24 In most cases, the Commission will review generic backfitting actions unless the Commission
25 has delegated ~~its the Commission's~~ authority to the EDO (although the Commission must review
26 all proposed backfits invoking the adequate protection exceptions). ~~This authority may have~~
27 ~~been redelegated to a program office director~~ (e.g., Section III.B.8 of MD 6.3, "The Rulemaking
28 Process," dated July 3, 2019, lists the rulemakings under 10 CFR 50.55a, "Codes and
29 standards," as being delegated from the EDO to the NRR Office Director.).

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.

30
31 ~~The backfitting appeals process described in Chapter 4 of this NUREG is not applicable to~~
32 ~~generic backfitting actions. Licensees have opportunities to raise backfitting concerns during~~
33 ~~the development of typical generic backfitting actions. For example, in rulemaking, stakeholders~~
34 ~~can comment on a proposed rule and the agency's discussion of backfitting in the proposed~~
35 ~~rule's SOC. A final rule is a final agency action that can be appealed in court. Orders can be~~
36 ~~challenged through the NRC's hearing process.~~

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

37 38 ~~1.2.5.2 —Facility-Specific Backfitting Actions~~

Commented [KA37]: Comment 4.1.18

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

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

3
4 ~~To determine an acceptable schedule for a licensee to implement a facility-specific backfitting~~
5 ~~action, the staff must consider the significance of the safety or security concern and the timing~~
6 ~~of other ongoing regulatory activities at the facility, such as planned construction, outages, or~~
7 ~~other maintenance, in accordance with the applicable backfitting regulations (e.g.,~~
8 ~~10 CFR 50.109(e)).~~

10 1.2.6 Issue Finality Provisions

11 Issue finality describes the treatment of a final Commission or staff decision on an approval
12 under 10 CFR Part 52. Approvals under 10 CFR Part 52 include ESPs, DCs, COLs, SDAs,
13 MLs, and renewals of these approvals. Once the final decision has been made, all matters and
14 issues associated with the decision are resolved and final. The 10 CFR Part 52 licensing
15 process enables an applicant to incorporate by reference, as part of its application, certain
16 previous Part 52 approvals in which the referenced approval is afforded issue finality. Similar to
17 the Backfit Rule, if the NRC, or an applicant referencing a 10 CFR Part 52 approval in its
18 application, proposes to change an existing Part 52 approval, then the NRC or applicant must
19 follow a disciplined process. Issue finality provisions in 10 CFR Part 52 provide criteria that the
20 NRC or applicant must satisfy to change an ESP, DC, COL, SDA, or ML. Issue finality provides
21 a degree of stability to these approvals just as backfitting provides regulatory stability in
22 10 CFR Parts 50, 70, 72, and 76. It also provides greater certainty and efficiency in the
23 licensing process for those applicants choosing to incorporate by reference a 10 CFR Part 52
24 approval. Furthermore, 10 CFR 50.109 applies to certain 10 CFR Part 52 approvals, as shown
25 in Table 1-1.

26 ~~Each of the 10 CFR Part 52 approvals has a unique set of issue finality requirements. The staff~~
27 ~~should be aware of the differences in requirements among the various approvals and between~~
28 ~~10 CFR Part 52 provisions and 10 CFR 50.109 when dealing with any final approval. For~~
29 ~~example, the DC issue finality regulations have criteria in addition to the adequate protection,~~
30 ~~compliance, or substantial increase in overall protection concepts found in the Backfit Rule.~~
31 ~~Where the issue finality regulations for these approvals have analogous requirements to the~~
32 ~~Backfit Rule (e.g., adequate protection exception), the staff must follow the Commission's policy~~
33 ~~describing the order in which the requirements are considered (i.e., consider adequate~~
34 ~~protection before considering any of the other issue finality provisions).~~

35
36 ~~The DC issue finality regulations recognize that there may be additional reasons to amend DC~~
37 ~~information. Such additional reasons could include providing detailed design information to~~
38 ~~replace design acceptance criteria, reducing unnecessary regulatory burden, contributing to~~
39 ~~increased standardization of the design, or correcting material errors. Although the issue finality~~
40 ~~regulations ensure that the NRC will maintain the stability of the licensing process by preserving~~
41 ~~the safety conclusions reached in the DC rulemaking, they also provide flexibility for~~
42 ~~amendments to the design.~~

43
44 ~~In addition, as reflected in 10 CFR 52.98, "Finality of combined licenses; information requests,"~~
45 ~~and 10 CFR 50.109(a)(1)(vii), different backfitting criteria might apply to different portions of a~~
46 ~~COL holder's licensing basis. For example, if a COL holder references an approved ESP and a~~
47 ~~DC, then: (1) 10 CFR 50.109 would apply to the portions of the licensing basis outside the~~
48 ~~scope of the referenced ESP and DC; (2) 10 CFR 52.30, "Finality of early site permit~~
49 ~~determinations," would apply with respect to the site characteristics, design parameters, and~~
50 ~~terms and conditions in the ESP; and (3) 10 CFR 52.63, "Finality of standard design~~

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 certifications," would apply to design matters resolved in the DC, unless the DC includes
2 specific issue finality provisions, in which case those specific provisions will govern.
3

4 The nature of issue finality may differ depending on the regulation and the information in
5 question. For example, 10 CFR Part 52, Appendix D, "Design Certification Rule for the AP1000
6 Design," Section VI, provides that nuclear safety issues within the scope of the certified design
7 are resolved and that "additional or alternative structures, systems, components, design
8 features, design criteria, testing, analyses, acceptance criteria, or justifications" are
9 unnecessary. However, Section VI does not accord such finality to operational requirements in
10 the design control document. For ESPs, 10 CFR 52.39 provides issue finality, but a COL,
11 construction permit, or operating license applicant referencing the ESP must "update the
12 emergency preparedness information that was provided under 10 CFR 52.17(b), and discuss
13 whether the updated information materially changes the bases for compliance with applicable
14 NRC requirements." For DC renewal, the NRC must meet the backfit-like criteria of
15 10 CFR 52.59(b) to impose other requirements, but to renew the DC, 10 CFR 52.59(a) requires
16 a finding of, among other things, compliance with the regulations in effect at initial certification.
17

18 **4.3.0 Independent Spent Fuel Storage Installations**

19 Part 72 of the NRC's regulations contains requirements for, among other things, ISFSIs and
20 Certificates of Compliance (CoCs) approving spent fuel storage cask designs. Typically, for an
21 ISFSI associated with a nuclear power plant, the licensee for the nuclear power plant is licensed
22 to operate the ISFSI. The NRC issues a CoC to the vendor of the associated cask design. The
23 Part 72 backfitting provisions in 10 CFR 72.62 involve the ISFSI but do not address CoCs. This
24 means that the user of the cask—the ISFSI licensee—is within the scope of 10 CFR 72.62 but
25 the CoC holder—the vendor—is not.
26

27 If the CoC holder decides to revise its NRC-approved cask design, or the NRC determines that
28 a change must be made to the design, such action would not constitute backfitting for the CoC
29 holder because the backfitting provisions do not apply to the CoC holder. The potential
30 backfitting would involve the ISFSI licensee using that particular cask and would depend on
31 whether the change is an "administrative correction," an "amendment," or a "revision."
32 Administrative corrections and amendments to CoCs have no backfitting implications.
33 Corrections, which are of an administrative or editorial nature and do not change the substantive
34 technical information of the CoC, are not the type of changes that were intended to be included
35 in the definition of backfitting. Users of previous versions of that cask can choose to apply the
36 administrative corrections or other changes authorized by a CoC amendment, but their decision
37 is entirely voluntary.
38

39 Revisions to CoCs are technical changes and supersede the CoC and, therefore, qualify as
40 backfitting for any licensee using the applicable cask. If an ISFSI licensee has purchased a
41 cask for which a revision is sought and the ISFSI licensee is made aware of the revision and
42 voluntarily agrees to implement the change, then the NRC would not be imposing the revised
43 technical change on the licensee, thereby eliminating the potential backfitting. If the ISFSI
44 licensee does not agree to implement the revision, then the staff would need to perform a
45 backfit analysis under 10 CFR 72.62 to impose the revision.
46

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

Commented [BH39]: Comment 4.1.16

Commented [BH40]: Comment 4.1.17

1
2 **4.13-1.3 Forward Fitting**

3 **4.13-1.3.1 Definition**

4 The NRC does not have a regulation ~~regarding on~~ forward fitting requirements, ~~but MD 8.4 does~~
5 ~~reflect.~~ The Commission's policy on forward fitting ~~is reflected in MD 8.4.~~ Forward fitting is
6 similar to backfitting in that the NRC imposes on an ~~affected entity licensee~~ a new or modified
7 requirement or staff interpretation of a requirement (i.e., ~~a~~ staff position, as defined in
8 Section 1.2.2.2 of this NUREG) that results in a modification of or addition to the systems,
9 structures, components, or design of a facility; or the design approval or manufacturing license
10 for a facility; or the procedures or organization required to design, construct, or operate a facility.
11 ~~Like backfitting, the definition of forward fitting has cause and effect elements.~~ The fundamental
12 difference between backfitting and forward fitting is that backfitting modifies NRC regulatory
13 approvals already held by an ~~affected entity licensee~~, whereas a forward fit happens when the
14 NRC's approval of an ~~affected entity licensee~~-initiated request for a licensing action includes a
15 condition that the ~~licensee affected entity~~ comply with a new or modified requirement or
16 regulatory staff position that the ~~affected entity licensee~~ did not request.

17
18 **4.13-2.1.3.2 Forward Fitting Justifications ~~Direct Nexus, Essentiality, and Cost~~**

19 Like the backfitting requirements, the forward fitting policy requires the NRC to justify and
20 document its ~~assessment analysis~~ of the forward fitting action to ensure reasoned and informed
21 NRC decisionmaking and transparency. ~~Under MD 8.4, states that the analysis the assessment~~
22 ~~must show that the proposed action meets the definition of a "forward fit" and~~ demonstrate that
23 (1) there is a direct nexus between the new or modified requirement or regulatory staff position
24 and the ~~affected entity licensee~~'s request, and (2) the imposition of the new or modified
25 requirement or regulatory staff position is essential to the NRC staff's determination of the
26 acceptability of the ~~affected entity licensee~~'s request. The staff must adequately explain why
27 each of these two elements is independently met. Then, ~~to complete the forward fitting~~
28 ~~assessment,~~ the staff must consider the costs of the proposed forward fitting action ~~unless the~~
29 ~~forward fit would be necessary for adequate protection.~~ Section 3.53 of this NUREG describes
30 how to conduct the cost evaluation that supports a proposed forward fitting action.

31
32 **4.14-1.4 Risk Considerations and Safety Significance**

33 In Directive Handbook Section ~~I.A. 124~~ of MD-8.4, the Commission requires the NRC staff to
34 consider risk insights, to the extent practical, for any proposed backfitting, ~~issue finality~~, or
35 forward fitting action. Because risk information forms part of the basis for any backfitting, ~~issue~~
36 ~~finality~~, or forward fitting action, the staff should document any risk information or analysis as
37 part of the basis for that action. For power reactor licensees, probabilistic risk assessment
38 (PRA) information should be included to the extent practical. In its 1995 PRA policy statement,
39 the Commission encouraged the use of PRA "in all regulatory matters to the extent supported
40 by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's
41 deterministic approach and supports the NRC's traditional defense-in-depth philosophy."
42 ~~(60 FR 42622; August 16, 1995).~~ PRA may aid the staff in quantifying the change in the overall
43 protection of the public, but a PRA is not a singular basis for backfit, ~~issue finality~~, or forward fit
44 ~~analyses or justifications assessments.~~ A quantitative estimate of risk is just one of the possible
45 considerations that can support an integrated and risk-informed justification.
46

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

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.

1 When the staff identifies an issue and is considering a backfitting or forward fitting action ~~or~~
2 ~~change to a 10 CFR Part 52 approval~~, the staff must ~~first~~ determine the safety significance
3 of the issue ~~following a risk-informed approach, such as using a PRA~~. This determination
4 should be made before considering whether the issue presents a backfitting, ~~issue finality~~, or
5 forward fitting concern. Safety significance can weigh heavily on proposed backfitting actions
6 that rely on the compliance exception justification. This may be true if a licensee has incurred
7 costs because of a staff position that the NRC seeks to change and implement through the
8 compliance exception. After many years of safe operation, it may be less obvious as to why
9 such a change is warranted when compliance was not previously mandated. If the licensee has
10 incurred costs in reasonable reliance on a particular NRC position, then the need to provide a
11 justification becomes more important. The fact that a ~~plant facility~~ has operated safely for a
12 ~~period of years does not mean~~, in ~~and of itself~~, ~~mean~~ that a condition that has persisted for
13 years should not be re-evaluated. ~~But~~ ~~However~~, when many years have passed before the NRC
14 determines that a regulation or requirement is not satisfied, and when the agency cannot
15 demonstrate that compliance is necessary for adequate protection, identifying the safety
16 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.

17 18 4.45-1.5 Communications with Licensees Affected Entities

19 In Directive Handbook Section I.A.11 of MD 8.4, the Commission emphasized how staff
20 discussions with licensees can raise backfitting issues:

21
22 "Any change to an NRC staff position that the NRC intends to communicate by
23 any means to a licensee(s) as being applicable to its facility may be identified as
24 backfitting either by the staff or by licensees. The means of communication can
25 be through the issuance of regulatory guidance, inspection reports, or generic
26 communications or through staff interactions with licensee personnel."

27
28 Furthermore, in Directive Handbook Section II.A.2 of MD 8.4, the Commission said that
29 communicating staff expectations to a licensee can constitute backfitting or forward fitting:

30
31 "If the NRC staff conveys an expectation that licensees change programs,
32 processes, procedures, or the physical plant by using or committing to use
33 voluntary guidance (e.g., Regulatory Guides or NRC-endorsed industry topical
34 reports) that is not already within the [licensing basis] for the identified purpose,
35 then the staff's communication of that expectation is considered backfitting or
36 forward fitting."

37
38 Definitive statements made by the staff to ~~a licensee~~ ~~an affected entity~~ that a specific action is
39 needed to comply with NRC requirements or to satisfy existing applicable staff positions may be
40 perceived as backfitting ~~or a change affecting issue finality~~. In a similar manner, if during a
41 licensing review of a ~~voluntary~~⁹ submittal, the ~~affected entity~~ ~~licensee~~ perceives that the staff is
42 pressuring ~~it~~ ~~the licensee~~ to adopt a specific staff position, then the ~~affected entity~~ ~~licensee~~ would

Commented [AK45]: Comment 4.5.29

⁹ 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.

1 ~~entity raises a backfitting, issue finality, or forward fitting concern, then the staff should orally~~
2 ~~discuss its understanding of the licensing basis without conveying an expectation of affected~~
3 ~~entity action. The staff should subject the proposed action to a backfitting or forward fitting~~
4 ~~screening. If the staff determines that the proposed staff action would not constitute backfitting~~
5 ~~or forward fitting, then the staff may proceed with the proposed staff action. If the staff~~
6 ~~determines that the proposed staff action could constitute backfitting or forward fitting and~~
7 ~~wishes to proceed with the action, then the staff needs to complete the backfitting or forward~~
8 ~~fitting assessment.~~

10 **4.16-1.6 Management and Oversight of Backfitting, Issue Finality, and** 11 **Forward Fitting**

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

18
19 The program offices (i.e., the Office of Nuclear Reactor Regulation (NRR) and the Office of
20 Nuclear Material Safety and Safeguards (NMSS)) have the obligation to impose backfitting or
21 forward fitting actions or change 10 CFR Part 52 approvals outside of rulemaking. The office of
22 the region that initiated a backfitting or forward fitting¹⁰ action or a change affecting issue finality
23 supports NRR or NMSS with its obligation to impose the ~~backfitting or forward fitting~~ action or
24 change. The Director of NRR or NMSS is responsible for generic backfitting actions and
25 facility-specific backfitting or forward fitting actions arising from licensing or other headquarters
26 actions, and the office staff performs the initial screening of the backfitting action and develops
27 the documented evaluation or backfit analysis. Generic backfitting actions may need EDO or
28 Commission approval unless otherwise delegated. Regional administrators are responsible for
29 facility-specific backfitting actions arising from inspection (i.e., regional staff performs the initial
30 screening of the backfitting action and supports NRR or NMSS in the development of the
31 documented evaluation or backfit analysis), but regional administrators do not impose
32 backfitting or forward fitting actions. The Director of NRR is also responsible for changes
33 affecting issue finality.

34
35 To ensure consistent implementation of the backfitting, issue finality, and forward fitting
36 processes across the program and regional offices, the Commission requires the staff to provide
37 the CRGR with an opportunity to review proposed backfitting (generic and facility-specific) and
38 forward fitting actions and changes affecting issue finality. The CRGR is an advisory committee
39 to the EDO, composed of senior managers from multiple NRC offices and one regional office,
40 established to ensure that proposed backfits and changes affecting issue finality are
41 appropriately justified in accordance with the backfitting and issue finality provisions in
42 10 CFR Chapter I and the NRC's backfitting and issue finality policies in MD 8.4 and that
43 forward fits are appropriately justified in accordance with the forward fitting policy in MD 8.4.
44

¹⁰ 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.

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.

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.¹¹ 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.

24
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

33
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 ~~ef~~to 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](#).

¹¹ [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.

1 **2.2 Question 1: Is the Proposed Action Excluded from the**
2 **Backfitting and Issue Finality Provisions?**

3 By answering Question 1, the staff determines whether the proposed action would fall outside
4 the purview of the backfitting and issue finality regulations. Certain actions are not subject to
5 the backfitting and issue finality requirements. None of the backfitting or issue finality provisions
6 expressly states sets forth these exclusions, but the Commission recognizes them as unsuitable
7 for backfitting and issue finality purposes because these proposed actions would not meet the
8 definition of "backfitting;"¹ or constitute changes affecting issue finality.

9
10 Matters that are outside the purview of the backfitting regulations include

11
12 Other matters outside the scope of the backfitting provisions include those that do not have a
13 direct link to and do not further a substantive radiological² public health and safety or common
14 defense and security objective. In addition, these actions that would not meet the definition of
15 "backfitting;" Such actions or constitute changes affecting issue finality include information
16 collection and reporting requirements;³ changes to NRC administrative procedures;⁴ corrections
17 of regulatory language, including typographical mistakes, misspellings, and or inadvertent
18 omissions (when the NRC's objective is expressly reflected in the regulatory record expressly
19 reflects the NRC's objective); and NRC organization and structure changes. Nevertheless, the
20 NRC must have legal authority to justify taking such actions. Information collection and
21 reporting requirements facilitate the NRC's regulatory oversight responsibility. Administrative
22 and organizational requirements enable the NRC to carry out its mission. For these proposed
23 actions, the staff should exit the backfitting process and proceed under an appropriate agency
24 process.

25
26 The following actions are typically outside the scope of backfitting or issue finality, but the staff
27 must determine if they meet the definition of "backfitting" or constitute changes affecting issue
28 finality on a case-by-case basis: NRC actions implementing mandatory statutory requirements
29 or requirements imposed by other Federal agencies, information collection and reporting
30 requirements,⁵ and appeal processes required of affected entities, which are not NRC
31 adjudicatory processes under 10 CFR Part 2 or backfitting, issue finality, and forward fitting
32 appeals described in Chapter 4 of this NUREG.⁶ In these situations, the NRC generally has no

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

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

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

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

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

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

1 discretion in the implementation of these statutory requirements or requirements imposed by
2 other Federal agencies. ~~Because~~ However, the NRC must ~~implement these requirements, the~~
3 ~~NRC does not need to justify any potential backfitting resulting from taking these actions, ensure~~
4 ~~that any related actions not directly required by statute or other agency action do not meet the~~
5 ~~definition of "backfitting" or constitute a change affecting issue finality~~. Information collection
6 and reporting requirements typically do not meet the definition of "backfitting" or constitute a
7 change affecting issue finality because they would not be a procedure or organization required
8 to design, construct, or operate a facility; the NRC ~~nonetheless~~ must ensure that any such
9 requirements do not meet the definition of "backfitting" or constitute a change affecting issue
10 finality. Requirements for appeal processes⁷ are also outside the purview of backfitting
11 provisions. ~~An appeal process protects an individual's due process, which is guaranteed by the~~
12 ~~Fifth Amendment to the U.S. Constitution: "No person shall ... be deprived of life, liberty, or~~
13 ~~property, without due process of law"~~ Although the Fifth Amendment requires the Federal
14 ~~Government to provide due process to persons, the NRC can, in implementing its own authority,~~
15 ~~ensure that its regulated entities provide adequate due process to their personnel through the~~
16 ~~entities' appeals processes that are consistent with Federal due process requirements.~~ Appeal
17 processes usually do not meet the definition of "backfitting" or constitute a change affecting
18 issue finality because they would not be a procedure or organization required to design,
19 construct, or operate a facility.

20
21 ~~Because the backfitting and issue finality provisions do not expressly identify these exclusions,~~
22 ~~for these proposed actions, the staff should consult the NRC Backfitting and Forward Fitting~~
23 ~~Community of Practice to assist with determining whether the proposed action would be~~
24 ~~excluded from backfitting or issue finality considerations.~~ For proposed actions that are outside
25 the scope of the backfitting regulations, the staff should exit the backfitting process and proceed
26 under an appropriate agency process. For proposed actions that are within the scope of the
27 backfitting or issue finality regulations, the staff should continue through the screening process.

29 **2.3 Question 2: Would the pProposed aAction aAffect aAny** 30 **eEntity tThat is wWithin the sScope of a bBackfitting or iIssue** 31 **fFinality pProvision?**

32 In ~~q~~Question 2, the staff must determine whether the affected entity is within the scope of ~~the a~~
33 backfitting or issue finality regulations. Table 1-1 lists the regulations that contain backfitting or
34 issue finality provisions. If the entity is not within the scope of ~~the se~~ backfitting regulations, then
35 ~~these~~ backfitting regulations do not apply, and the staff can exit the backfitting or issue finality
36 process and issue the proposed action or staff position under an appropriate agency process
37 without further screening. If the entity is within the scope of ~~the a~~ backfitting or issue finality
38 regulations, then the staff should continue with the screening process. The following list
39 ~~sections contains describe~~ the entities within the scope of ~~the a~~ backfitting or issue finality
40 provisions (i.e., affected entities). Affected entities with licensed facilities remain within the
41 scope of a backfitting or issue finality provision when the facility is in a decommissioning phase,
42 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.

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

1 under 10 CFR 70.60, "Applicability," such a facility in a decommissioning phase is not within the
2 scope of the 10 CFR Part 70 backfitting provision.

3
4 **2.3.1 Power Reactors Licensed under 10 CFR Part 50**

5 **2.3.1**

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

- 9 – holder of a limited work authorization (10 CFR 50.10, "License required; limited work
10 authorization")
- 11 – holder of a construction permit (10 CFR 50.50, "Issuance of licenses and
12 construction permits")
- 13 – applicant for an initial operating license (10 CFR 50.50)⁸
- 14 – holder of an initial operating license (10 CFR 50.56, "Conversion of construction
15 permit to license; or amendment of license," and 10 CFR 50.57, "Issuance of
16 operating license")
- 17 – applicant for a renewed operating license (10 CFR Part 54, "Requirements for
18 renewal of operating licenses for nuclear power plants")
- 19 – ~~(There are no backfitting provisions in Part 54. However, the regulatory structure of~~
20 ~~Part 54 bounds what the staff can review in these applications, as described in~~
21 ~~Section 5.16 of this NUREG.)~~
- 22 – holder of a renewed operating license (10 CFR Part 54)

23
24 The Backfit Rule applies to a holder of a power reactor construction permit or operating license
25 issued under 10 CFR Part 50. This means that the NRC would have to meet the criteria in
26 10 CFR 50.109 to change the issued construction permit or operating license. The Backfit Rule
27 does not apply to all aspects of the construction permit or operating license. As with the other
28 backfitting provisions in Table 1-1, the scope of 10 CFR 50.109 generally includes the
29 modification of, or addition to, structures, systems, or components (SSCs) and the procedures
30 or organization required to operate the facility.

31
32 Backfitting ordinarily does not apply to the renewal of an operating license under
33 10 CFR Part 54. A license renewal review is prospective in nature, as the review is aimed at a
34 renewed license that has not yet been issued and is a matter of future aging management. The
35 review will address aging management or ensure an integrated approach to achieve aging
36 management. The Commission determined in the 1995 nuclear power plant license renewal
37 final rule (60 FR 22461; May 8, 1995) that 10 CFR 50.109 does not apply to matters within the
38 scope of the renewal of power reactor licenses under 10 CFR Part 54. In large measure,
39 10 CFR 54.4, "Scope," and 10 CFR 54.21, "Contents of application—technical information," limit
40 the scope of a license renewal review. In part, 10 CFR 54.30(a) states that licensed activities
41 will be conducted in accordance with the current licensing basis. This requirement is followed
42 by 10 CFR 54.30(b), which states that the licensee's compliance in this regard is not the subject
43 of the license renewal review. This means that any proposed staff action on topics other than
44 aging management taken under the current license should not be part of the license renewal
45 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

⁸ 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.

1 the NRC issues the renewed license, 10 CFR 50.109 applies to the entire license with very
2 limited exceptions.

3
4 The NRC does not apply the backfitting provisions to nonpower production and utilization
5 facilities, including radioisotope production facilities, research reactors, and testing facilities,
6 licensed under 10 CFR Part 50. The regulatory basis for the 1985 and 1988 Backfit Rule
7 rulemakings addressed only commercial nuclear power reactors. Moreover, the NRC practice
8 has been to apply the Backfit Rule only to commercial nuclear power reactors licensed under
9 Sections 103 and 104b of the Atomic Energy Act of 1954, as amended (AEA). In contrast, the
10 Commission has consistently excluded from the scope of the Backfit Rule nonpower facilities
11 licensed under AEA Sections 103, 104a, or 104c. In the Staff Requirements Memorandum
12 (SRM) to SECY-86-17, "Final Rule; Limitation on the Use of Highly Enriched Uranium (HEU)
13 in Research and Test Reactors," dated February 14, 1986, the Commission declined to apply
14 the Backfit Rule in that rulemaking, stating, "[T]he backfit rule should not be applied to this
15 amendment of the regulations which relates only to nonpower reactors."

17 2.3.2 pPower rReactors lLicensed and aApproved under 10 CFR Part 52^H

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

- 20 – holder of an early site permit (ESP) (10 CFR 52.39, "Finality of early site permit
21 determinations")
- 22 – applicant for renewal of an ESP (10 CFR 52.31, "Criteria for renewal")
- 23 – applicant for a design certification (DC), after issuance of the final DC rule
24 (10 CFR 52.63, "Finality of standard design certifications")¹⁰
- 25 – applicant for renewal of a DC during the rulemaking for renewal (10 CFR 52.59,
26 "Criteria for renewal")
- 27 – applicant for a combined license (COL) if referencing an ESP, standard design
28 approval (SDA), DC, or manufacturing license (ML) (10 CFR 52.83, "Finality of
29 referenced NRC approvals; partial initial decision on site suitability")
- 30 – holder of a COL (10 CFR 52.98, "Finality of combined licenses; information
31 requests")
- 32 – applicant for renewal of a COL (10 CFR Part 54)
- 33 – holder of a renewed COL (10 CFR 52.98)
- 34 – holder of an SDA (10 CFR 52.145, "Finality of standard design approvals;
35 information requests")
- 36 – holder of an ML (10 CFR 52.171, "Finality of manufacturing licenses; information
37 requests")
- 38 – applicant for renewal of an ML (10 CFR 52.179, "Criteria for renewal")
- 39
- 40

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.

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

¹⁰ 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.

1 The Commission provided issue finality for 10 CFR Part 52 approvals and licenses in 1989 and
2 amended those provisions in 2007. Applicants referencing an ESP, DC, SDA, or ML have issue
3 finality for only the information within the scope of the ESP, DC, SDA, or ML. Different issue
4 finality provisions apply to renewal of an approval than apply during the term of the approval.
5 For example, during the 20-year term of an ESP, the NRC cannot impose a change to the ESP
6 without meeting the criteria in 10 CFR 52.39. The holder can seek renewal of that ESP for
7 another 20 years. To impose new requirements on that ESP holder at the time the NRC issues
8 the renewed ESP, the agency would have to satisfy the criteria in 10 CFR 52.31. Similarly, a
9 COL applicant can reference an NRC approved ESP or DC in its application, and certain
10 matters concerning that ESP or DC are considered resolved, such that changes to the ESP or
11 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.

12
13 Renewal of a COL under 10 CFR Part 54 would be similar to renewal of an operating license,
14 except that Section VI.B of the DC appendices in 10 CFR Part 52 provides issue resolution in
15 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.

16
17
18 **2.3.3 Materials Licenses under 10 CFR Part 70**

Commented [BH66]: Comment 4.2.7

19 The backfitting provision in 10 CFR 70.76 applies to licensees authorized to engage in specific
20 activities and possess special nuclear material above a critical mass pursuant to
21 10 CFR Part 70, Subpart H (10 CFR 70.76).

22 **2.3.4 Materials Licensees under 10 CFR Part 72**

Commented [BH67]: Comments 4.1.17, 4.2.7

23 The backfitting provision in 10 CFR 72.62 applies to holders of a general or specific license for
24 an independent spent fuel storage installation (ISFSI) (10 CFR 72.62) or holders of a license for
25 a monitored retrievable storage installation (10 CFR 72.62). Typically, for an ISFSI associated
26 with a nuclear power plant, the licensee for the nuclear power plant is licensed to operate the
27 ISFSI. The NRC issues a certificate of compliance (CoC) to the vendor of the associated spent
28 fuel storage cask design. The backfitting provisions in 10 CFR 72.62 involve the ISFSI but do
29 not address CoCs. This means that the user of the cask—the ISFSI licensee—is within the
30 scope of 10 CFR 72.62 but the CoC holder—the vendor—is not.

31
32 If the CoC holder decides to revise its NRC-approved cask design, or the NRC determines that
33 a change must be made to the design, such action would not constitute backfitting for the CoC
34 holder because the backfitting provisions do not apply to the CoC holder. The potential
35 backfitting would involve the ISFSI licensee using that particular cask and would depend on
36 whether the change is an “administrative correction,” an “amendment,” or a “revision.”
37 Administrative corrections and amendments to CoCs have no backfitting implications.
38 Corrections, which are of an administrative or editorial nature and do not change the substantive
39 technical information of the CoC, were not intended to be included in the definition of
40 “backfitting.” Users of previous versions of that cask can choose to apply the administrative
41 corrections or other changes authorized by a CoC amendment, but their decision is entirely
42 voluntary.

43
44 Revisions to CoCs are technical changes and supersede the CoC and, therefore, qualify as
45 backfitting for any licensee using the applicable cask. However, documentation provided by a
46 CoC holder indicating that an ISFSI licensee that may be impacted by the revision voluntarily
47 supports the revision and will willingly comply with the revised CoC eliminates potential
48 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.

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

6
7 Regulatory Issue Summary 2017-05, "Administration of 10 CFR Part 72 Certificate of
8 Compliance Corrections and Revisions," dated September 13, 2017, contains more detail about
9 the CoC change process and backfitting considerations for administrative corrections and
10 revisions to CoCs.

11 **2.3.5 Materials Licensees under 10 CFR Part 76**

12
13 ~~The backfitting provision in 10 CFR 76.76 applies to a holder of a CoC certificate of compliance~~
14 ~~for a gaseous diffusion plant. (10 CFR 76.76)~~
15 ~~The rest of this section provides more details as to how backfitting regulations apply to these~~
16 ~~entities.~~

17
18 ~~The Backfit Rule applies to a holder of a power reactor construction permit or operating license~~
19 ~~issued under 10 CFR Part 50. This means that the NRC would have to meet the criteria in~~
20 ~~10 CFR 50.109 to change the issued construction permit or operating license. The Backfit Rule~~
21 ~~does not apply to all aspects of the construction permit or operating license. As with the other~~
22 ~~backfitting provisions in Table 1-1, the scope of 10 CFR 50.109 generally includes the~~
23 ~~modification of, or addition to, structures, systems, or components (SSCs) and the procedures~~
24 ~~or organization required to operate the facility. Further, 10 CFR 50.109 applies to certain~~
25 ~~Part 52 approvals, as shown in Table 1-1 and discussed in Section 1.2.6 of this NUREG.~~

26
27 ~~The Commission provided issue finality for Part 52 approvals and licenses in 1989 and~~
28 ~~amended these provisions in 2007. Each of the approvals issued under 10 CFR Part 52 has~~
29 ~~issue finality for the duration of that approval. For example, a holder of an ESP can maintain~~
30 ~~that approval for a term of up to 20 years. During that 20-year term, the NRC cannot impose a~~
31 ~~change to the ESP without meeting the criteria provided in 10 CFR 52.39. The holder can seek~~
32 ~~renewal of that ESP for another 20 years. For the NRC to impose new requirements on that~~
33 ~~ESP holder at the time the NRC issues the renewed ESP, the NRC would have to satisfy the~~
34 ~~criteria in 10 CFR 52.31. Similarly, a COL applicant can reference an NRC-approved ESP or~~
35 ~~DC in its application, and certain matters concerning that ESP or DC are considered resolved,~~
36 ~~such that changes to the ESP or DC are governed by the applicable ESP or DC issue finality~~
37 ~~provision.~~

38
39
40 ~~The NRC's policy is not to apply the backfitting provisions to non-power production and~~
41 ~~utilization facilities, including radioisotope production facilities, research reactors, and testing~~
42 ~~facilities, licensed under 10 CFR Part 50. Historically, the NRC expressed the regulatory basis~~
43 ~~for 10 CFR 50.109 solely in terms of nuclear power reactors. For example, the NRC's~~
44 ~~Advanced Notice of Proposed Rulemaking, Policy Statement, Proposed Rule, and Final Rule for~~
45 ~~the 1985 revision of 10 CFR 50.109 involved only nuclear power reactors. As a result, the NRC~~
46 ~~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 50.⁴⁴ 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 ~~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~~general ~~A~~applicability to ~~D~~domestic
35 ~~L~~icensing of ~~B~~byproduct ~~M~~material," 10 CFR Part 40, "Domestic ~~L~~icensing of ~~S~~source
36 ~~M~~material," 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

⁴⁴ 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).

1 10 CFR part that contains the backfitting or issue finality provision, then the proposed NRC
2 action would be subject to a backfitting or issue finality assessment (for that affected entity).

3
4 The definition of "backfitting" in the Commission's regulations supports this approach. For
5 example, under 10 CFR 70.76, backfitting is a modification of, or addition to, the SSCs of a
6 facility, or the procedures or organization required to operate a facility. For a proposed NRC
7 action to "inextricably affect" a 10 CFR Part 70 licensee's activities, the proposed NRC action
8 would need to affect the Part 70-related SSCs of the licensee's facility or the Part 70-related
9 procedures or organization required to operate its facility. The NRC's statements in the 2013
10 Federal Register notice (78 FR 29016) for draft Regulatory Guide 7009, "Establishing Quality
11 Assurance Programs for Packaging Used in Transport of Radioactive Material," support this
12 approach:

13
14 However, the exception to this principle is not applicable to the issuance of this
15 regulatory guide, which addresses QA [quality assurance] for transportation of
16 radioactive materials. Nuclear power plant licensees, for example, are protected
17 by backfitting requirements in 10 CFR 50.109, and (depending upon the
18 circumstance) issue finality requirements in 10 CFR part 52. Nonetheless,
19 quality assurance governing transportation of certain radioactive materials is not
20 an inextricable part of the licensed activity in 10 CFR parts 50 and 52, viz. the
21 design, construction and operation of a nuclear power plant.

22
23 To help make that determination, the staff should follow these steps:

24
25 Identify all the NRC-regulated entities affected by the proposed action.

26
27 Identify all the NRC-regulated entities affected by the proposed action that are within the scope
28 of a backfitting or issue finality provision.

29
30 a. For those NRC-regulated entities that are not within the scope of a backfitting or issue
31 finality provision, the staff can exit the backfitting process. The NRC can still consider taking the
32 proposed action, but the staff does not need to consider the backfitting implications of the
33 proposed action for these entities.

34
35 b. For those NRC-regulated entities that are within the scope of a backfitting or issue
36 finality provision and are nuclear power reactor licensees, go to step 3.

37
38 c. For those NRC-regulated entities that are within the scope of a backfitting or issue
39 finality provision, are authorized to conduct activities involving NRC-regulated materials (e.g.,
40 under Part 70) but not a nuclear power reactor license, and are authorized to conduct activities
41 under a part that does not contain a backfitting provision (e.g., Part 40):

42
43 i. if the proposed action affects the activities under the part that does not contain a
44 backfitting provision (e.g., Part 40), then no backfitting provision would apply to these entities.
45 The NRC can still consider taking the proposed action, but the staff does not need to consider
46 the backfitting implications of the proposed action for these entities.

