NRC Response to Public Comments

Draft NUREG-1409, "Backfitting Guidelines," Revision 1

(Docket No. NRC-2018-0142)

ADAMS Accession No. ML21006A434
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NRC RESPONSE TO PUBLIC COMMENTS
DRAFT NUREG-1409, "BACKFITTING GUIDELINES," REVISION 1
(Docket No. NRC-2018-0142)

1.0 Introduction

This document presents the U.S. Nuclear Regulatory Commission's (NRC's) responses to written public comments received on draft NUREG-1409, "Backfitting Guidelines," Revision 1, published in Enclosure 1 to SECY-20-0021, "Draft NUREG-1409, 'Backfitting Guidelines,' Revision 1," dated March 16, 2020. The NRC made the draft NUREG-1409 available for public comment on March 23, 2020 (Volume 85 of the *Federal Register* (FR), page 16278 (85 FR 16278); Agencywide Documents Access and Management System (ADAMS) Accession No. ML18109A498), for a 60-day public comment period. In recognition of the impacts of the Coronavirus Disease 2019 (COVID-19) public health emergency across the Nation, the NRC extended the public comment period by the *Federal Register* notice (FRN) published on May 15, 2020 (85 FR 29358), to allow more time for members of the public to develop and submit comments.

In developing the final version of NUREG-1409, Revision 1, the NRC considered all comments provided in response to the draft NUREG. If, as a result of its review of a public comment, the NRC changed the NUREG, then the NRC's comment response describes the change the staff made in the NUREG.

2.0 Comment Overview

In response to publication of the draft NUREG, the NRC received the 13 comment submissions identified in Table 1. The NRC staff reviewed the comment submissions and annotated distinct comments with alphanumeric identifiers. Accordingly, a single submission may have several distinct comments associated with it, and the NRC's comment responses identify which distinct comments are addressed by each comment response. Several comment submissions endorsed Comment Submission No. 8. The NRC did not annotate comments endorsing Comment Submission No. 8.

During the public comment period, on April 28, 2020, the NRC held a Category 3 public meeting to discuss the draft NUREG with external stakeholders. The meeting summary is available at ADAMS Accession No. ML20141L770. The NRC provided stakeholders with additional information about the draft NUREG to facilitate informed comments on the draft NUREG.

Table 1. Comment Submissions on Draft NUREG-1409, Revision 1

Comment Submission No.	Submitter Affiliation	Comment No. Identifier	Incoming ADAMS Accession No.	Annotated Version ADAMS Accession No.*
1	Nuclear Energy Institute (NEI)	N/A**	ML20101F148	N/A**
2	URENCO USA (UUSA)	UUSA-##	ML20182A115	ML20352A190
3	STARS Alliance, LLC (STARS)	STARS-##	ML20211M254	ML20352A202 (also endorses Submission No. 8)
4	Ralph Caruso	RC-##	ML20211M281	ML20352A204
5	Anonymous NRC Staff Member(s)	ANSM-##	ML20211M291	ML20352A210
6	Samuel Miranda	SM-##	ML20211M308	ML20352A008
7	Southern Nuclear Operating Company	N/A	ML20211M324	ML20352A009 (endorses Submission No. 8)
8	Nuclear Energy Institute (NEI)	NEI-##	ML20211M340	ML20352A010
9	PSEG Nuclear LLC	N/A	ML20211M371	ML20352A013 (endorses Submission No. 8)
10	Roy Mathew	RM-##	ML20211M390	ML20352A017
11	Exelon Generation Company, LLC (EGC)	EGC-##	ML20213A748	ML20352A018 (also endorses Submission No. 8)
12	J.J. Stryker	JJS-##	ML20218A313	ML20352A021
13	Florida Power & Light Company and NextEra Energy (FPL)	FPL-##	ML20218A315	ML20352A055

* The NRC annotated distinct comments within the comment submissions with alphanumeric identifiers (e.g., NEI-1, with NEI being the comment submission affiliation and “1” being the distinct NRC-assigned comment number within the submission). The annotated comments are in ADAMS at Accession No. ML20352A006.

** In this comment submission, the NEI requested the NRC to extend the period for submitting comments. The NRC extended the comment period. The NEI did not provide any other comments in this submission.

3.0 Comment Categorization

The NRC organized the comments into general categories. In general, the NRC responded to each distinct comment unless the NRC grouped similar comments together, in which case, the NRC responded to the "binned" similar comments as a single comment. The NRC organized the comments into the following eight categories:

(1) Comments on the Abstract, the Executive Summary, and Chapter 1 of the Draft NUREG (including general comments)

(2) Comments on Chapter 2 of the Draft NUREG

(3) Comments on Chapter 3 of the Draft NUREG

(4) Comments on Chapter 4 of the Draft NUREG

(5) Comments on Chapter 5 of the Draft NUREG

(6) Comments on Chapter 6 of the Draft NUREG

(7) Comments on the Draft NUREG's References and Appendices

(8) Out-of-Scope Comments

4.0 NRC Response to Comments

4.1 Comments on the Abstract, the Executive Summary, and Chapter 1 of the Draft NUREG

Comment 4.1.1
The Abstract did not distinguish the backfitting requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) 50.109, "Backfitting" (Backfit Rule), from the issue finality provisions in 10 CFR Part 52, "Licenses, certifications, and approvals for nuclear power plants." (SM-65)

NRC Response
The NRC agrees with this comment. The abstract is a 1-page, high-level summary of NUREG-1409, Revision 1, so describing issue finality as a "concept similar to backfitting that applies only to certain nuclear power reactor-related approvals under 10 CFR Part 52" is sufficient. Sections 1.2.6 and 2.3 of the draft NUREG provide a more detailed description of issue finality. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.1.2
In the Executive Summary, issue finality is likened to backfitting ("Issue finality is a concept similar to backfitting that applies only to the holders of certain nuclear power reactor-related approvals under 10 CFR Part 52") and then linked to forward fitting ("Issue finality within 10 CFR Part 52 defines the changes the NRC can require for an approved facility license, permit, or design."). The NRC should clarify this discrepancy. (SM-66)

NRC Response
The NRC disagrees with this comment. The statement in the draft NUREG, "Issue finality within 10 CFR Part 52 defines the changes the NRC can require for an approved facility license, permit, or design," is not related to forward fitting. Issue finality concerns potential changes to an approved facility license, permit, or design (i.e., a facility license, permit, or design that has already been approved). Forward fitting concerns potential changes to an application under review by the NRC.

Nevertheless, the NRC recognizes that this statement in the draft NUREG could have been clearer and revised the statement in the draft NUREG executive summary.

Comment 4.1.3
10 CFR 50.109 regulates the NRC, not its licensees. The NRC is using the draft NUREG to implement an expanded set of requirements that do not exist in the NRC's regulations. This could be a violation of Executive Order 13891, "Promoting the Rule of Law Through Improved Agency Guidance Documents." (SM-67)

The NRC did not use notice-and-comment rulemaking, as required under 5 USC 551, to establish a rule that would codify forward fitting. The NRC does not have the authority to impose forward fitting requirements based upon the draft NUREG. The NRC can continue to conditionally approve license amendment requests. However, licensees cannot appeal any conditions that are attached to the NRC staff's license amendment request approvals by labeling them "forward fits" and then applying the forward fitting appeals guidance contained in NUREG-1409. The NRC has no authority over "forward fitting" and "forward fitting" appeals. This could be a violation of Executive Order 13892, "Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication." (SM-01, SM-02, SM-27, JJS-02)

The licensee may not formally submit a backfitting appeal in accordance with this NUREG, or any other NUREG. A NUREG is not a regulation. The licensee must formally submit a backfitting appeal in accordance with 10 CFR 50.109, or another applicable backfitting regulation. (SM-41)

NRC Response
The NRC disagrees with these comments. As noted in one of the comments, 10 CFR 50.109 does not impose legally binding requirements on members of the public. Therefore, the use of NUREG-1409 to provide guidance on the Backfit Rule does not impose requirements. Further, neither forward fitting nor NUREG-1409 is a legally binding requirement on the public. Therefore, notice-and-comment rulemaking is not required to establish the forward fitting process.

The NRC is authorized by the Atomic Energy Act of 1954, as amended (AEA), to license and regulate the civilian use of radioactive materials. Under this authority, the NRC can impose conditions on its approvals to provide reasonable assurance of adequate protection of the public health and safety and to promote the common defense and security. As backfitting and forward fitting provisions are not legally binding requirements on licensees, the process by which a

licensee can appeal a backfitting or forward fitting action need not be a regulation or other legally binding requirement on licensees.[1]

Executive Order 13891, dated October 15, 2019, and Executive Order 13892, dated October 16, 2019, were revoked by Executive Order 13992, "Revocation of Certain Executive Orders Concerning Federal Regulation," dated January 20, 2021.

The NRC did not revise the draft NUREG in response to these comments.

Comment 4.1.4
There is no clear explanation why these revisions to NUREG-1409 are needed. The NRC does not identify a problem, with supporting details, from previous backfitting actions or other licensing actions that were problematic. Without the details, this is an arbitrary and capricious rulemaking. (RC-01)

The draft NUREG does not identify the NRC requirements, guidance, criteria, and procedures that the Committee to Review Generic Requirements (CRGR) changed and were included in Management Directive (MD) 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests." The draft NUREG does not identify the rationale or even the origins of many of the revisions it publishes. (SM-04)

The draft NUREG omits any reference to Exelon's backfit appeals of 2015 and 2016 and how they were reviewed by the NRC staff and the NRC's Executive Director for Operations (EDO). The omission is significant because some of the guidance in NUREG-1409 can be traced directly to events of those appeals. At the same time, the draft NUREG fails to institutionalize lessons learned from the Exelon appeals. (SM-03, SM-08, SM-33, SM-46, SM-56)

NRC Response
The NRC disagrees with these comments. The draft NUREG, on page xii and in Section 1.1, explains the bases for the revisions to NUREG-1409. In summary, the NRC has not updated NUREG-1409 in 30 years and, as a result, the document does not address the backfitting provisions in 10 CFR Part 70, "Domestic licensing of special nuclear material"; 10 CFR Part 72, "Licensing requirements for the independent storage of spent nuclear fuel, high-level radioactive waste, and reactor-related greater than Class C waste"; or 10 CFR Part 76, "Certification of gaseous diffusion plants"; the issue finality provisions in 10 CFR Part 52; or the forward fitting policy. Also, the NRC's EDO tasked the NRC staff with assessing the agency's backfitting requirements, policy, guidance, criteria, training, and knowledge management, which led to updates to MD 8.4, dated September 20, 2019, and NUREG-1409.

The NRC also notes that the revisions to NUREG-1409 have a reasoned basis and are not arbitrary and capricious. The draft NUREG cites the backfitting and issue finality requirements and policy from the NRC's regulations and MD 8.4 and the forward fitting policy in MD 8.4 and provides guidance to implement these requirements and policies.

NUREG-1409 is intended to incorporate lessons learned into guidance that implements the Commission's current policies and regulations rather than pointing to historical documents pertaining to backfitting. The 2017 CRGR report (ADAMS Accession No. ML17174B161) is

[1] Other appeal processes exist outside of the NRC's regulations, such as how operating reactor licensees can appeal the NRC's safety significance determination of inspection findings as described in NRC Inspection Manual Chapter 0609, Attachment 2 (ADAMS Accession No. ML18187A186).

publicly available and discusses the lessons learned from past agency actions. The CRGR also annually reviews the NRC's implementation of backfitting.

The NRC did not revise the draft NUREG in response to these comments.

Comment 4.1.5
In light of *Michigan v. Environmental Protection Agency*, 135 S. Ct. 2699 (2015) (*Michigan v EPA*), the U.S. Supreme Court case mentioned in footnote 4 on page 1-3 of the draft NUREG, the NRC may consider noting that, although the NRC did not originally recognize a statutory basis for the Backfit Rule, current precedent interprets the Administrative Procedure Act to require consideration of costs where not otherwise directed by the AEA. (FPL-01)

NRC Response
The NRC agrees, in part, with this comment. The NRC does consider the costs to its regulated entities from complying with new requirements that are not required by the AEA. However, as stated in MD 8.4, the consideration of costs to its regulated entities to comply with a new requirement applies to all NRC actions, not just those that involve the backfitting process, that are not needed to ensure adequate protection. Even in situations where NRC action is necessary for adequate protection of the public health and safety or the common defense and security, the NRC would consider costs when there is more than one means to implement the adequate protection requirement. This consideration of costs would inform the decision on how to proceed in the most economically effective manner.

The NRC did not revise the draft NUREG in response to this comment.

Comment 4.1.6
10 CFR 50.109 applies to commercial or industrial production or utilization facilities, not just nuclear power reactors. The NRC should include an explanation of why the NRC has not applied 10 CFR 50.109 to AEA section 104 licensees. (NEI-01)

NRC Response
The NRC agrees with this comment. The NRC revised the draft NUREG to provide additional explanation about the NRC's application of the Backfit Rule to NRC actions that affect licensees under 10 CFR Part 50, "Domestic licensing of production and utilization facilities," other than nuclear power reactor licensees.

Comment 4.1.7
"Licensee" is defined in 10 CFR 50.4. Use of this term in NUREG-1409, Revision 1, in a manner that is inconsistent with the Part 50 definition may cause confusion. Because the Backfit Rule applies to only some licensees and applies to some non-licensed applicants, the term "affected entities," used in Table 1-1 of the draft NUREG, would be a more appropriate term to use. (ANSM-01)

The term "licensee" in the draft NUREG includes a Certificate of Compliance (CoC) under 10 CFR Part 76. Footnote 5 of the draft NUREG states that "this NUREG does not provide specific guidance for implementation of 10 CFR 76.76." By including the CoC under the generic term "licensee," it is not clear what guidance is intended to apply to the CoC under Part 76. All references to Part 76 should be removed since this regulation is obsolete given that the CoCs under Part 76 have been terminated and most likely cannot be restored. (ANSM-02)

NRC Response
The NRC agrees, in part, with these comments. To avoid confusion that could result from using the term "licensee" in NUREG-1409, Revision 1, as shorthand for the long list of applicants and licensees in Section 2.3 of the draft NUREG that are within the scope of backfitting, forward fitting, and, for 10 CFR Part 52 entities, issue finality, the NRC uses the term "affected entity."

However, the NRC did not remove all references to 10 CFR Part 76 from NUREG-1409, Revision 1. There are very few of these references, and NUREG-1409, Revision 1, refers only once to CoCs in the context of 10 CFR Part 76. Otherwise, in NUREG-1409, Revision 1, the NRC uses the term "Certificate of Compliance" and the abbreviation "CoC" in reference to 10 CFR Part 72.

The NRC revised the draft NUREG consistent with this response.

Comment 4.1.8
There are no clear definitions provided in NRC regulations or in any legally binding regulatory documents concerning the definition of key terms such as "licensing basis" and "staff positions" used when backfitting or forward fitting actions are taken by the NRC in accordance with 10 CFR 50.109. The NRC needs to add definitions for "licensing basis" and "staff positions" either in 10 CFR 50.2 or 10 CFR 50.109 or in any legally binding NRC document. Alternatively, the NRC can use the definition of "current licensing basis" in 10 CFR 54.3. (RM-01, RM-02)

NRC Response
The NRC disagrees with these comments. The draft NUREG provides a description of "staff position" in Section 1.2.2.2 and the categories of information that constitute a licensing basis from the NRC Office of Nuclear Reactor Regulation (NRR) Office Instruction LIC-100, "Control of Licensing Bases for Operating Reactors," dated January 7, 2004, in footnote 3 on page 1-2. . Placing these "definitions" in the NRC's regulations would be unnecessary because they do not need to be legally binding. These terms are used in NUREG-1409, Revision 1, only in the context of backfitting, forward fitting, and issue finality, which are not legally binding requirements on affected entities, as also discussed in the NRC Response to Comment 4.1.3.

Regarding the definition of "current licensing basis" in 10 CFR Part 54, "Requirements for renewal of operating licenses for nuclear power plants," the NRC applies that definition only in the context of aging management evaluations for power reactor license renewals. The 10 CFR Part 54 definition is too broad for the purposes of NUREG-1409, Revision 1, because backfitting, forward fitting, and issue finality concern only certain parts of that definition. For example, some, if not all, of a licensee's "commitments remaining in effect that were made in docketed licensing correspondence such as licensee responses to NRC bulletins, generic letters, and enforcement actions" may not be relevant for backfitting, forward fitting, and issue finality.

The NRC did not revise the draft NUREG in response to this comment.