47
48 ii. if the proposed action affects the activities under the part that does contain a backfitting
49 provision (e.g., Part 70), then continue to Section 2.4 of this NUREG.

50
51 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.¹²

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.

¹² 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.

1 **2.34.2.4 Question 3: Would the Proposed Action Constitute**
2 **Backfitting or Affect Issue Finality?**

3 In answering Question 3, the staff determines whether the proposed action constitutes
4 backfitting (or affects issue finality). To determine whether the proposed action constitutes
5 backfitting, the answer to each of the following five questions must be “yes/YES”:

- 6
7 (1) Is there either—
8
9 (a) a new or changed (e.g., amended, revised, or modified) NRC requirement (e.g., a
10 regulation or order), or
11
12 (b) a new or changed staff interpretation of an NRC requirement?
13
14 (2) Is the NRC imposing¹³ the new or changed requirement or interpretation on an
15 applicable entity?
16
17 (3) Will there be a modification or addition to—
18
19 (a) SSCs or design of the entity's facility;
20
21 (b) The design (including but not limited to a DC, SDA, approval or ML) of the entity's for
22 a facility; or
23
24 (c) The procedures or organization required for designing, constructing, or operating the
25 entity's facility?
26
27 (4) Is the modification or addition (third question above) the result of the new or changed
28 requirement or interpretation (first question) that is being imposed (second question)?
29
30 (5) Will the imposition of the new or changed NRC requirement or interpretation occur after
31 the point that the applicable backfitting provision begins to apply (e.g., as specified in
32 10 CFR 50.109(a)(1)(i) through (vii))?
33

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

38
39 The fourth question listed above captures the cause and effect elements of backfitting described
40 in Section 1.2.2.2 of this NUREG: would the cause (i.e., the imposition of a new or changed
41 requirement or interpretation) result in the effect (i.e., the modification or addition)?

42
43 The staff should use a similar process for determining whether a proposed action affects issue
44 finality under 10 CFR Part 52. For proposed actions that affect the issue finality of a
45 10 CFR Part 52 approval, the staff should go to Section 2.6.4 of this NUREG for guidance on
46 determining whether that proposed action satisfies the criteria in the issue finality provision that
47 applies to the Part 52 approval. However, the staff should also recognize that issue finality for
48 some entities involves matters other than adequate protection, compliance, and substantial

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

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

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.¹⁴
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.

¹⁴ 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

1
2 **2-35.4-2.5.1 Question 4a: Do ~~e~~One or ~~b~~Both of the ~~a~~Adequate ~~p~~Protection**
3 **~~e~~Exceptions to the ~~r~~Requirement of ~~p~~Preparing a ~~b~~Backfit ~~a~~Analysis**
4 **~~a~~Apply?**

5 **2-35.4-2.5.1.1 Background**

6 If the staff determines that the agency must impose a backfitting action to ensure that a facility
7 provides adequate protection to the public health and safety and is in accord with the common
8 defense and security, or if the Commission decides that the agency needs to define or redefine
9 the level of protection ~~ef~~to the public health and safety or common defense and security that
10 should be considered as adequate, then the ~~Atomic Energy Act of 1954, as amended (AEA),~~
11 requires that regulatory action be implemented. The staff would prepare a documented
12 evaluation. The responsible staff should seek advice from the Office of the General Counsel
13 (OGC) and Office of Enforcement on imposition of all adequate protection actions. ~~If one or~~
14 ~~both of the adequate protection exceptions applies to~~ the backfitting action ~~involves an issue of~~
15 ~~adequate protection,~~ then the backfitting justification must either be reviewed and approved by
16 the Commission or provided to the Commission sufficiently in advance of the issuance of the
17 backfitting action to enable the Commission to change the proposed action if it chooses to do
18 so. ~~If the documented evaluation is not ready before the agency needs to take an immediate~~
19 ~~adequate protection action, then the justification presented to the Commission can be~~
20 ~~transmitted through a different means (e.g., a briefing).~~

21
22 The concept of adequate protection is limited to considerations of radiological public health and
23 safety and common defense and security (i.e., it is limited to human health effects from
24 radiological¹⁵ releases and does not include the economic impacts that may ensue). ~~as This is~~
25 ~~discussed in SECY-12-0110, "Consideration of Economic Consequences within the~~
26 ~~U.S. Nuclear Regulatory Commission's Regulatory Framework," dated August 14, 2012, and~~
27 ~~confirmed by the Commission in its SRM for SECY-12-0110, dated March 20, 2013. Although~~
28 ~~the NRC discusses adequate protection in several agency guidance documents (e.g., "Staff~~
29 ~~RequirementsSRM—COMSAJ-97-008—Discussion of Safety and Compliance," dated~~
30 ~~August 25, 1997), the AEA does not explicitly define the term "adequate protection" and the~~
31 ~~equivalent phrase "no undue risk." With respect to "adequate protection," the Commission said~~
32 ~~in the 1988 Backfit Rule statement of considerations (SOC) that it "can still make sound~~
33 ~~judgments about what 'adequate protection' requires, by relying upon expert engineering and~~
34 ~~scientific judgment, acting in the light of all relevant and material information." For example, the~~
35 ~~Commission concluded that greater uncertainty was associated with the capability of nuclear~~
36 ~~power plants to withstand extreme external events as a result of lessons learned from the~~
37 ~~Fukushima accident, and it decided that new requirements needed to be imposed as a matter of~~
38 ~~adequate protection (i.e., beyond-design-basis external events could present undue risk). The~~
39 ~~Commission imposed these new requirements by Order EA-12-049, "Issuance of Order To~~
40 ~~Modify Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis~~
41 ~~External Events," dated March 12, 2012, to provide additional capability to address~~
42 ~~beyond design basis such~~ events. This backfitting action shows that adequate protection
43 requirements can be imposed to provide greater defense-in-depth.

44
45 There is an important nuance in how the backfitting regulations view issues of adequate
46 protection for materials licensees. The provisions within 10 CFR 70.76 consider the worker

¹⁵ 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).
19

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.
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.
49

Commented [KA84]: Comment 4.2.16

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

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 goal¹⁶ 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 ~~cannot~~ 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

¹⁶ _____ 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.

1 exception was the final rule amending 10 CFR 50.61, "Fracture toughness requirements for
2 protection against pressurized thermal shock events," because the underlying phenomenon
3 would not have presented an adequate protection issue for several years.

4
5 2-35.1-3-2.5.1.3 Documenting Adequate Protection Evaluations

6 For any backfitting action that meets the definition and requirements for adequate protection
7 backfitting, the staff must prepare a documented evaluation of the type discussed in
8 10 CFR 50.109(a)(6), 70.76(a)(4), or 76.76(a)(4) in lieu of a backfit analysis. To impose the
9 backfitting action, the staff must find that the action is necessary for adequate protection.
10 Because there are two options for invoking the adequate protection exceptions, the documented
11 evaluation must include the basis for invoking the selected exception and must clearly explain
12 which option is being used and why. The staff must also describe the safety or security risk if
13 the action is not taken. No further explanation is necessary to justify the backfitting action and it
14 should be implemented without consideration of cost, except if there are multiple ways to
15 implement the action and the NRC prescribes one way to comply with requirements or to
16 achieve adequate protection. In that case, cost may be a factor in selecting the action, provided
17 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.

18
19 The Director of the Office of Nuclear Reactor Regulation (NRR) or the Director of the Office of
20 Nuclear Material Safety and Safeguards (NMSS) responsible for issuing the backfitting action
21 must approve any documented evaluation, and The NRC staff should send a copy of the
22 documented evaluation should be sent to the EDO and appropriate regional administrator, if
23 applicable, before the staff transmitting the backfitting documentation to the licensee affected
24 entity.

25
26 Appendix C to this NUREG contains a guide for drafting a documented evaluation to justify an
27 adequate protection backfitting action.

28
29 2-35.2-2.5.2 Question 4b: Does the eCompliance eException to the
30 Requirement of pPreparing a bBackfit aAnalysis aApply?

31 2-35.2-1-2.5.2.1 Background

32 If, in answering eQuestion 4a, the staff determines that the neither adequate protection
33 exception applies to the backfitting action does not represent an issue of adequate protection,
34 then the staff proceeds to eQuestion 4b to determine whether the backfitting action is necessary
35 to ensure compliance with the license or the rules and orders of the NRC, or with written
36 licensee commitments¹⁷ that were incorporated in the license. If so, a backfit analysis is not
37 required, although some consideration of costs is required. Instead, NRR or NMSS staff
38 prepares a documented evaluation of the type discussed in 10 CFR 50.109(a)(6), 70.76(a)(6),
39 and 76.76(a)(6), with a finding that the action is necessary to ensure compliance. Under
40 10 CFR 72.62(b), the NRC requires backfitting if it is necessary to bring an ISFSI independent
41 spent fuel storage installation or monitored retrievable storage installation into compliance with a
42 license or the Commission's orders or rules, or into conformance with the licensee's written
43 commitments. NRR or NMSS staff must seek advice from OGC and the Office of Enforcement
44 on the imposition of all compliance backfits, including the proposed implementation schedule.

Commented [BH87]: Comment 4.2.19

¹⁷ 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.

1
2 Understanding the difference between the NRC issuing a violation and the NRC imposing a
3 change to the licensing basis through a backfitting action based on the compliance exception is
4 fundamental to the use of the compliance exception. In both cases, the NRC has determined
5 that a licensee does not comply with a requirement. If the NRC has not made this determination
6 (i.e., there is no requirement that the licensee is not complying with), then neither a violation nor
7 a compliance backfitting action would be appropriate. In contrast to a violation, a compliance
8 backfitting action occurs when the licensee previously received NRC approval of a method
9 demonstrating compliance with a requirement, but the staff has since determined that, because
10 of an omission or mistake of fact made at the time of, or before, the NRC's previous approval, |
11 the licensee's conformance with that method does not constitute compliance with the
12 requirement. In this case, the staff would need to change its previous approval (i.e., impose a
13 new or changed staff position) to ensure the licensee complies with the requirement. This
14 would not result in a violation.

15
16 When questions arise concerning a potential violation that will necessitate a detailed review of
17 the facility's licensee's licensing basis or a complex technical evaluation, the inspectors should
18 contact the appropriate licensing project manager ~~for advice~~, use the Very Low Safety
19 Significance Issue Resolution process in the NRC's Inspection Manual Chapter 0612, "Issue
20 Screening," dated December 12, 2019, if applicable, or, if necessary, initiate the technical
21 assistance request process for the appropriate office to consider the regulatory, licensing, and
22 technical aspects of the issue.

23
24 2-35.2-2.5.2.2 Compliance Exception Determinations

25 In the 1985 Backfit Rule SOC, the Commission stated the following:-⁴

26
27 The compliance exception is intended to address situations in which the licensee
28 has failed to meet known and established standards of the Commission because
29 of omission or mistake of fact. It should be noted that new or modified
30 interpretations of what constitutes compliance would not fall within the exception
31 and would require a backfit analysis and application of the standard."
32

33 As approved by the Commission in SRM-COMSECY-16-0020, dated November 29, 2016, and
34 as further explained in the NRC Solicitor's 2016 memorandum to the eChairman of the
35 Committee to Review Generic Requirements, the staff should determine that an omission or
36 mistake of fact exists within the scope of the exception under 10 CFR 50.109(a)(4)(i),
37 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
38 following three conditions exist:
39

- 40 (1) The staff, whether by ~~its~~the staff's own error or by licensee, applicant, or third-party error
41 or omission, at or before the time of the staff's determination that a known and
42 established standard of the Commission was satisfied—
43
44 – incorrectly perceived facts,
45 – performed or failed to recognize flawed analyses, or
46 – failed to draw inferences from those facts or analyses.
- 47 (2) The staff's error is deemed an error as judged by the standards and practices that were
48 prevailing among professionals or experts in the relevant area at the time of the
49 determination in question.

1 (3) The facts, analyses, or inferences have now been properly perceived, performed, or
2 drawn.

3
4 ~~For example, the NRC typically invokes the compliance exception when all of the following~~
5 ~~three conditions/statements are met/true:~~

6
7 (1) The NRC approved or found acceptable a licensee's method of compliance with a
8 requirement.

9
10 (2) The staff determines that the licensee's method of compliance does not meet the
11 requirement because of an error or omission related to the NRC's approval.

12
13 (3) If the NRC had known about the error or omission at the time it issued the approval, the
14 ~~NRC agency~~ would not have approved the licensee's method of compliance.

15
16 ~~If more than one error or omission occurred, the staff needs to consider whether knowledge of~~
17 ~~only one of the errors or omissions, or a combination of errors, omissions, or both, could have~~
18 ~~resulted in a different outcome.~~

19
20 To justify a compliance exception, the staff must show that the error or omission, which may
21 have been committed by any involved party, must be traced to the licensing basis in effect at the
22 time of the approval at issue, and the NRC decision was inconsistent with prevailing
23 professional standards and practices ~~in existence~~ at the time it made the approval ~~at issue~~. The
24 understanding of what constituted proper implementation of the regulations, standards, and
25 practices must have been widely known or understood by professionals at the time. This is not
26 restricted to the regulatory positions of the NRC but includes any applicable industry or
27 professional standards and practices ~~in existence~~ at the time the original determination was
28 made.

29
30 An omission can occur when a licensee, applicant, or third party does not do one ~~or more~~ of the
31 following:

- 32
- 33 • ~~Provide~~ information to the NRC (or other necessary Federal agency the NRC relies
34 ~~upon~~ in its approval decision) that should have been submitted in connection with
35 obtaining the NRC approval at issue.
 - 36 • ~~Consider~~ or address information that the NRC requires to be considered or addressed
37 in connection with obtaining an NRC approval (e.g., development of an application or
38 preparation of an applicant response to an NRC request for additional information).
 - 39 • ~~Consider or address information that the NRC requires be addressed through a legal~~
40 ~~obligation (e.g., for nuclear power plant licensees, the change control provisions of~~
41 ~~10 CFR 50.59, "Changes, tests, and experiments").~~

42
43 The NRC can "incorrectly perceive facts" when it receives correct information but misinterprets it
44 or fails to recognize when the licensee or third party provides information that is incomplete,
45 inaccurate, or both.

46
47 The applicant's, licensee's, or third party's error or omission must be relevant and material to
48 the NRC's approval that is now regarded as incorrect. An omission or error—even those now
49 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

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

3
4 Understanding the meaning of the governing requirement is important. If the governing
5 requirement is in the *Code of Federal Regulations*, then the meaning and underlying purpose of
6 that requirement should have been established when the agency issued the regulation in a final
7 rule. The staff should first review the language of the regulation. If the meaning of the
8 regulation is not clear, then the staff should review the supporting SOC for the final rule and any
9 guidance that the NRC found to be an acceptable means for implementing or complying with the
10 requirement. If the license contains the governing requirement (e.g., a license condition or
11 technical specification), then the ~~meaning and underlying purpose should be explained in the~~
12 application and any supplements ~~made to it~~ should explain the meaning and underlying
13 purpose.

14
15 Equally important to understanding the applicable requirement is identifying the NRC approval
16 of the means by which the licensee has demonstrated that it would meet the requirement
17 (e.g., the licensee's methodology for demonstrating compliance). If the license contains the
18 governing requirement, then the governing requirement would be based on an NRC approval
19 (e.g., a license amendment and associated basis, documented in the safety evaluation, for its
20 conclusions underlying the approvals).

21
22 Sometimes, the NRC's conclusion may be perceived to include an implied approval (i.e., an
23 unstated NRC approval that can be inferred from an express NRC approval). To constitute an
24 implied approval, the approval must be part of an expressly stated NRC determination that an
25 NRC agency requirement was met (e.g., NRC approval of a licensee's use of an industry
26 standard to demonstrate compliance with an NRC regulatory requirement). Next, the subject
27 ~~matter~~ of the implied approval must be a direct and necessary aspect of the subject ~~matter~~ of
28 the express approval (e.g., the licensee's methodology for implementing the standard). Finally
29 the NRC's approval documentation must expressly discuss the subject ~~matter~~ of the implied
30 approval ~~must be expressly discussed in the NRC's approval documentation~~ (e.g., the NRC's
31 safety evaluation references the methodology but does not make an acceptability finding on the
32 methodology). If the implied approval meets these three criteria, then it is considered an NRC
33 approval for purposes of the compliance exception.

34
35 The compliance exception does not apply in either of the following situations:

- 36
37
- 38 • The staff's error occurred while the staff was using standards and practices that, at the
39 time of the original NRC determination, were not commonly recognized as the prevailing
40 professional standards and practices.
 - 41 • The NRC evaluated the error using professional standards and practices that were
42 developed or accepted after the time of the NRC determination (e.g., the staff
43 determines that the licensee's method of compliance does not meet the requirement
44 based on a changed staff position or new standards and practices that became known
45 after the NRC determination at issue). Such issues may constitute justifiable backfitting;
46 however, backfitting would need to be justified through adequate protection or a
47 cost-justified substantial increase in overall protection.
- 48

49 A change in the NRC's position as to whether a licensee's design conforms to a performance
50 standard is likely to be met with the argument that the new position does not reflect consistency
51 with a "known and established standard," but; rather, it is a new or modified interpretation of |

1 what constitutes compliance, which the Commission said in the 1985 Backfit Rule SOC would
2 fall outside the compliance exception.

3 4 Consideration of Costs

5
6 In a 2015 decision, *Michigan v. Environmental Protection Agency*, the United States Supreme
7 Court held that, unless Congress has indicated otherwise, a Federal agency should consider the
8 costs imposed on a regulated entity to comply with a new regulation. This decision had direct
9 implications for the NRC's application of the backfitting provisions, especially the compliance
10 exception. This decision did not affect the NRC's implementation of adequate protection
11 backfitting because the AEA requires implementation of adequate protection actions without the
12 need to consider costs. The Court's decision also did not change the NRC's approach to any
13 backfitting action based on a substantial increase in overall protection because this type of
14 backfitting must be cost-justified. However, the decision revealed a need to revisit the NRC's
15 implementation of the compliance exception to the backfit analysis requirement. Specifically,
16 the Commission did not view, as consistent with the *Michigan v. Environmental Protection*
17 *Agency* Supreme Court ruling, the practice of ensuring compliance with a requirement without
18 consideration of cost, as allowed under prior policy and guidance on the use of the compliance
19 exception. In SRM-COMSECY-16-0020, as further explained in the Solicitor's-2016
20 memorandum, the Commission directed the staff to consider costs when using the compliance
21 exception.

22
23 Although the extent of the cost consideration will necessarily be facility specific, factors that may
24 be relevant are (1) the amount of time that has elapsed since the approval or decision that is
25 now at issue and (2) the safety or security risk if the NRC does not take the backfitting action.

26
27 When the compliance backfitting issue is identified shortly after the NRC issues its approval
28 (e.g., within 2 years), a staff-prepared cost estimate of imposing the backfitting action using
29 information developed during the original justification may be sufficient to satisfy the
30 consideration of cost policy. But if significant time (e.g., more than 10 years) has passed since
31 the staff made the decision in question (e.g., more than 10 years) for which the staff
32 determin~~ing~~es that a regulation or requirement is not satisfied, then the staff should identify the
33 benefits of compliance and compare these benefits to the cost of achieving and maintaining
34 compliance to ensure that costs have been adequately considered. The staff should apply a
35 graded approach¹⁸ to the consideration of costs when justifying a backfitting action using the
36 compliance exception, with the level of cost consideration increasing from minimal consideration
37 involving issues with very recent NRC approvals to a more thorough consideration of costs for
38 issues with NRC approvals that occurred a significant time ago. The results of the cost
39 consideration are used to inform the decision.

40
41 If a risk-informed evaluation shows that imposing the compliance backfit would result in at least
42 a discernible safety benefit, then the staff should further inform the regulatory decision process
43 with a consideration of the costs and benefits of the proposed compliance backfit. The staff is
44 given substantial flexibility, in accordance with Commission direction, to determine how much
45 cost consideration is appropriate based on the specifics of each case, the identified risk, and the
46 elapsed time since the approval or decision at issue.

47
¹⁸ 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.

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

10
11 Appendix B to this NUREG contains a compliance exception worksheet that the staff should use
12 to determine the applicability of the compliance exception.

13 14 2.35.2.3-2.5.2.3 Documenting Compliance Exception Evaluations

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

21
22 The office director responsible for issuing the backfitting action must approve any documented
23 evaluation, ~~and The staff should send~~ a copy ~~of the documented evaluation should be sent~~ to
24 the EDO and appropriate regional administrator before ~~the staff transmitting~~ the backfitting
25 documentation to the licensee. If ~~the staff~~ cannot justify the proposed action using the
26 compliance exception, ~~and the staff~~ cannot justify a cost-beneficial substantial safety
27 enhancement, then the staff must document its conclusions as described in Chapter 6 of this
28 NUREG.

29
30 **2.36.2.6 Question 5: Does the ~~p~~Proposed ~~b~~Backfitting ~~a~~Action ~~e~~Constitute a
31 ~~e~~Cost-~~j~~Justified ~~s~~Substantial ~~i~~Increase in the ~~e~~Overall ~~p~~Protection of ~~p~~Public
32 ~~h~~Health and ~~s~~Safety or the ~~e~~Common ~~d~~Defense and ~~s~~Security, or ~~d~~Does the
33 ~~e~~Change ~~a~~Affecting ~~i~~Issue ~~f~~Finality in the ~~p~~Proposed ~~a~~Action ~~s~~Satisfy an ~~i~~Issue
34 ~~f~~Finality ~~e~~Criterion?**

35 2.36.1-2.6.1 Background

36 If the staff determines that it cannot justify its proposed action using either of the adequate
37 protection exceptions or the compliance exception to the requirement to conduct a backfit
38 analysis, then the staff needs to consider whether it can justify the proposed action using a
39 backfit analysis. In a two-part test, the staff must first show that the proposed action would
40 provide a substantial increase in the overall protection of the public health and safety or the
41 common defense and security. If the staff can reach that conclusion, then it must determine
42 whether the direct and indirect costs of implementing the backfitting action are justified in view
43 of the increased protection. These standards appear in 10 CFR 50.109(a)(3), 70.76(a)(3),
44 72.62(c), and 76.76(a)(3); and in certain issue finality regulations under 10 CFR Part 52.

45
46 If the proposed action is not shown to result in a substantial increase in overall protection, the
47 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.~~

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.

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

1 10 CFR Part 50 licensees) for submission of information, or adopting a regulation
2 requiring the submission of the necessary information. Any information requests to the
3 public or affected stakeholders must meet applicable legal requirements such as those
4 of the Paperwork Reduction Act. The staff should not communicate with the licensee
5 about the possible backfitting until after receiving management's approval to do so.
6

- 7 • The NRC can explain the efforts it took to obtain the information or explain that the
8 information is not reasonably available or known to any entity and proceed with a
9 qualitative determination of benefits and costs.
- 10 • The NRC can withdraw or end its efforts to backfit ~~or impose a change affecting issue~~
11 ~~finality.~~

12
13
14 Averted offsite costs that result from an estimated decrease in accident frequency or severity
15 that are tied directly to public health and safety are considered benefits (i.e., safety
16 enhancement). The intent of the Backfit Rule is to consider as benefits only averted offsite
17 deaths and adverse health effects that result from an estimated decrease in accident frequency
18 or severity attributable to the proposed backfitting. The staff should treat averted costs, such as
19 onsite and offsite property damage as defined in NUREG/BR-0058, as an offset against other
20 licensee costs to calculate the net backfit cost. The backfit analysis should clearly state that
21 costs of averted onsite and offsite property damage are not counted as a benefit, and these
22 costs are considered after the staff has determined that the proposed action will result in a
23 substantial increase in the overall protection of the public health and safety or the common
24 defense and security.
25

26 Notably, the substantial increase in overall protection must pertain to the "overall protection of
27 the public health and safety or common defense and security." The Commission explained in
28 the 1985 Backfit Rule SOC that the principal purpose of this standard was "to ensure that both
29 [the proposed backfit's] negative and positive effects are taken into account in deciding whether
30 the backfit is justified." The backfit's effects on protection provided by the facility ~~plant~~ as a
31 whole, not just the part of the ~~plant~~ facility being backfitted, is the "overriding consideration."
32

33 The backfitting provisions in 10 CFR 72.62 differ from the backfitting requirements for nuclear
34 power reactor licensees by specifically including occupational safety within the provisions of
35 10 CFR 72.62(b) and (c)(1). Under 10 CFR 72.62(b), the NRC must consider occupational
36 health and safety in terms of adequate protection, and 10 CFR 72.62(c)(1) directs the NRC to
37 consider occupational health and safety in determining whether the proposed action would
38 result in a substantial increase in overall protection as part of a backfit analysis. In
39 10 CFR 50.109(c) and 10 CFR 70.76(b), the backfitting provisions require the NRC to consider
40 radiological exposure (and hazardous chemicals under 10 CFR 70.76(b)) of facility employees
41 only as part of a backfit analysis. Therefore, in addition to considering members of the public,
42 cost-justified backfit analyses that are performed to satisfy these regulations need to also
43 consider onsite personnel when analyzing the substantial increase in the overall protection
44 resulting from the proposed action.
45

46 The Commission has also directed the staff to evaluate the NRC's regulatory actions that affect
47 nuclear power plants for conformity with the NRC's policy statement on safety goals for the
48 operation of nuclear power plants. The 1986 policy statement sets out two qualitative safety
49 goals and two quantitative health objectives. Both the safety goals and health objectives apply
50 only to the risks to the public from the accidental or routine release of radioactive materials from
51 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.

1 considered to be generic safety enhancement backfits that are subject to the substantial
2 additional protection standard at 10 CFR 50.109(a)(3). A safety goal evaluation is not
3 necessary for new requirements within the exceptions at 10 CFR 50.109(a)(4)(i)–(iii) or for a
4 facility-specific cost-justified substantial increase in overall protection backfitting. If the
5 proposed safety goal screening criteria in NUREG/BR-0058 are satisfied (i.e., any decision
6 except a no-action decision), then the NRC considers that the substantial additional protection
7 standard is met for the proposed new or revised requirement.

8 9 2.36.3-2.6.3 Documenting a Backfit Analysis

10 A backfit analysis must consider the factors listed in the applicable 10 CFR provisions and any
11 other information relevant and material to the proposed backfitting. In ~~40 CFR Part 50,~~
12 10 CFR 50.109(c), the NRC lists the relevant factors that must be included in a backfit analysis:

- 13
14 1. statement of the specific objectives that the proposed backfit is designed to achieve;
- 15
16 2. general description of the activity that would be required by the licensee or applicant to
complete the backfit;
- 17
18 3. potential change in the risk to the public from the accidental offsite release of radioactive
material;
- 19
20 4. potential impact on the radiological exposure of facility employees;
- 21
22 5. installation and continuing costs associated with the backfit, including the cost of facility
downtime or the cost of construction delay;
- 23
24 6. the potential safety impact of changes in plant or operational complexity, including the
relationship to proposed and existing regulatory requirements;
- 25
26 7. the estimated resource burden on the NRC associated with the proposed backfit and the
availability of such resources;
- 27
28 8. the potential impact of differences in facility type, design, or age on the relevancy and
practicality of the proposed backfit; and
- 29
30 9. whether the proposed backfit is interim or final and, if interim, the justification for
imposing the proposed backfit on an interim basis.

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

36
37 Similar to documented evaluations, the Director of NRR or NMSS, whichever is responsible for
38 issuing the backfitting action (for facility-specific backfitting) or the Commission (for generic
39 backfitting such as rulemakings) must approve any backfit analysis. ~~A-The staff should send a~~
40 copy of the backfit analysis should be sent to the EDO and appropriate regional administrator
41 before ~~the staff~~ transmittings the backfitting documentation to the licensee.

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

3
4 **2.36.4-2.6.4 Issue Finality**

Commented [BH94]: Comment 4.2.37

5 Each of the 10 CFR Part 52 approvals has a unique set of issue finality requirements. The staff
6 should be aware of the differences in requirements among the various approvals and between
7 10 CFR Part 52 provisions and 10 CFR 50.109 when dealing with any final approval. For
8 example, the DC issue finality regulations have criteria in addition to the adequate protection,
9 compliance, or substantial increase in overall protection concepts found in the Backfit Rule.
10 Where the issue finality regulations for these approvals have analogous requirements to the
11 Backfit Rule (e.g., adequate protection exception), the staff must follow the Commission's policy
12 describing the order in which the requirements are considered (i.e., consider adequate
13 protection before considering any of the other issue finality provisions).

14
15 The DC issue finality regulations recognize that there may be additional reasons to amend DC
16 information. These reasons could include providing detailed design information to replace
17 design acceptance criteria, reducing unnecessary regulatory burden, contributing to increased
18 standardization of the design, or correcting material errors. Although the issue finality
19 regulations ensure that the NRC will maintain the stability of the licensing process by preserving
20 the safety conclusions reached in the DC rulemaking, they also provide flexibility for
21 amendments to the design.

22
23 In addition, as reflected in 10 CFR 52.98 and 10 CFR 50.109(a)(1)(vii), different backfitting
24 criteria may apply to different portions of a COL holder's licensing basis. For example, if a COL
25 holder references an approved ESP and a DC, then: (1) 10 CFR 50.109 would apply to the
26 portions of the licensing basis outside the scope of the referenced ESP and DC,
27 (2) 10 CFR 52.39 would apply to the site characteristics, design parameters, and terms and
28 conditions in the ESP, and (3) 10 CFR 52.63 would apply to design matters resolved in the DC,
29 unless the DC includes specific issue finality provisions, in which case those specific provisions
30 will govern.

31
32 The nature of issue finality may differ depending on the regulation and the information in
33 question. For example, 10 CFR Part 52, Appendix D, "Design Certification Rule for the AP1000
34 Design," Section VI, provides that nuclear safety issues within the scope of the certified design
35 are resolved and that "additional or alternative structures, systems, components, design
36 features, design criteria, testing, analyses, acceptance criteria, or justifications" are
37 unnecessary. However, Section VI does not accord such finality to operational requirements in
38 the design control document. For ESPs, 10 CFR 52.39 provides issue finality, but a COL,
39 construction permit, or operating license applicant referencing the ESP must "update the
40 emergency preparedness information that was provided under 10 CFR 52.17(b), and discuss
41 whether the updated information materially changes the bases for compliance with applicable
42 NRC requirements." For DC renewal, the NRC must meet the backfit-like criteria of
43 10 CFR 52.59(b) to impose other requirements, but to renew the DC, 10 CFR 52.59(a) requires
44 a finding of, among other things, compliance with the regulations in effect at initial certification.
45 For proposed actions that affect the issue finality of a Part 52 approval, the staff must determine
46 whether that proposed action satisfies the criteria in the issue finality provision that applies to
47 the Part 52 approval. Because the issue finality provisions in Part 52 vary by approval, the
48 details of the criteria will depend on the Part 52 approval.

49 The staff may need to prepare a backfit analysis as described in this Section 2.6 or an analysis
50 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, 2019~~, 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 as a condition¹ 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.

¹ 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.

1
2 ~~(3)~~ The staff's proposed action is the imposition of either—

3
4 (a) ~~a~~—a new or changed (e.g., ~~amended, revised, or modified~~) NRC requirement
5 (e.g., ~~a regulation or order~~); or

6
7 ~~(b)~~ a new or changed staff interpretation of an NRC requirement.

8
9 ~~(4)~~ The imposition of the new or changed requirement or interpretation will result in a
10 modification or addition to ~~any of the following: the licensee's—~~

11
12 ~~(a)~~ systems, structures, or components of ~~its the affected entity's~~ facility;

13
14 ~~(b)~~ design (including but not limited to ~~design certification, standard design approval, or~~
15 manufacturing license) of ~~its the affected entity's~~ facility; or

16
17 ~~(c)~~ procedures or organization required for designing, constructing, or operating ~~its the~~
18 ~~affected entity's~~ facility-

19
20 ~~(5)~~ The new or changed NRC requirement or interpretation being imposed on the ~~licensee~~
21 ~~affected entity~~ is a condition of the NRC's approval of the ~~affected~~
22 ~~entity/licensee~~-initiated licensing action.

23
24 ~~(6)~~ The ~~licensee's affected entity's~~ underlying request ~~did NOT does not~~ propose to comply
25 with the staff's proposed new or revised requirement or interpretation. ~~This means that~~
26 ~~the affected entity's initial submittal of the requested licensing action and any written~~
27 ~~supplements do not include, as part of the licensing action, a proposal to comply with the~~
28 ~~staff's new or revised requirement or interpretation. Commitments offered in the affected~~
29 ~~entity's requested licensing action would not constitute legally binding requirements if the~~
30 ~~NRC approves the requested licensing action, so such commitments would not~~
31 ~~constitute the affected entity's proposal to comply with the staff's new or revised~~
32 ~~requirement or interpretation. Section 5.1.1.6 of this NUREG contains more information~~
33 ~~on commitments.~~

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

34
35 If one or more of the statements is not true, then the proposed action is not forward fitting. ~~For~~
36 ~~example, the staff's proposed action cannot be a requirement or staff position that is already in~~
37 ~~the affected entity's licensing basis (statement 3). Or, if the proposed action is similar to an~~
38 ~~action described in Section 2.2 of this NUREG (i.e., would not meet the definition of backfitting~~
39 ~~and, therefore, the definition of forward fitting), then the staff should consider the guidance in~~
40 ~~Section 2.2 to determine whether the proposed action is within the scope of forward fitting. The~~
41 ~~staff should document that conclusion as described in Chapter 6 of this NUREG and proceed to~~
42 ~~take the proposed action. If the second statement is not true, then the staff needs to assess the~~
43 ~~proposed action for backfitting. If one or more of the other statements is not true, then the staff~~
44 ~~may take the proposed action without justifying it as a forward fit or backfit. However, if all the~~
45 ~~statements are true, then the staff's proposed action constitutes meets the definition of a~~
46 ~~"forward fitting," and the staff must justify the proposed action to impose it.~~

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

47
48 ~~Forward fitting can occur in various ways. The NRC would be forward fitting a licensee if the~~
49 ~~staff required the licensee to use a newer version of a regulatory guide to demonstrate~~
50 ~~compliance with an existing requirement than the version the licensee proposed to use in its~~

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.

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

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.

6
7 ~~Forward fitting could occur if the NRC issues a guidance document that supersedes an existing~~
8 ~~guidance document. If the agency requires licensees to use the new, modified guidance~~
9 ~~document in future licensing actions, then such action could constitute forward fitting. For this~~
10 ~~reason, when the staff issues modified guidance documents, the staff should consider whether it~~
11 ~~needs to withdraw or supersede the existing guidance document. Section 5.8 of this NUREG~~
12 ~~contains a discussion of withdrawing and superseding guidance documents.~~

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

13
14 ~~Other examples of forward fitting include the following:~~

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.

15
16 ~~imposing a license condition that was not part of the licensee's request (e.g., requiring an~~
17 ~~approach that the staff finds more acceptable than, or preferable to, the licensee's requested~~
18 ~~action);~~

19 ~~escalating regulatory commitments into licensing conditions; or~~

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

24 25 3.3 Forward Fitting Justification Justifying Forward Fits and Documenting the 26 Analyses

Commented [BH105]: Comments 4.3.3. 4.3.4

27 ~~The NRC justifies the forward fit by showing in the forward fitting assessment that the following~~
28 ~~criteria are met: (1) there is a direct nexus between the new or modified requirement or~~
29 ~~regulatory staff position and the affected entity's request, and (2) the imposition of the new or~~
30 ~~modified requirement or regulatory staff position is essential to the NRC staff's determination of~~
31 ~~the acceptability of the affected entity's request.~~

32
33 ~~A direct nexus between the new or modified requirement or regulatory staff position and the~~
34 ~~affected entity's request occurs when both of the following statements are true:~~

Commented [BH106]: Comment 4.3.4

35
36 (1) The affected entity's requested change would create:

37
38 (a) a safety or security issue, or

39
40 (b) a noncompliance with a requirement that is already in the affected entity's licensing
41 basis or a new requirement the affected entity proposed in its requested change,

42
43 that would not exist but for NRC approval of the requested change without a condition.