Comment 4.1.9
The NRC needs to define the term "regulatory bases" for NRC staff decisions and interpretations that support staff positions. A definition (e.g., whether bases must be documented and, if so, in what form) is needed to understand how NRC staff positions are formed, which is needed when attempting to determine whether there has been an omission or mistake of fact as related to application of the compliance exception. (UUSA-09)

NRC Response
The NRC disagrees with this comment. "Regulatory basis" is a term used throughout NRC activities, not just for backfitting, forward fitting, and issue finality. Thus, defining "regulatory basis" would be beyond the scope of this NUREG. Within the draft NUREG, the NRC uses the term "regulatory basis" only once and "regulatory bases" only twice outside the scope of rulemaking. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.1.10
Section 1.2.2.2 of the draft NUREG should be revised to explain the cause and effect context for how previously applicable staff positions fit within backfitting. The Commission provided such an explanation in the Statement of Considerations (SOC) for the 1985 backfitting final rule. Additional examples of staff positions from the 1990 version of NUREG-1409 should be included in Revision 1. The description of generic staff positions should be expanded to show how they could lead to backfitting. (NEI-03, NEI-13, STARS-02)

NRC Response
The NRC agrees, in part, with these comments. The NRC agrees that the addition of the cause and effect explanation would be helpful to users of the NUREG. The NRC disagrees with some of the comments' examples of staff positions (e.g., regulation, which the definition of "backfitting" distinguishes from a staff position). The suggested insertion about safety evaluations is unnecessary given the sentences immediately preceding and following the insertion. The suggested insertion concerning NRR LIC-100 is specific to nuclear power licenses, whereas the NRC intended for the discussion to be license-neutral as much as possible. The Chapter 5 discussion of withdrawing guidance already addresses the suggested text regarding generic staff positions. The NRC revised Section 1.2.2.2 of the draft NUREG as a result of this comment.

Comment 4.1.11
The discussion of NRC inspection reports should be clarified. If an NRC inspection reviews the adequacy of an SSC or a licensee program established to meet NRC requirements, then the findings and conclusions of the inspection report should be at least substantial evidence of a staff position. Any other result would create great uncertainty for licensees as to whether they are in compliance, even after the NRC has reviewed SSCs or licensee programs during inspections. (UUSA-10)

NRC Response
The NRC disagrees with this comment. The comment appears to inadvertently link the inspection process with the licensing process where the processes should not overlap. Inspections should not establish licensing decisions. Rather, many NRC inspections assess a licensee's performance in implementing its licensing basis on a risk-informed sampling basis by identifying areas for which the licensee is not meeting requirements or self-imposed standards. Therefore, the NRC staff intended for the draft NUREG to discourage the NRC staff from writing inspection reports that establish licensing decisions (e.g., determining the adequacy of an already approved license or proposed changes to the license). The draft NUREG's caution about inspection report statements in Section 1.2.2.2 explains why inspection reports should not establish staff positions on the adequacy of a facility's licensing basis nor document positive assessments of licensee performance (i.e., those statements could inadvertently create a licensing-related staff position).

If an inspector perceives an inadequacy with the licensing basis, then the inspector may follow the backfit process, which is separate from the inspection process. Inspectors may also come

across situations or conditions at a facility where it is not clear whether the facility is complying with governing requirements or the licensing basis documentation may be ambiguous in that regard. The NRC has processes to address these issues, which may not involve backfitting.

The NRC did not revise the draft NUREG in response to this comment.

Comment 4.1.12
The NRC staff does not accept inspection report findings of compliance as NRC approval. This position is likely to lead to abuse and only encourage licensees to seek advice from inspectors. This would remove the impartiality of the inspection staff. Typically, such statements in inspection reports are not properly vetted and not sufficiently detailed to provide a basis for the statement. The NRC should instead discourage the use of such statements and follow the current practice of stating that the staff did not identify any issues. (ANSM-08)

NRC Response
The NRC agrees with this comment. The NRC staff intended the example in the draft NUREG on page 1-5, lines 34–39, to illustrate how inspection report language can result in staff positions and backfitting issues. The NRC used that example to discourage such language. The NRC revised the draft NUREG as a result of this comment.

Comment 4.1.13
NUREG-1409, Revision 1, should clearly articulate that the NRC staff's safety evaluations or inspection report statements are considered staff's views or opinions but are not considered staff positions that are part of a plant's licensing basis when staff proposes backfitting or forward fitting actions. (RM-03)

NRC Response
The NRC agrees, in part, with this comment. The NRC staff's safety evaluations are not staff views or opinions. They are staff positions but are typically not part of a plant's licensing basis. As stated in the draft NUREG on page 1-5, lines 17–21, safety evaluations are staff positions "on whether a licensee's proposed means for implementing or complying with a governing requirement is acceptable and results in compliance with the requirement. The safety evaluation is generally not part of the licensing basis unless specifically incorporated by the licensee or required as a condition of approval by the staff." The NRC did not revise the draft NUREG in response to this comment.

Comment 4.1.14
Section 1.2.2.1 of draft NUREG-1409, Revision 1, should be revised to better explain how requirements are germane to the implementation of the backfitting regulations. (NEI-02)

NRC Response
The NRC agrees, in part, with this comment. Some of the comment's suggested edits could improve draft NUREG-1409, whereas some of the suggested edits are redundant with other text and, therefore, unnecessary. The NRC revised Section 1.2.2.1 of the draft NUREG as a result of this comment.

Comment 4.1.15
There is no basis for the administrative exemption in the NRC's regulations. The NRC's Office of the General Counsel raised concerns in SECY-93-086 about the NRC appearing arbitrary and capricious if it used the exemption. The administrative exemption could lead to the type of uncertainty that the rule was designed to prevent. Allowing such unfettered administrative

discretion does not comport with the recent limitations on an agency's interpretation of its own regulations set forth by the U.S. Supreme Court in *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019). An administrative exception from the Backfit Rule is not the type of agency interpretation of a genuinely ambiguous regulation that the courts would countenance under *Kisor*. At a minimum, the exemption should be limited to situations where the public has the opportunity for notice and comment on the proposed action. (NEI-04, UUSA-11, ANSM-09)

NRC Response
The NRC disagrees with these comments. Although the AEA does not explicitly authorize exemptions, the U.S. Supreme Court has recognized that "an agency's authority to proceed in a complex area [of] regulation by means of rules of general application entails a concomitant authority to provide exemption procedures in order to allow for special circumstances." *United States v. Allegheny-Ludlum Steel Corp.*, 406 U.S. 742, 755 (1972). The NRC has used the administrative exemption only twice, and both instances involved very special circumstances: the events of September 11, 2001 ("Aircraft Impact Assessment; Final Rule," 74 FR 28112; June 12, 2009), and the March 11, 2011, events at the Fukushima Dai-ichi nuclear power plant (Order EA-12-051, "Order Modifying Licenses With Regard to Reliable Spent Fuel Pool Instrumentation," dated March 12, 2012). The *Kisor* decision is not applicable to the Commission's exemption authority.

The Commission's staff requirements memorandum for SECY-93-086, "SECY-93-086—Backfit Considerations," dated June 30, 1993, considered the administrative exemption only in the context of rulemaking: "The Commission therefore concludes that such exceptions should be promulgated only if the proposal not to apply the Backfit Rule to the proposed rulemaking is made the subject of notice and comment." Order EA-12-051 showed that the Commission could extend the exemption to nonrulemaking actions that the Commission found "may not meet the requirements specified in the Backfit Rule but nevertheless should be adopted by the NRC." Order EA-12-051, page 7. The Commission determined that the order would result in a significant enhancement to the protection of the public health and safety but did not have sufficient information to complete a backfit analysis. That decision was "a highly exceptional action limited to the insights associated with the extraordinary underlying circumstances of the Fukushima Dai-ichi accident and the NRC's lessons learned. Furthermore, the extensive stakeholder engagement and broad endorsement for timely action support the Commission's judgment that immediate action to commence implementation of the spent fuel monitoring requirements is warranted at this time. In addition, pursuant to 10 CFR 2.202, the NRC finds that the public health, safety, and interest require that this Order be made immediately effective" (emphasis added). Id. For nonrulemaking actions, the NRC can invoke the administrative exemption only with extensive stakeholder engagement, a need for timely action, and broad endorsement for timely action.

The NRC revised draft NUREG-1409 to add the criteria from Order EA-12-051 for nonrulemaking uses of the administrative exemption.

Comment 4.1.16
The information about issue finality in Section 1.2.6 of the draft NUREG should be moved to Chapter 2. (NEI-05)

NRC Response
The NRC agrees, in part, with this comment. Having the primary description of issue finality in Chapter 2 places the substantive issue finality discussion in one place, which makes the NUREG easier to use. The NRC kept a high-level description of issue finality in Chapter 1 as

an introduction to that concept, consistent with the introductions to backfitting and forward fitting in Chapter 1. The NRC revised Sections 1.2.6 and 2.3 of the draft NUREG as a result of this comment.