44
45 (2) The NRC's proposed condition would address the issue or noncompliance.
46

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 protection² 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

² However, as explained in Management Directive 8.4, forward fits will not usually be justifiable as necessary
for adequate protection because the NRC already had an opportunity to consider whether the new or
changed requirement or staff position was necessary for adequate protection of the public health and safety.
This occurred when the NRC established or modified the requirement or regulatory staff position and the
NRC determined whether the resulting position should be imposed as a backfit on existing facilities. Under
the mandatory backfitting provisions of 10 CFR 50.109(a)(5), 70.76(a)(5), and 76.76(a)(5), and the portions
of 10 CFR 72.62(b) on backfitting necessary to ensure adequate protection of the public health and safety, if
such a change were necessary to ensure adequate protection of the public health and safety when the new
or modified requirement or regulatory staff position was made, the NRC would have been required to impose
it as a backfit. Because such a backfit has not been imposed if the staff is considering a forward fit, it is
unlikely that a change could be justified as necessary to ensure adequate protection of the public health and
safety.

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.

1 noncompliance, which is not permissible under the NRC's regulations (e.g., under
2 10 CFR 50.92(a) and 10 CFR 50.57, the Commission cannot issue an amendment to an
3 operating license until finding that, among other things, the facility will operate in conformity with
4 the Atomic Energy Act of 1954, as amended, and the rules and regulations of the Commission).

5
6 If the proposed action cannot satisfy the direct nexus or essential definition, then the proposed
7 action is not a justified forward fit. The staff should document that conclusion as described in
8 Chapter 6 of this NUREG. If the staff intends to pursue the imposition, then the staff must
9 consider the action in accordance with the backfitting guidance in Chapter 2 of this NUREG.

10
11 If the proposed action satisfies the direct nexus and essential definitions, then the NRC staff
12 may communicate the results of the forward fitting screening and justification to the requesting
13 affected entity. Section 5.1.4 of this NUREG contains guidance for NRC staff communications
14 with the affected entity about the safety or security issue or compliance issues preventing NRC
15 approval and the options available to the NRC staff and affected entity. Each communication to
16 an affected entity of a proposed or issued forward fitting action should include the forward fitting
17 assessment for the action and instructions on the use of the appeals process (see Chapter 4 of
18 this NUREG for more information on the appeals process). Subsequently, if the staff decides to
19 pursue the forward fit, then it needs to consider the costs of the proposed forward fit in
20 accordance with Section 3.5 of this NUREG and determine the appropriate action.

21
22 ~~Whenever the staff intends to forward fit a licensee, the staff must justify the forward fit. The~~
23 ~~NRC justifies the forward fit through an analysis that shows the following criteria are met: (1)~~
24 ~~there is a direct nexus between the new or modified requirement or regulatory staff position and~~
25 ~~the licensee's request and (2) the imposition of the new or modified requirement or regulatory~~
26 ~~staff position is essential to the NRC staff's determination of the acceptability of the licensee's~~
27 ~~request. The staff must also consider the costs of the forward fitting action unless adequate~~
28 ~~protection is involved, as discussed below. The staff should identify the benefits of the forward~~
29 ~~fit and compare these benefits to the cost of implementation. Based on a risk-informed~~
30 ~~evaluation, if the safety benefit of imposing the forward fit is determined to be very low or~~
31 ~~negligible, then the staff should no longer consider imposing the forward fit. For forward fits~~
32 ~~having greater safety benefit, the staff should further inform the regulatory decision process by~~
33 ~~considering the costs and benefits of the proposed forward fit. The Commission gives the staff~~
34 ~~substantial flexibility to determine how much cost consideration is appropriate based on the~~
35 ~~specific facts of each case and the identified risk.~~

36
37 ~~The first criterion's "direct nexus between the new or modified requirement or regulatory staff~~
38 ~~position and the licensee's request" means that the requirement or staff position must relate~~
39 ~~directly to the specific subject matter of all or part of the licensee's request for NRC approval.~~
40 ~~For example, if the licensee's license amendment request concerns the emergency diesel~~
41 ~~generators, then the new or modified requirement or regulatory staff position that the staff wants~~
42 ~~to impose on the licensee cannot involve the height of the fence surrounding the protected area.~~
43 ~~If the staff wished to impose a proposed action that does not have a direct nexus to the~~
44 ~~licensee's request, then it would have to perform a backfitting assessment.~~

45
46 ~~The second criterion is that the imposition of the new or modified requirement or regulatory staff~~
47 ~~position is essential for the NRC staff to make a finding that the licensee's requested licensing~~
48 ~~action is acceptable (i.e., without the imposition, the staff could not make its safety or security~~
49 ~~finding). What is essential to make such a determination will vary depending on the type of~~
50 ~~request. For example, for license amendments, Title 10 of the Code of Federal Regulations (10~~
51 ~~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."

1 perform a site-specific regulatory analysis of the forward fit unless the forward fit is necessary
2 for adequate protection of the public health and safety.³

3 4 **3.4 Forward Fitting Screening and Justification Scenarios**

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

10 11 **3.4.1 NRC Condition Meets Definitions of “Forward Fit,” “Direct Nexus,” and** 12 **“Essential”**

13 The NRC identifies a safety or security issue or noncompliance that would result from NRC
14 approval of the LAR without imposing a condition to address the issue or noncompliance. The
15 issue or noncompliance would prevent the NRC from making the findings necessary to approve
16 the LAR. The NRC’s proposed condition to address the issue or noncompliance is not already
17 within the affected entity’s licensing basis.

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

30
31
32 The NRC could discuss the staff’s concern about the LAR with the affected entity in accordance
33 with Section 5.1.4 of this NUREG. If the affected entity does not supplement its LAR to address
34 the issue or withdraw the LAR, then the NRC has options, including denying the LAR or
35 pursuing the forward fit.
36

Commented [KA116]: Comment 4.3.15

³ 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.

1 **3.4.2 NRC Condition Meets Definitions of “Forward Fit” and “Essential” but Not “Direct**
2 **Nexus”**

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

11
12 The NRC’s proposed condition meets the definition of a “forward fit” because the condition
13 would impose a staff position that modifies an SSC as a condition of the NRC’s approval of an
14 affected entity-initiated request for a licensing action when the underlying request does not
15 propose to comply with the staff position. However, the NRC’s proposed condition does not
16 meet the definition of “direct nexus” because the LAR did not create the noncompliance (i.e., the
17 noncompliance existed before submittal of the LAR). The definition of “essential” is met
18 because the NRC’s proposed condition would be necessary to make the safety or security
19 finding to support the NRC’s approval of the affected entity’s request.

20
21 Because the NRC’s proposed condition does not meet the definition of “direct nexus,” the NRC
22 cannot pursue forward fitting. However, the NRC’s condition could constitute backfitting
23 because the NRC would be imposing a new staff position on the affected entity. Thus, the
24 “causal” element of backfitting would be met. The NRC could discuss the staff’s concern about
25 the LAR with the affected entity. If the affected entity does not voluntarily supplement its LAR to
26 address the issue, then the NRC may need to perform a backfitting assessment to determine if
27 it can pursue backfitting before completing its review of the LAR. Alternatively, the NRC could
28 deny the LAR and pursue backfitting to correct the previous licensing error. Sections 2.4
29 and 5.1.4 of this NUREG contain additional guidance on the relationship between backfitting
30 and licensing actions.

31
32 **3.4.3 NRC Condition Meets Definitions of “Forward Fit” and “Direct Nexus” but Not**
33 **“Essential”**

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

42
43 The NRC’s proposed condition meets the definition of a “forward fit” because the condition
44 would impose a staff position that modifies an SSC as a condition of the NRC’s approval of an
45 affected entity-initiated request for a licensing action when the underlying request does not
46 propose to comply with the staff position, and the proposed condition is a new or changed
47 requirement or staff position (i.e., it is not already within the affected entity’s licensing basis).
48 The definition of “direct nexus” is met because (1) the affected entity’s requested change, if
49 approved by the NRC without a condition, would create a safety or security issue that would not

1 exist but for the change, and (2) the NRC condition would address that issue. However, the
2 definition of “essential” is not met because the proposed condition would not be necessary to
3 make the safety or security finding to support the NRC’s approval of the affected entity’s
4 request.

5
6 The NRC cannot justify a forward fitting action. The NRC could assess the proposed condition
7 for backfitting. If backfitting can be justified, then the NRC could discuss the staff’s concern
8 about the LAR with the affected entity in accordance with Section 5.1.4 of this NUREG.

9
10 **3.4.4 NRC Condition Meets Definition of “Forward Fit” but Not “Direct Nexus” or**
11 **“Essential”**

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

24
25 Furthermore, the condition would improperly introduce a nonmaterial issue that is outside the
26 scope of the LAR. The NRC’s regulations limit intervention in proceedings to matters within the
27 scope of the proceeding and material to the findings the NRC must make to issue the LAR. Just
28 as the NRC regularly denies intervention petitions attempting to introduce matters outside the
29 scope of the proceeding and required findings, the NRC staff cannot introduce matters outside
30 the scope of the LAR.

31
32 However, the NRC’s condition could constitute backfitting. The NRC determined that it could
33 approve the LAR. If the NRC’s approval of the LAR without the condition is considered the
34 applicable staff position, then the NRC’s condition of the approval would be imposing a staff
35 position that is new or different from the previously applicable staff position. Thus, the “causal”
36 element of backfitting would be met. The NRC would need to subject the condition to a
37 backfitting assessment.

38
39 **3.5 Cost Considerations**

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

44
45 The standards for considering costs are different for forward fitting and backfitting. In a backfit
46 analysis, the NRC must show that the proposed agency action would be cost-justified. For a
47 compliance backfit or a forward fit, the NRC must only consider costs to inform the decision
48 whether to take the backfitting or forward fitting action. During the forward fitting process, the
49 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
36 Appendix C to this NUREG contains a guide for drafting a forward fit analysis-assessment to
37 justify support a forward fitting action. Unlike a backfit analysis described in Section 2.6 of this
38 NUREG, a forward fit analysis-assessment contains the staff's evaluation of the proposed action
39 against the definitions of a "forward fit," and the "direct nexus," and "essential" and to the staff's
40 finding" criteria, and the staff's consideration of the costs of the forward fit, or its basis for
41 determining that the forward fit involves adequate protection.
42
43

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.

1 **4 BACKFITTING AND FORWARD FITTING MANAGEMENT DIRECTIVE**
2 **8.4 APPEALS**

3 **4.1 Introduction**

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

13 The U.S. Nuclear Regulatory Commission (NRC) provides a process in Management
14 Directive (MD) 8.4 by which an affected entity#licensees (i.e., one of the entities listed in
15 Section 2.3 of this NUREG) may appeal a proposed or issued staff actions on the basis that
16 when the licensee-affected entity concludes believes the staff did not properly follow the perform
17 a backfitting or forward fitting assessment process. This NUREG refers to a backfitting or
18 forward fitting appeal as an "MD 8.4 appeal."¹ Each communication of a backfitting or forward
19 fitting action issued to a licensee must include instructions on the use of the appeal process. If
20 the licensee elects to file a backfitting or forward fitting appeal when it receives the written staff
21 action, the licensee must submit the appeal in writing, in accordance with Section 50.4, "Written
22 communications," of Title 10 of the Code of Federal Regulations (10 CFR), with a copy to the
23 appropriate regional administrator and program office director (i.e., depending on the licensee,
24 the Director for either the Office of Nuclear Reactor Regulation (NRR) or the Office of Nuclear
25 Material Safety and Safeguards (NMSS)). For a second level appeal, the licensee must submit
26 the written appeal in accordance with 10 CFR 50.4, with a copy to the Executive Director for
27 Operations (EDO).
28
29

30 The NRC will not accept oral appeals of backfitting or forward fitting actions or appeals
31 submitted by a third party. In these cases, the staff will not consider any appeal until it receives
32 a written appeal from a licensee. If the NRC initiated a staff action using an order, the appeal
33 process described in this section does not apply. After the NRC issues an order, appeals are
34 governed by the provisions of 10 CFR Part 2, "Agency Rules of Practice and Procedure,"
35 Subpart B, "Procedure for Imposing Requirements by Order, or for Modification, Suspension, or
36 Revocation of a License, or for Imposing Civil Penalties," as specified in Management Directive
37 (MD) 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information
38 Requests," dated September 20, 2019.
39

40 For backfitting or forward fitting appeals, licensees have two levels of appeal: a first level appeal
41 at the office director level² and a second level appeal to the EDO. Licensees-Affected entities
42 can use the backfitting or forward fitting MD 8.4 appeal process only in either of the following
43 situations:

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

² In accordance with MD 8.4, the regional administrator is not the official 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 • The NRC staff imposed (or will impose) a new or revised applicable staff position or
4 requirement on the affected entity/licensee that the staff determined was not (or will not

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

5 be) backfitting or forward fitting; but that the affected entity/licensee believes is (or will be)
6 backfitting or forward fitting.
7
8 • The NRC staff imposed (or will impose) a new applicable staff position or requirement on
9 the licensee-affected entity that the staff determined was (or will be) backfitting or
10 forward fitting; but that the affected entity/licensee believes was (or is) not properly
11 justified. This includes an appeal to modify or withdraw a backfitting action for which the
12 staff conducted a backfit analysis or an appeal claiming that a backfitting action justified
13 by one or more of the adequate protection or compliance exceptions in fact must be
14 justified through a backfit analysis.

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

15 Affected entities/licensees have two levels of appeal: a first-level appeal at the office director
16 level³ and a second-level appeal to the Executive Director for Operations (EDO). References to
17 the MD 8.4 appeal process in this NUREG include the first-level appeal and second-level
18 appeal, unless otherwise specified. If the NRC already completed the MD 8.4 appeal process
19 for an issue (i.e., the NRC completes the first-level appeal and the second-level appeal, or the
20 NRC completes the first-level appeal and the opportunity for the affected entity to submit a
21 second-level backfit appeal has elapsed), then the NRC will not accept another MD 8.4 appeal
22 for the issue throughout its processing of the agency action unless the NRC substantively
23 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.

24 Affected entities may raise concerns about the NRC staff's application of the backfitting
25 regulations and forward fitting policy during interactions with the NRC staff, as discussed in
26 Section 1.5 of this NUREG. Raising a backfitting or forward fitting concern does not constitute
27 submission of an MD 8.4 appeal. If an affected entity wants to appeal a proposed or issued
28 staff action, then the affected entity may follow the process described in Section 4.2 of this
29 NUREG. Appendix A to this NUREG provides a flowchart showing the MD 8.4 appeal process.
30 If, during a backfitting or forward fitting appeal process, the Director of NRR or NMSS for a
31 first-level appeal, or the EDO for a second-level appeal, determines the appealed action
32 constitutes unjustified backfitting or forward fitting, then the responsible office director, EDO, or
33 designee must document the decision, request Office of the General Counsel (OGC) review of
34 the decision, and inform the licensee in writing. The office director, EDO, or delegate, as
35 applicable, may exit the appeal process at any time without completing all of the process steps
36 (e.g., holding a public meeting).

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

³ 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.

1 **4.2 Using the Management Directive 8.4 Appeal Process**

2 **4.2.1 Submitting an Appeal**

3 The NRC accepts appeals only from those affected entities that are the subject of the staff
4 action that is the basis of the appeal.⁴ The NRC does not accept MD 8.4 appeals of proposed
5 or issued NRC actions submitted by anyone other than an affected entity, including NRC staff⁵
6 who disagree with an agency action.

Commented [KA137]: Comment 4.4.20

7
8 MD 8.4 appeals should be submitted in writing. For appeals to the Director of the Office of
9 Nuclear Reactor Regulation (NRR), the affected entity should submit the appeal in accordance
10 with 10 CFR Section 50.4, "Written communications," or 10 CFR 52.3, "Written communications,"
11 as applicable, of Title 10 of the Code of Federal Regulations (10 CFR), with a copy to the
12 appropriate regional administrator, and program office director (i.e., depending on the licensee,
13 For appeals to the Director for either the Office of Nuclear Reactor Regulation (NRR) or of the
14 Office of Nuclear Material Safety and Safeguards (NMSS), the affected entity should submit the
15 appeal in accordance with 10 CFR 70.5, "Communications," or 10 CFR 72.4, "Communications,"
16 as applicable, with a copy to the appropriate regional administrator. For a second-level appeal
17 to the EDO, the affected entity should submit the appeal in accordance with 10 CFR 50.4,
18 10 CFR 52.3, 10 CFR 70.5, or 10 CFR 72.4, as applicable, with a copy to the applicable office
19 director and regional administrator Executive Director for Operations (EDO). The affected entity
20 should also specify in its written appeal whether it requests that the NRC host a public meeting
21 with the affected entity to discuss its appeal.

Commented [KA138]: Comment 4.4.13

22
23 The affected entity's authorized representative should sign the appeal. The appeal should state
24 the capacity of the person signing; the signatory's address, phone number, and e-mail address;
25 and the date of signature. The signature of a person signing an appeal is a representation that
26 the appeal has been subscribed in the capacity specified with full authority, that the individual
27 has read it and knows the contents, that to the best of the individual's knowledge, information,
28 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.

29
30 An affected entity should submit its first-level appeal within 30 calendar days of the issuance
31 date of the NRC's proposed or issued staff action (unless otherwise specified by the NRC in its
32 written communication to the affected entity of the proposed or issued staff action). The
33 first-level appeal should include sufficient documentation to justify the affected entity's
34 basis for the appeal. The affected entity's licensee should indicate deficiencies in the staff's
35 position or provide other information that is relevant and material to the staff's action or
36 position and supports the affected entity's licensee's position for the appeal.

37
38 A second-level appeal is an appeal of the outcome of the first-level appeal. The affected
39 entity's licensee may not request a second-level appeal until the NRC issues its decision on a
40 first-level appeal. If an affected entity wishes to submit a second-level appeal, then the
41 affected entity should submit a second-level appeal within 30 calendar days of the date of
42 the NRC's response to the first-level appeal decision unless otherwise specified by the NRC.

⁴ 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.

⁵ The NRC staff may choose to use the Differing Professional Opinion or nonconcurrency processes.

1
2 **4.2.2 Stakeholder Participation**

3 Members of the public can participate in any public meeting associated with the MD 8.4 appeal
4 (except when MD 8.4 appeals meetings are closed because, for example, safeguards,
5 proprietary, or other sensitive information will be discussed). There may be other opportunities
6 to participate in proceedings related to a change to a facility's license (e.g., through the
7 submission of a hearing or intervention request related to a license amendment; a petition via
8 10 CFR 2.206, "Requests for action under this subpart"; or general correspondence).
9 Sections 4.3.1.3 and 4.3.2.3 provide additional information about the level of public participation
10 in MD 8.4 appeal public meetings.

Commented [KA140]: Comment 4.4.12

11
12 **4.2.3 Draft or Proposed Generic Documents or Actions for Comment**

13 The backfitting appeals process is not applicable to generic documents or actions
14 (e.g., guidance, communications, and rulemakings). As discussed in Chapter 5 of this NUREG,
15 the NRC must perform a backfitting assessment of proposed generic documents or actions.
16 Stakeholders have opportunities to raise backfitting concerns during the development of typical
17 generic documents or actions by submitting comments expressing their concerns. For example,
18 in rulemaking, stakeholders can comment on a proposed rule and the agency's discussion of
19 backfitting in the proposed rule's statement of considerations. The NRC will not process such
20 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.

21
22 **4.2.4 Appeals of NRC Actions Subject to 10 CFR Part 2 Proceedings**

23 An affected entity may submit an MD 8.4 appeal on a proposed or issued NRC action.
24 However, the regulations in 10 CFR Part 2 for hearings and disputing violations take
25 precedence over the MD 8.4 appeal process. The guidance in this section describes how the
26 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.

27
28 **4.2.4.1 Orders and Management Directive 8.4 Appeals**

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

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

40
41 If the affected entity chooses to request a hearing on an issued order, then the MD 8.4 appeal
42 process does not apply. Rather, the provisions of 10 CFR Part 2, Subpart B, "Procedure for
43 Imposing Requirements by Order, or for Modification, Suspension, or Revocation of a License,
44 or for Imposing Civil Penalties," would apply, as specified in MD 8.4. Any backfitting issues
45 could be raised within the 10 CFR Part 2 proceeding. The Atomic Safety and Licensing
46 Board (ASLB) is responsible for the resolution of the hearing, including any backfitting concerns
47 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

Commented [AK144]: Comments 4.4.15, 4.4.16, 4.4.17

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).

1
2 b. The NRC may issue the inspection report with an unresolved item to track the
3 concern and complete the MD 8.4 appeal process before dispositioning the
4 unresolved item. The NRC may document an unresolved item in an initial
5 inspection report to track the concern, note the existence of the MD 8.4 appeal in
6 the report, and complete the MD 8.4 appeal process to determine how to
7 disposition the unresolved item in a subsequent report. The NRC's inspection
8 manual chapters contain additional guidance on how to treat the timing of a
9 violation if it is upheld after the NRC completes the MD 8.4 appeal process. If
10 the NRC completes the MD 8.4 appeal process for the issue, then the NRC will
11 not accept another MD 8.4 appeal for that issue.

12
13 c. The NRC may process the MD 8.4 appeal before issuing the inspection report or
14 violation. If the MD 8.4 appeal is denied and the violation is upheld, then the
15 NRC will not process another MD 8.4 appeal for the issue.

16
17 2. If the NRC did not already complete the MD 8.4 appeal process for the issue, and if the
18 affected entity submits an MD 8.4 appeal after the NRC issues a choice or conference
19 letter documenting an apparent violation, then the NRC will typically complete the
20 MD 8.4 appeal process prior to its disposition of the violation. If the MD 8.4 appeal is
21 denied and the violation is upheld, then the NRC will not process another MD 8.4 appeal
22 after issuance of the violation (e.g., during resolution of a disputed or denied violation).

23
24 3. If an affected entity chooses to deny or dispute a violation that the NRC has issued on
25 the basis that the violation constitutes unjustified backfitting, then the affected entity
26 should follow the instructions in the correspondence for contesting the violation under
27 10 CFR 2.201. The affected entity should formally submit its basis for disputing the
28 violation, including its backfitting concerns or an MD 8.4 appeal if the NRC has not
29 already completed the MD 8.4 appeal process for that issue. The content of the affected
30 entity's submittal should be consistent with the NRC Enforcement Manual for disputed
31 nonescalated or escalated actions and MD 8.4, if applicable.

32
33 a. MD 8.4 Appeal but no Disputed Violation. The regulations in 10 CFR Part 2 require
34 the NRC to specify in its communication to the affected entity a due date for the
35 affected entity to submit a response to a cited violation, including a denial of the
36 violation. This due date also applies to submitting a first-level MD 8.4 appeal if the
37 NRC has not already processed an MD 8.4 appeal for that issue. If the affected
38 entity pursues an MD 8.4 appeal after the NRC issues an inspection report or
39 violation and the affected entity submits the appeal without disputing or denying the
40 violation in accordance with 10 CFR 2.201, then the denied or disputed violation
41 timeline could expire before resolution of the MD 8.4 appeal. In that situation, the
42 affected entity would not be able to deny or dispute the violation after the MD 8.4
43 appeal process concludes.

44
45 b. Disputed Violation but no MD 8.4 Appeal. If an affected entity denies or disputes a
46 violation under 10 CFR 2.201 based, in full or in part, on a claim of unjustified
47 backfitting but is not explicit in its communication for denying or disputing the
48 violation that it is also submitting an MD 8.4 appeal, then the NRC will (1) inform the
49 entity, as part of its receipt confirmation of the disputed violation, that the NRC will
50 not accept an MD 8.4 appeal after the NRC completes the disputed or denied
51 violation process, and (2) if the NRC has not already completed the MD 8.4 appeal

1 process for the issue, then request that the entity confirm whether it wants the NRC
2 to treat its disputed violation as an MD 8.4 appeal in parallel with the disputed
3 violation process. If the entity states that it does not want to use the MD 8.4 process,
4 then the NRC will complete the disputed violation process and will not accept an
5 MD 8.4 appeal after the NRC completes the disputed or denied violation process. If
6 the entity states that it does want the NRC to consider its disputed violation in the
7 MD 8.4 appeal process, then the NRC will follow and complete the MD 8.4 appeal
8 process before responding to the denied or disputed violation. The NRC should not
9 disposition the denied or disputed violation until after an MD 8.4 second-level appeal
10 is resolved or, if the affected entity does not submit an MD 8.4 second-level appeal,
11 then the opportunity for the affected entity to submit an MD 8.4 second-level appeal
12 has elapsed.

13
14 c. Disputed Violation and MD 8.4 Appeal. The most efficient use of NRC and affected
15 entity resources would be for the affected entity to provide the MD 8.4 appeal and
16 10 CFR 2.201 denial or dispute in the same correspondence if the affected entity
17 denies or disputes a violation based on a claim of unjustified backfitting. If an
18 affected entity denies or disputes a violation under 10 CFR 2.201 and includes an
19 MD 8.4 appeal in its correspondence, then the NRC will follow and complete the
20 MD 8.4 appeal process before responding to the denied or disputed violation if the
21 NRC has not already processed an MD 8.4 appeal for that issue. The NRC should
22 not disposition the denied or disputed violation until after a second-level appeal is
23 resolved or, if the affected entity does not submit a second-level appeal, the
24 opportunity for the affected entity to submit a second-level backfit appeal has lapsed.

25 4.2.5 Appeals Associated with Licensing Actions

26
27 An affected entity may submit an MD 8.4 appeal on a proposed or issued licensing action. The
28 most efficient appeals approach is to provide the affected entity an opportunity to submit an
29 MD 8.4 appeal before the NRC issues the licensing action.

30 4.2.5.1 Appeals Submitted Before Issuing a Licensing Action

31
32 Chapter 5 of this NUREG describes how the NRC can communicate a proposed backfitting or
33 forward fitting action during the processing of a licensing action. Upon receipt of an NRC letter
34 containing the NRC staff's proposed backfit or forward fit and associated assessment, an
35 affected entity may submit an MD 8.4 appeal of the proposed action within the time specified in
36 the NRC's letter. If the affected entity submits an MD 8.4 appeal, and the NRC grants the
37 affected entity's appeal, then the agency will continue its review of the requested licensing
38 action. If the NRC denies the appeal, then the agency has options, including denying the
39 requested licensing action or conditioning its approval with the backfit or forward fit. In that
40 situation, the NRC will not process another MD 8.4 appeal of the issued action if the NRC did
41 not substantively change the proposed backfit or forward fit in the time between the appeal
42 decision and issuance of the action.

43 4.2.5.2 Appeals Submitted After Issuing a Licensing Action

44
45 An affected entity may submit an MD 8.4 appeal after the NRC issues a licensing action if it did
46 not already appeal the specific issue before the agency issued the licensing action. Office-level
47 implementing procedures describe the staff actions to take upon conclusion of the appeals
48 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

1
2 **4.3 NRC Processing of Appeals**

3 If, during the MD 8.4 appeal process, the office director of NRR or NMSS for a first-level appeal,
4 or the EDO for a second-level appeal, determines that the appealed action constitutes
5 unjustified backfitting or forward fitting, then the responsible office director, EDO, or designee
6 must document the decision, request Office of the General Counsel (OGC) review of the
7 decision, and inform the affected entity in writing. The responsible office director, EDO, or
8 designee, as applicable, may issue a decision on an appeal at any time without completing all
9 the process steps (e.g., holding a public meeting) in this section of the NUREG.

10
11 **4.3.1 First-Level Appeals**

12 4.3.1.1 Receipt of Backfitting or Forward Fitting Appeals and Initiation of the
13 First-Level Appeals Process

- 14 (a) The ~~first-level~~ appeals process begins ~~upon when~~ the NRC ~~s receipt of~~ receives an
15 affected entity's written appeal of a proposed or issued staff action. If the affected
16 entity did not provide a copy of its appeal to the applicable office director of NRR or
17 NMSS, then the NRC staff should ensure that the applicable office director receives
18 a copy of the appeal. First-level appeals addressed to the EDO will be redirected to
19 the appropriate office director for the first-level appeal process.
- 20
- 21 (b) Upon receipt of a ~~first-level backfitting or forward fitting~~ appeal, the NRC staff should
22 notify the following individuals or designees and provide them with a copy of the
23 appeal:
- 24
- 25 1. the Backfitting and Forward Fitting Community of Practice through the NRR or
26 NMSS representatives, as applicable members in the applicable program and
27 regional offices;
 - 28 2. the managers in charge of the offices, divisions, and branches that proposed or
29 issued the action in question and, if not any other organizations that issued the
30 action in question, that are responsible for the technical, regulatory, or policy
31 areas in question;
 - 32 3. the Deputy General Counsels;
 - 33 4. the director of the Office of Enforcement;
 - 34 5. the chair ~~person~~ man of the Committee to Review Generic Requirements;
 - 35 6. the regional administrator for the affected entity that submitted the appeal ~~affected~~
36 facility; and
 - 37 7. the licensing project manager for the affected entity ~~licensee~~ that submitted the
38 appeal.

39
40 4.3.1.2 Determination of Oversight Responsibility and First-Level Appeal Screening

41
42 The NRC will accept appeals from only those licensees for which the NRC action
43 constitutes a backfit or forward fit and only if they are subject to the backfitting
44 provisions in 10 CFR Chapter I. The NRC will not accept appeals from NRC staff⁶
45 who disagree with an agency action or position. Licensees should submit written

⁶ NRC staff should utilize the Differing Professional Opinion or non-concurrence processes.

1 appeals within 90 days of receiving the NRC's written action or staff position or
2 30 days after the NRC issues its decision on a directly related disputed violation.

3
4 The first-level appeal must include sufficient documentation to justify the licensee's basis
5 for the appeal. The licensee must indicate deficiencies in the staff's position or
6 provide other information that is relevant and material to the staff's action or position
7 and supports the licensee's position for the appeal.

8
9 The licensee may not request a second-level appeal until the NRC issues its decision on
10 a first-level appeal.

11 **4.2 Initial Review of a First-Level Appeal and Determination** 12 **of Oversight Responsibility**

13
14 (c) Upon receipt of a backfitting or forward fitting appeal, the NRC staff should notify the
15 following individuals or designees and provide them with a copy of the appeal:

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

26
27
28 (a) The Director of NRR or NMSS, ~~depending on the licensee as appropriate,~~ will
29 oversee the first-level appeal process and issue the decision on the appeal. This
30 office director (hereafter referred to as the ~~R~~responsible ~~M~~anager) will coordinate
31 the review of the first-level appeal with the regional administrator overseeing the
32 affected ~~licensee entity~~ and, as applicable, the ~~D~~irector of the Office of Nuclear
33 Security and Incident Response.

34
35 (b) ~~The responsible manager (or designee) determines if the submitted appeal meets~~
36 ~~the applicable criteria in Section 4.2 of this NUREG. Within 4520 business days of~~
37 ~~the date when the NRC's receives receipt of the appeal (i.e., the date the document~~
38 ~~is declared an Official Agency Record in the NRC's Agencywide Documents Access~~
39 ~~and Management System), the R~~responsible ~~M~~anager should respond to the
40 ~~affected entity/licensee by acknowledging receipt of the appeal and communicating~~
41 ~~either the staff's review plans for staff review or, if the appeal does not meet at least~~
42 ~~one of the applicable criteria in Section 4.2 of this NUREG, request that the affected~~
43 ~~entity follow the Section 4.2 criteria.~~
44

1 4.2.1.4.3.1.3 *Review of the First-Level Appeal*

2 (a) The ~~R~~responsible ~~M~~anager may appoint a panel to review documentation
3 associated with the appeal and NRC action ~~or position~~ at issue. This panel, if
4 appointed, should consist of individuals who are independent from the ~~initial~~ action ~~or~~
5 ~~position~~ at issue (i.e., ~~the~~ individuals did not take part in developing, reviewing, or
6 approving the ~~initial~~ staff action). A manager at the deputy division director level or
7 higher should chair the panel, and ~~members~~hip should include an attorney from OGC
8 and staff or management with the appropriate technical and regulatory expertise and
9 experience to thoroughly evaluate the action ~~or position~~ at issue. The remaining
10 steps assume that a panel has been appointed. If not, the ~~R~~responsible ~~M~~anager
11 assumes responsibility for the actions in this section that a panel would otherwise
12 conduct.

13
14 (b) If the affected entity did not indicate in its submitted appeal that it requests a public
15 meeting, then the panel must offer the affected entity a public meeting to discuss
16 its appeal. The panel may also hold a public meeting with the NRC staff responsible
17 for the appealed staff action to discuss the facts associated with the appealed action.
18 However, this does not preclude the panel from holding nonpublic (internal) meetings
19 with the NRC staff to discuss the facts of the appealed action or to consult with
20 agency experts.

21
22 A public meeting with the affected entity, NRC staff, or both would be a Category 1
23 public meeting and should occur. To the extent practical, this public meeting should
24 occur within 45- calendar days of the NRC's receipt of the appeal. The panel will not
25 make any regulatory decisions may be made at this an MD 8.4 appeal public
26 meeting; rather, the meeting discussion should focus on factfinding. The panel will
27 give members of the public an opportunity to speak and question the panel or staff.
28 The panel has the discretion to determine how many public meetings it will hold
29 (e.g., whether to hold separate meetings with the staff and affected entity if the
30 affected entity chooses to participate or to combine the meetings), the style of
31 information exchange, and the roles of meeting attendees. The panel should clarify
32 this information in the meeting notice.

33
34 The panel should prepare and issue summaries of all MD 8.4 appeal public
35 meetings with the affected entity. ~~licensee~~ should be prepared and placed in the
36 NRC's Agencywide Documents Access and Management System as specified in
37 MD 3.5, "Attendance at NRC Staff-Sponsored Meetings." Discussions involving
38 sensitive (e.g., proprietary or security-related) information with the staff and affected
39 entity must be closed meetings in accordance with other NRC processes; however,
40 the NRC staff would notice the meetings and issue a redacted meeting summary in
41 accordance with MD 3.5. If the affected entity declines its opportunity for a public
42 meeting, and if the panel decides not to need to meet with the NRC staff responsible
43 for the appealed action, then the NRC will not hold a public meeting.

44
45 The responsible manager and panel members must not have substantive
46 discussions (i.e., conversations beyond giving a simple status of the process and
47 scheduling logistics) about the appeal with the affected entity or its representatives
48 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

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

5
6 The panel must consider all supporting staff analyses, ~~affected entity/licensee~~-submitted
7 analyses, and any other information that is relevant and material to the appeal.

8
9 ~~4.2.1.2~~ 4.3.1.4 *Response to the First-Level Appeal*

10 (a) The panel ~~will document~~s its recommendation on whether to grant or deny the
11 appeal in a memorandum from the panel chair ~~person~~ to the ~~R~~responsible
12 ~~M~~anager. The memorandum ~~should comprehensively document~~s the basis for the
13 panel's recommendation.

14
15 (b) The ~~R~~responsible ~~M~~anager ~~will evaluate~~s the information and recommendation
16 provided by the panel ~~and decides whether to grant or deny the appeal~~. The
17 ~~R~~responsible ~~M~~anager ~~will draft-develops~~ a response letter to the ~~affected~~
18 ~~entity/licensee~~ that comprehensively documents the basis for the ~~R~~responsible
19 ~~M~~anager's decision and ~~submits~~ the draft response letter to OGC for its review.
20 Subsequently, the ~~R~~responsible ~~M~~anager ~~will inform~~s the appropriate Deputy EDO
21 before communicating the outcome in writing to the ~~affected entity/licensee~~. ~~To the~~
22 ~~extent practical, the Responsible Manager should transmit the written response to~~
23 ~~the licensee within 90 calendar days of receipt of the appeal.~~

24
25 ~~(c) To the extent practical, the responsible manager should transmits the written~~
26 ~~response letter to the affected entity within 90 calendar days of receipt of the appeal.~~

27
28 ~~(d) If the NRC is granting the appeal, then the agency must initiate appropriate actions~~
29 ~~to ensure that the affected entity's licensing basis reflects the outcome of the appeal~~
30 ~~process (e.g., issuing an order or withdrawing or not issuing a violation request for~~
31 ~~additional information).~~

32
33 ~~(e) If the NRC is denying the appeal (i.e., the Rresponsible Mmanager determines~~
34 ~~that the proposed or issued staff action is justified backfitting or forward fitting, or that~~
35 ~~the proposed or issued staff action is not backfitting or forward fitting), then the~~
36 ~~NRC's response letter should inform the affected entity/licensee that it may either~~
37 ~~appeal the decision to the EDO within 30 calendar days of the date of the response~~
38 ~~letter (or another duration determined by the responsible manager).~~

39
40 ~~or~~The NRC's response letter should also state that if the ~~affected entity/licensee~~
41 ~~does not submit a second-level appeal by the date stated in the response letter, then~~
42 ~~(1) if the NRC already issued the action, then the NRC expects the affected entity will~~
43 ~~take actions to comply into compliance with the agency's NRC's issued~~
44 ~~action/decision, or (2) if the NRC has not issued the action yet, then the agency will~~
45 ~~issue the proposed action with which the NRC expects the affected entity will~~
46 ~~comply. The response letter must ensure that the time to file a second-level appeal~~
47 ~~is no more than the amount of time for the licensee to come into compliance with the~~
48 ~~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.