Comment 4.1.17
The information about independent spent fuel storage installations (ISFSIs) in Section 1.2.7 of the draft NUREG should be moved to Chapter 2. (NEI-06)

NRC Response
The NRC agrees with this comment. Describing ISFSIs in Chapter 2 would place all the ISFSI discussion in one place, which would make the NUREG easier to use. The NRC revised Sections 1.2.7 and 2.3 of the draft NUREG as a result of this comment.

Comment 4.1.18
The draft NUREG's examples of facility-specific backfitting actions in Section 1.2.5.2 raise several questions and are too focused on reactors. (ANSM-11)

NRC Response
The NRC agrees with this comment. The examples of facility-specific backfitting in Section 1.2.5.2 of the draft NUREG are less than clear and include only reactors. In its attempts to revise Section 1.2.5.2, the NRC realized that the section was not needed. The NRC combined the discussion of facility-specific backfitting with the content of Section 1.2.5.1. The NRC also carried forward from Section 2.4 of the 1990 version of NUREG-1409 the definition of a facility-specific backfitting action as one that involves positions unique to a particular affected entity or facility. An affected entity's docket number can also be referenced to provide further specificity. The NRC revised the draft NUREG consistent with this response.

Comment 4.1.19
MD 8.4 states that changes or updates to ASME Code requirements in 10 CFR 50.55a are an example of regulatory actions that do not meet the definition of "backfitting." The example in the draft NUREG on page 1-9, lines 6-11, is inconsistent with that position. The delegation to the NRR Office Director for the 10 CFR 50.55a rulemaking does not include changes to 10 CFR 50.55a that would be subject to the Backfit Rule. (ANSM-10)

NRC Response
The NRC agrees with this comment. The delegation from the EDO to the NRR Office Director for rulemakings related to 10 CFR 50.55a, "Codes and standards," was not an appropriate example of the redelegation, below the EDO, of Commission authority to review generic backfits. The NRC revised NUREG-1409, Revision 1, to remove the 10 CFR 50.55a example.

Comment 4.1.20
NRC staff should not screen out potential backfitting issues based solely on risk. NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Rev. 5 provides that "regulatory initiatives involving new requirements to prevent core damage should result in a reduction of at least $1x10^{-5}$ in the estimated mean value core damage frequency (CDF). This risk threshold is too restrictive because for many NRC regulations, the base CDF is in the range 10^{-4} to 10^{-5} and may not meet the initial risk screening for staff to impose any requirements. Hence the backfitting process can never be implemented by the staff for any regulatory improvements for overall protection of the public (i.e., maintaining nuclear safety when operating experience and events reveal design bases issues). (RM-05)

NRC Response
The NRC agrees, in part, with this comment. The Backfit Rule ensures that the NRC does not impose generic requirements having marginal overall safety benefit or costs not commensurate with the benefits. The NRC does not screen out potential backfit issues based solely on risk, although reduction in risk is a consideration for determining whether the proposed regulatory change meets the backfitting standard for substantial increase in overall protection. In some cases, if the CDF risk reduction does not meet the $1x10^{-5}$ per reactor-year risk threshold in NUREG/BR-0058, then the staff performs further analysis to determine whether the proposed safety enhancement is appropriate for implementation. The second part of the backfit analysis establishes whether the benefits exceed the costs. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.1.21
The draft NUREG does not explain how the CRGR ascertained in 2017 that the ten listed offices should bear backfitting responsibilities. It also does not explain how backfitting and forward fitting responsibilities could be borne by only two offices, NRR and NMSS. What are the comparative purposes and functions of the member offices in the Backfitting and Forward Fitting Community of Practice, with respect to the CRGR's list of offices with backfitting responsibilities (i.e., NMSS, NRO, NRR, NSIR, OGC, RES, and the four NRC regional offices)? Do NRO, NSIR, OGC, RES, and the four NRC regional offices have any backfitting responsibilities, other than, perhaps, rendering advice as members of the Backfitting and Forward Fitting Community of Practice? What is the mix of competencies that would become available in the membership of the NRC Backfitting and Forward Fitting Community of Practice? What are the requirements for individual membership on the NRC Backfitting and Forward Fitting Community of Practice? According to the draft NUREG, on page 1-14, line 22, "[T]he primary responsibility for issuing backfitting and forward fitting actions belongs to NRR and NMSS." Does this make the NMSS and NRR members of the Community of Practice the experts in this body? If yes, then please describe how the guidance sets qualification requirements that apply, specifically, to the NMSS and NRR members of the Community of Practice. NUREG-1409, Revision 1, should make it clear that the newly established Community of Practice is limited to an advisory role. There should also be some guidance regarding disagreements between NRR or NMSS, and members of the Community of Practice. How is the advice of the NRC Backfitting and Forward Fitting Community of Practice to be valued and used? (SM-07, SM-09, SM-13, SM-14, SM-15)

NRC Response
The NRC agrees, in part, with these comments. MD 8.4 establishes which offices have backfitting and forward fitting responsibilities. MD 8.4 lists 14 offices plus the CRGR, although the Office of New Reactors (NRO) was merged into NRR after the issuance of MD 8.4. The licensing offices (NRR and the Office of Nuclear Material Safety and Safeguards (NMSS)) are responsible for evaluating and processing proposed backfits and forward fits and decisions affecting the licensing basis of licensees and facilities. NRR is also responsible for changes affecting issue finality.

The NRC's Backfitting and Forward Fitting Community of Practice (CoP) developed a charter in 2020 (ADAMS Accession No. ML20234A443), to establish roles and responsibilities for CoP members and procedures for CoP activities. Following the issuance of NUREG-1409, Revision 1, the staff will update office-level implementing procedures, training, and qualifications to reflect the new policy and guidance. The NRC revised the draft NUREG to add discussion of the CoP charter and the role of the CoP as an advisory body.

Comment 4.1.22
NUREG-1409, Revision 1, should include a sample of each forward fitting and backfitting evaluation as examples to illustrate and demonstrate how the NRC evaluates and documents potential forward fitting and backfitting actions in accordance with 10 CFR 50.109 for power reactors. (RM-04)

NRC Response
The NRC disagrees with this comment. Forward fitting and backfitting evaluations are fact-specific. Therefore, an example will be helpful only for the NRC action being evaluated in that example. The appendices to NUREG-1409, Revision 1, explain to the NRC staff how to document its backfitting and forward fitting assessments. The NRC did not revise the draft NUREG in response to this comment.

4.2 Comments on Chapter 2 of the Draft NUREG

Comment 4.2.1
NUREG-1409, Revision 1, should be a policy document providing guidance on backfitting and forward fitting principles. Procedures necessary to ensure consistent application of these principles should not be in NUREG-1409, Revision 1, and belong in inspection guidance, office procedures, etc. (NEI-07)

NRC Response
The NRC disagrees with this comment. The Commission sets agency policy. In MD 8.4, the Commission established the policies for backfitting, forward fitting, and issue finality. To ensure proper and consistent implementation of those policies across the agency, the staff needs a single source of guidance. NUREG-1409, Revision 1, contains that substantive backfitting, forward fitting, and issue finality guidance. The NRC staff also needs implementation procedures that describe the NRC processes and responsibilities for NRC staff members to carry out that guidance (e.g., project management). As a result of the changes to the draft NUREG, the NRC will revise certain implementation procedures to remove any substantive backfitting, forward fitting, and issue finality guidance and to support the processes established in the draft NUREG (e.g., backfitting assessments, appeals). These implementation procedures will include office- or application-specific guidance (e.g., inspection manual chapters and NRR office instructions). The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.2
The NRC should re-structure Chapter 2 of the draft NUREG to emphasize the steps needed to identify and justify backfitting actions. (NEI-08)

NRC Response
The NRC agrees with this comment. The NRC made some of the suggested changes to the structure and flow of Chapter 2 as indicated in its responses to other comments.

Comment 4.2.3
The list of six questions should include whether there has been a prior licensee-specific or generic backfitting decision or similar or relevant precedent (e.g., an initial claim or appeal) that would bear on the screening being done at the time. (UUSA-12)

NRC Response
The NRC disagrees with this comment. A licensee's licensing basis should reflect any prior backfitting actions. Chapter 5 of NUREG-1409, Revision 1, explains that, before assessing a proposed action for backfitting, the NRC expects that the licensing basis will be known. Also, the backfitting screening questions include a check as to whether the NRC is imposing a new requirement or new staff position. The staff would have to understand the licensee's licensing basis to answer this question. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.4
The NRC should remove Question 1 of the six questions that constitute the draft NUREG's identification and justification process. The NRC should not assume a proposed agency action is outside the scope of backfitting or issue finality simply because the action falls into a certain pre-defined category. (NEI-09)

NRC Response
The NRC agrees, in part, with this comment. Each agency action needs to be assessed for potential backfitting or issue finality considerations. Whether a certain action is outside the scope of backfitting often depends on whether the action would meet the applicable definition of "backfitting." Some agency actions are not going to meet that definition (e.g., changes to NRC administrative procedures such as 10 CFR Part 2, "Agency rules of practice and procedure"; corrections of regulatory language, including typographical mistakes, misspellings, or inadvertent omissions (when the NRC's objective is expressly reflected in the regulatory record); and NRC organization and structure changes) and, therefore, can be dismissed from a backfitting assessment at the onset of the assessment. However, some agency actions that were listed in the draft NUREG as outside the purview of backfitting (e.g., NRC actions implementing mandatory statutory requirements or requirements imposed by other Federal agencies, appeals processes such as 10 CFR 73.56(I), information collection and reporting requirements) could meet the definition of "backfitting" and, therefore, should be subject to a backfitting assessment.

The NRC revised the draft NUREG by removing the discussion of certain agency actions from the category of actions that would be considered outside the purview of backfitting and issue finality. However, the NRC did not remove Question 1.

Comment 4.2.5
Explain why the NRC has no discretion in the implementation of requirements that are imposed by other agencies. For example, suppose the DOE demands that all utilities that are in possession of plutonium fuel immediately surrender it to the DOE. This could require expensive, unplanned refueling outages that would not be justifiable in a backfit analysis. Would the NRC staff rely upon the "no discretion" clause in this guidance to mollify the protesting licensees? (SM-21)

NRC Response
If another Federal agency with proper authority requires an NRC licensee to take an action that is not inconsistent with the AEA and the NRC's regulations, then the NRC cannot prevent that agency from doing so. The licensee's recourse to challenge the other agency's action would be through the other agency. When another agency requires the NRC to take an action that is not

inconsistent with the AEA and the NRC's regulations, that agency must be authorized by statute to do so. That statute would provide the authority to require the NRC to implement that action.

The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.6
The right to appeal may be "outside the purview" of backfitting provisions, but appeal processes and their implementation are well within the domain of NRC staff backfitting guidelines. (SM-19)

NRC Response
The NRC disagrees with this comment. In Section 2.2 of the draft NUREG, the NRC states, "Requirements for appeal processes are also outside the purview of backfitting provisions," which does not mean that the right to appeal is "outside the purview of backfitting provisions." The comment does not state why appeals processes are within the domain of NRC staff backfitting guidelines. Appeals processes required of affected entities (e.g., 10 CFR 26.39, "Review process for fitness-for-duty policy violations," and 10 CFR 73.56(l), "Review procedures") usually do not meet the definition of "backfitting" because they would not be a procedure or organization required to design, construct, or operate a facility. The NRC revised the draft NUREG to provide this explanation.

Comment 4.2.7
As a result of removing the draft NUREG Question 1, the draft NUREG Question 2 would become the new Question 1 concerning whether the proposed agency action would affect an entity within the scope of a backfitting or issue finality provision. NUREG-1409, Revision 1, should list each of the entities within the scope of backfitting or issue finality and include a description of these entities. The comments include suggested text for these discussions. (NEI-10, 10(a)-(f))

NRC Response
The NRC agrees, in part, with these comments. Because the NRC did not remove draft NUREG Question 1, draft NUREG Question 2 remains as Question 2 in NUREG-1409, Revision 1. The NRC gave each group of affected entities its own section, listing the affected entities within the group and providing the discussion of that group immediately after the list. This makes NUREG-1409, Revision 1, easier to use than the draft NUREG. The NRC also revised some of the discussions as suggested by the comments. The NRC disagrees with the suggested text for the discussion of issue finality. Although the NRC moved most of the section on issue finality from Chapter 1 to a new section in Chapter 2, the NRC kept the list of 10 CFR Part 52 entities in Question 2 with the discussion of issue finality in Section 2.3 of the draft NUREG.

Comment 4.2.8
The NRC should identify the materials licensees that are not within the scope of any backfitting provisions. (NEI-10(g))

NRC Response
The NRC disagrees with this comment. If a materials licensee is not among those listed in Section 2.3 of the draft NUREG that are within the scope of a backfitting provision, then that licensee is outside the scope of backfitting provisions. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.9
When a proposed NRC action may affect entities within the scope of backfitting and entities outside the scope of backfitting, the NRC must assess that proposed action for backfitting against the entities within the scope of backfitting. Also, a change to a regulation that does not contain a backfitting provision (e.g., 10 CFR Part 55) could affect a licensee licensed under a CFR Part that does contain a backfitting provision (i.e., a power reactor licensed under 10 CFR Part 50) and should be treated as a backfit. The process described in the draft NUREG to address these situations is inconsistent with NRC precedent. The comments cited the May 16, 2013 draft Regulatory Guide DG-7009 FRN (78 FR 29016); the 1991 10 CFR Part 20 final rule (56 FR 23360; May 21, 1991); and the 2013 10 CFR Part 40 final rule (78 FR 32309; May 29, 2013). (NEI-10(h), NEI-12, UUSA-05, UUSA-06)

NRC Response
The NRC agrees, in part, with these comments. The NRC revised its approach in the draft NUREG for determining the backfitting implications of proposed actions that would affect entities within the scope of backfitting and entities outside the scope of backfitting. In general, a proposed NRC action that would affect an activity regulated by a 10 CFR part that does not contain a backfitting or issue finality provision is not subject to a backfitting or issue finality assessment. For a licensee that is within the scope of a backfitting or issue finality provision, if the proposed NRC action would inextricably affect that licensee's activities regulated under the same 10 CFR part that contains the backfitting or issue finality provision, then the proposed NRC action would be subject to a backfitting or issue finality assessment (for that licensee).

This approach is supported by the definition of "backfitting" in the Commission's regulations. For example, under 10 CFR 70.76, "Backfitting," backfitting is a modification of, or addition to, the structures, systems, and components (SSCs) of a facility, or the procedures or organization required to operate a facility. For a proposed NRC action to "inextricably affect" the activities of a 10 CFR Part 70 licensee, the proposed NRC action would need to affect the 10 CFR Part 70-related SSCs of the licensee's facility or the 10 CFR Part 70-related procedures or organization required to operate its facility. The NRC's statements in the FR notice for DG-7009 (78 FR 29016; May 16, 2013) support this approach:

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

Comment 4.2.10
As a result of removing the draft NUREG Question 1, the draft NUREG Question 3 would become the new Question 2 concerning whether the proposed agency action would meet the definition of "backfitting." The five questions under draft NUREG Question 3 should be revised to three questions under new Question 2. Focusing on the proper application of the definition of "backfitting" will aid in the simplification of the backfitting program, which would allow for practical and predictable implementation. (NEI-11, STARS-04)

NRC Response
The NRC disagrees with these comments. Because the NRC did not remove draft NUREG Question 1, draft NUREG Question 3 remains as Question 3 in NUREG-1409, Revision 1. Also, the NRC did not revise the questions in draft NUREG Question 3 as suggested by the commenters. These questions break down the definition of "backfitting" into separate parts, requiring the NRC staff to compare its proposed action to each part of the definition. For example, a proposed action could be a new or changed requirement or staff position (first question), but it may not be imposed on an applicable entity (second question) (e.g., the rulemaking that established 10 CFR 50.61a, "Alternate fracture toughness requirements for protection against pressurized thermal shock events"). However, the NRC added a discussion of the cause-and-effect aspects of these questions consistent with the NRC Response to Comment 4.1.10.

Comment 4.2.11
New Question 2 should explain what a new or changed requirement is and that a new or changed requirement meets the causal element of the definition of "backfitting." (NEI-11(a))

NRC Response
The NRC disagrees with this comment. Because the term "requirement" is significant to understanding backfitting and was used throughout Chapter 1 of the draft NUREG, the NRC placed the discussion of the term "requirement" in Chapter 1 of the draft NUREG. The discussion of the "causal" elements of a backfit are in Chapter 1, as discussed in the NRC Response to Comment 4.1.10. The comment did not provide adequate justification for changing that approach or repeating the discussion in Chapter 2. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.12
New Question 2 should describe the second causal element (i.e., new interpretation or staff interpretation that is different from a previously applicable staff interpretation). The NUREG should include new subsections for the discussion of a "new interpretation" and a "staff interpretation that is different from a previously applicable staff interpretation" and move the discussion of "staff positions" in draft NUREG Section 1.2.2.2 to new Question 2. (NEI-11(b)-(d))

NRC Response
The NRC disagrees with these comments. Separate subsections for new interpretations and staff interpretations that are different from previously applicable staff interpretations are not necessary. The discussion of the "causal" elements of a backfit are in Chapter 1, as discussed in the NRC Response to Comment 4.1.10. The comments did not provide adequate justification for changing that approach. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.13
Backfitting can occur without an imposition of a staff position via a legally binding requirement. For example, the Commission stated in MD 8.4 that the staff's conveyance of an expectation that a licensee "change programs, processes, procedures, or the physical plant by using or committing to use voluntary guidance (e.g., Regulatory Guides or NRC-endorsed industry topical reports) that is not already within the [licensing basis] for the identified purpose" is considered backfitting or forward fitting. The Commission's long-standing position is that a proposed staff action must meet the backfitting requirements before being finalized. As the Commission noted in the 1985 backfitting final rule SOC, "Safety and sound management require that analysis precede imposition of a new or modified regulatory requirement or staff

position." NUREG-1409, Revision 1, should describe these circumstances. (NEI-11(e), EGC-12)

NRC Response
The NRC agrees with this comment. Backfitting can occur without an imposition of a staff position through a legally binding requirement. For example, the issuance of a 10 CFR 50.54(f) request for information that asks an affected entity to state when it will implement a staff position not currently in that entity's licensing basis would meet the definition of "backfitting" despite not involving the imposition of a legally binding requirement.