16
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).

20 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.

30
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:

37
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~~man~~ of the Committee to Review Generic Requirements;

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

8
9 4.3.2.2 Determination of Oversight Responsibility and Second-Level Appeal Screening

- 10 a. The EDO oversees the second-level appeal process and issues the decision on the
11 appeal.
12
13 b. The EDO (or designee) determines if the submitted appeal meets the applicable
14 criteria in Section 4.2 of this NUREG. Within 1520 business days of agency the
15 NRC's receipt of the appeal, the EDO (or designee) should respond to the affected
16 entity licensee by acknowledging receipt of the appeal and communicating either
17 high level the staff's review plans or, if the appeal does not meet at least one of the
18 applicable criteria in Section 4.2 of this NUREG, request that the affected entity
19 follow the Section 4.2 criteria for staff review.
20
21

22 ~~4.2.1.3~~ _____

23 ~~4.2.1.4~~ _____

24 ~~4.2.1.5~~ 4.3.2.3 Review of the Second-Level Appeal

- 25 a. The EDO may appoint a panel to review documentation submitted by the licensee
26 affected entity with the second-level appeal, the results of the first-level appeal, and
27 the ~~initial proposed or issued action or position~~ at issue. The panel should consist of
28 managers at the deputy division director level or higher and an attorney from OGC,
29 each with the appropriate technical and regulatory expertise and experience to
30 thoroughly evaluate the action ~~or position~~ at issue, ~~and who~~ Panel members should
31 ~~not~~ have ~~not~~ previously participated in the ~~initial proposed or issued action or staff~~
32 ~~position~~ nor first-level appeal. The members of the panel should collectively have
33 expertise in both the technical issues and the regulatory issues at hand. The
34 remaining steps assume that a panel has been appointed. If not, the EDO ~~(or their~~
35 ~~designee)~~ assumes responsibility for the actions in this section that a panel would
36 otherwise conduct.
37
38 b. Pursuant to Section 4.2.2 above, the affected entity should have specified in its
39 second-level appeal whether it wants the NRC to hold a public meeting for the
40 affected entity to discuss its appeal. If the affected entity did not indicate in its
41 submitted appeal that it requests a public meeting, then the panel The NRC must
42 offer the affected entity licensee a public meeting in which the second level appeal
43 can be discussed with the panel reviewing the appeal.
44

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

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

3
4 A public meeting with the affected entity, NRC staff, or both would be a Category 1
5 public meeting and should occur, to the extent practical, within 45 calendar days of
6 the NRC's receipt of the second-level appeal. The panel will not make any
7 regulatory decisions ~~may be made at this an MD 8.4 appeal public meeting; rather,~~
8 the meeting discussion should focus on factfinding. The panel will allow an
9 opportunity for members of the public to speak and ask questions of the panel or
10 staff. The panel has the discretion to determine how many public meetings it will
11 hold (e.g., whether to hold separate meetings with the staff and affected entity if the
12 affected entity chooses to participate or to combine the meetings), the style of
13 information exchange, and the roles of meeting attendees. The panel should clarify
14 this information in the meeting notice.

15
16 The NRC staff panel should prepare and issue summaries of all MD 8.4 appeal public
17 appeal meetings with the affected entity licensee within 30 calendar days of the
18 meeting, as specified in MD 3.5. Discussions involving sensitive (e.g., proprietary or
19 security-related) information with the staff and affected entity must be closed
20 meetings in accordance with other NRC processes; however, the NRC staff would
21 notice the meetings and issue a redacted meeting summary in accordance with
22 MD 3.5. If the affected entity declines its opportunity for a public meeting, and if the
23 panel decides not to meet with the NRC staff responsible for the appealed action,
24 then the NRC will not hold a public meeting.

25
26 The EDO and panel members must not have substantive discussions
27 (i.e., conversations beyond giving a simple status of the process and scheduling
28 logistics) about the appeal with the affected entity or its representatives during any
29 closed drop-in visits, in accordance with MD 3.5.

Commented [AK149]: Comment 4.4.13

30
31 ~~b. The panel must offer a non-public internal meeting to the originating staff of the NRC~~
32 ~~action.~~

33 ~~c.~~

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

36
37 ~~d-c.~~ The panel ~~should~~ must consider all supporting staff analyses, affected entity
38 licensee-submitted analyses, and any other information that is relevant and material
39 to the appeal.

40
41 4.2.1.6-4.3.2.4 Response to the Second-Level Appeal

- 42
43 a. The panel will document its recommendation on whether to grant or deny the
44 appeal in a memorandum from the panel chairperson to the EDO. The
45 memorandum ~~should~~ documents the basis for the panel's recommendations.
- 46
47 b. The EDO will evaluate the information and recommendation provided by the panel
48 and ~~make a decision on whether to grant or deny~~ the appeal. The EDO will
49 ~~draft~~ prepares a response letter to the affected entity licensee that comprehensively
50 documents the basis for the EDO's decision and submits the draft response letter to
OGC for its review.

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

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 information¹ constitutes a requirement or a staff position for the purposes of backfitting, issue finality, and forward fitting (e.g., regulatory commitments that were not escalated into requirements). ~~Some licensing basis information~~² 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

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

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

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

1 [are typically made through rulemaking or a notice of interpretation. Section 5.2.2 of this](#)
2 [NUREG has additional guidance on SOCs.](#)

3
4 [5.1.1.1.2 General Design Criteria for Nuclear Power Reactors](#)

5 The Atomic Energy Commission (AEC) published the proposed general design criteria (GDC) [in](#)
6 [the Federal Register \(FR\)](#) on July 11, 1967 ([32 FR 10213](#)). The proposed rulemaking was
7 intended to ~~provide guidance to~~ applicants in developing the principal design criteria (PDC) to
8 include in applications for construction permits. The AEC stated that these GDC would not add
9 any new requirements but were intended to describe more clearly the Commission requirements
10 at that time to assist applicants in preparing applications. The AEC published the final
11 rule- ([36 FR 3255](#)) that added [Title 10 of the Code of Federal Regulations \(10 CFR\)](#), Part 50,
12 Appendix A, "General Design Criteria for Nuclear Power Plants," on February 20, 1971, with an
13 effective date of May 21, 1971. In accordance with Staff Requirements Memorandum
14 (SRM)-SECY-92-223, "Resolution of Deviations Identified During the Systematic Evaluation
15 Program," dated September 18, 1992, the Commission decided not to apply the Appendix A
16 GDC to plants with construction permits issued before May 21, 1971. The Commission stated
17 in this SRM that the staff had evaluated these plants on a plant-specific basis and determined
18 them to be safe, that current regulatory processes are sufficient to ensure that plants continue to
19 be safe and comply with the intent of the GDC, and that backfitting the GDC would provide little
20 or no safety benefit.

21
22 The GDC establish the necessary design, fabrication, construction, testing, and performance
23 requirements for structures, systems, and components (SSCs) important to safety and the
24 minimum requirements for development of the PDC for water-cooled nuclear power reactors.
25 The GDC, most of which are performance-based standards, provide minimum requirements for
26 establishing the PDC and general safety of the plant. For some design areas, many [affected](#)
27 ~~entities/licenses~~ [\(i.e., entities listed in Section 2.3 of this NUREG\)](#) have adopted the applicable
28 GDC as the PDC for the plant. The 10 CFR Part 50 licensing process requires approval of an
29 applicant's PDC as a condition for granting a construction permit. Before the NRC can issue an
30 operating license, and as a basis for the NRC's finding of reasonable assurance of adequate
31 protection of [the](#) public health and safety and the common defense and security, the
32 Commission must find that the facility has been built in accordance with the PDC and any
33 NRC-approved changes. Thus, for [10 CFR](#) Part 50 licensees with construction permits issued
34 since 1971 (when the GDC were promulgated), the Commission has already concluded that the
35 design basis of the plant, as reflected in the PDC, meets or exceeds the minimum criteria in the
36 GDC.

37
38 Similarly, the 10 CFR Part 52 licensing processes also require certain applicants to establish the
39 PDC for the plant. For water-cooled nuclear power plants, the NRC established the minimum
40 requirements for PDC in Appendix A to 10 CFR Part 50. For non-light-water reactors
41 [\(non-LWRs\)](#), the NRC ~~has published guidance on establishing PDC for these designs in issued~~
42 Regulatory Guide 1.232, "Guidance for Developing Principal Design Criteria for Non-Light-Water
43 Reactors."
44

45 In accordance with COMSECY-16-0020 and the NRC Solicitor's 2016 memorandum on the use
46 of the GDC to justify a backfitting action and, more specifically, the compliance exception, the
47 staff should first confirm whether other parts of a license, such as technical specifications,
48 incorporate the pertinent aspects of the GDC, and, if so, use those facility-specific requirements
49 instead of the GDC. The license approval process will typically yield more specific requirements
50 than those in the GDC. The NRC can use the GDC as the source of a requirement for purposes

1 of invoking the compliance exception only if a GDC provides more than just a performance
2 standard and has not been superseded through the approval of the PDC (and requirements
3 derived from those PDC that are clearly meant to address the GDC at issue) and technical
4 specifications. Therefore, for 10 CFR Part 50 licensees with construction permits issued
5 since 1971, and for all 10 CFR Part 52 approval holders required to describe their PDC in their
6 applications, a GDC can be regarded as a requirement in those circumstances in which where
7 the GDC is prescriptive, in nature, and the technical specifications, other licensee requirements
8 derived from the GDC, and the PDC do not address the matter in question.

9 10 5.1.1.2 Orders

11 For the purposes of this NUREG, "enforcement orders" are orders issued to ensure compliance
12 with existing requirements and do not involve a change in staff position and, therefore, should
13 not constitute backfitting or a change affecting issue finality. Section 5.4 of this NUREG has
14 additional guidance on enforcement orders. For the purposes of this NUREG, "safety or
15 security orders" are those orders that involve backfitting actions justified by adequate protection
16 compliance, or cost-justified substantial increases in overall safety or security or changes to a
17 10 CFR Part 52 approval that satisfy the applicable issue finality criteria. ~~Because an order~~
18 ~~amends a license, an order issued to require a licensee to take actions to maintain or increase~~
19 ~~the protection of the public health and safety or the common defense and security generally~~
20 ~~would constitute backfitting, unless the action is an already applicable requirement, or an~~
21 ~~already applicable and imposed staff position.~~

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

22 23 5.1.1.2.1 Imminent Threat Analyses

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

Commented [KA156]: Comment 4.5.24

38 39 5.1.1.2.2 Confirmatory Orders

40 ~~Confirmatory orders that confirm licensee commitments and impose requirements in excess of~~
41 ~~previously applicable staff positions are not backfitting.~~ The NRC issues a confirmatory order
42 to ensure ~~the~~ that a licensee complies with certain commitments it voluntarily made to the NRC
43 by ~~making~~ turning them commitments into legally binding requirements. A confirmatory order
44 that confirms a licensee's commitments and imposes requirements in excess of previously
45 applicable staff positions are not backfitting or changes affecting issue finality, because the
46 licensee agrees to the confirmatory terms of the order requirements and waive their hearing
47 rights before the NRC issues the orderance.

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

1 5.1.1.3 Exemptions

Commented [BH158]: Comment 4.5.4

2 The NRC may exempt an affected entity from certain NRC regulations provided that the
3 requirements in the pertinent exemption regulation (e.g., 10 CFR 50.12 and 10 CFR 70.17, both
4 titled, "Specific exemptions") are met. The NRC's basis for concluding that an exemption
5 request is acceptable is documented in its approval of the request and may create a facility-
6 specific staff position. Any conditions of approval specified in the exemption are requirements.
7

8 5.1.1.4 Mandated Licensing Basis Documents

Commented [AK159]: Comment 4.5.3

9 Various regulations specify the content, change control, and reporting requirements for
10 mandated licensing basis documents, such as the updated final safety analysis report, technical
11 specifications bases, quality assurance program, security plan, and emergency plan for
12 operating nuclear power reactors. These regulations include 10 CFR 50.59, "Changes, tests
13 and experiments"; 10 CFR 50.54, "Conditions of licenses"; and 10 CFR 50.71, "Maintenance of
14 records, making of reports." Sections 1.2.2.2, 5.1.1.5, and 5.1.3.4 of this NUREG discuss the
15 relationship among staff positions, licensee changes to its licensing basis, and NRC safety
16 evaluations. Once the NRC issues a safety evaluation signifying staff acceptance of the
17 programs described in (or to be added to) a mandated licensing basis document, thereby
18 creating a staff position, a licensee should be able to conclude that the content of the mandated
19 licensing basis document satisfies applicable NRC requirements if the licensee complies with
20 the change control and reporting requirements for the document. If the NRC subsequently
21 decides that a staff position in a safety evaluation is incorrect, then agency actions related to
22 that decision are subject to a backfitting or issue finality assessment.
23

24 5.1.1.5 Change Control Processes

25 Several regulations establish change control requirements, such as 10 CFR 50.59;
26 10 CFR 50.54(a) and (p)–(q); 10 CFR 52.98(b)–(c); 10 CFR 70.72, "Facility changes and
27 change process"; and 10 CFR 72.48(c) ~~Title 10 of the Code of Federal Regulations (10 CFR)~~
28 ~~Sections 50.59, 50.54(a), 50.54(p), 50.54(q), 52.98(b)–(c), 70.72, and 72.48(c).~~ These change
29 control requirements grant licensees the authority to make changes to their licensing bases
30 without prior U.S. Nuclear Regulatory Commission (NRC) review and approval, provided that
31 the change meets the specified criteria in each change control requirement that governs
32 whether prior NRC review and approval ~~is~~ are necessary. Licensee implementation of changes
33 using these change control requirements is subject to NRC inspection.
34

35 Changes that licensees make to their licensing bases in accordance with change control
36 requirements can be considered "staff positions" for purposes of backfitting, issue finality, and
37 forward fitting because the establishment of the regulations and requirements for the change
38 control programs provided the NRC's position that changes made in compliance with such
39 regulations and requirements are acceptable to the NRC staff. Any future NRC-imposed
40 modifications to the changes would be subject to backfitting, issue finality, and forward fitting
41 considerations. ~~If the change processes are used properly, then the licensee can reasonably~~
42 implement the change without concern about future enforcement action and with the assurance
43 that any future NRC imposed modifications to the changes would be subject to backfitting
44 considerations. ~~This is consistent with the underlying premise of regulatory stability established~~
45 within the backfitting, issue finality, and forward fitting policies regulations and the NRC's
46 Principles of Good Regulation. However, a licensee that improperly ~~implements~~ makes a
47 change to its licensing basis under one of these change control requirements would be in
48 violation of the requirement.

Commented [KA160]: Comment 4.5.5

1
2 5.1.1.6 Commitments

3 The backfitting provisions in 10 CFR 50.109(a)(4)(i), 70.76(a)(4)(i)–(ii), 72.62(b), and
4 76.76(a)(4)(i) provide that the NRC can impose a backfitting action to ensure a licensee’s
5 compliance with its license or NRC requirements or conformance with written licensee
6 commitments. A nuclear power plant’s licensing basis contains “commitments” that describe a
7 method for complying with regulations or requirements; commitments that were made in
8 docketed licensing correspondence such as licensee responses to NRC generic
9 communications, information requests, or enforcement actions; and commitments documented
10 in licensee event reports that detail the method or process to comply with regulations or
11 requirements. Commitments are also specifically stated in the licensing basis documents for
12 fuel facilities.

13
14 However, not every commitment in the licensing basis is a “written commitment” as intended by
15 10 CFR 50.109, 70.76, 72.62, and 76.76. Management Directive (MD) 8.4, “Management of
16 Backfitting, Forward Fitting, Issue Finality, and Information Requests,” dated September 20,
17 2010, provides that, in the backfitting context, a written commitment is a commitment that
18 has been submitted to the NRC on the docket, has been incorporated into the license, and
19 directly relates to how the licensee complies with a requirement.

20
21 Regulatory commitments made by nuclear power reactor licensees are not legally binding
22 requirements on licensees and, therefore, are not enforceable ~~unless the NRC issues an order.~~
23 If a regulatory commitment ~~was/were~~ escalated into a legally binding requirement (e.g., a
24 license condition), then that regulatory commitment would cease being a regulatory commitment
25 upon its escalation. Therefore, for nuclear power reactor licensees, the staff ~~would/may~~ need to
26 take a backfitting, issue finality, or forward fitting action to escalate a regulatory commitment into
27 a requirement if the licensee did not voluntarily ask the NRC to do so. Similarly, if a regulatory
28 commitment is incorporated into a mandated licensing basis document, then the commitment
29 becomes subject to change control requirements for the mandated licensing basis document
30 and ceases being controlled under the licensee’s commitment management program.
31 Therefore, for nuclear power reactor licensees, the staff may need to take a backfitting, issue
32 finality, or forward fitting action to require the licensee to incorporate a regulatory commitment
33 into a mandated licensing basis document if this incorporation is not already required by
34 regulation or if the licensee did not voluntarily ask the NRC to do so. For fuel facility licensees,
35 a commitment by a licensee is a legally binding requirement once it is referenced (i.e., “tied
36 down”) by a license condition, which may require a backfitting or forward fitting action.

37
38 Most commitments begin as voluntary (e.g., the licensee submits through docketed
39 correspondence regulatory commitments that the NRC did not request). The staff may
40 determine that to approve a licensee’s request, ~~a commitment must be converted to the staff~~
41 would need to impose the commitment as a legally binding requirement (e.g., convert the
42 commitment into a license condition) as a condition of its approval; however, the staff must
43 screen this action for its potential to be backfitting or forward fitting, or backfitting, or a change
44 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

1 **5.1.2 Licensing Basis Verifications**

2 **5.1.2.1 Differing Views**

3 An important task in assessing potential backfitting for any facility is to identify and review NRC
4 records and interact with licensees to understand the prevailing issue within the context of the
5 licensing basis. In some cases, differing views (i.e., between the staff and licensee or among
6 the staff) about the appropriateness of backfitting actions originate in differing **views**
7 **understandings** of the **subject facility's** licensing basis ~~for the subject facility~~. The processes
8 discussed in this NUREG assume that backfitting, **issue finality**, or forward fitting assessments
9 of proposed staff actions begin with a correct understanding of the existing licensing basis.
10 Therefore, ~~before beginning a backfitting, issue finality, or forward fitting assessment, the NRC~~
11 ~~must verify the licensing basis using informal or formal processes internal to the NRC~~
12 ~~(e.g., routine staff interactions or technical assistance requests), the staff should first identify~~
13 ~~and resolve any differing views about the licensing basis (e.g., through the technical assistance~~
14 ~~request process discussed in Section 5.21 of this NUREG) and ensure that the licensing basis~~
15 ~~is understood before beginning a backfitting or forward fitting assessment or pursuing~~
16 ~~enforcement.~~ The NRC licensing project manager for the facility is the initial point of contact for
17 work related to identifying and reviewing the **licenseefacility's** licensing basis.

Commented [AK164]: Comment 4.5.23

18 **5.1.2.2 Technical Assistance Requests**

19 The ~~NRC may use its~~ technical assistance request processes ~~is designed~~ to support NRC
20 offices and regions ~~by addressing questions raised by NRC staff about licensing bases in~~
21 ~~answering questions that arise from regulatory activities.~~ In terms of backfitting, ~~the~~ requests
22 having the greatest relevance **to backfitting and issue finality generally** are those that involve
23 determining whether a **particular licensing basis requires the licensee to address a safety or**
24 **security issue** ~~licensee is meeting its licensing basis.~~ ~~However, backfitting, issue finality, and~~
25 ~~their associated activities (i.e., screening, justifying, and issuing) are outside the scope of the~~
26 ~~technical assistance request processes.~~ As discussed in Section 1.2.2.2 of this NUREG,
27 ~~technical assistance request conclusions are not staff positions, nor are they intended to~~
28 ~~establish new staff positions for the purposes of backfitting.~~ ~~Nevertheless, a conclusion could~~
29 ~~become a staff position if it is used as the documented basis for further staff action.~~ ~~Until or~~
30 ~~unless a conclusion is used for that purpose, it is an internal agency communication, and such~~
31 ~~communications generally are not staff positions.~~ If the technical assistance request process
32 supports a conclusion that the licensee is meeting its licensing basis, then the staff should follow
33 the technical assistance request process for communicating the results to the requesting office
34 or region. If the staff proposes a change to the licensing basis, then it must exit the technical
35 assistance request process and subject the proposed action to a backfit or **issue finality**
36 **assessment.** The response to a technical assistance request may determine that a licensee is
37 meeting its licensing basis, but the requesting staff's concern could be whether the licensing
38 basis is adequate. In that case, the technical assistance request process will redirect the staff
39 to the backfitting process for consideration of further NRC action. Backfitting and its associated
40 activities (i.e., screening, justifying, and issuing) are outside the scope of the technical
41 assistance request process.
42
43

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.

1 ~~5.1.2—Requested Licensing Actions~~The backfitting provisions do not apply to voluntary
2 ~~licensee requests for changes to its licensing basis. “Voluntary” is considered to be any~~
3 ~~action or request to the NRC by the licensee that was made of the licensee’s own accord~~
4 ~~without the force of a legally binding requirement or an NRC representation of further~~
5 ~~licensing or enforcement action. Unless required by the NRC, initial license applications,~~
6 ~~license amendment requests, and license renewal applications are considered voluntary.~~
7 ~~NRC review and approval of any of these actions is not backfitting.~~

8 ~~5.1.3—~~

9 ~~5.1.4—The NRC review of applications is limited by the scope of the request and to the~~
10 ~~areas affected by the requested technical and regulatory changes. All other portions of~~
11 ~~the licensing basis that are not affected by the application are within the scope of the~~
12 ~~backfitting provisions, unless the staff can justify and document the technical or~~
13 ~~regulatory reasons for including these portions of the licensing basis into its review.~~

14 ~~5.1.5—~~

15 ~~5.1.6—The regulations in 10 CFR Part 54 delineate the scope of license renewal reviews.~~
16 ~~A license renewal review is prospective in nature, as the review is aimed at a renewed~~
17 ~~license that has not yet been issued and is a matter of future aging management. The~~
18 ~~review will address aging management or ensure an integrated approach to achieve~~
19 ~~aging management. The Commission determined in the 1995 nuclear power plant license~~
20 ~~renewal final rule that 10 CFR 50.109 does not apply to matters within the scope of the~~
21 ~~renewal of power reactor licenses under 10 CFR Part 54. In large measure, the scope of a~~
22 ~~license renewal review is limited by 10 CFR 54.4, “Scope,” and 54.21, “Contents of~~
23 ~~applications—technical information.” Section 54.30(a) states, in part, that licensed~~
24 ~~activities will be conducted in accordance with the current licensing basis.³ This~~
25 ~~requirement is followed by 10 CFR 54.30(b), which states that the licensee’s compliance~~
26 ~~in this regard is NOT the subject of the license renewal review. This means that any~~
27 ~~proposed staff action on topics other than aging management taken under the current~~
28 ~~license during the application review could be subject to a backfitting assessment. Once~~
29 ~~the NRC issues the renewed license, 10 CFR 50.109 applies to the entire license with very~~
30 ~~limited exceptions.~~

31 ~~5.1.7—~~

32 ~~5.1.3 The Commission’s forward fitting policy applies to requested licensing actions~~
33 ~~and license renewal requests other than Part 54 renewals, although the imposition of a~~
34 ~~condition in a Part 54 proceeding outside the normal scope of Part 54 license renewals~~
35 ~~could constitute forward fitting.~~

36 5.1.3.1 Preapplication Meetings

37 An affected entity may request a preapplication or presubmittal meeting with the NRC to discuss
38 a licensing action the affected entity plans to request. Through these meetings, which are
39 typically public, the affected entity can improve the NRC’s review efficiency by discussing the

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

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.

1 purpose and proposed contents of the planned application or submittal and helping the NRC
2 identify information it may need to complete the review. However, the NRC staff should not
3 make statements during the meeting or in the meeting summary that appear to be conditioning
4 its approval of the request, if submitted, to avoid unjustified backfitting or forward fitting or
5 changes that affect issue finality. For example, the staff should not state, "The NRC will not
6 approve this request unless the affected entity provides the following information or takes the
7 following actions." Rather, the NRC staff may emphasize the findings it is required to make,
8 critical information needed to complete an acceptance review, and any concerns with the
9 affected entity's planned application or submittal.

10 11 5.1.3.2 *Initial Licensing*

12 As the Commission explained in the ~~1989~~ 10 CFR Part 52 final rule statement of considerations
13 (SOC) (54 FR 15372; April 18, 1989), applicants (for licenses, permits, and regulatory approvals
14 such as design certifications) are not, with certain exceptions, within the scope of either the
15 backfitting provisions or any issue finality provisions. The backfitting and issue finality
16 regulations include language delineating when those provisions begin; and, with some
17 exceptions, they begin after the issuance of a license, permit, or approval
18 (e.g., 10 CFR 50.109(a)(1)(iii), 10 CFR 52.98(a)). Furthermore, Neither the backfitting
19 provisions nor the issue finality provisions, with certain exceptions, are intended to apply to NRC
20 actions that substantially change the expectations of current and future applicants. Applicants
21 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.

22
23 One of the exceptions to this general principle occurs when a 10 CFR Part 52 applicant (e.g., a
24 combined license applicant) references a 10 CFR Part 52 license or approval (e.g., an early site
25 permit, a design certification rule, or a standard design approval) with specified issue finality
26 provisions. The 10 CFR Part 52 licensing processes provide regulatory stability to applicants
27 referencing those approvals. The other exception occurs under 10 CFR Part 50. Once the
28 NRC issues a construction permit, backfitting provisions apply to the construction permit holder.⁴
29 For an operating license applicant relying on a construction permit, matters described in the
30 construction permit cannot be changed without meeting the backfitting provisions.

31
32 A change in a staff position before issuance of any license (or other approval under
33 10 CFR Part 52) is not considered backfitting or a change affecting issue finality because, in this
34 situation, the safety evaluation does not constitute the NRC's final position until the NRC issues
35 the license (or other approval). The backfitting and issue finality provisions do not become
36 effective until the NRC issues the license (or other approval).

37
38 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),
39 and 52.157(f)(30) establish the version of NUREG-0800, "Standard Review Plan for the Review
40 of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," that the staff should
41 anticipate applicants for new LWR facilities to reasonably rely upon in the development of their

⁴ 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~~ six months before the date of docketing of the operating license application for a facility with a construction permit issued before October 21, 1985. Therefore, until six months before the date of docketing of an operating license application for either of the Bellefonte units, any change in regulation or staff position that meets the definition of "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 The Commission's forward fitting policy would generally does not apply when an applicant files
12 anto the initial licensing action for a new facility ~~for which there is no SRP.~~

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.

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.

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.

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.

1 5.1.3.5 Section 10 CFR 50.55a Requests

2 The provisions of 10 CFR 50.55a, “Codes and standards,” allow affected entities/licenses to
3 request relief from certain requirements in 10 CFR 50.55a and to propose alternative
4 requirements. These provisions for requesting relief and proposing alternative requirements are
5 found in 10 CFR 50.55a(f)(6)(i) and (g)(6)(i). The NRC calls these requests “relief requests.”⁵
6 Under 10 CFR 50.55a(z), affected entities/licenses can propose alternatives to certain
7 requirements in 10 CFR 50.55a. The NRC calls these requests “proposed alternatives.”

8 Granted relief requests and authorized alternatives can establish facility-specific staff positions.

Commented [AK174]: Comment 4.5.36

9
10 5.1.3.5.1 Relief Requests

11 Under 10 CFR 50.55a(f)(6)(i) and (g)(6)(i), the NRC may grant relief from certain requirements
12 that are impractical at a particular facility and impose alternative requirements if the Commission
13 determines that the alternative requirements are authorized by law, will not endanger life or
14 property or the common defense and security, and are otherwise in the public interest giving
15 due consideration to the burden upon the affected entity/licensee that could result if the NRC
16 imposed the requirements on the facility. The affected entity can propose these alternative
17 requirements, or the NRC can develop them can be proposed by the licensee or developed by
18 the NRC. NRC-imposed alternative requirements do not constitute backfitting or forward fitting
19 or a change affecting issue finality because 10 CFR 50.55a(f)(6)(i) and (g)(6)(i) allow such
20 impositions. If the NRC intends to impose requirements that are not alternatives to the
21 requirements from which the NRC granted the affected entity/licensee relief (i.e., the NRC’s
22 proposed requirements are not related to the requirements from which the affected
23 entity/licensee is seeking relief), then the NRC agency would need to subject those proposed
24 requirements to a backfitting, issue finality, or forward fitting assessment before it imposes the
25 requirements. However, the NRC should not improperly introduce non-material issues that are
26 outside the scope of the requirements from which the affected entity is seeking relief.

Commented [BH175]: Comment 4.5.36

27
28 5.1.3.5.2 Proposed Alternatives

29 Under 10 CFR 50.55a(z), the NRR Office Director may authorize the use of alternatives to the
30 requirements of 10 CFR 50.55a(b) through (h) or portions thereof. A proposed alternative must
31 be submitted by the affected entity/licensee and authorized by the NRC prior to before the
32 affected entity implements the alternative. In contrast to 10 CFR 50.55a(f)(6)(i) and
33 (g)(6)(i), which permit the NRC, on its own initiative, to impose alternative requirements in
34 certain circumstances, 10 CFR 50.55a(z) does not have such a provision permit the NRC to
35 impose alternatives to the requirements. Furthermore, even when the NRC authorizes an
36 alternative under 10 CFR 50.55a(z), the affected entity can continue to comply with current
37 requirements; therefore, it is not possible for the NRC to impose an alternative under
38 10 CFR 50.55a(z). The NRC also cannot modify or add to the affected entity’s proposed
39 alternative; otherwise, the requirement in 10 CFR 50.55a(z) for an alternative to be submitted
40 and authorized would no longer be met. An affected entity can supplement its submittal of its
41 own volition if the NRC or affected entity identifies issues with the proposed
42 alternative. Therefore, if the NRC intends to impose an alternative to the requirement, then the
43 NRC would need to subject its proposed alternative to a backfitting or forward fitting
44 assessment.

Commented [AK176]: Comment 4.5.35

⁵ 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.

1 5.1.3.6 License Transfers

2 A license transferee that is not an existing licensee for the license being transferred is treated as
3 an initial license applicant for a new facility. Because, with few exceptions, backfitting cannot
4 apply to the NRC's actions on an application for an initial license, a license transferee is
5 generally outside the scope of backfitting. The forward fitting policy generally applies to
6 situations involving an existing licensee. When a license transferee is not an existing licensee
7 for the license being transferred, any conditions imposed on the license transferee would not be
8 subject to forward fitting considerations unless the NRC requires the license transferee to
9 address a change in requirements or staff positions from those in the version of the SRP or
10 other relevant guidance documents applicable to the license being transferred.

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

11 5.1.4 Communicating Potential Backfits, Changes Affecting Issue Finality, or Forward
12 Fits during Licensing

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

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

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

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

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

1 change affecting issue finality, or forward fitting and, therefore, should have been subjected to
2 the appropriate screening and justification before its communication to the affected entity.

3
4 If, after these communications with the affected entity, the NRC determines that it cannot
5 approve a requested licensing action without imposing a new or changed requirement or staff
6 position as a condition of its approval, then the NRC staff can either (1) pursue a backfit, change
7 affecting issue finality, or forward fit, as applicable, or (2) deny the application. If the staff
8 pursues the backfit, change affecting issue finality, or forward fit, then it will need to obtain
9 Office Director approval to complete the applicable cost considerations for the backfit, change
10 affecting issue finality, or forward fit. If the proposed requirement or staff position would be a
11 cost-justified substantial increase in overall protection backfit, then the staff should consider
12 whether to pursue that backfit separately from the licensing action. The staff must prepare the
13 backfit, issue finality, or forward fit assessment and submit it to the Office Director for approval
14 and offer the Committee to Review Generic Requirements the opportunity to review the
15 package, as described in Section 1.6 of this NUREG.

16
17 If, after obtaining Office Director approval, the NRC staff intends to condition its approval of the
18 licensing action on a proposed backfit, change affecting issue finality, or forward fit, then it must
19 send the affected entity a letter containing the staff's proposed backfit, change affecting issue
20 finality, or forward fit and associated assessment and offering an opportunity to submit an
21 MD 8.4 appeal of the proposed action by a specified date. The affected entity could then either
22 not respond to the NRC's letter (in which case the NRC staff may either issue the approval with
23 the condition or deny the application) or respond by supplementing its application to address the
24 safety or security issue or non-compliance, submitting an MD 8.4 appeal of the proposed
25 backfitting, change affecting issue finality, or forward fitting, or withdrawing the application.
26 Chapter 4 of this NUREG provides additional guidance on the MD 8.4 appeal process.

27 28 **5.2 Generic Processes**

29 **5.2.1 Regulatory Analyses**

30 Regulatory analyses are different from backfit analyses and are required for almost all
31 regulatory actions. The NRC uses regulatory analyses to evaluate the costs and benefits of
32 proposed regulatory actions. A regulatory analysis typically compares alternative approaches to
33 the proposed regulatory action to support informed decisionmaking. A regulatory analysis
34 measures all the benefits and costs of a proposed action (whereas in contrast, a backfit analysis
35 supports one type of regulatory approach (i.e., an imposition of new requirements or new staff
36 positions interpreting existing requirements on entities listed in Section 2.3 of this NUREG that
37 are within the scope of the backfitting provisions listed in Table 1-1). A backfit analysis
38 considers whether a particular proposed backfit would result in a substantial increase in the
39 overall protection of the public health and safety or the common defense and security and, if so,
40 whether the direct and indirect costs of implementation for that affected entity are justified in
41 view of this increased protection. The costs identified in the regulatory analyses can be used,
42 therefore, in determining whether a backfit can be justified only certain factors as discussed in
43 Section 2.6 of this NUREG). Regulatory analyses help the staff provide adequate justification
44 for the proposed action and document a clear explanation of why the staff recommends the
45 ~~proposed~~ action. The staff provides instructions for performing regulatory analyses in
46 NUREG/BR-0058.

Commented [AK180]: Comment 4.5.27

1 **5.2.2 Rulemaking**

2 The NRC staff typically begins its rulemaking process by requesting Commission approval of a
3 rulemaking plan. ~~Rulemaking plans contain a discussion of the potential backfitting and issue~~
4 finality implications of the contemplated rulemaking. In the rulemaking process, ~~t~~The NRC must
5 justify the proposed and final rules under applicable backfitting or issue finality requirements.
6 The NRC ~~and~~ includes this justification discussion in the SOCs for proposed and final rules.
7 Lengthy backfitting ~~and issue finality~~ discussions can be ~~a~~standalone documents summarized
8 in the SOCs. ~~Rulemaking plans contain a discussion of the potential backfitting implications of~~
9 the contemplated rulemaking. Many rules have an associated guidance document that provides
10 an acceptable means for implementing the new or amended rule. The backfitting and issue
11 finality implications of the guidance document need to be considered within the backfitting and
12 issue finality assessment supporting issuance of the rule. The SOCs typically include
13 the guidance document's backfitting and issue finality discussion. Because rulemakings are not
14 regulatory actions associated with a licensee requests for licensing actions submitted by
15 affected entities, it is not possible for rulemakings to do not involve forward fittings.

Commented [AK181]: Comment 4.5.32

16
17 **5.2.2.1 Rulemaking Process**

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

Commented [KA182]: Comment 4.5.33

Commented [KA183]: Comment 4.5.32

28
29 A proposed rule would explain the Commission's intention to establish new requirements,
30 change existing requirements, or both. Any one of these proposed new or changed
31 requirements could constitute backfitting or affect the issue finality of a 10 CFR Part 52
32 approval. As part of a proposed rulemaking issued for public comment, the NRC provides its
33 supporting backfitting and issue finality assessment for any proposed new or changed
34 requirements that could impact an affected entity. The public is invited to comment on this
35 backfitting and issue finality assessment, and the NRC considers those comments and all other
36 public comments in drafting the final rule and the supporting backfitting and issue finality
37 assessment.

38
39 The final rule published by the NRC reflects the Commission's consideration of public
40 comments on the proposed rule, including any comments on the backfitting and issue finality
41 assessment. The NRC must revise the final rule's backfitting and issue finality assessment to
42 the extent that comments on the proposed rule warrant such revision.

43
44 **5.2.2.2 Voluntary Consensus Standards**

45 Voluntary consensus standards document a consensus reached by the sponsoring organization
46 that the code or standard provides an acceptable process or criteria to accomplish the task
47 addressed by the code or standard. Congress requires consideration of voluntary consensus
48 standards under the National Technology Transfer and Advancement Act of 1995 (NTTAA)

1 (Pub. L. 104-113, 110 Stat. 775), which is codified in various sections of Title 15 of the
2 U.S. Code. In accordance with the note in 15 U.S.C. § 272, the NRC may decline to use a
3 voluntary consensus standard if its use would be “inconsistent with applicable law or otherwise
4 impractical.” The Office of Management and Budget (OMB) established policies on the
5 implementation of the NTTAA in OMB Circular A-119, “Federal Participation in the Development
6 and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,” revised
7 in 2016. Both the NTTAA and OMB Circular A-119 require that “agencies must consult with
8 voluntary consensus standards bodies and must participate with such bodies in the
9 development of standards when consultation and participation is in the public interest and is
10 compatible with their missions, authorities, priorities, and budgetary resources.”

11
12 The NRC participates in the consensus process for codes and standards that are later adopted
13 into ~~the NRC’s~~ regulations. In the consensus process, the NRC provides its views on the
14 codes and standards, and this communication supports a constructive consensus process. This
15 communication, including votes, is not considered backfitting or forward fitting.
16

17 Two prominent consensus standards the NRC uses are the American Society of Mechanical
18 Engineers (ASME) Boiler and Pressure Vessel Code and the ASME Code for Operation and
19 Maintenance of Nuclear Power Plants. These codes, ~~as incorporated into NRC regulations at~~
20 ~~10 CFR 50.55a with any applicable exceptions and clarifications, provide~~ requirements for
21 power reactor ~~applicants and licensees because the codes are incorporated into NRC~~
22 ~~regulations at 10 CFR 50.55a.~~ The ~~agency’s~~ regulations are periodically updated ~~these~~
23 ~~regulations~~ to incorporate by reference later editions of the ~~two ASME Boiler and Pressure~~
24 ~~Vessel Code and the ASME Code for Operation and Maintenance of Nuclear Power Plants~~
25 ~~Codes~~. The NRC describes its approach to these rulemakings in NUREG/BR-0058,
26 Appendix D, “~~Guidance on Regulatory Analysis Related to ASME Code Changes.~~”

27 In the SRM to SECY-00-0011, “Evaluation of the Requirement for Licensees to Update Their
28 Inservice Inspection and Inservice Testing Programs Every 120 Months,” dated April 13, 2000,
29 the Commission rejected an NRC staff proposal to consider as backfits rulemakings that list
30 updated ASME ~~e~~Code editions. Therefore, such rulemakings, with or without conditions on
31 aspects of the ASME ~~e~~Codes, are not generally backfits. In addition, a new condition on a new
32 code provision that is not present in an earlier ~~e~~Code edition would not be backfitting.
33

34 However, the general rule that these rulemakings are not backfits has three
35 exceptions: (1) when the rulemaking imposes substantially different (i.e., more than incremental
36 changes for technical or safety reasons) conditions or exceptions on the use of an ASME ~~e~~Code
37 provision already incorporated by the NRC; (2) when the rulemaking incorporates a new
38 provision of the ASME ~~e~~Code that is substantially different from existing requirements; or
39 (3) when the rulemaking requires that ~~licensees-affected entities~~ adopt provisions of the ASME
40 ~~e~~Code on an expedited schedule (i.e., sooner than the 120-month updating interval in
41 10 CFR 50.55a).
42

43 5.2.2.3 Voluntary Relaxations

44 A relaxation is the modification of a regulatory requirement that reduces the obligations of a
45 licensee or class of licensees. In almost every case, a relaxation is structured to ~~provide~~ give
46 licensees the option of continuing as previously licensed (that is, maintaining the status quo) or
47 following the new, relaxed regulatory requirement or staff position. ~~With one exception, such a~~
48 ~~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.](#)⁶
2 When the NRC relaxes requirements, ~~the NRC~~ it 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~~ [of](#) regulatory requirements include the 2004 final rule promulgating
10 10 CFR 50.69, ~~which provided for~~ "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~~ [either 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 **5.2.3 Guidance Documents**

Commented [AK186]: Comments 4.2.13, 4.3.8, 4.5.16

26
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.](#)⁷
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 ~~•~~ [if](#) ~~the~~ [the](#) staff intends, at the time it issues the guidance, to impose the positions on an
40 [affected entity/licensee](#) (typically through further NRC action). ~~Staff guidance is also~~
41 ~~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 license incorporates a guidance document, then that version of the guidance document becomes a requirement. A licensee may incorporate, by reference, a guidance document into its licensing basis through the 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

1 guide in its regulatory processes, but the staff does not intend to use the guidance in a manner
2 that would constitute backfitting or forward fitting or affect issue finality, as applicable. When
3 ~~notifying the NRC provides~~ the public ~~with notice~~ through the *Federal Register* of the issuance
4 of a regulatory guide, the NRC should include in the *Federal Register* notice a discussion of the
5 backfitting, forward fitting, and issue finality implications of the issuance of the guidance
6 document.

8 5.2.3.2 *Interim Staff Guidance*

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

18 5.2.3.3 *Standard Review Plans*

19 SRPs delineate the scope and depth of the staff's review of ~~licensee~~ submittals associated with
20 various licensing activities ~~and can be considered staff positions for purposes of backfitting,~~
21 ~~issue finality, or forward fitting.~~ If the staff uses acceptance criteria that are more stringent than
22 those stated in the applicable SRPs, or if it proposes ~~licensee~~ actions ~~that the affected entity~~
23 ~~take~~ that are more stringent than or in addition to those specified in the applicable SRPs, then
24 these criteria and actions may be considered ~~either forward fitting or~~ backfitting, ~~a change~~
25 ~~affecting issue finality, or forward fitting,~~ depending on whether the actions are associated with a
26 licensing request or with an existing condition at the facility, and the facility has a license.
27 Application of an SRP to an operating facility after the NRC issues the license is generally
28 considered backfitting ~~or a change affecting issue finality~~ unless that version of the SRP is part
29 of the ~~licensee~~ facility's licensing basis.

Commented [AK191]: Comment 4.5.37

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

36 5.2.3.4 *Withdrawing Guidance Documents*

37 To withdraw a guidance document, the NRC typically must already have ~~located~~ the guidance
38 ~~located~~ in other documents, determined that the guidance concerns an aspect of a facility's
39 design or operation that is no longer used as a means to meet the governing requirements, or
40 concluded that the guidance ~~cannot~~ no longer be used to comply with applicable requirements.
41 If the guidance can be found in other locations or is no longer needed, then withdrawing the
42 guidance document has no substantive impact on ~~licensees~~ affected entities. However, if the
43 NRC determines that the guidance document should be withdrawn because ~~the it contains~~
44 methods ~~contained that~~ are no longer an acceptable means of complying with the applicable
45 requirements, then withdrawing that guidance document could constitute backfitting ~~or a change~~
46 ~~affecting issue finality~~ for those ~~licensees~~ affected entities using the guidance document. The
47 backfitting ~~or a change affecting issue finality~~ would occur through another regulatory action,
48 such as an order removing the guidance document from the license. That regulatory action

1 would need to justify the backfitting or satisfy the applicable issue finality criteria. If the
2 withdrawal of the guidance document requires issuance of a *Federal Register* notice, then the
3 staff should generically address the backfitting, forward fitting, and issue finality implications of
4 withdrawing the guidance document in the *Federal Register* notice.

5.1.8 Superseding Guidance Documents

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

5.2.4 Topical Reports

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

29 If an affected entity submits its own topical report or a vendor's "draft" topical report (e.g., one
30 that the NRC has not approved) as the affected entity's topical report with an application as
31 justification for its requested licensing action, then NRC conditions of approval should be
32 assessed for backfitting, issue finality, or forward fitting implications. Restrictions on the use of the
33 draft topical report by that licensee could be considered forward fits. If the affected entity
34 submits information that the NRC is reviewing for the first time, the NRC has no existing staff
35 position applicable to the licensing action under review, and the staff is considering determines
36 that it may need to impose a condition of its approval that would meet the definitions of a
37 "forward fit," "direct nexus," and "essential," then the staff needs to perform a site-specific cost
38 consideration specific to the affected entity to complete the forward fit assessment. However,
39 the communications with the licensee for this first-of-a-kind review should not be done in a
40 manner that conveys expectations as to how the licensee should proceed. The staff can and
41 should communicate to the licensee issues it identifies during the review. The staff must ensure
42 that its communication does not limit the licensee in choosing how to resolve the issues.
43 Section 3.3 of this NUREG contains more additional guidance on forward fitting, and these
44 situations. Section 5.1.4 of this NUREG has guidance on how to communicate staff proposals,
45 backfits, changes affecting issue finality, and forward fits during licensing activities.

47 As described in Section 1.2.2.2 of this NUREG, NRC approval of a licensing action involving an
48 NRC-approved topical report can establish a facility-specific staff position. However, the NRC
49 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 **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 **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~~ have 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~~ seeks 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 **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

1 significance of the issue to be addressed. The NRC's acknowledgment of a licensee's
2 response to a 10 CFR 50.54(f) request for information does not establish a staff position. If the
3 NRC subsequently sends the licensee written correspondence about the acceptability of the
4 information for some regulatory purpose, then that correspondence would constitute an NRC
5 position for that regulatory purpose.

Commented [KA198]: Moved from Section 1.2.2.2

6
7 Letters, bulletins, and generic letters requesting information under 10 CFR 50.54(f) may
8 promulgate new or revised staff positions and may ask licensees to state in their responses
9 whether they have adopted or will adopt these new positions. However, in When issuing these
10 information requests, the NRC cannot require a licensee to adopt the new staff position.
11 Conveying an expectation that the licensee will adopt the new staff position would be
12 considered unless the NRC has followed the backfitting or a change affecting issue finality
13 regulations. As a matter of practice, the NRC staff should carefully consider the potential to
14 raise backfitting and issue finality concerns issues in information requests.

15
16 The staff may use a bulletin or generic letter to justify a ~~staff-staff~~-recommended action or
17 schedule. If a bulletin or generic letter requests a response, and the staff is not satisfied with
18 that response, then subsequent staff action to direct further action by a licensee (e.g., an order)
19 may be backfitting or a change affecting issue finality and should be assessed as such. The
20 licensee's only obligation on the part of the licensee is to respond to the bulletin or generic
21 letter. A licensee's response to the generic letter may contain licensing basis information. If the
22 licensee adopts a recommendation from the generic letter, and the NRC does not respond to
23 that correspondence, then the licensee's response likely constitutes a regulatory commitment,
24 which the licensee may be able to remove in accordance with its commitment management
25 program. If the NRC does respond to the licensee and accepts the response as addressing the
26 issue in the generic letter, then how that information is considered in the licensing basis will
27 depend on the manner of the licensee's and the NRC's correspondence (e.g., whether the
28 licensee responded through a license amendment request, incorporated the information into a
29 mandated licensing basis document, or made regulatory commitments; or whether the NRC
30 ordered the licensee to modify its license, took enforcement action, or took another approach).
31 The generic letter itself does not constitute ~~the a~~ requirement or licensing basis information.

32 33 **5.2.8 Policy Statements**

34 Under the Administrative Procedure Act ~~As compared to an NRC regulation, an NRC~~ policy
35 statement does not establish a legally binding requirement. An NRC policy statement is the
36 policy of the Commission; therefore, a Commission policy statement cannot be a regulatory staff
37 position interpreting the Commission's regulations. To make a policy statement a requirement
38 for a licensee, the NRC staff would issue a facility-specific licensing action (e.g., a safety or
39 security order) involving a policy statement to create a facility-specific staff position. Such an
40 action would be subject to a backfitting, issue finality, or forward fitting assessment. The NRC
41 can also make a policy statement generically applicable by conducting a rulemaking that
42 creates or amends regulations that implement the principles described in the policy
43 statement. Thus, a policy statement, unlike an NRC regulation, is not directly enforceable. Any
44 action to enforce the Commission's interpretation or policy in a specific case must be done
45 through a subsequent rule or order subject to the applicable backfitting regulations or forward
46 fitting policy.

Commented [AK199]: Comment 4.5.26

1 **5.3 Inspection Processes**

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

7
8 In the normal course of inspections, ~~the an NRC~~ inspector may examine and identify findings or
9 violations in specific technical or regulatory areas. Identifying findings or violations ~~usually~~
10 ~~does must~~ not involve backfitting or issue finality, but it may if the establishment of the NRC's
11 position can be reasonably understood to exceed the governing requirement or a licensee's
12 self-imposed standard that is included in the licensing basis. If an NRC inspector identifies a
13 concern with the adequacy of the current licensing basis, then that concern must be
14 dispositioned in accordance with the backfitting and issue finality process discussed in this
15 NUREG. NRR or NMSS, as appropriate, will coordinate any backfitting actions or changes
16 affecting issue finality resulting from such concerns.

17
18 Inspections may include the review of activities that were previously inspected. Many
19 inspections are done on a sampling basis, and the focus areas may differ from one inspector to
20 another. A different inspection conclusion (e.g., one resulting in identified findings versus one
21 that does not—refer to the caution in Section 4.2.2-2-5.3.2 of this NUREG) likely does not
22 involve ~~may not constitute~~ backfitting or affect issue finality because (1) most inspections use a
23 sampling methodology, (2) circumstances surrounding the activity may have changed, (3) the
24 focus of the inspection may be different, (4) the licensing basis may have changed,
25 (5) maintenance that was previously committed to may not have been accomplished, or
26 (6) other factors have been considered.

27
28 **5.3.1 Oral Communications**

29 ~~Likewise, a~~ An inspector's discussion of ~~findings~~ proposed findings and violations with the
30 licensee-affected entity is not considered backfitting or a change affecting issue finality. During
31 these discussions, the licensee-affected entity may agree that certain changes are appropriate
32 in response to the inspector's findings. This would not constitute backfitting or a change
33 affecting issue finality if the inspector does not indicate that specific actions are the only way to
34 satisfy the staff when the licensing basis does not require the specific action. An inspector's
35 suggestions to consider an applicable guidance document or NRC-endorsed topical report to
36 resolve the findings are not backfitting or changes affecting issue finality as long as if the
37 inspector does not convey an expectation that the licensee-affected entity must use the
38 guidance document or topical report.

39
40 **5.3.2 Inspection Reports**

41 ~~The NRC staff must not document backfitting actions or changes affecting issue finality in an~~
42 ~~inspection report. Thus, the staff expects that f~~ Findings or violations documented as part of the
43 NRC's inspection activities would ~~must~~ not involve backfitting or changes affecting issue finality.
44 However, ~~if an licensee-affected entity concludes~~ believes that a finding or violation ~~finding or~~
45 violation in an written NRC inspection report is a new or changed staff position that is not part of
46 the licensing basis, then the licensee-affected entity can initiate a backfitting an MD 8.4 appeal
47 as described in Chapter 4 of this NUREG.
48

Commented [KA200]: Comment 4.5.21

Commented [AK201]: Comment 4.5.22

Commented [AK202]: Comment 4.1.12

Commented [KA203]: Comment 4.5.22

1 As discussed in Section 1.2.2.2 of this NUREG, the NRC establishes facility-specific staff
2 positions through its facility-specific correspondence discussing the regulatory bases for its
3 decisions (e.g., inspection reports). Inspection reports can contain staff positions, but the staff
4 must not use inspection reports to create staff positions about the adequacy of the licensing
5 basis (e.g., “the licensee is in compliance”). An inspection report that states, “The NRC
6 inspectors did not identify any findings or violations of more than minor significance,” does not
7 create a staff position. This statement acknowledges the possibility that there were
8 non-compliances but that the inspectors did not identify them in the report (e.g., because of the
9 sampling nature of the inspection process, or because any identified noncompliances were
10 minor). However, if the inspection report states, “The licensee complied with [Requirement X],”
11 then that language would constitute a staff position on the adequacy of how the licensee
12 complied with that requirement. If the NRC subsequently determines there is a non-compliance
13 with “Requirement X” related to the inspected sample, then the NRC may need to treat that
14 determination as a change in staff position subject to the backfitting provisions because of the
15 staff position created by the prior statement in the inspection report. Therefore, in inspection
16 reports, the NRC should avoid making statements such as, “The licensee complied with
17 [Requirement X].”

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

Commented [AK205]: Comment 4.1.12

19 **5.3.3 Licensing Basis Questions**

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

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

24 If licensing basis questions arise during an inspection, and the inspectors determine that the
25 significance of the issue does not immediately screen as having very low safety significance,
26 then the inspectors should contact the applicable appropriate licensing project manager to resolve
27 the issue through routine staff interactions. If applicable, the staff may also for advice and, if
28 necessary, initiate the technical assistance request process for the appropriate office to
29 consider the regulatory, licensing, and technical aspects of the issue. ~~The outcome of this~~
30 ~~process may need to be assessed for backfitting implications.~~ Section 5.21.2 of this NUREG
31 contains additional guidance on this matter licensing basis interpretations and using the
32 technical assistance request process. The process may conclude with the region pursuing a
33 violation (e.g., the issue of concern is a violation of a requirement in the licensing basis).
34 However, if the process conclusion does not support a violation (e.g., the issue of concern is
35 based on a position that is not in the affected entity’s licensing basis), then the staff should exit
36 the technical assistance request process and consider whether to propose a change to the
37 affected entity’s licensing basis, which would be subject to a backfitting or issue finality
38 assessment.

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

47 **5.4 Enforcement Processes**

48 The NRC issues enforcement sanctions, including orders other than “safety or security orders,”
49 notices of violation (NOVs) or non-cited violations (NCVs), when a licensee or non-licensee

1 violates a legally binding requirement. The staff should take extra caution when reviewing
2 regulatory requirements, ~~such as an operating reactor's and~~ licensing basis ~~information~~, cited in
3 an enforcement action to ensure that the enforcement action is, in fact, citing only legally
4 binding requirements. A citation that improperly reflects a new or modified requirement or staff
5 position ~~constitutes~~ meets the definition of "backfitting," ~~and could constitute a change affecting~~
6 ~~issue finality.~~

8 **5.4.1 Violations**

9 An NOV may require an ~~affected entity~~ licensee to respond to the NOV by providing the
10 corrective steps that it either has taken or will take to ~~achieve fully compliance~~ with NRC
11 requirements. As such, requiring a response to an NOV that ~~includes a description of an~~
12 ~~affected entity~~ licensee's proposed corrective action is not backfitting ~~or a change affecting issue~~
13 ~~finality because such a response is already a requirement for the affected entity.~~ The ~~affected~~
14 ~~entity's~~ commitments in the description of a corrective action are not backfits ~~or changes~~
15 ~~affecting issue finality because they are the affected entity's means for restoring compliance~~
16 ~~with an already applicable requirement.~~ A statement or recommendation by the staff for the
17 ~~affected entity~~ licensee to consider actions in response to an NOV is not backfitting ~~or a change~~
18 ~~affecting issue finality because such communications are not impositions, provided that the~~
19 ~~affected entity recognizes that it is not obligated to follow the staff recommendations.~~ However,
20 if the staff ~~is not satisfied with the licensee's proposed corrective actions and asks the affected~~
21 ~~entity~~ licensee to take additional actions beyond those needed to meet requirements, then those
22 additional actions, if imposed (e.g., by order) by the NRC, may constitute backfitting ~~or changes~~
23 ~~affecting issue finality because the staff may be imposing new requirements on the~~
24 ~~licensee~~ affected entity. If the staff is not satisfied with a licensee's actions in response to any
25 NOV, then subsequent discussions and considerations should remain in the enforcement
26 process. The guidance in this section does not preclude inspectors from assessing corrective
27 actions and issuing applicable enforcement actions.

28
29 A ~~finding of a~~ violation for ineffective or untimely corrective actions is not backfitting ~~or a change~~
30 ~~affecting issue finality if the affected entity is required to take effective and timely corrective~~
31 ~~actions (i.e., there is no new requirement or staff position).~~ However, ~~the~~ NRC staff imposition
32 of a requirement that the ~~affected entity~~ licensee must take a certain action may ~~constitute~~ meet
33 ~~the definition of "backfitting," or constitute a change affecting issue finality~~ unless the action is in
34 accordance with an existing staff position that applies to the facility and is included in the
35 licensing basis. If the imposed action is beyond what is required under the ~~affected~~
36 ~~entity~~ licensee's licensing basis, then the action would be backfitting ~~or a change affecting issue~~
37 ~~finality.~~

38
39 ~~Licensee a~~ Actions ~~taken by an affected entity~~ to correct violations of the requirements in its
40 licensing basis are not backfits ~~or changes affecting issue finality because there is no imposition~~
41 ~~of a new or changed requirement or staff position.~~ Discussions during enforcement conferences
42 and oral responses to an ~~affected entity~~ licensee's questions ~~regarding on~~ corrective actions to
43 restore compliance with the requirements in the licensing basis are not backfitting ~~or changes~~
44 ~~affecting issue finality~~ unless the staff attempts to limit the ~~affected entity~~ licensee to a specific
45 action that is not expressly required or attempts to impose some action beyond requirements.

46
47 Chapter 4 of this NUREG describes how the NRC would respond to an ~~affected entity's licensee~~
48 ~~concerns of unjustified backfitting or changes affecting issue finality associated with proposed~~
49 ~~and issued violations. The licensee may formally submit a backfitting appeal in accordance with~~
50 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 Certifications, and Approvals for Nuclear Power Plants."
- 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~~icenses for ~~N~~uclear ~~P~~ower ~~P~~lants."

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 [licensing of Special Nuclear 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,
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- 11 10 CFR Part 72. *U.S. Code of Federal Regulations*, Title 10, "Energy," Part 72, "Licensing
12 [Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level](#)
13 [Radioactive Waste, and Reactor-Related Greater Than Class-C Waste."](#)
- 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 [Gaseous Diffusion Plants."](#)
- 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
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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~~
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2 ADAMS Accession No. ML12261A553.

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4 Licensees," ~~dated~~ June 29, 1995. ADAMS Accession No. ML12299A717.

5 SECY-95-300, "Nuclear Energy Institute's Guidance Document, 'Guideline for Managing NRC |
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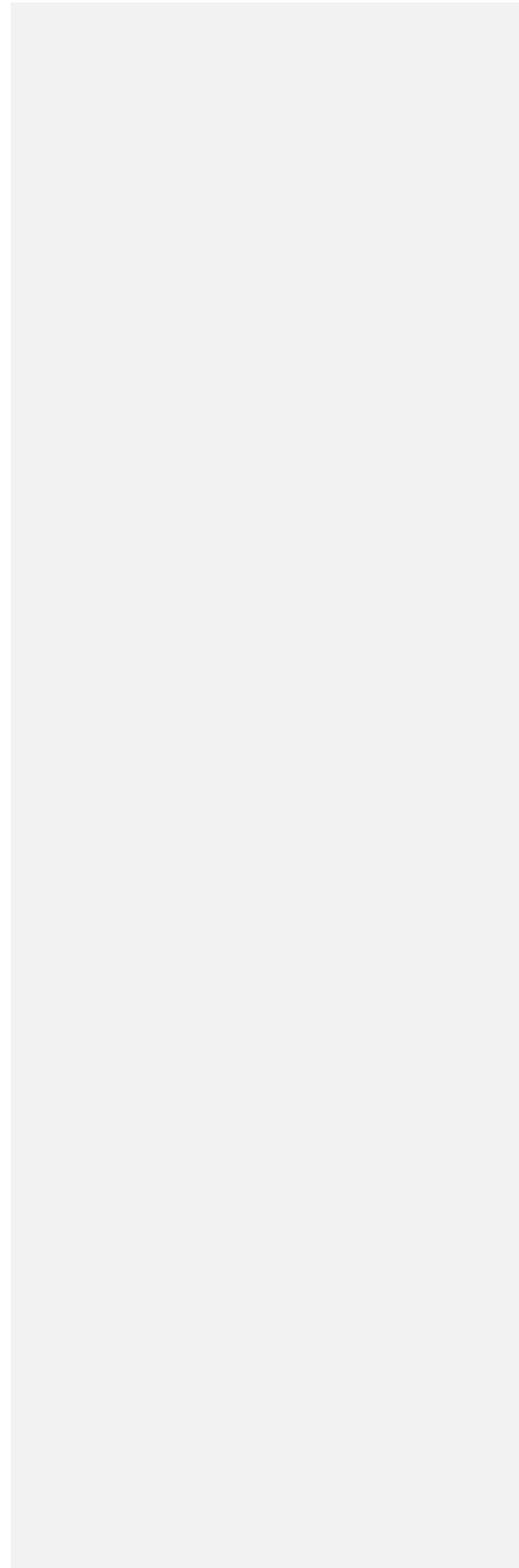
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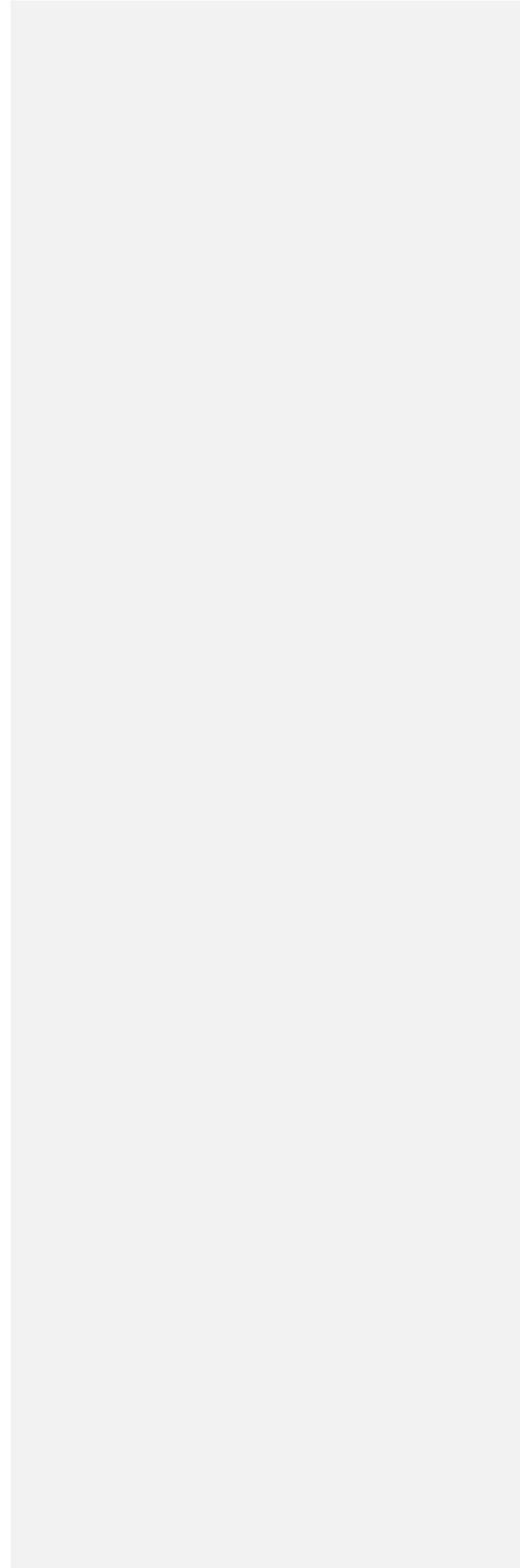


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APPENDIX A - BACKFITTING FLOWCHARTS

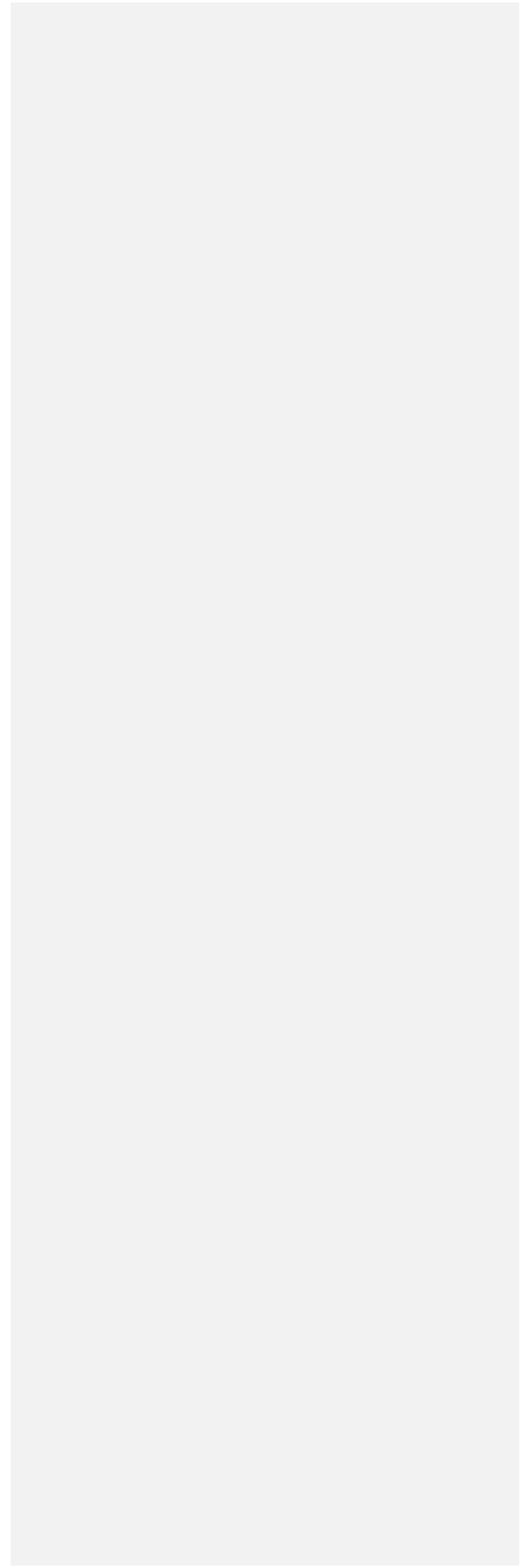
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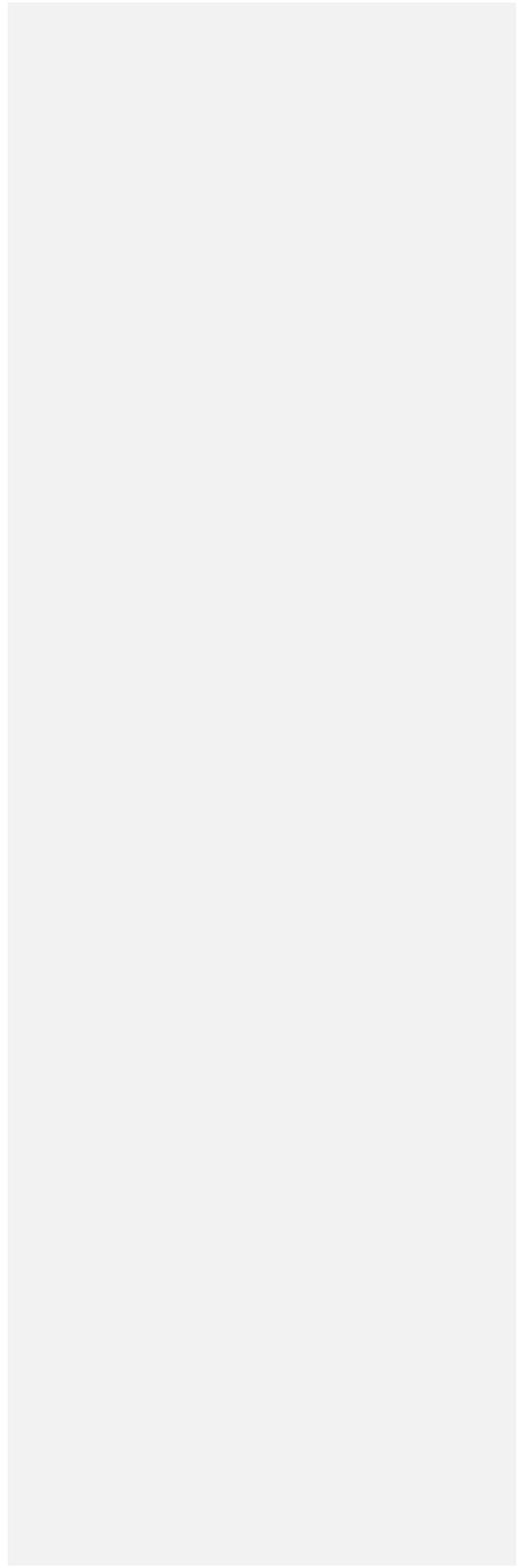
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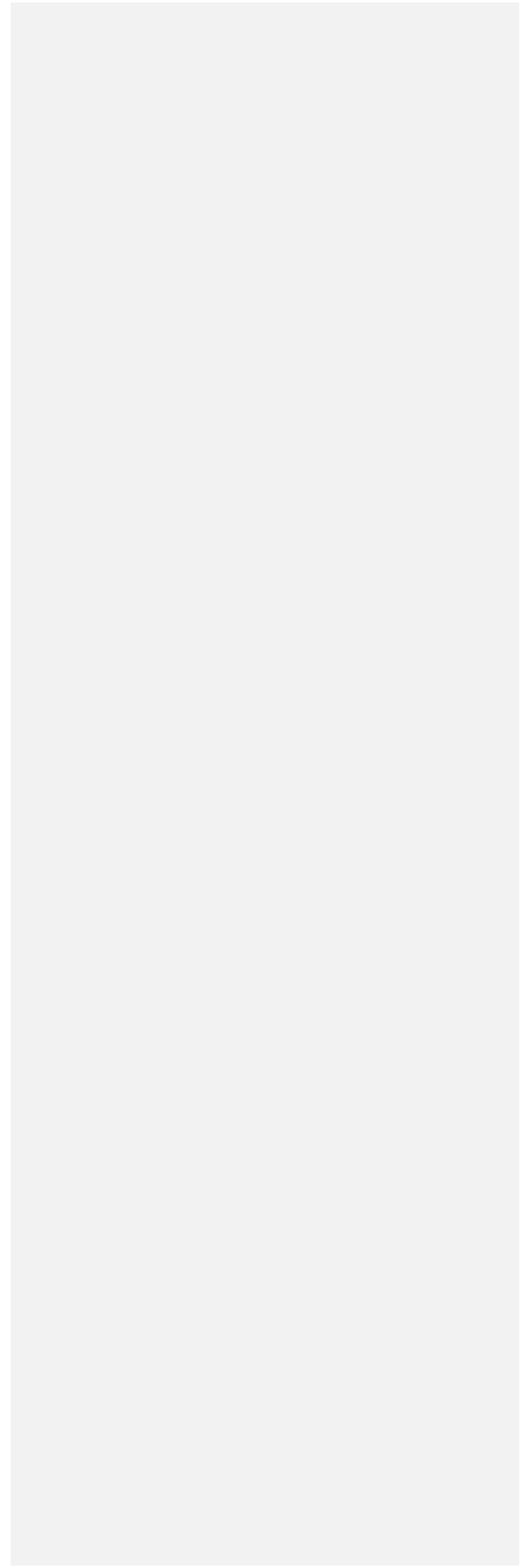