The NRC revised the draft NUREG by including in Section 5.2.3 a list of ways that backfitting could occur without imposition through a legally binding requirement.

Comment 4.2.14
NUREG-1409, Revision 1, should include a subsection to explain the timing provisions in backfitting regulations. (NEI-14)

NRC Response
The NRC disagrees with this comment. The last question in the draft NUREG's Question 3 already addresses the timing provisions in backfitting regulations. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.15
Section 2.4 of the draft NUREG reads that if the regional administrator determines that a proposed staff action constitutes backfitting, then the regional administrator will forward the issue to the office director for disposition. This implies that a licensee could file a backfit appeal with the regional administrator, before beginning the first-level appeal described in the draft NUREG. It seems there are three levels of appeal available to the licensee, not just two. If this is true, it should be addressed in the guidance. (SM-23)

NRC Response
The NRC disagrees with this comment. The discussion in the draft NUREG noted in the comment is outside the appeals process and refers to a backfitting concern that was raised by an NRC regional office. The specific sentence cited in the comment follows this introductory sentence in the draft NUREG: "As soon as practical after identification of a potential backfitting issue, the staff should present the potential backfitting action to the responsible office director or regional administrator, who then reviews the issue and determines whether the action constitutes backfitting." The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.16
NUREG-1409, Revision 1, should clearly state that the Commission reviews and approves the use of the adequate protection exception to the requirement to prepare a backfit analysis. For imminent adequate protection issues, the NRC staff should provide its documented evaluation to the Commission as soon as practicable after imposition of the backfit. (NEI-15)

NRC Response
The NRC agrees with this comment. The Commission determines when an agency action is necessary to ensure adequate protection or to define or redefine the level of protection that is adequate. For imminent adequate protection issues, the NRC staff should provide its documented evaluation to the Commission as soon as practicable after imposition of the backfit. This is consistent with 10 CFR 50.109(a)(6): "If immediately effective regulatory action is

required, then the documented evaluation may follow rather than precede the regulatory action." The NRC revised the draft NUREG to clarify that, although the backfitting justification must be presented to the Commission before taking the imminent adequate protection backfitting action, if the documented evaluation is not ready before the agency needs to take the action, then the justification presented to the Commission can be transmitted through a different means (e.g., a briefing).

Comment 4.2.17
NUREG-1409, Revision 1, should clearly state that the NRC staff must inform and obtain Commission approval when considering generically applicable adequate protection backfits. The staff should inform the EDO of potential adequate protection backfits "once the staff has determined that the adequate protection exception may apply and the staff has begun developing a documented evaluation for the adequate protection exception, not when the staff first considers adequate protection." (NEI-16)

NRC Response
The NRC agrees, in part, with this comment. The NRC agrees with the substance of the comment but does not agree that any changes need to be made to the NUREG. The draft NUREG provided guidance consistent with this comment on page 2-11, lines 23–26: "The staff should inform the Commission when the staff is considering any generically applicable adequate protection backfitting actions to enable the Commission to decide whether it wishes to review and approve the action or otherwise direct the staff." The draft NUREG, on page 2-11, lines 26–31, contained the same language as used in the comment regarding staff communication with the EDO about adequate protection backfitting actions: "Such notifications should occur once the staff has determined that the adequate protection exception may apply and the staff has begun developing a documented evaluation for the adequate protection exception, not when the staff first considers adequate protection." The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.18
Question 4a asks whether "one or both of the adequate protection exceptions…apply." It discusses one adequate protection exception, not two. What is the second adequate protection exception? (SM-24)

NRC Response
In the draft NUREG, lines 33–36 on page 1–6 (the first two bullets) and lines–9 on page 2–9 explain the two exceptions. The first exception is when the NRC determines that the agency must impose a backfitting action to ensure that a facility provides adequate protection to public health and safety and is in accord with the common defense and security. The second exception is when the Commission decides that the agency needs to define or redefine the level of protection of public health and safety or the common defense and security that should be considered as adequate.

The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.19
The adequate protection and compliance exceptions are not mutually exclusive. The NRC should not bypass the compliance test because an issue is of historical, but not imminent, adequate protection. The real question in determining whether a new regulatory action "is necessary to ensure that the facility provides adequate protection" under the Backfit Rule is whether adequate protection is provided at the time the new regulatory action is being

considered, not whether a prior regulatory action was deemed necessary for adequate protection in the past. The application of the backfit rule to a dispute over compliance with an adequate protection requirement cannot simply end at the adequate protection exception but must undergo the compliance exception test. Any other result would render the compliance exception meaningless. Whether the adequate protection issue could result in imminent harm is relevant to each use of the exception, so NUREG-1409, Revision 1, should state that all documented evaluations for adequate protection should address whether the issue is imminent. (NEI-17, NEI-18, STARS-03, ECG-02)

NRC Response
The NRC agrees, in part, with these comments. The NRC agrees that the use of the adequate protection exceptions requires the NRC to determine whether its proposed action is necessary to ensure adequate protection, not whether the requirement at issue was originally determined to be necessary for adequate protection. This was explained in Section 2.5.1 of the draft NUREG. However, just because an adequate protection action is not imminent does not mean the staff should consider the compliance exception. An adequate protection action is an action the NRC must take, notwithstanding whether the harm is imminent. Also, the draft NUREG states that when the staff determines that a backfitting action is necessary for adequate protection of the public health and safety or the common defense and security, the staff must prepare an imminent threat analysis that determines whether immediate action is necessary. In response to these comments, the NRC changed the phrase “involve adequate protection” in the draft NUREG’s executive summary and Section 2.5 to “one of the adequate protection exceptions applies” and made similar changes throughout the draft NUREG.

Comment 4.2.20
Regarding the compliance exception, NUREG-1409, Revision 1, should emphasize the importance of distinguishing between a situation in which a licensee fails to meet a known and established standard due to an omission or mistake of fact from the NRC seeking to impose a new or different interpretation of an existing requirement. (NEI-19)

NRC Response
The NRC disagrees with this comment. NUREG-1409, Revision 1, does not need to further emphasize the distinction between these types of situations because the draft NUREG provided a narrative discussion of the compliance exception criteria plus a checklist to guide the NRC staff in determining whether a proposed action meets each of the compliance exception criteria. For example, the first item in the checklist notes that a “compliance backfit requires that an applicable requirement be in place, and the NRC’s proposed backfitting action is not changing this requirement.” The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.21
New NRC guidance, even in response to generic findings or lessons learned within the industry, should be treated as reflecting a “new or modified interpretation of what constitutes compliance,” which the Commission said in the 1985 final rule SOC would fall outside the compliance exception. (UUSA-16)

NRC Response
The NRC agrees, in part, with this comment. The draft NUREG included the 1985 final rule SOC language on page 2-13, lines 11–13: “It should be noted that new or modified interpretations of what constitutes compliance would not fall within the [compliance] exception and would require a backfit analysis and application of the standard.” However, whether new NRC guidance would apply to a licensee and would be a new or modified interpretation of what

constitutes compliance for that licensee is a fact-specific determination. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.22
NUREG-1409, Revision 1, should reflect that when the NRC, with full and correct information, has accepted a licensee's design or program as conforming to applicable standards, the licensee is entitled to a presumption of compliance. Such acceptance could occur during initial licensing, in response to a licensing action (e.g., license amendment request), or as part of the NRC's review or inspection of a licensee's implementation of an NRC regulatory requirement. This presumption of compliance promotes regulatory stability and should be the starting point for any compliance exception evaluation. Only if the NRC can clearly show an omission or mistake of fact, should it be allowed to revisit its prior acceptance and the licensee's continued compliance. (UUSA-14, UUSA-15)