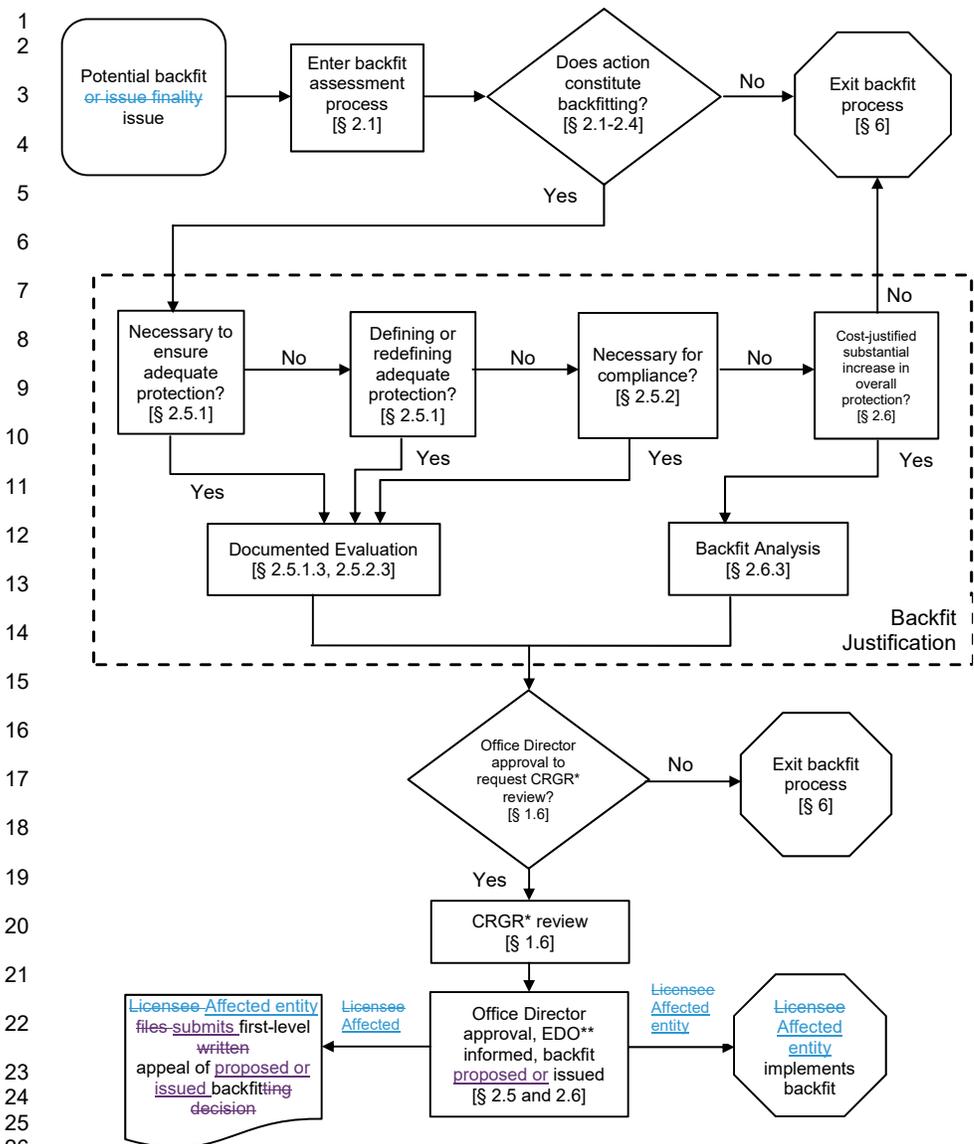
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FLOWCHART 1

NRC BACKFITTING PROCESS FLOWCHART





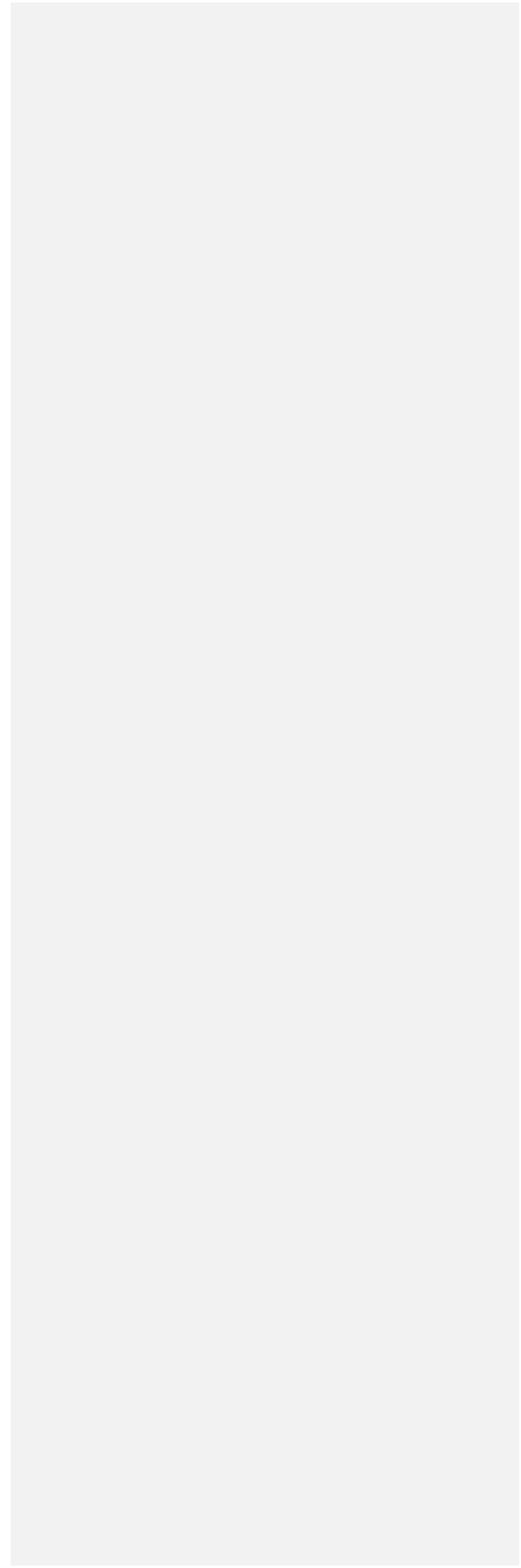


27 *Committee to Review Generic Requirements

28 **Executive Director for Operations

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

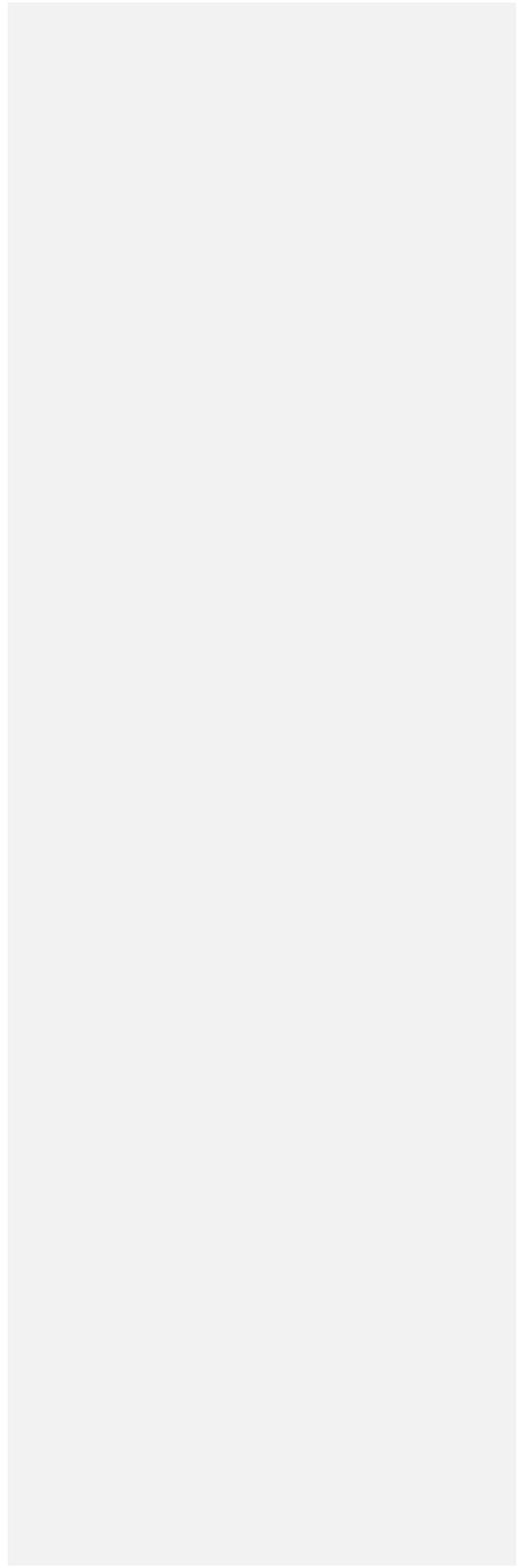
30 **Figure A-1: NRC-Backfitting Process Flowchart**

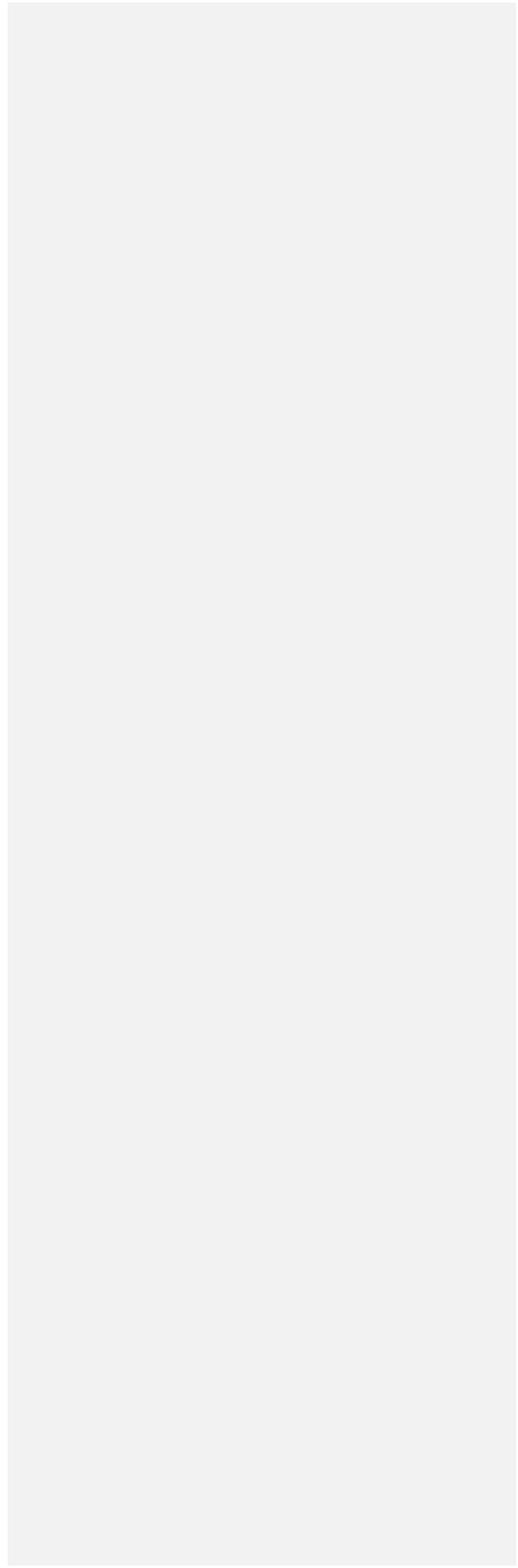


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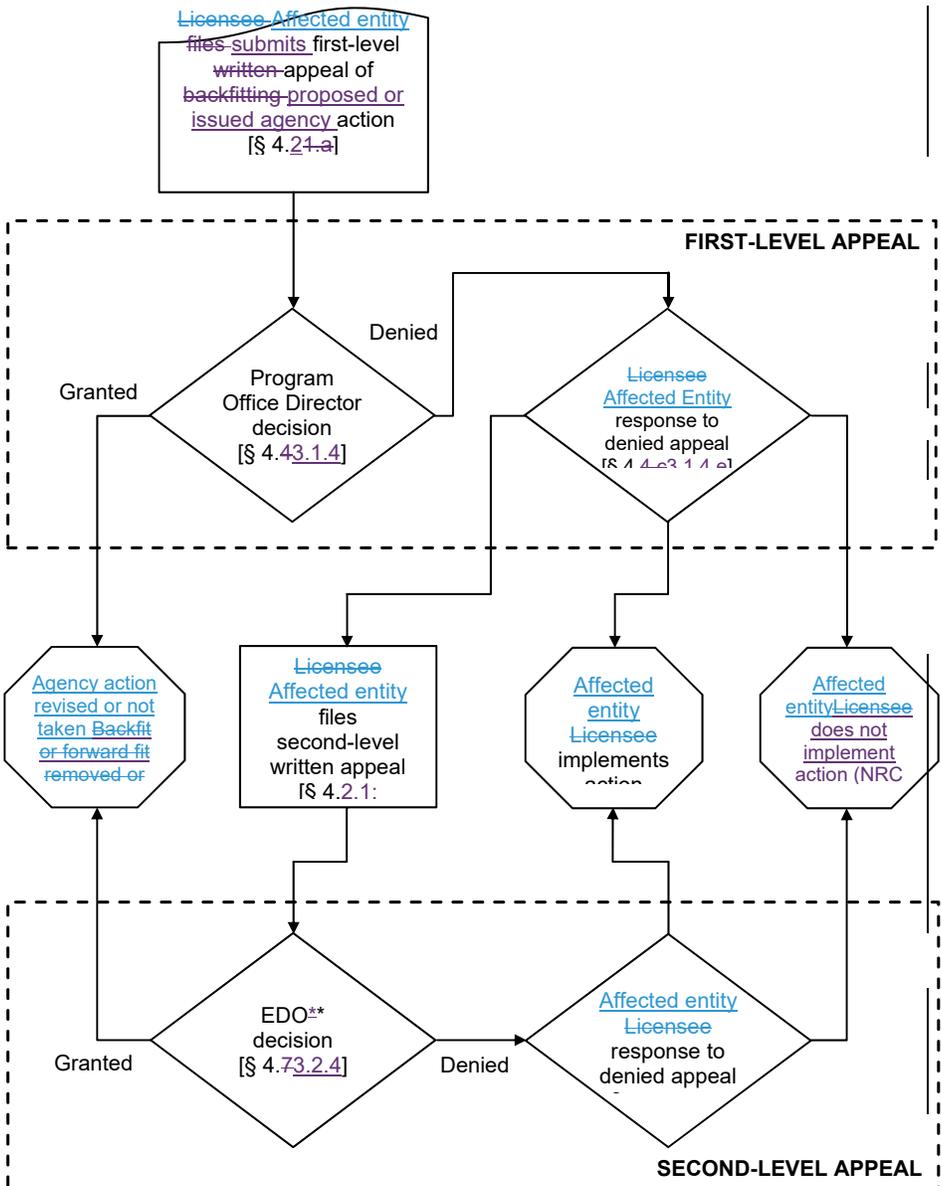
FLOWCHART 2

BACKFITTING-MANAGEMENT DIRECTIVE 8.4 APPEAL PROCESS FLOWCHART |





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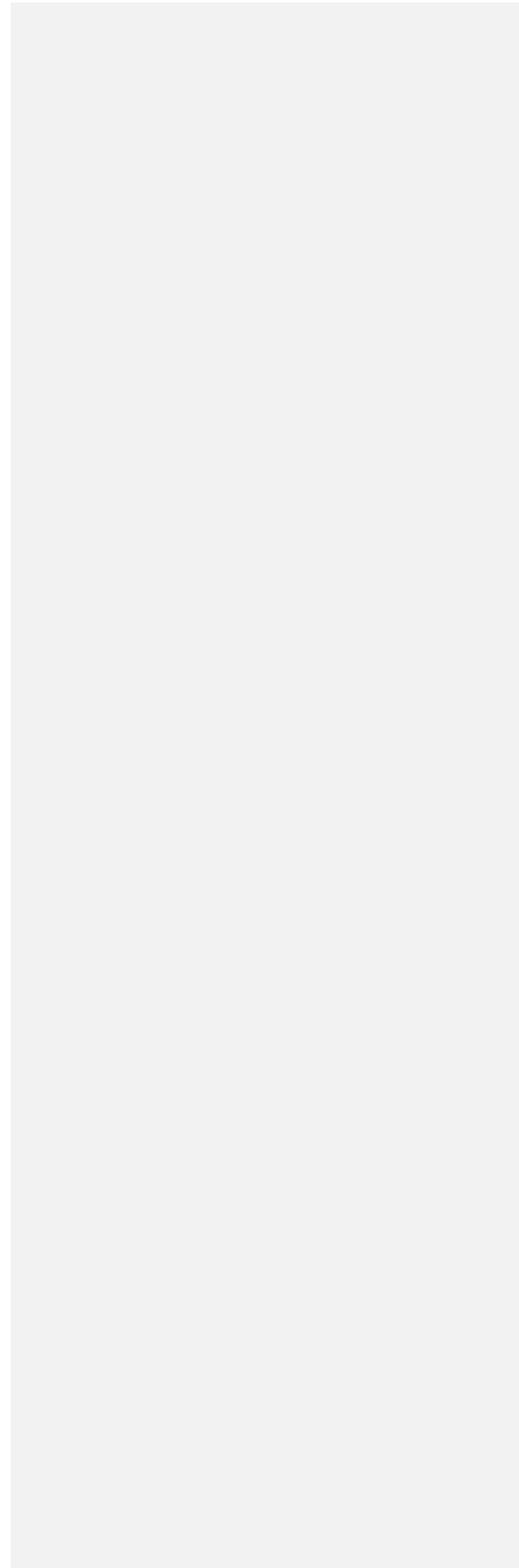
* U.S. Nuclear Regulatory Commission; ** Executive Director for Operations
 Note: This flowchart may not capture all scenarios involving appeals.

Figure A-2. Backfitting Appeal Process Flowchart

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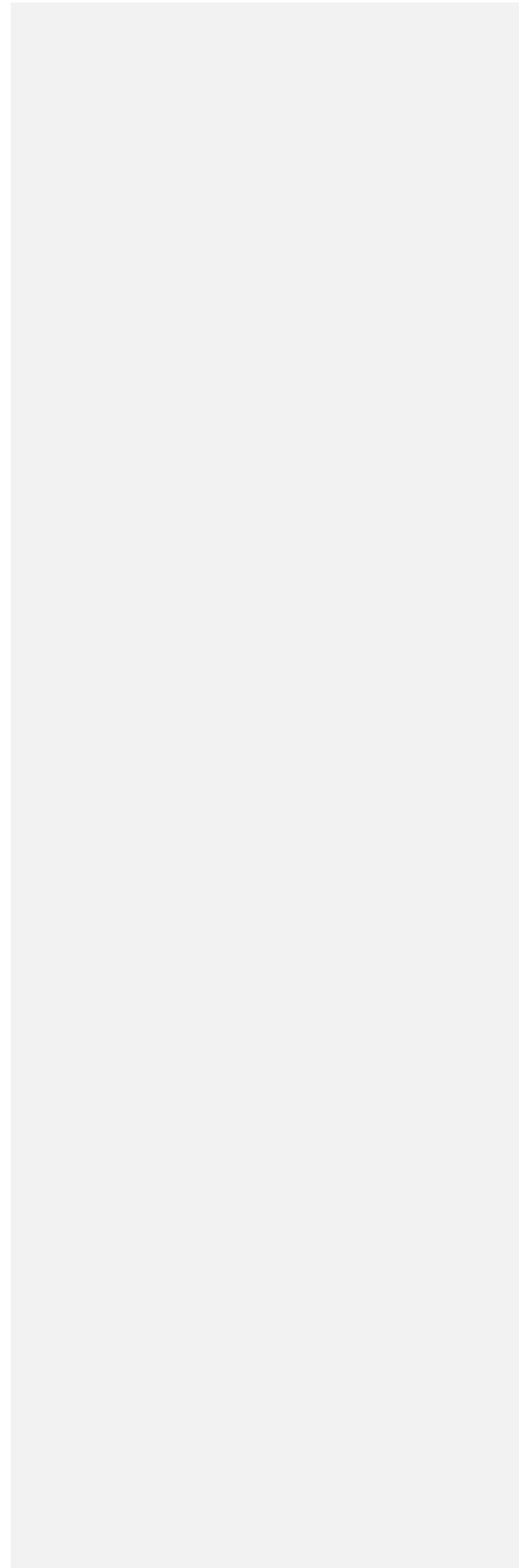
APPENDIX B – WORKSHEETS

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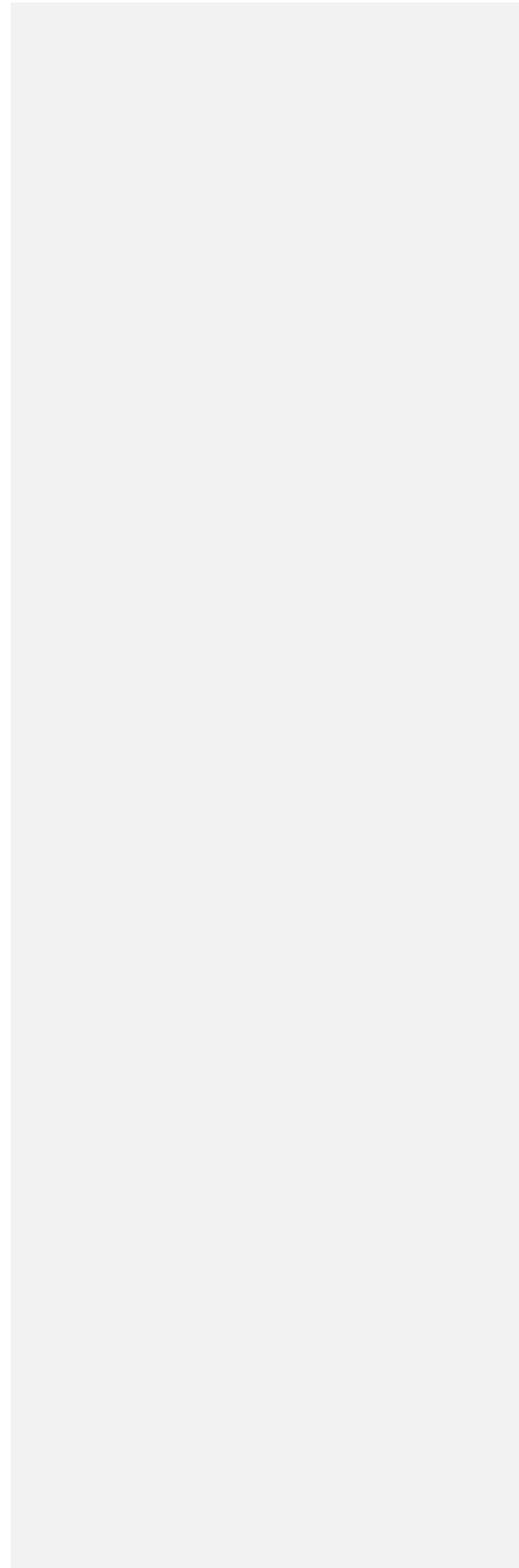
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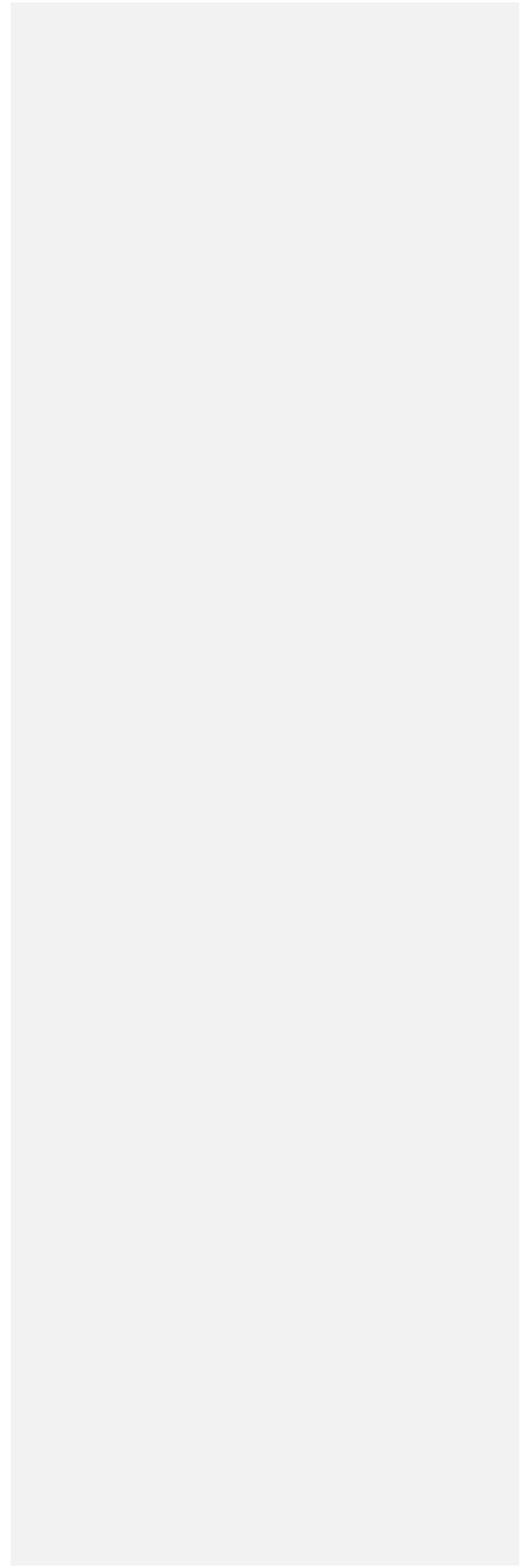


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WORKSHEET 1

BACKFITTING AND ISSUE FINALITY WORKSHEET





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

BACKFITTING AND ISSUE FINALITY WORKSHEET <u>(continued)</u>		
Justification		
Step	Action	Notes
5	Obtain <u>Office of Nuclear Reactor Regulation (NRR) or 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"> • Ddescription of the answers to the backfitting Screening questions. • Hf readily available, descriptions of any safety, risk, and/or cost-benefit insights, including whether the issue is one of adequate protection and, if it is not, whether the proposed action could be justified using the compliance exception or a backfit analysis. <p>If approved, proceed to the next step; if the proposed action meets a definition of "backfitting," if the proposed action satisfies an issue finality provision in 10 CFR Part 52, then proceed to sStep 9.</p> <p>If not approved, then address the NRR or NMSS Ooffice Director's concerns and re-seek approval. If not approved, then document the basis for the Ooffice Director'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"> • Perform an imminent threat analysis. • Refer to NUREG-1409, Section 2.5.1. • If the proposed action is necessary to ensure adequate protection, then, depending on timing, draft a documented evaluation to invoke the "necessary to ensure adequate protection" exception using Guide 1 in NUREG-1409, Appendix C. • If the proposed action is necessary to define or redefine the level of protection considered adequate, then depending on timing, draft a documented evaluation to invoke the "necessary to define or redefine the level of protection considered adequate" exception using Guide 1 in NUREG-1409, Appendix C. • Proceed to sStep 10. <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 Step 10.</p> <p>If not, then proceed to the next step.</p>
8	Ask: Could the proposed action provide a cost-justified substantial increase in overall protection?	<p>Prepare a backfit analysis using Guide 3 in NUREG-1409, Appendix C. Refer to NUREG-1409, Section 2.6.</p> <p>If the increase in overall protection is not judged to be substantial, or it is substantial but the costs would not be justified by the increase in overall protection, then document this and exit the backfitting process.</p> <p>If the proposed action would be a cost-justified substantial increase in overall protection, then proceed to Step 10.</p>
9	If the proposed action satisfies an issue finality provision in 10 CFR Part 52, then follow the direction provided in the issue finality provision.	The issue finality provision may direct you to one of the preceding steps in this justification process. Otherwise, proceed to the next step.
10	Provide the NRR or NMSS Office Director the documented evaluation or backfit analysis and obtain approval to request CRGR review.	<p>If approved, then proceed to the next step.</p> <p>If not approved, then address the NRR or NMSS Office Office Director's concerns and re-seek approval. If not approved, then document the basis for the Office Office Director's decision and exit the backfitting or issue finality process.</p>
11	Meet with the Committee to Review Generic Requirements (CRGR) .	<p>Prepare the materials for meeting with the CRGR. See CRGR Charter and Procedures. Afterwards, address any issues identified by the CRGR.</p> <p>Proceed to the next step.</p>

BACKFITTING AND ISSUE FINALITY WORKSHEET (continued)

Justification		
Step	Action	Notes
12	Submit the final documented evaluation or backfit analysis to the NRR or NMSS Office Director (and/or OEDO or Commission) for approval.	<p>If approved, then proceed with the proposed action <u>to the next step.</u></p> <p>If not approved, then address the NRR or NMSS Office Director's <u>Director's</u> concerns and re-seek approval. If <u>still</u> 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>

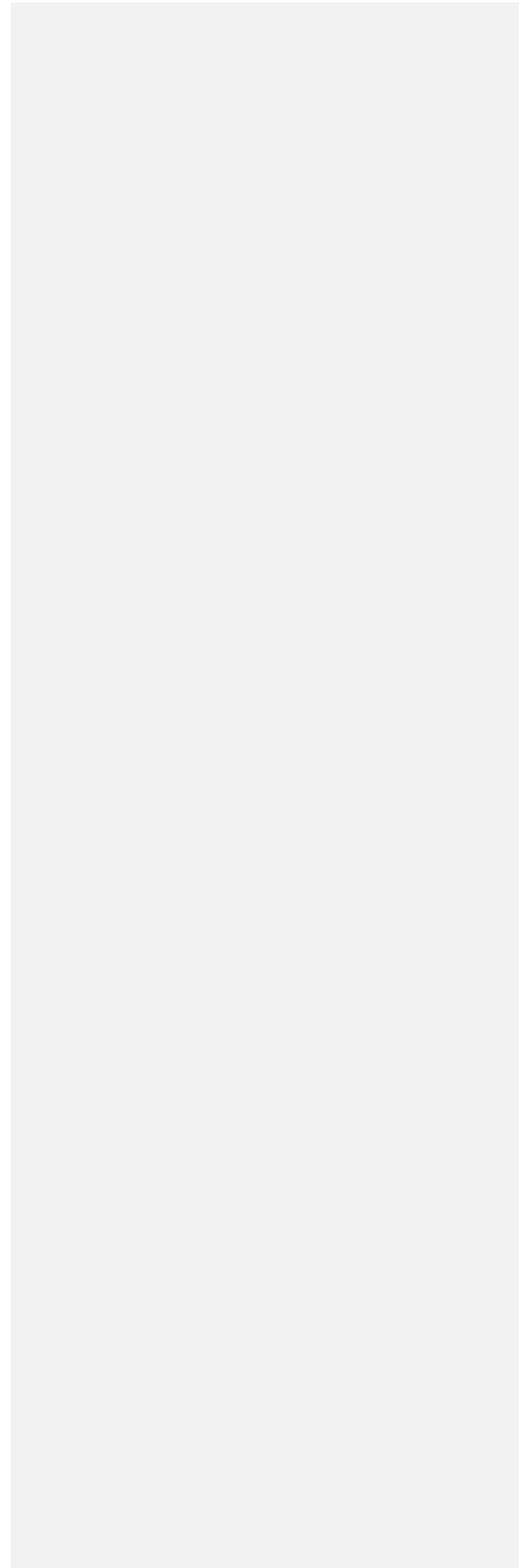
Commented [KA212]: Staff added this step to show where the appeal process could be offered for proposed backfits.

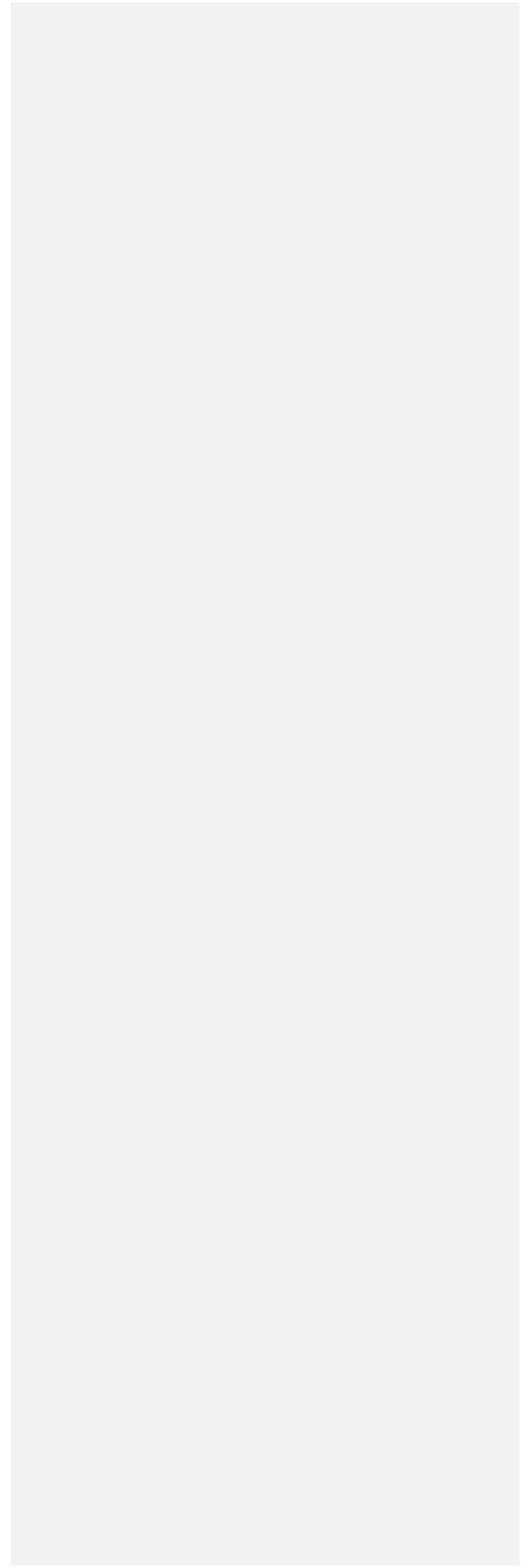
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WORKSHEET 2

COMPLIANCE EXCEPTION CHECKLIST





COMPLIANCE EXCEPTION CHECKLIST		
The Requirement		
Step	Action	Notes
1	The NRC has identified an NRC requirement for which it seeks compliance.	A compliance backfit requires that an applicable requirement be in place, and the NRC's proposed backfitting action is not changing this requirement.
2	The identified requirement must have been "known and established" (i.e., the requirement cannot be implied or subjective) at the time of the NRC's approval.	Confirm timing of requirement. If not contemporaneous with the NRC's approval, then the compliance exception cannot be used.
3	The NRC consistently interpreted and applied the identified requirement.	If the NRC's interpretation was consistently applied at the time of approval, then state that finding with a supporting basis. If there were inconsistent interpretation and application were inconsistent , then it is much less likely that an error or omission can be shown to have occurred. Note that conclusion with a supporting basis.
4	The NRC approved the licensee's method of compliance with the requirement.	Note the approval type and date and describe supporting information that indicates the NRC's interpretation and application of the requirement in its approval.
The Error or Omission		
Step	Action	Notes
5	The NRC has identified at least one an error or omission—either the NRC's own error, or the omission or error of the licensee, applicant, or a third party (e.g., a vendor or another government agency), through any of the following : <ul style="list-style-type: none"> incorrect perception or understanding of the facts failure to recognize flawed analyses failure to draw direct inferences from those facts or analyses 	Describe the error(s) or omission(s).

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 an 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 an 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

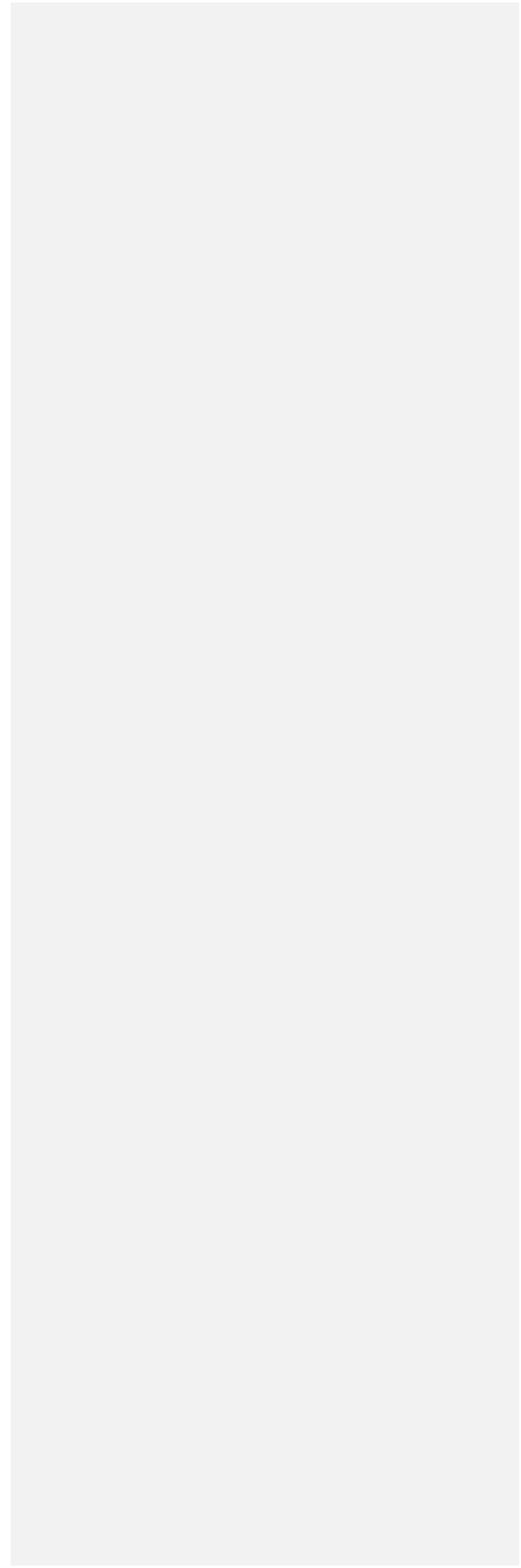
Step	Action	Notes
10	Costs of the compliance backfitting are considered in the NRC's documented evaluation of the backfitting action.	Discuss briefly what the corrective action would cost, and how long the facility has been in the current situation.