NRC Response
The NRC agrees, in part, with these comments. An NRC finding that a licensee's program or methodology meets the applicable requirement creates an ongoing presumption of compliance with that requirement. However, that finding should not occur during an inspection because inspections should not reach conclusions about the adequacy of the licensing basis (e.g., "the licensee is in compliance"). Also, the presumption can be overcome by a determination that an omission or mistake of fact occurred at the time that the finding was made. This can occur when the omission or mistake of fact criteria are satisfied. These criteria were described on page 2-13 of the draft NUREG and are based on the Commission policies in MD 8.4. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.23
If the NRC staff becomes aware of an omission or mistake of fact, which would have prevented the staff from approving the licensee's method of compliance, then the existence of said noncompliance indicates that it is necessary to implement corrective adequate protection actions. (SM-25)

NRC Response
The NRC agrees, in part, with this comment. NUREG-1409, Revision 1, does not prescribe licensee corrective actions. Rather, it focuses on the backfitting process. The existence of a noncompliance may indicate the need for corrective actions, but other NRC processes (e.g., inspection and enforcement) would provide the proper NRC oversight of any licensee corrective actions. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.24
The definition of "substantial" should be more objective and specific than some "rational" judgment of the staff. This guidance regarding the definition of "substantial" is useless. (SM-26)

NRC Response
The NRC disagrees with this comment. As explained on page 2-17 of the draft NUREG—

> In the 1985 Backfit Rule SOC, the Commission stated that "substantial" means "important or significant in a large amount, extent, or degree."
> …
> The definition of "substantial" is ultimately a regulatory and policy determination. The determination, however, must be rational (i.e., not illogical) and supported by evidence or fact, as applicable.

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

The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.25
Simply stating in MD 8.4 that safety margin, which MD 8.4 considers an important part of a compliance backfitting analysis, "may not be quantifiable" is like stating that the NRC staff will know it when they see it. The NRC should clarify the concept of safety margin as applied in the backfitting context, with a focus on providing an objective definition of "safety margin." (UUSA-07)

NRC Response
The NRC disagrees with this comment. The term "safety margin" is used outside the context of backfitting, so defining that term is outside the scope of the draft NUREG. Furthermore, the safety margin for a particular issue or facility will depend on the facts and circumstances of each determination. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.26
In the discussion of the compliance exception, the NRC should replace "error" with "mistake of fact" to avoid confusion from using both terms. (NEI-20)

NRC Response
The NRC disagrees with this comment. The Commission used "error" and "mistake of fact" interchangeably in MD 8.4 when discussing the compliance exception and defined "mistake of fact" by different types of errors. The NRC does not envision any potential confusion from using "error" and "mistake of fact." The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.27
The 10 CFR 50.59 process should not be used as an example of an omission. A licensee uses 10 CFR 50.59 to determine when a license amendment is needed to make a change to its facility. That regulation does not specify what information needs to be provided to the NRC to make the change. The NRC cannot approve a change to a facility if the licensee did not describe the change. (ANSM-13)

NRC Response
The NRC agrees with this comment. The regulation at 10 CFR 50.59, "Changes, tests and experiments," is not a good example of an omission for purposes of the compliance exception. If a licensee does not consider or address information that the NRC requires be addressed through a legal obligation, such as in the licensee's implementation of the 10 CFR 50.59 process, then the licensee may have violated the legal obligation (e.g., not following the 10 CFR 50.59 process correctly could be a violation of 10 CFR 50.59). The NRC removed this portion of the draft NUREG.

Comment 4.2.28
The NRC staff should work with the industry to add examples to NUREG-1409 Revision 1, to illustrate the proper use of the compliance exception under the standard articulated in 1985 by the Commission. The NRC should also publish an illustrative, non-exhaustive list of performance standards that can be a basis for a compliance exception (e.g., General Design Criteria (GDC), Quality Assurance (QA) standards) after the NRC and industry develop some common examples to illustrate this principle. Many of the compliance exception issues have arisen due to a lack of clarity in how to interpret and apply generally worded, non-prescriptive provisions of the GDC or QA standards. (UUSA-13, UUSA-02, NEI-57)

NRC Response
The NRC disagrees with these comments. Examples will not be helpful because whether the NRC can use the compliance exception, and whether a GDC can support a compliance exception, will be fact-specific determinations. The compliance exception checklist in Appendix B, Worksheet 2, of the draft NUREG illustrates this specificity. Therefore, an example will be helpful only for the NRC action being evaluated in that example. Also, NUREG-1409, Revision 1, provides the guidelines for the NRC staff to properly implement the compliance exception. NUREG-1409, Revision 1, directs the NRC staff to consider factors other than the GDC—technical specifications, Principle Design Criteria (PDC), and other requirements—before relying on the GDC. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.29
The NRC staff should not be directed to prepare a cost justification for a compliance-based backfit. A compliance-based backfit does not add safety. It merely restores safety. Costs cannot be weighed against benefits when no benefits exist. Safety and costs are not relevant to the correction of errors or omissions (committed by the licensee and/or the NRC staff). The U.S. Supreme Court decision (*Michigan v. EPA*) doesn't require additional cost considerations because sufficient cost considerations were already required, as part of the Backfit Rule, decades before the court issued its decision.

When the costs of compliance backfitting are considered in the staff's evaluation, the compliance exception is no longer an exception. It becomes subject to dispute, by licensees, who could, and would, present their own cost considerations that indicate the backfit is not justified. Consideration of the costs of compliance backfitting effectively deletes the compliance exception from the Backfit Rule. (SM-05, SM-06, SM-12)

NRC Response
The NRC agrees, in part, with these comments. The NRC agrees that it should not prepare a cost-benefit justification for a compliance backfit. Instead, the NRC considers the costs of the backfit in its documented evaluation supporting the invocation of the compliance exception as directed by the Commission in MD 8.4. The NRC also considers the benefits, but the benefits are not required to outweigh the costs. In Section 2.5.2.2 of NUREG-1409, Revision 1, the subsection entitled "Consideration of Costs" explains how the staff should consider costs. Appendix C.2, the guide for a documented evaluation of a compliance exception, also provides guidance. Although licensees may present their own cost information, costs are not the sole factor in determining whether to invoke the compliance exception.

For decades, the NRC has used regulatory analyses, which are different from backfit analyses, to consider the costs of imposing requirements. However, the 1988 Backfit Rule did not require the NRC to consider costs when invoking the compliance exception. The draft NUREG's footnote 4 and its reference to the U.S. Supreme Court's *Michigan v. EPA* decision serve to

clarify that the NRC considers the costs to the licensee when using the compliance exception in the Backfit Rule.

The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.30
The NRC should not have to consider cost in cases of willful omission, false statements, or failure to correct errors. As written, the draft NUREG may incentivize applicants to withhold pertinent information during the review of licensing actions. In addition, if errors or omission are identified before implementation of a change, then the NRC staff should not have to consider costs. (ANSM-12)

NRC Response
The NRC disagrees with this comment. Willfulness and incomplete or inaccurate information are discouraged through traditional enforcement methods (e.g., civil penalties) and investigations, some of which can result in potential bans from working in the nuclear industry. Further, cost considerations inform the overall decision whether to proceed with a compliance backfit. That decision is not based on cost, and a compliance backfit does not have to be cost justified. The costs are separate and distinct from whether the mistake was a result of willful acts. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.31
The draft NUREG implies that the NRC staff could forgo a backfitting or forward fitting action, for a particular plant, "after many years of safe operation." The NRC is relying on the Monte Carlo, or Gambler's Fallacy, in which a certain random event is less likely or more likely to occur, given a previous event or a series of events. However, the record of random events is not an indicator of future random events. Overall past performance, for all operating plants, is skewed when serious accidents remove plants from the operating plant database (e.g., Three Mile Island, Fukushima Dai-ichi). Similarly, consideration of the "time period of the noncompliance" is irrelevant when considering the use of the compliance exception. Step 10 of the compliance backfit checklist in Appendix B of the draft NUREG does not provide any evidence that the regulator can reliably estimate the cost of a corrective action. Consideration of "how long the facility has been in the current situation" invites the use of the Gambler's Fallacy to decide questions that affect the public health and safety. The NRC staff should not be advised to factor the Gambler's Fallacy into its compliance backfit evaluations. (SM-16, SM-60)

NRC Response
The NRC disagrees with this comment. The comment presents an interpretation of the draft NUREG that was not intended by the NRC. Whether a facility has operated safely for many years would be one factor, but not the only factor, in deciding whether to take a backfitting action. As stated on page 1-12 of the draft NUREG—

> The fact that a plant has operated safely for a period of years does not mean, in and of itself, that a condition that has persisted for years should not be re-evaluated. But when many years have passed before the NRC determines that a regulation or requirement is not satisfied, and when the agency cannot demonstrate that compliance is necessary for adequate protection, identifying the safety significance should be the first step in ensuring that [a staff position that

the NRC seeks to change and implement through the compliance exception] is still warranted.