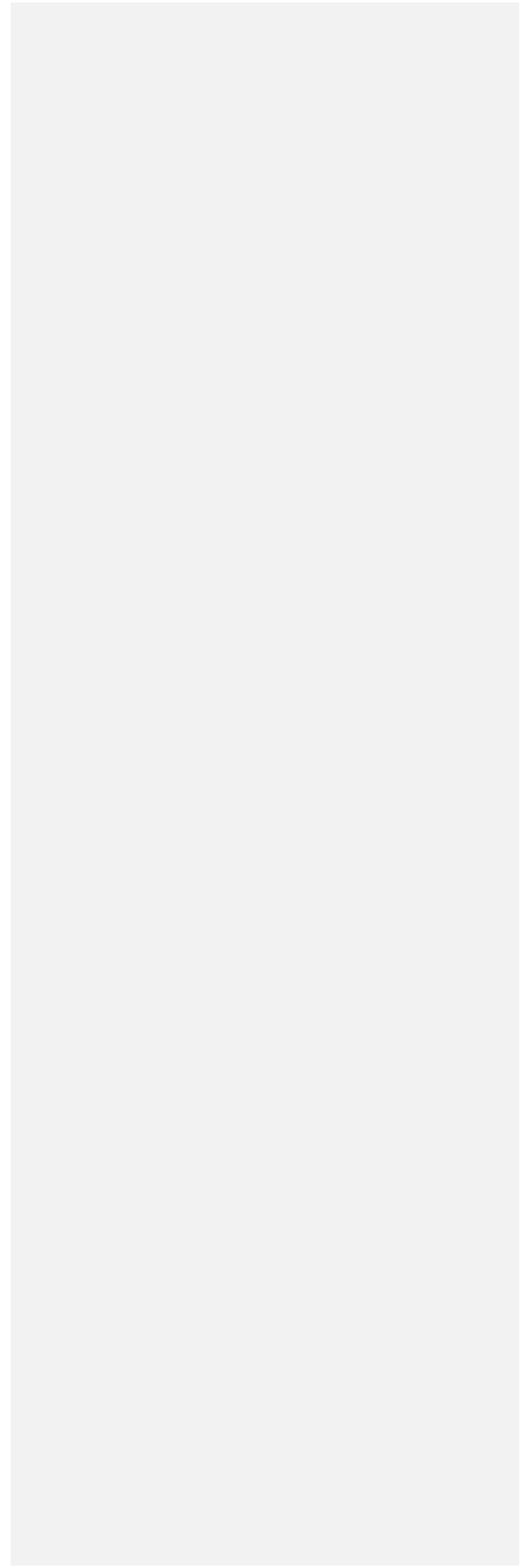
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WORKSHEET 3

FORWARD FITTING WORKSHEET





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

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?	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.

FORWARD FITTING WORKSHEET <u>(continued)</u>		
Justification		
Step	Action	Notes
6	Ask: Is there a direct nexus between the proposed action and the affected entity 's request? <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> <u>2. The NRC's proposed action would address the issue or non-compliance.</u>	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> If the answer is "yes," then proceed to the next step.

1

7	Ask: Is the proposed action essential to the staff 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>)?	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> If the answer is "yes," then proceed to the next step.
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>	If approved, then proceed to the next step. 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.
9	Using the guidance in Section 5.1.4 of this NUREG, communicate the NRC's issue with the application and the NRC's proposed option for addressing the issue with the affected entity.	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. If the affected entity either does not respond or does not respond in a manner that addresses the staff's concerns, then the staff must decide if it wishes to deny the application or pursue the forward fit. If the staff decides to pursue the forward fit, then proceed to the next step.

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<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 developing and documenting the full <u>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 Office Director</u>:</p> <ul style="list-style-type: none"> • The responses to the first seven <u>nine</u> steps of this W <u>worksheet</u>. • If readily available, descriptions of any safety, risk, or cost-benefit insights. <p>If approved, then proceed to the next step.</p> <p>If not approved, then address the <u>NRR or NMSS Office Director's</u> concerns and re-<u>seek</u> approval. If <u>still</u> not approved, then document the basis for the <u>Office Director'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>

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

4013	If the CRGR agrees to review the package, then follow the procedures for submitting documents to the CRGR.	Prepare the materials for the CRGR as specified in the CRGR Charter and Procedures . Afterwards, address any issues identified by the CRGR. Proceed to the next step.
4414	Submit the final forward fit analysis assessment to the NRR or NMSS Office Director for approval.	If approved, then proceed with the proposed action next step . If not approved, then address the NRR or NMSS Office Director's concerns and re-seek approval. If still not approved, then document the basis for the decision, place a note to file in ADAMS, exit the forward fitting process, and do not take the proposed action. Do not proceed to the next step .
15	Provide the proposed forward fit to the affected entity for an opportunity to submit an MD 8.4 appeal.	If the affected entity does not submit an MD 8.4 appeal, then proceed with the forward fit . 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 .

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APPENDIX C -- GUIDES

INSTRUCTIONS FOR USING GUIDES

These guides provide instructions to the U.S. Nuclear Regulatory Commission (NRC) staff on how to develop a documented evaluation, backfit analysis, or forward fit ~~analysis~~assessment. ~~The staff can use E~~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.

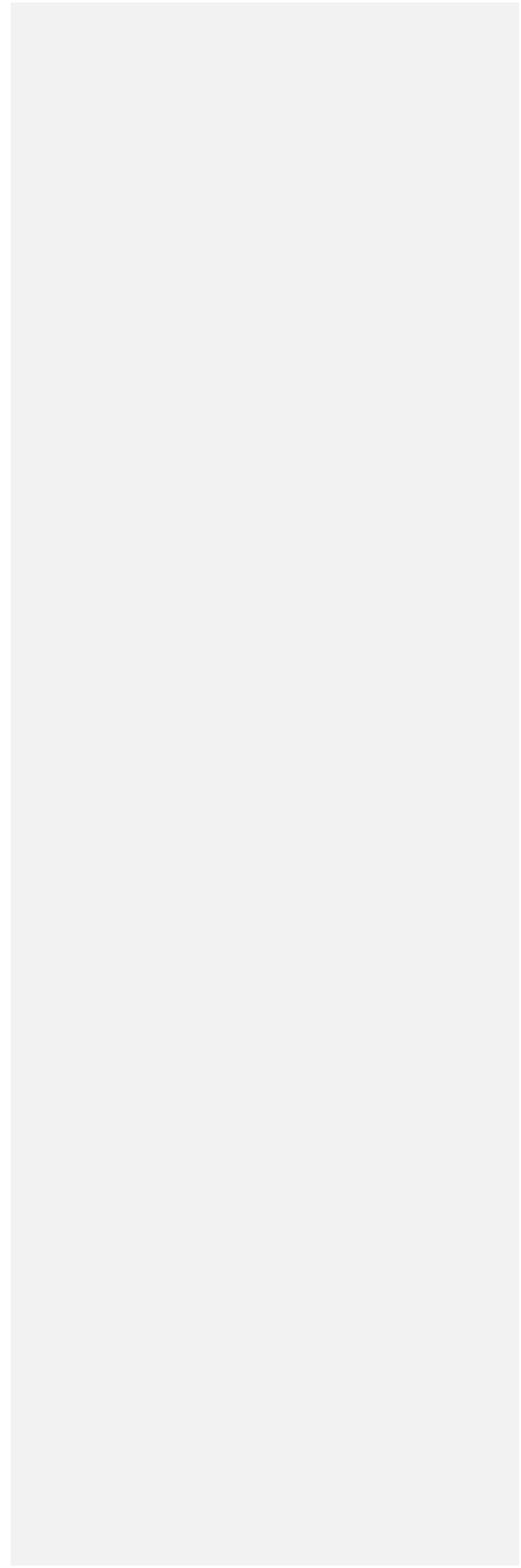
Although the NRC's various backfitting provisions in Title 10 of the *Code of Federal Regulations* (10 CFR) Chapter I refer to a "documented evaluation" to support an NRC decision to use the adequate protection or compliance exceptions, the NRC may also use these guides to develop a documented evaluation 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.

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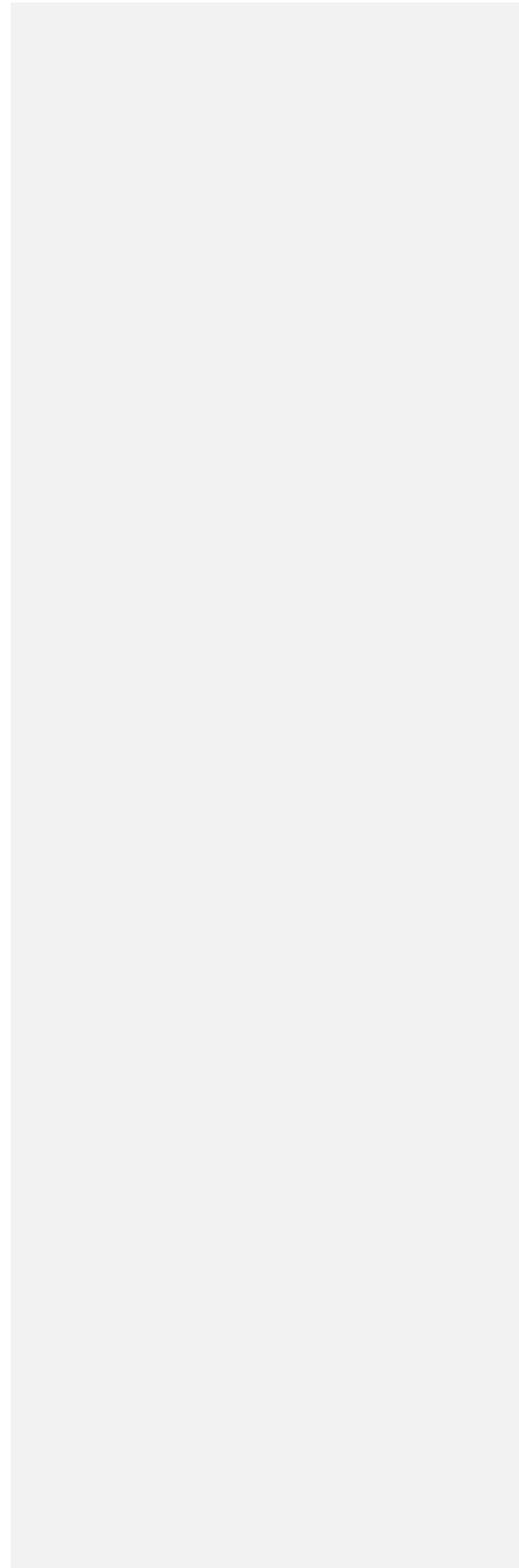
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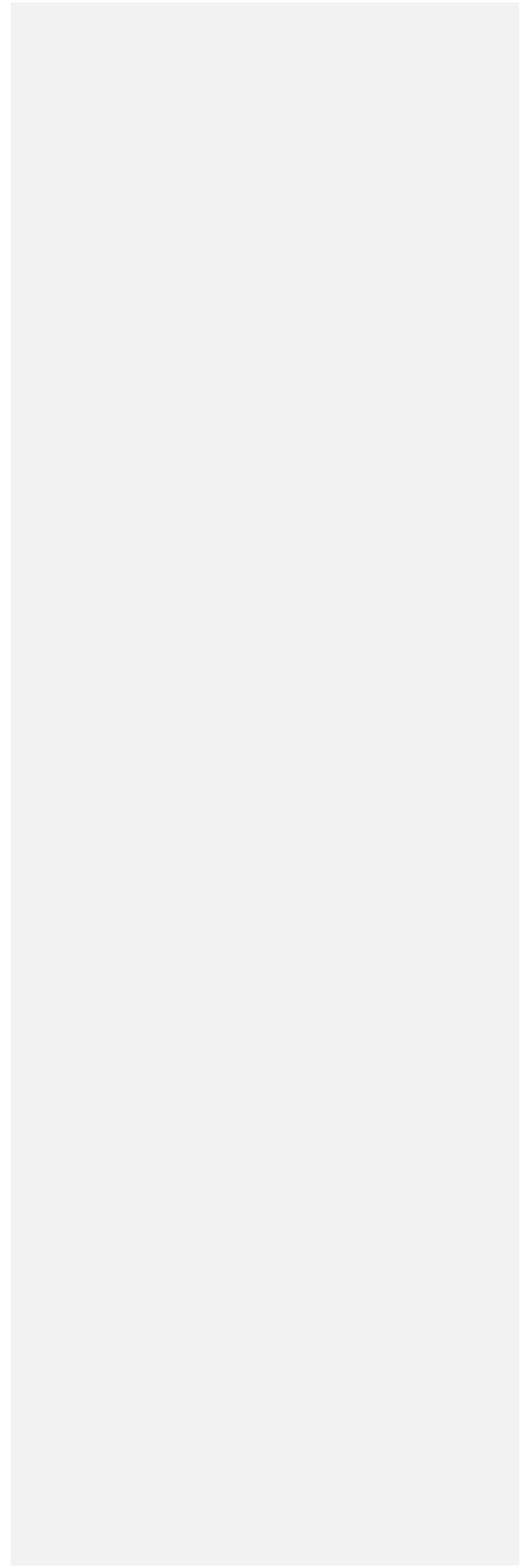


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GUIDE 1

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





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DOCUMENTED EVALUATION

TITLE OF PROPOSED BACKFITTING

AFFECTED ENTITY/LICENSEE NAME

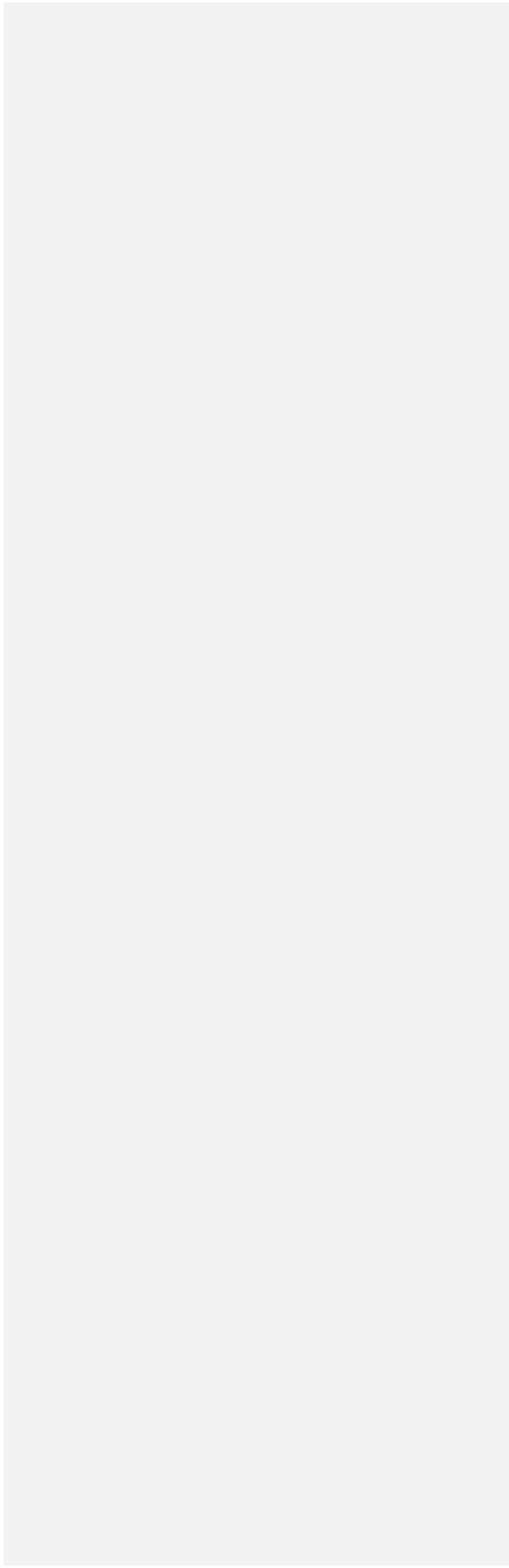
FACILITY NAME

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



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

2
3 Summarize the proposed backfitting action (a more detailed description will be provided later)
4 and the staff's conclusion. Describe the enforcement, licensing, or rulemaking context.

5
6 II. BACKGROUND

7
8 Concisely describe the historical and procedural facts that led to the proposed NRC backfitting.
9 Summarize the entity's or entities' licensing bases and the safety or security context for the
10 proposed backfitting action.

11
12 III. PROPOSED BACKFITTING [NUREG-1409, Revision 1, Sections 2.3, and 2.4]

13
14 Describe the proposed backfitting. The description should include the following:

- 15
16 • the key substantive elements of the proposed backfitting and its purpose;
- 17
18 • the entities upon which ~~chem~~ the proposed backfitting would be imposed;
- 19
20 • risk insights;
- 21
22 • the regulatory method (e.g., order, adoption of final regulation) by which the backfitting
23 would be imposed; ~~and~~
- 24
25 • the expected time, event, or occurrence by which implementation of the proposed
26 backfitting must be completed.

27
28 IV. ADEQUATE PROTECTION EXCEPTION APPLICABILITY [NUREG-1409, Revision 1,
29 Section 2.5.1]

30
31 Describe the basis for invoking one or both of the adequate protection exceptions from the
32 requirement to perform a backfit analysis, including why compliance with existing applicable
33 requirements does not or will not provide reasonable assurance of adequate protection (i.e., a
34 condition of undue risk to public health and safety¹ exists despite compliance with requirements)
35 and how the backfitting action addresses the condition of undue risk. If the staff determines that
36 it cannot invoke one or both of the adequate protection exceptions, describe the basis for that
37 determination and skip to Section VII.

38
39 V. IMMINENT THREAT ANALYSIS [NUREG-1409, Revision 1, Section 5.1.1.2.1]

40
41 If there is a basis for invoking one or both of the adequate protection exceptions, then describe
42 the basis for determining whether an imminent threat exists that warrants an immediate agency
43 action.

44

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

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
- 10 • State that a regulatory analysis was prepared to identify alternatives.
 - 11 • Provide the title, date, and the applicable Agencywide Documents Access and
12 Management System (ADAMS) accession number of the regulatory analysis.
 - 13
 - 14 • Summarize the regulatory analysis's approach (including selection criteria) ~~for to~~
15 identifying reasonable alternatives to the proposed backfitting for providing adequate
16 protection.
 - 17

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

22
23 B. Cost Considerations [NUREG-1409, Revision 1, Section 2.6.2]

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

32
33 The cost considerations section must describe the following:

- 34
- 35 • the costs for the proposed backfitting and each identified reasonable alternative,
36 identifying each cost input or element that was integrated to develop the overall cost
37 estimate;
 - 38
 - 39 • uncertainties in each cost input or element;
 - 40
 - 41 • sensitivity of results to changes to cost inputs or elements; ~~and~~
 - 42
 - 43 • overall conclusion on cost considerations, limited to a determination that the proposed
44 backfitting is either—of the following:
 - 45
 - 46 ○ the least costly of the identified alternatives for achieving reasonable assurance
47 of adequate protection; ~~or~~
 - 48
 - 49 ○ comparable in cost to the identified alternatives for achieving reasonable
50 assurance of adequate protection.

1
2 Include a table organizing the cost results for each identified alternative and showing major
3 categories or elements of costs if it will help the reader to understand the NRC's consideration
4 of costs.
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
7 C. Summary
8

9 Document the basis for the NRC's determination that the proposed backfitting is the most
10 cost-effective method of achieving this protection. If one of the alternatives is the most
11 cost-effective, then explain why that alternative is not being pursued.
12

13 VII. CONCLUSION
14

15 If the NRC determines that one or both of the proposed or final backfitting involves adequate
16 protection exceptions applies to the proposed backfitting action in accordance with the
17 applicable regulations and provisions, then document this decision, and a summary of its basis,
18 and state that the NRC has not prepared a backfit analysis to support the proposed backfitting.
19

Commented [KA216]: Comment 4.2.19

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

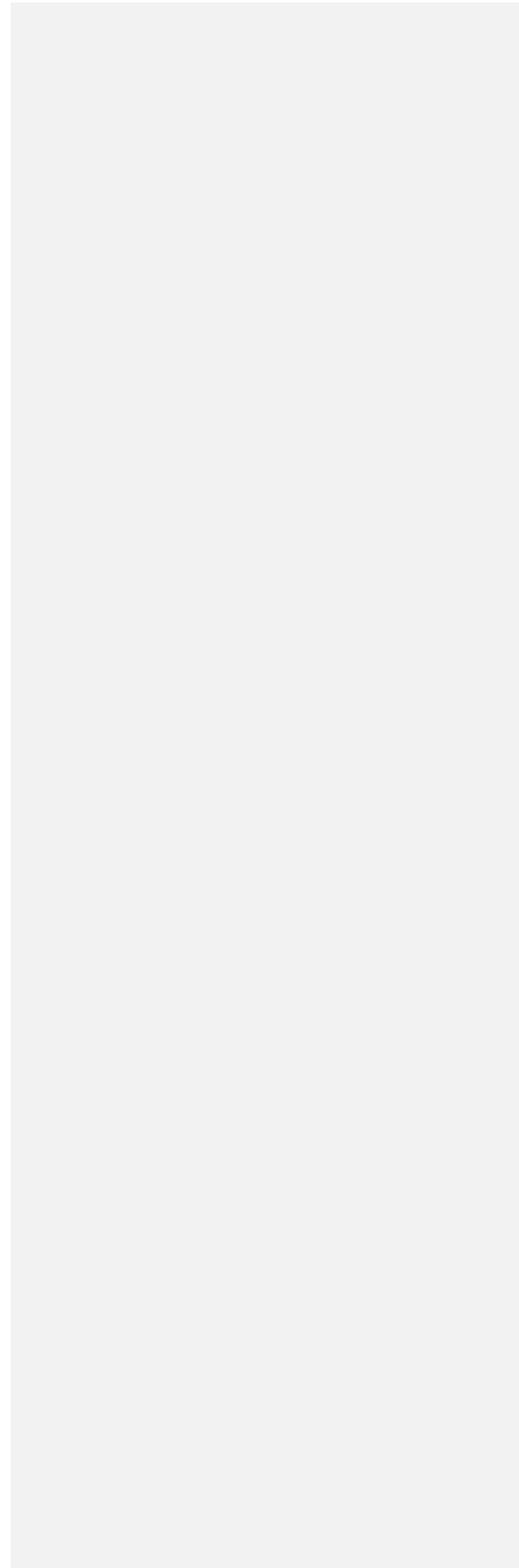
28 VIII. REFERENCES
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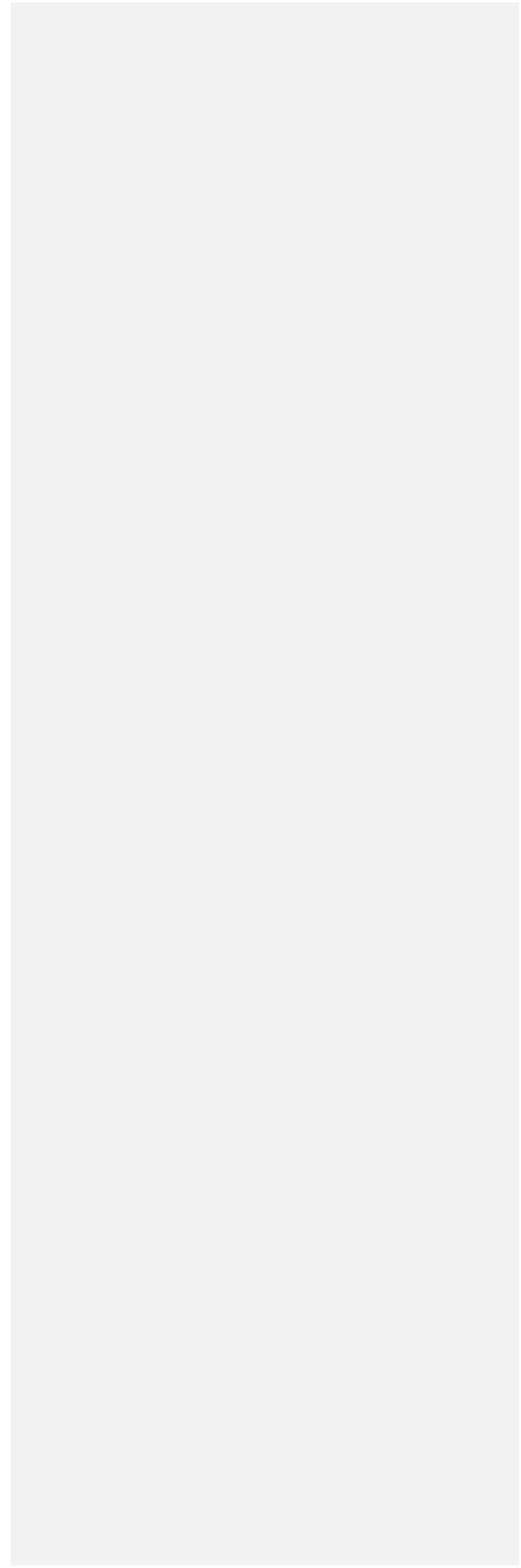
30 List the sources referenced in the documented evaluation.
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GUIDE 2

**DOCUMENTED EVALUATION FOR USING
THE COMPLIANCE EXCEPTION**





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DOCUMENTED EVALUATION

TITLE OF PROPOSED BACKFITTING

AFFECTED ENTITY/LICENSEE NAME

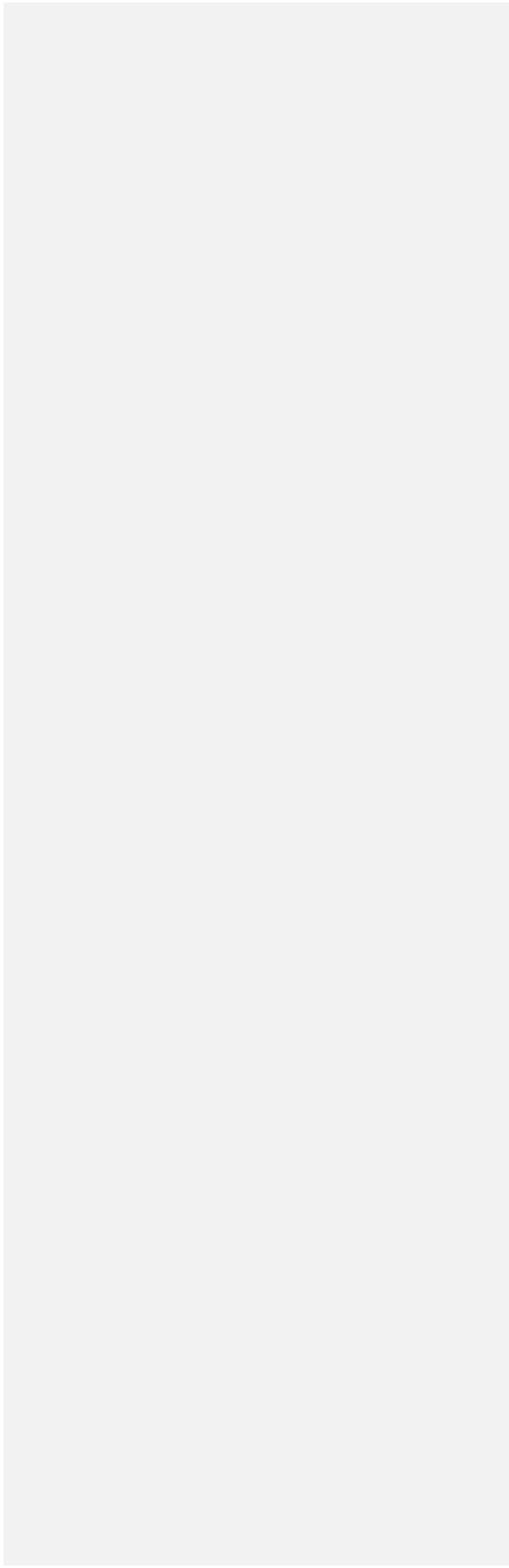
FACILITY NAME

DOCKET NOS.

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

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- III. PROPOSED BACKFITTING
- IV. ADEQUATE PROTECTION EXCEPTION APPLICABILITY
- V. COMPLIANCE EXCEPTION APPLICABILITY
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 - 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



1 I. INTRODUCTION [NUREG-1409, Revision 1, "Backfitting Guidelines," Section 2.5.2.3]
2
3 Summarize the proposed backfitting action (a more detailed description will be provided later),
4 the requirement with which NRC seeks licensee compliance, and the staff's conclusion. Briefly
5 describe the enforcement, licensing, or rulemaking context.
6

7 II. BACKGROUND
8
9 Concisely describe the historical and procedural facts that led to the proposed NRC backfitting.
10 Summarize the entity's or entities' licensing bases and the safety or security context for the
11 proposed backfitting action.
12

13 III. PROPOSED BACKFITTING [NUREG-1409, Revision 1, Sections 2.3, 2.4]
14
15 Describe the proposed backfitting, and why this is considered backfitting. The description will
16 include the following:
17

- 18 • the key substantive elements of the proposed backfitting and its purpose;
- 19
- 20 • the entities upon which ~~chem~~ the proposed backfitting would be imposed;
- 21
- 22 • risk insights;
- 23
- 24 • the regulatory method (e.g., order, adoption of final regulation) by which the backfitting
25 would be imposed; ~~and~~
- 26
- 27 • the expected time, event, or occurrence by which implementation of the proposed
28 backfitting must be completed-
29

30 IV. ADEQUATE PROTECTION EXCEPTION APPLICABILITY [NUREG-1409, Revision 1,
31 Sections 2.5.1.2 and 2.5.1.3]
32

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

Commented [KA217]: Comment 4.2.19

35
36 V. COMPLIANCE EXCEPTION APPLICABILITY [NUREG-1409, Revision 1,
37 Sections 2.5.2.1 and 2.5.2.2]
38

39 A. Requirement

40
41 1. Applicable Requirement
42

43 Describe the NRC requirement with which the NRC seeks the licensee's compliance. Cite the
44 source of the requirement.
45

46 2. Timing of Requirement
47

48 Document whether the requirement existed and was known by the NRC and licensee and
49 established at the time of the NRC's approval.
50

1 3. Application and Interpretation of the Requirement

2
3 Document whether the NRC consistently interpreted and applied the identified requirement at
4 the time of the NRC's approval. Provide a concise and clear history of the NRC's interpretation
5 and application of the ~~NRC~~ requirement.

6
7 4. Approval

8
9 Describe the NRC's approval of the licensee's method of compliance with the requirement.
10 Describe when and in which NRC documents the ~~NRC agency~~ approved the licensee's
11 compliance. If there were any limitations or caveats to the NRC's approval that are relevant and
12 necessary to understand the nature and scope of the ~~NRC's~~ original approval, then document
13 those with the explanation for the limitations or caveats.

14
15 B. Error or Omission

16
17 1. Description of Error or Omission

18
19 Describe the NRC's error and, if applicable, the licensee's or third party's error or omission
20 leading to the NRC's error. More than one error or omission may have occurred. Also describe
21 when the error occurred. The description of the NRC's error must document the following:

Commented [BH218]: Comment 4.7.2.

- 22
23 • the NRC's incorrect perception or understanding of the facts;
24
25 • the NRC's flawed analyses or failure to recognize flawed analyses;~~or~~
26
27 • the NRC's failure to draw direct inferences from those facts or analyses.

28
29 Document the basis showing that the omission or error occurred either at the time of ~~the NRC's~~
30 ~~approval~~ or before the NRC's approval (e.g., the licensee or third party made the error while
31 preparing its flawed analyses).

32
33 2. Applicability of Standards and Practices

34
35 Document the basis showing that the staff's error would have been deemed an error as judged
36 by the methodologies, standards, and practices ~~that were~~ prevailing among professionals or
37 experts in the relevant area at the time of the NRC's approval. Also note whether the staff's
38 error occurred while the staff was using standards and practices that, at the time of the original
39 NRC determination, were not commonly recognized as the prevailing professional standards
40 and practices. In that case, the staff cannot invoke the compliance exception.

41
42 3. Relationship of Error to Approval

43
44 Explain why the NRC would not have issued its approval if it had known of the error or omission.
45 Demonstrate that the facts, analyses, or inferences that are claimed to be an error are now
46 properly perceived, performed, or drawn, and the error or omission is directly and substantially
47 responsible for the NRC approval that the NRC now regards as incorrect.

48

1 C. Summary

2
3 Document whether it is appropriate to invoke the compliance exception to performing a backfit
4 analysis based on the discussion above.

5
6 VI. COST CONSIDERATIONS [NUREG-1409, Revision 1, Sections 2.5.2.2 and 2.6.2]

7
8 A. Description of the Cost Consideration Approach

9
10 Summarize the NRC's overall approach to considering cost as part of this documented
11 evaluation. If costs are not quantified, explain why they are not, and indicate any additional
12 factors and considerations that will be addressed to put the cost consideration in an appropriate
13 perspective.

14
15 B. Cost of the Proposed Backfitting

16
17 Document the methodology for considering costs with respect to the timing of the NRC's
18 approval (e.g., the level of cost consideration increases from minimal consideration involving
19 issues with very recent NRC approvals to a more thorough consideration of costs for issues with
20 NRC approvals that occurred a significant time ago). Discuss the quantitative data and
21 information for costs, then provide a qualitative consideration of costs of the proposed action
22 and the factors affecting the costs, such as the following:

- 23
- 24 • the overall magnitude of costs imposed on the ~~licenseeregulated entities~~;
 - 25
 - 26 • the availability of cost information and the costs of obtaining information if the NRC does
27 not have the information;
 - 28
 - 29 • the time between the original NRC decision and the imposition of the backfitting and the
30 NRC and ~~licenseeregulated entities~~ experience with the costs of current compliance (if
31 applicable); ~~and~~
 - 32
 - 33 • stakeholder feedback associated with the proposed compliance backfitting.
 - 34

35 C. Benefits of the Proposed Backfitting

36
37 Discuss the quantitative and qualitative information in Section 4V.B of this guide as it relates to
38 the benefits of the proposed action.

39
40 VII. CONCLUSION

41
42 If the NRC determines that the proposed ~~or final~~ backfitting is needed to ensure compliance with
43 the applicable regulations or provisions, then document this decision, and a summary of its
44 basis, and state that the NRC has not prepared a backfit analysis to support the proposed
45 backfitting.

46
47 If the NRC has determined that the proposed backfitting is not necessary for compliance under
48 the applicable backfitting provisions, then document this decision and its basis.

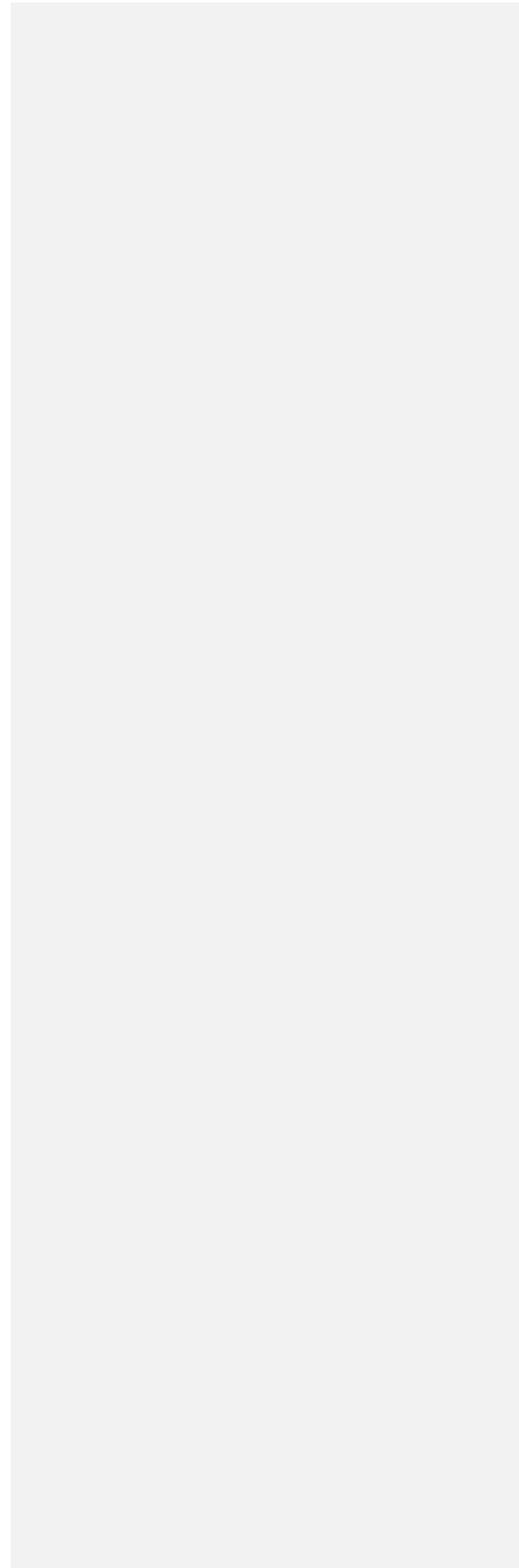
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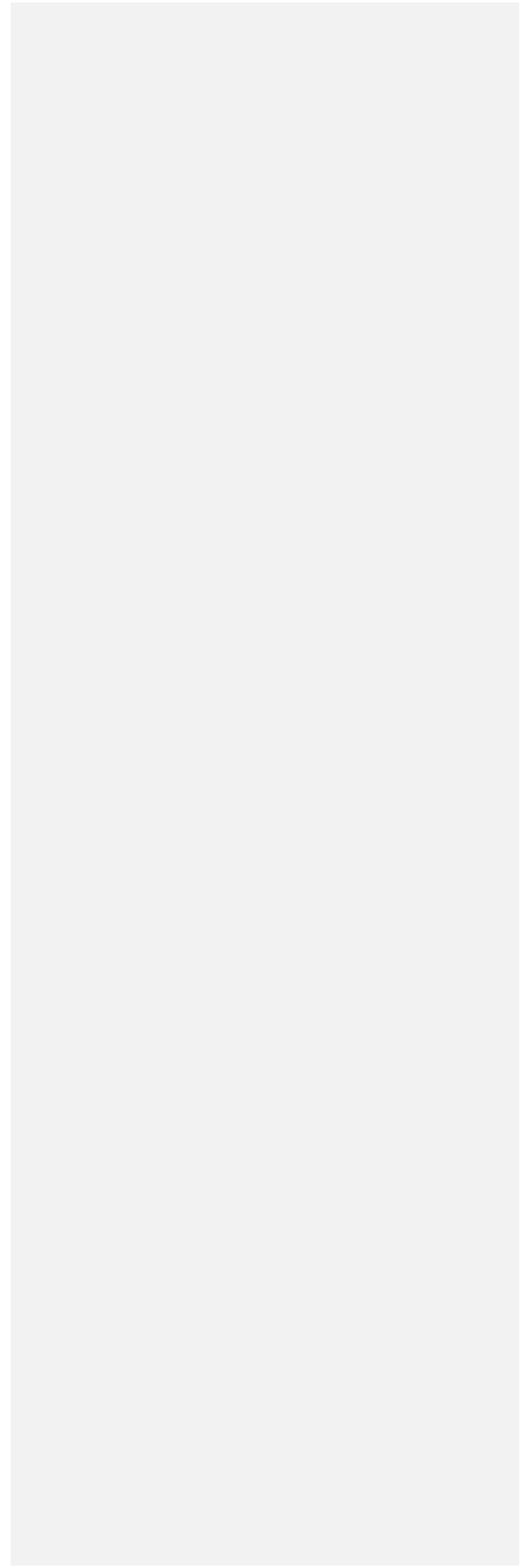
1 VIII. REFERENCES

2

3 List the sources referenced in the documented evaluation.

4

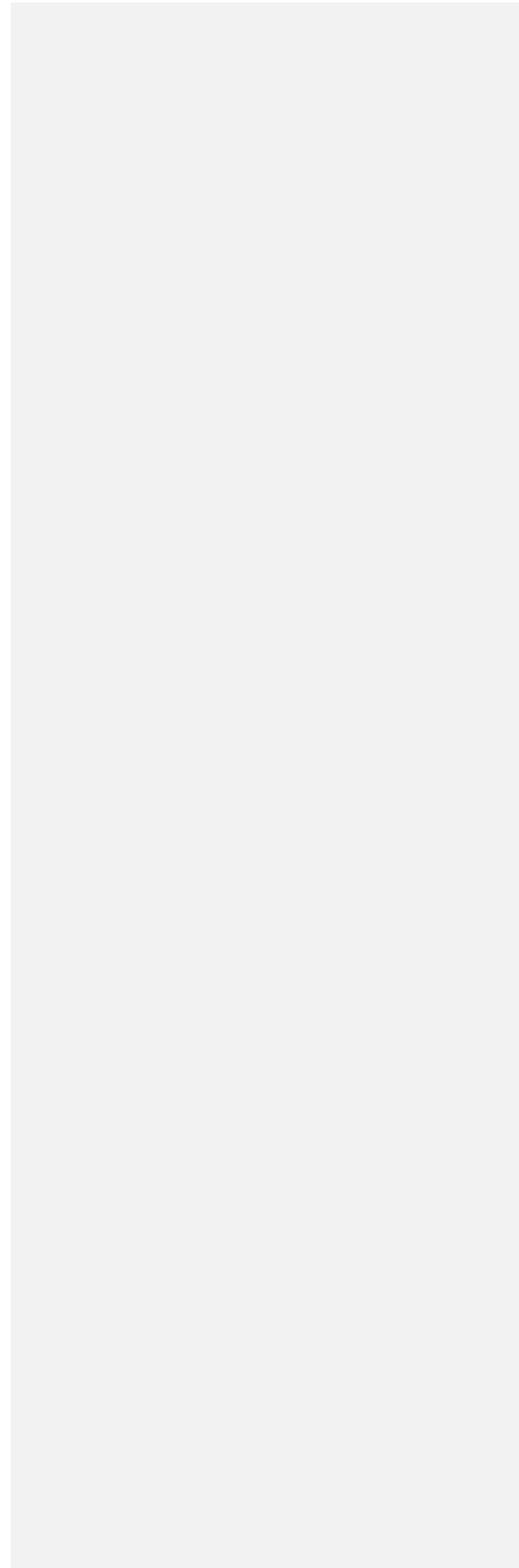


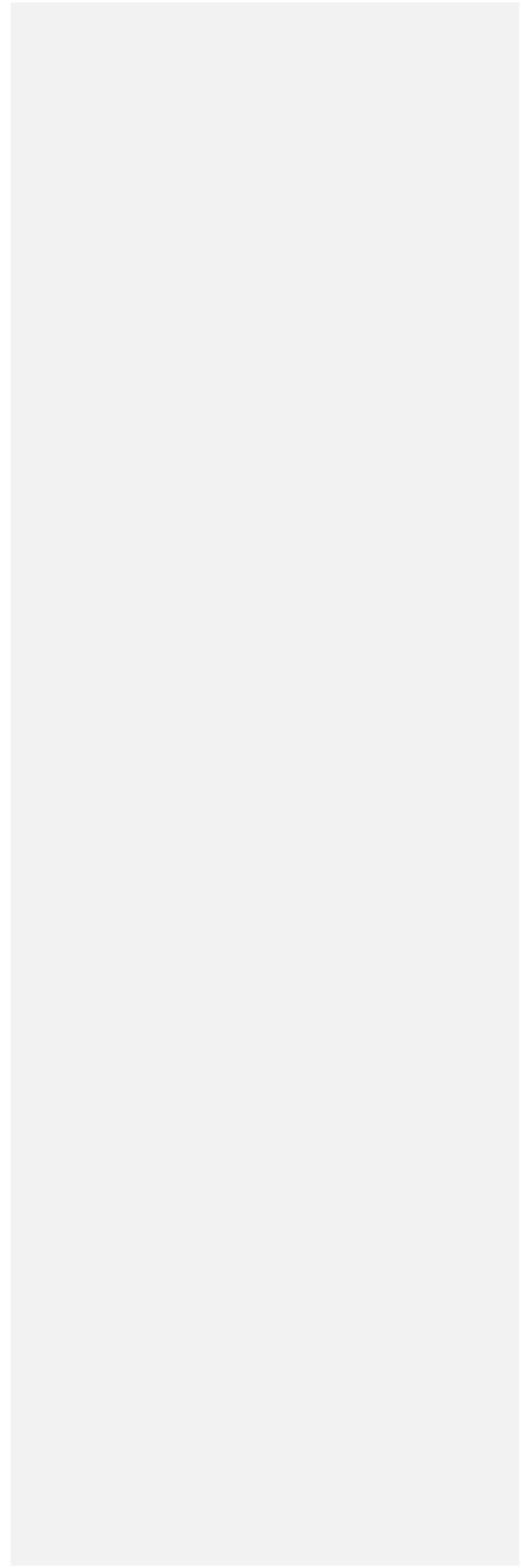


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GUIDE 3

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





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BACKFIT ANALYSIS

TITLE OF PROPOSED BACKFITTING

AFFECTED ENTITY/LICENSEE NAME

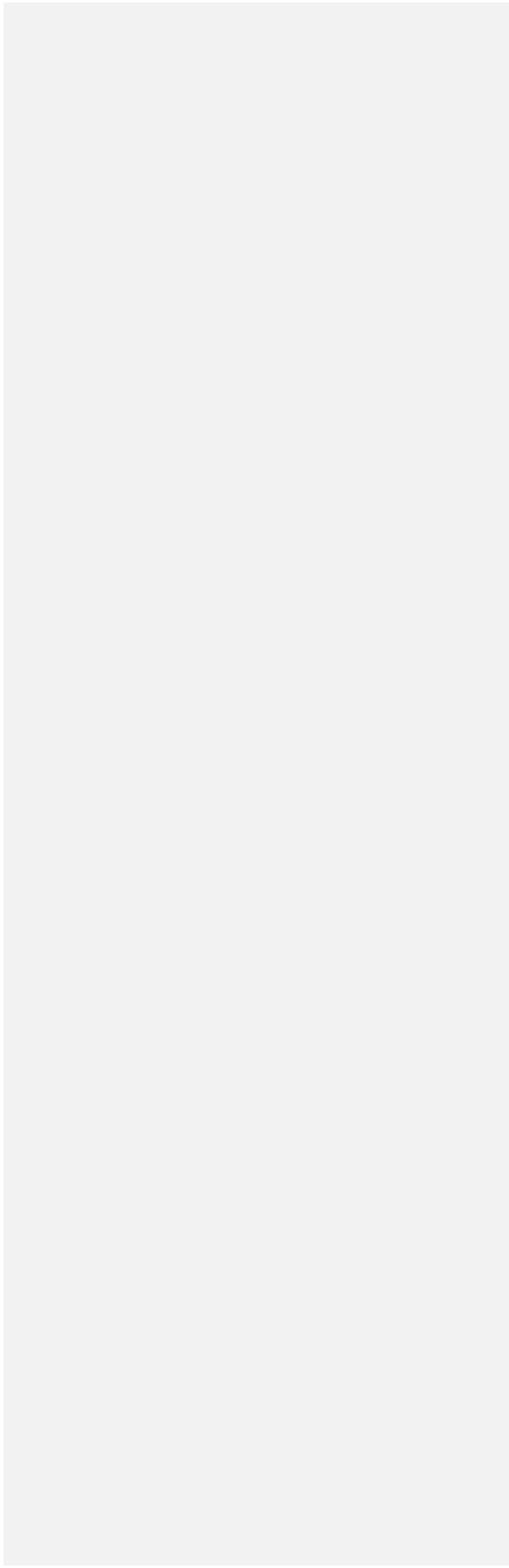
FACILITY NAME

DOCKET NOS.

CONTENTS

A table of contents is recommended when the ~~documented evaluation~~ backfit analysis is longer than ~~3~~ three pages.

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



1 I. INTRODUCTION [NUREG-1409, Revision 1, "Backfitting Guidelines," Section 2.6.3]
2
3 Summarize the proposed backfitting action (a more detailed description will be provided later)
4 and the staff's conclusion. Briefly describe the enforcement, licensing, or rulemaking context.
5
6 II. BACKGROUND
7
8 Concisely describe the historical and procedural facts that led to the proposed NRC backfitting.
9 Summarize the entity's or entities' licensing bases and the safety or security context for the
10 proposed backfitting action.
11
12 If the NRC is issuing a proposed rule, then describe ~~its~~ the proposed rule's purpose.
13
14 III. PROPOSED BACKFITTING [NUREG-1409, Revision 1, Sections 2.3, 2.4]
15
16 Describe the proposed backfitting, why this is considered backfitting, and the applicable
17 backfitting regulation (e.g., 10 CFR 50.109(a)(1), 10 CFR 70.76(a)(1), ~~etc.~~). The description will
18 include the following:
19
20 • the key substantive elements of the proposed backfitting and its purpose;
21
22 • the entities upon ~~which~~ the proposed backfitting would be imposed;
23
24 • risk insights;
25
26 • the regulatory method (e.g., order, adoption of final regulation) by which the backfitting
27 would be imposed; ~~and~~
28
29 • the expected time, event, or occurrence by which implementation of the proposed
30 backfitting must be completed.
31
32 For rulemaking involving the adoption of new regulations or revisions to existing regulations,
33 describe the specific provisions in the proposed regulation(s) falling within the definition of
34 "backfitting" and the action or prohibition in the identified regulatory provision(s). Also explain
35 why the provisions constitute backfitting under the applicable backfitting definition.
36
37 For generic actions such as imposition of positions given in a guidance document, identify the
38 specific provision(s) of the proposed guidance falling within the definition of "backfitting," and
39 describe the recommended action or prohibition in that provision of the guidance. Explain why
40 the provisions constitute backfitting under the applicable backfitting definition. For a guidance
41 document, explain the manner in which the "guidance" is to be imposed on the relevant entities.
42
43 For facility-specific action such as an order, identify the specific provisions of the order falling
44 within the definition of "backfitting," and describe the required action or prohibition in that
45 provision of the order. Then, explain why the order's provisions constitute backfitting under the
46 applicable backfitting definition.
47

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

3
4 Describe why the proposed backfitting action does **not** involve the adequate protection or the
5 compliance exceptions to the requirement to perform a backfit analysis.

6
7 V. BENEFITS [NUREG-1409, Revision 1, Section 2.6.2]

8
9 Describe the benefits of the proposed backfitting action. Document that the NRC identified
10 quantitative and qualitative benefits of the proposed backfitting action, if applicable.

11
12 The benefits discussion should reflect a consideration of the nine factors in 10 CFR 50.109(c)(1)
13 through (9); 10 CFR 70.76(b)(1) through (9); and 10 CFR 76.76(b)(1) through (9), as applicable.
14 If the staff prepared a separate discussion of each of the nine factors as an attachment to the
15 backfit analysis, then the attachment should be referenced at each appropriate point in the
16 benefits discussion to demonstrate how the information developed in response to those nine
17 factors was ultimately reflected in the discussion of benefits.

18
19 If the backfit analysis does not show a substantial increase in benefits, **then** document the basis
20 for this finding, and do not include the guide's sections on cost and the cost-justification in the
21 backfit analysis.

22
23 A. Quantitative Benefits

24
25 Describe the present value of the quantified benefits to public health and safety² or the common
26 defense and security that would be realized if the proposed backfitting is implemented. List and
27 describe each of the quantitative benefits. Section VII of this guide describes the
28 characterization of the quantitative benefits as a substantial increase. If the backfit analysis
29 does not include a quantitative evaluation of benefits, then this section of the backfit analysis
30 must explain why such a quantitative evaluation was not performed.

31
32 To the extent that the backfitting will achieve markedly different benefits for different kinds or
33 classes of affected entities, the quantitative discussion of benefits should reflect those
34 differences, including an explanation of why the benefit differs between the different classes of
35 entities.

36
37 Summarize the limitations of whatever quantitative information is used. Discuss the uncertainty
38 of quantitative benefits. Usually, this will be a summary of the uncertainty discussion in the
39 regulatory analysis and a presentation of the numerical range of uncertainty in the cost figures if
40 the backfitting is in the context of a rulemaking.

41
42 Quantitative benefits should be presented in a table to facilitate the reader's understanding of
43 each benefit element and the overall integration of benefits for the proposed backfitting. Table 1
44 is an example of such a table, although other formats may be more appropriate.

45

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

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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 safety³ or the common defense and security that would be realized if the proposed backfitting is implemented. List and describe each of the qualitative benefits. Section VII of this guide describes the characterization of the qualitative benefits as a substantial increase.

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

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

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

2

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>		

3
4 VI. COSTS [NUREG-1409, Revision 1, Section 2.6.2]

5
6 Document that the NRC identified quantitative costs (i.e., costs that are amenable to
7 quantitative evaluation) and qualitative (i.e., non-quantifiable) costs, if applicable, that would be
8 incurred if the proposed backfitting were implemented.

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

16
17 A. Quantitative Costs

18
19 Document the NRC's estimates for the costs of implementing the proposed backfitting
20 (e.g., document a range in dollars and any discount rate percentages). If the backfit analysis
21 does not include a quantitative evaluation of costs, then this section of the backfit analysis must
22 explain why a quantitative evaluation was not performed. List and describe the costs, which
23 may be organized according to their nature of the costs or their relative magnitude.

24
25 To the extent that the backfitting will impose markedly different costs for different kinds or
26 classes of affected entities, the quantitative discussion of costs should reflect those differences,
27 including an explanation of why the cost differs between the different classes of entities.

28
29 Summarize the limitations of whatever quantitative information is used, including a discussion of
30 the uncertainty of quantitative costs. Usually, this will be a summary of the uncertainty
31 discussion in the regulatory analysis and a presentation of the numerical range of uncertainty in
32 the cost figures if the backfitting is in the context of a rulemaking.

33
34 Quantitative costs should be presented in a table to facilitate the reader's understanding of each
35 cost element and the overall integration of costs. Table 3, below, is an example of such a table,
36 although other formats may be more appropriate.
37

1 **Table 3. Quantitative Costs of the Proposed Backfitting**
2

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>

3
4 B. Qualitative Costs

5
6 Mention that the NRC assessed the qualitative costs ~~were assessed~~ using the methods
7 described in Appendix A to NUREG/BR-0058. Describe the qualitative costs to public health
8 and safety⁴ or the common defense and security that would be realized if the proposed
9 backfitting is implemented. List and describe each of the qualitative costs.

10
11 Qualitative costs should be presented in a table to facilitate the reader's understanding of each
12 qualitative cost element and the overall consideration of qualitative costs for the proposed
13 backfitting. Table 4, below, is an example of such a table, although other formats may be more
14 appropriate.
15

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

1
2

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>		

3
4

VII. COST-JUSTIFICATION DETERMINATION

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9

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.

10
11
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13
14
15
16

Document whether the quantitative and qualitative benefits constitute a substantial increase in overall protection, and whether the costs of implementing the proposed backfitting are justified given the substantial increase in overall protection to the public health and safety⁵ or the common defense and security attributable to the proposed backfitting. Describe the rationale for the conclusion that the costs of the backfitting are justified, which refers to Table 5 below, a comparison of costs and benefits.

17
18
19

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>

20

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

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

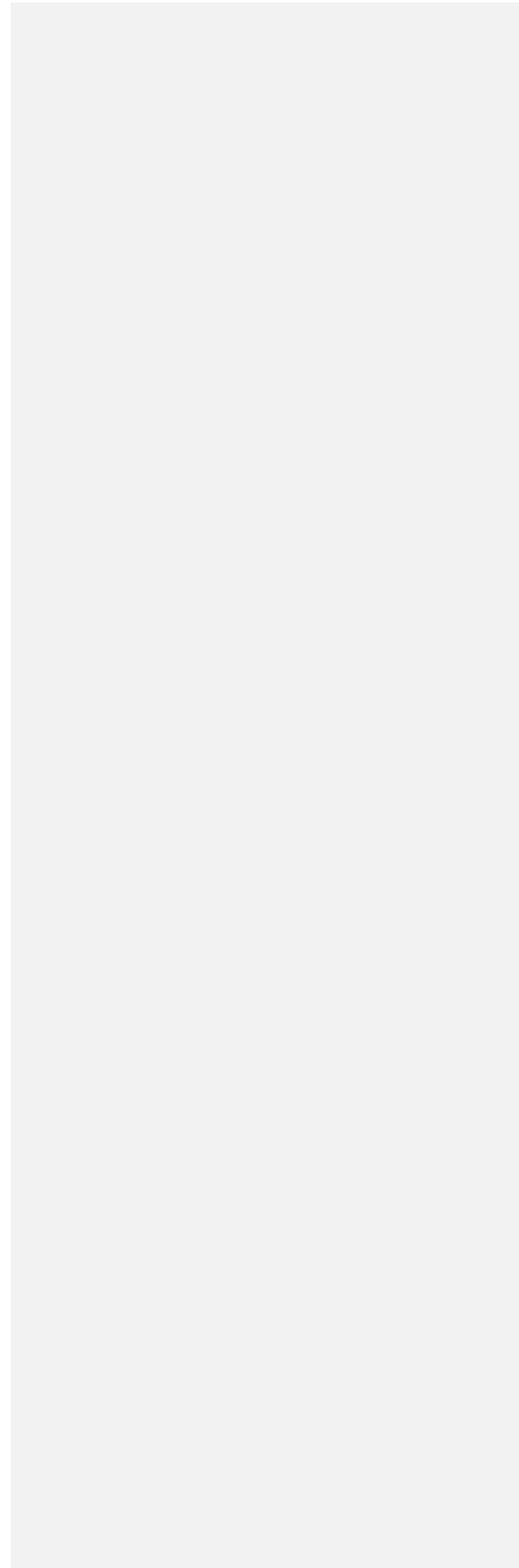
24
25 Consider including an attachment containing the evaluation of factors in 10 CFR 50.109(c)(1)
26 through (9), 10 CFR 70.76(b)(1) through (9), and 10 CFR 76.76(b)(1) through (9), as applicable.
27 This optional attachment ~~is optional and~~ may be included at the discretion of the staff. The staff
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
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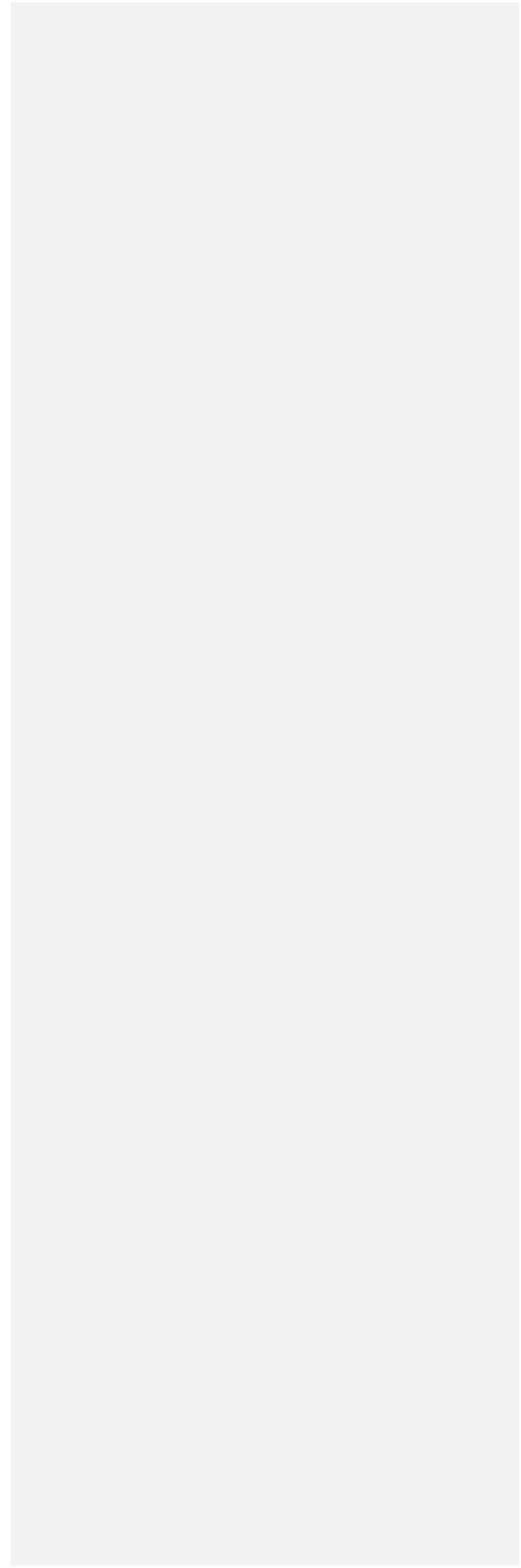
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GUIDE 4

FORWARD FIT ~~ANALYSIS~~ASSESSMENT

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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

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

2
3 In the first paragraph, reference the licensing action, summarize its subject, and list related
4 correspondence.

5
6 In the next paragraph, concisely describe the proposed forward fitting action (a more detailed
7 description will be provided later) and the staff's conclusion.

8
9 II. BACKGROUND

10
11 Concisely summarize the historical and procedural facts that led to the proposed forward fitting.
12 Include a more detailed discussion (than in the introduction) of the staff's concerns about
13 applicable aspects of the requested licensing action with which the staff took issue.

14
15 III. PROPOSED FORWARD FITTING

16
17 A. ~~Forward Fitting Definition Screening~~ [NUREG-1409, Revision 1, Section 3.2]

18
19 Describe in detail the key elements of the proposed staff action meeting the definition of a
20 "forward fitting," explained in a manner that makes it clear why the proposed staff action, if
21 adopted and imposed, meets the definition of a "forward fitting." The definition must be
22 identified by citation of Management Directive 8.4, "Management of Backfitting, Forward Fitting,
23 Issue Finality, and Information Requests," Directive Handbook Section I.B.1, dated
24 September 20, 2019.

25
26 B. Justification [NUREG-1409, Revision 1, Section 3.3]

27
28 1. Direct Nexus

29
30 Describe how the proposed staff action meets the definition of "direct nexus," is directly related
31 to the licensee's licensing action request.

32
33 2. Essential to the NRC's Determination

34
35 Describe how the proposed staff action meets the definition of "is essential," to the NRC's
36 determination of the acceptability of the licensee's request.

37
38 3C. Cost Consideration [NUREG-1409, Revision 1, Section 3.35]

39
40 ~~Would approval of the requested licensing action require the forward fit to maintain adequate~~
41 ~~protection of public health and safety? If so, then document that conclusion and how the~~
42 ~~proposed action enables this to occur, and do not consider the costs of the proposed action. If~~
43 ~~not, would approval of the requested licensing action require the forward fit to ensure~~
44 ~~compliance with governing requirements? If so, then document that determination, how the~~
45 ~~proposed action enables this to occur, and the staff's consideration of the costs of the proposed~~
46 ~~action.~~

47
48 Costs are considered only for purposes of informing the decision whether to take the forward
49 fitting action. Compare the costs of all methods of implementing the forward fit. The least costly
50 alternative should be selected. When there is only one method to implement the forward fit,
51 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.

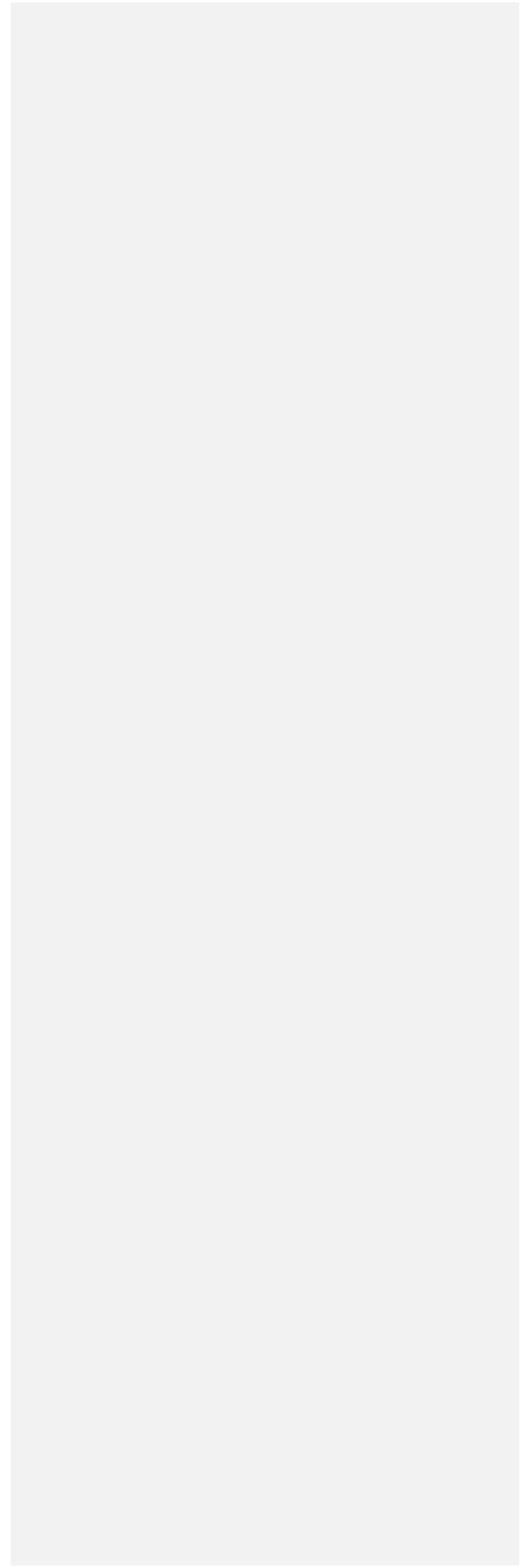
Commented [BH220]: Edits in Section III.C of this guide reflect changes to Section 3.5 of this NUREG.

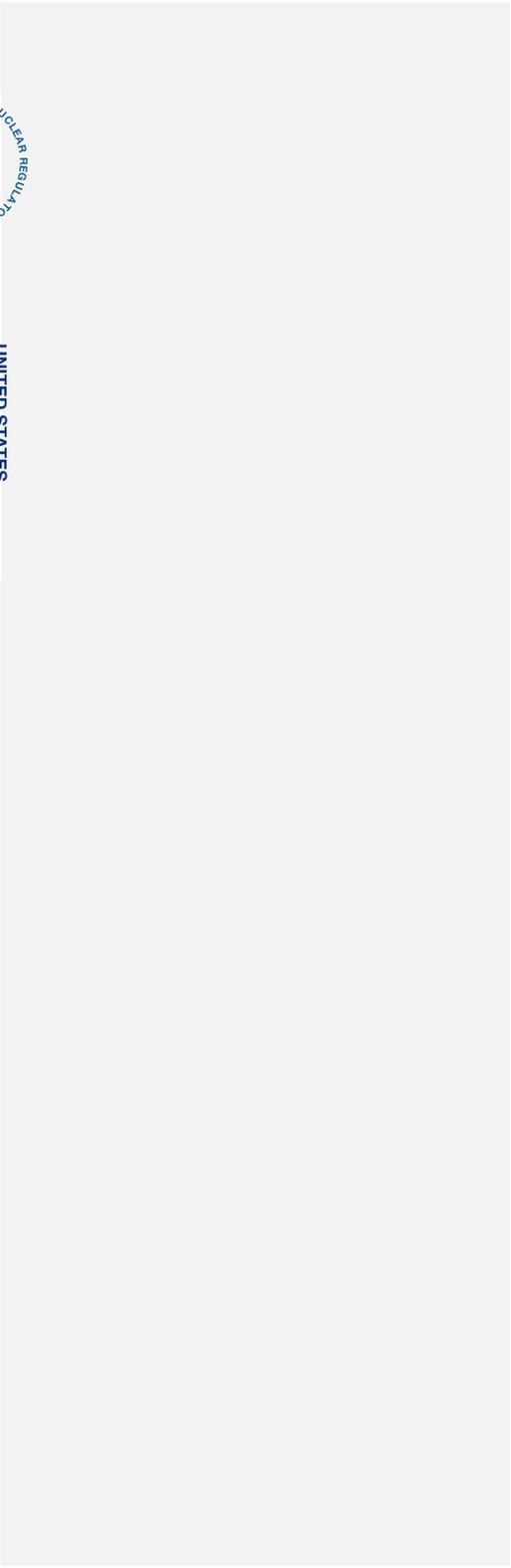
1 ~~costs associated with its request, then exclude those costs from the cost estimate for the~~
2 ~~forward fit.~~
3
4 A regulatory analysis may be used to demonstrate the staff's cost consideration.
5 NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory
6 Commission," provides guidance on the preparation of a regulatory analysis.
7
8 ~~If the proposed action consists of a new or modified regulatory staff position and the prior~~
9 ~~regulatory staff position is available for use by the applicant and applicable to the licensing~~
10 ~~action under review, then perform a site-specific regulatory analysis of the proposed~~
11 ~~action. Describe the conclusion of that analysis.~~
12
13 ~~If the proposed action consists of a new or modified regulatory staff position and the prior~~
14 ~~regulatory staff position is no longer available for use by the applicant, if the forward fit would~~
15 ~~impose a generic staff position on the affected entity (i.e., a staff position that is not within that~~
16 ~~affected entity's licensing basis), then perform the facility-specific the staff should have~~
17 ~~performed a regulatory analysis using the generic regulatory analysis done by the staff when the~~
18 ~~staff issued the generic new or modified staff position, that replaced the prior staff position.~~
19 ~~The staff should use that generic regulatory analysis, if available, to inform the site-specific~~
20 ~~regulatory analysis. If no prior staff position existed and, thus, no applicable regulatory~~
21 ~~analysis exists, then document the costs of the proposed action.~~
22
23 ~~If more than one forward fit was considered, describe the alternatives and the costs and benefits~~
24 ~~associated with them.~~
25
26 IV. CONCLUSION
27
28 Document whether the analysis assessment above justifies a forward fit and the basis for that
29 conclusion.
30
31 V. REFERENCES
32
33 List the documents referenced in this analysis assessment.
34
35

<p>NRC FORM 335 (12-2010) NRCMD 3.7</p> <p style="text-align: center;">U.S. NUCLEAR REGULATORY COMMISSION</p> <p style="text-align: center;">BIBLIOGRAPHIC DATA SHEET <i>(See instructions on the reverse)</i></p>	<p>1. REPORT NUMBER (Assigned by NRC, Add Vol., Supp., Rev., and Addendum Numbers, if any.)</p> <p style="text-align: center;">NUREG-1409, Rev. 1</p>				
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<p>11. ABSTRACT (200 words or less)</p> <p>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."</p>					
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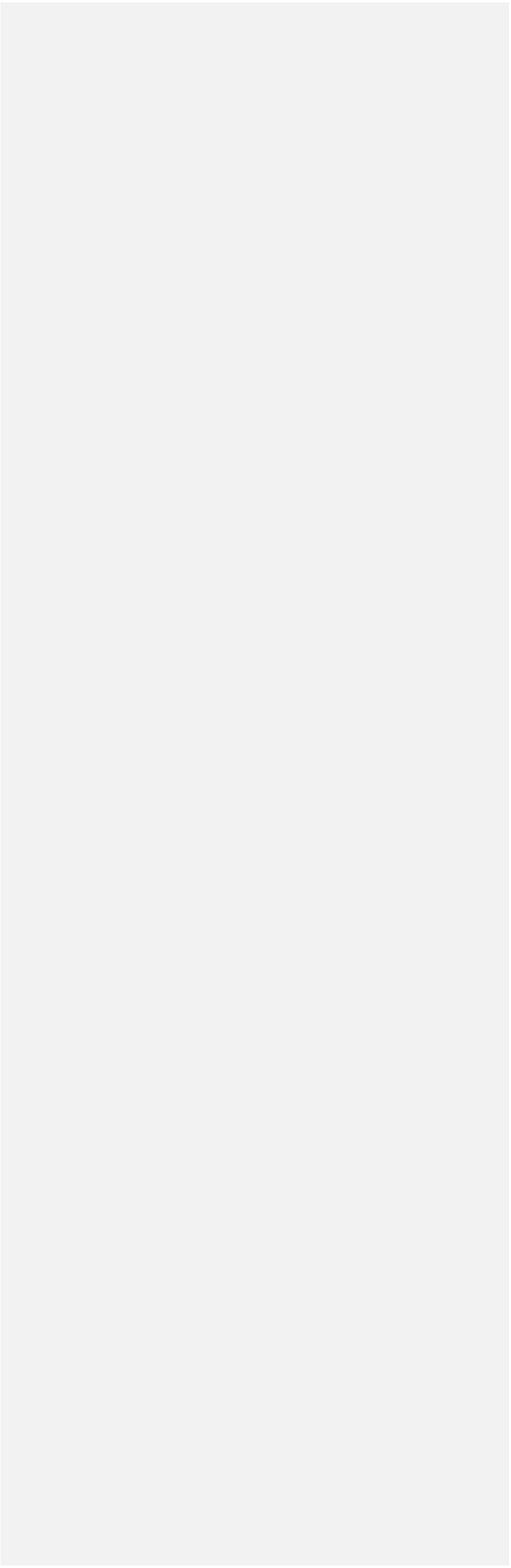
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