The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.32
In Appendix B to the draft NUREG, on page B-11, Step 3, the NRC refers to "inconsistent interpretation" but does not explain the difference between "inconsistent interpretation" and "new or modified interpretation." An "inconsistent interpretation" implies that an error is less likely. However, a "new or modified interpretation" implies that there is no error. (SM-58)

NRC Response
The NRC agrees, in part, with this comment. The compliance exception checklist in the draft NUREG included the term "inconsistent interpretation," but that term is not defined in the draft NUREG. An "inconsistent interpretation" of the applicable requirement means the NRC's application of the requirement differed among applicable licensees. For example, the NRC may have required some licensees to meet certain criteria that other licensees did not have to meet for compliance with the same requirement. The conclusion that the NRC inconsistently interpreted a requirement is based on a review of the NRC's historical application of the requirement. A "new or modified interpretation" of a requirement is based on a review of a proposed action the NRC is currently planning to take.

The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.33
The NRC should remove the compliance exception from 10 CFR 50.109 and write it into a new rule, which would not be linked, in any way, to backfitting or forward fitting. The new rule would be designed to correct errors and/or fill in omissions to make a plant's licensing basis accurately reflect the plant's as-built design and/or authorized operation. The new rule would not be subject to any cost considerations, whatsoever. It would be comparable to a warranty that preserves and implements the NRC's mandate to protect the public health and safety. (SM-63c)

NRC Response
The NRC disagrees with this comment. The suggested rulemaking would conflict with the *Michigan v. EPA* U.S. Supreme Court decision (see NRC Response to Comment 4.2.29) and Commission policy to perform regulatory analyses consistent with Executive orders related to cost-benefit reform and decisionmaking. The comment does not present any support for changing the current compliance exception framework. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.34
NUREG/BR-0058 covers cost-justified substantial increases in overall protection backfits, so the NRC should not cause potential confusion or inconsistencies with much discussion of these backfits in NUREG-1409, Revision 1. (NEI-21)

NRC Response
The NRC disagrees with this comment. NUREG/BR-0058 provides guidance on performing regulatory analyses, which include costs and benefits beyond those considered in a backfit analysis. Thus, regulatory analyses can inform backfit analyses, but NUREG/BR-0058 will not provide guidance on performing backfit analyses and the backfit analysis criteria. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.35
Absent a change to 10 CFR 50.109, the NRC staff may consider qualitative factors; but may not use them in regulatory analyses and backfit analyses. However, this did not deter the EDO's backfit appeal review panel (BARP) from invoking "engineering judgment" to justify the EDO's decision to grant Exelon's appeal of NRR's backfit order. (SM-18)

NRC Response
The NRC disagrees with this comment. The comment is incorrect that the NRC may not use qualitative factors in regulatory analyses and backfit analyses. On page 2-18 of the draft NUREG, the NRC stated the following:

> In SRM-SECY-93-086, "Backfit Considerations," the Commission explained that the "substantial increase" criterion "allow[s] for qualitative consideration of factors to determine that a given proposed rule would substantially increase safety." In accordance with SRM-SECY-14-0087, "Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," dated March 4, 2015, this consideration of qualitative factors does not authorize an expansion of such consideration in regulatory analyses and backfit analyses. Instead, the staff should use qualitative factors in a judicious and disciplined manner to inform decisionmaking, in limited cases, when quantitative analyses are not possible or practical (e.g., due to lack of methodologies or data).

Thus, the NRC can consider qualitative factors in regulatory analyses and backfit analyses. All NRC backfitting decisions are risk-informed and, as a result, consider relevant available quantitative and qualitative risk information to support the decision. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.36
In 1993, the Advisory Committee on Reactor Safeguards (ACRS) sent the then-NRC Chairman a letter informing the Commission that it did not need to change the substantial increase test because if the Commission wanted to impose a "seemingly worthwhile change" that could not meet the substantial increase criterion, the Commission already had "adequate authority to enforce actions that are appropriate in the public interest, and any weakening of the rule is likely to bring back the conditions the rule was originally designed to fix" (ADAMS Accession No. ML031900132). The ACRS' view of NUREG-1409 with respect to 10 CFR 50.109, and the NRC staff's use of qualitative factors could mean that 10 CFR 50.109 must not be strengthened (e.g., by favoring a licensee's backfit appeal) as well as not be weakened. Why is this NUREG-1409 guidance being revised in 2020 (in lieu of a change to 10 CFR 50.109), 27 years after the ACRS issued its letter to the NRC chairman? (SM-20)

NRC Response
The NRC disagrees with this comment. As noted in the NRC Response to Comment 4.2.35, the NRC may use qualitative factors in backfit analyses. This strengthens the Backfit Rule by allowing the NRC to consider relevant available quantitative and qualitative risk information to support its decisions. The NRC is updating NUREG-1409 to reflect the last 30 years of experience with the Backfit Rule, including lessons-learned, and to align it with the 2019 revision to MD 8.4. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.2.37
Chapter 2 of NUREG-1409, Revision 1, should contain a new section on issue finality that would be populated by moving existing text from other parts of NUREG-1409. (NEI-22)

NRC Response
The NRC agrees with this comment. Consistent with the NRC Response to Comment 4.1.16, the NRC revised the draft NUREG to create a new section for issue finality in Chapter 2.

4.3 Comments on Chapter 3 of the Draft NUREG

Comment 4.3.1
The Commission's long-standing position is that the requirements of 10 CFR 50.109 apply to the license amendment process. (NEI-23)

NRC Response
The NRC agrees, in part, with this comment. In the 1985 final rule SOC, the Commission said, "If a licensee believes that the amendment process is being used by the staff to impose a backfit, the licensee may invoke the rule under § 50.109." This is also true for almost any NRC action. However, in the comment's discussion of the 1993 Standard Technical Specifications Policy Statement (58 FR 39132; July 22, 1993), the comment appears to mischaracterize the adequate protection and compliance exceptions. They are not "exceptions to the backfitting rules." They are exceptions to the requirement to perform a backfit analysis under 10 CFR 50.109(a)(3).

In response to other comments, the NRC revised the draft NUREG regarding forward fitting, which should result in some impositions that might occur during licensing reviews being addressed as backfits, consistent with the implications in this comment.

Comment 4.3.2
In his letter to Ms. Ellen Ginsburg, Nuclear Energy Institute, dated July 14, 2010 (ADAMS Accession No. ML101960180) (Burns letter), then-NRC General Counsel Stephen G. Burns showed that backfitting actions are not the same as forward fitting actions and explained how the NRC staff would be limited in imposing backfits on license amendment applicants. (NEI-24, NEI-25)

NRC Response
The NRC agrees with these comments. The Burns letter delineated the difference between guidance documents subject to the Backfit Rule and guidance documents that the staff intended to be "forward fitting." Backfitting actions would occur when the NRC staff intended guidance to become (through further NRC action) legally binding upon a licensee, or the NRC staff's expectation was that licensees "voluntarily" adopt the "guidance" to resolve a safety or regulatory issue. As described in the Burns letter, forward fitting would occur if the staff intended to apply the guidance to future applicants or applications from existing licensees for license amendments, requests for exemptions, and other requests for dispensation from compliance with otherwise-applicable legally binding requirements. The Burns letter described the two conditions that forward fits would need to meet (i.e., direct nexus and essential consideration) in such circumstances.

The NRC did not revise the draft NUREG in response to this comment because the forward fitting guidance already includes the concepts of direct nexus and essentiality.

Comment 4.3.3
Forward fitting should be limited to the aspects of voluntary licensee requests for licensing basis changes that result in the licensee standing in the shoes of a pure applicant (i.e., an applicant for a new facility). A licensee that voluntarily requests changes to its licensing basis stands in the shoes of a pure applicant only to the extent that the requested changes create unique safety or security issues that must be addressed through imposition of the proposed forward fit for the purposes of ensuring or redefining adequate protection, or ensuring continued compliance with a legally binding requirement applicable to the facility. (NEI-26, STARS-05, EGC-03)

NRC Response
The NRC agrees, in part, with these comments. MD 8.4 indicates that forward fits generally do not include instances when an applicant files an initial licensing action for a new facility. Recognizing that constraint, the NRC does agree that an affected entity's voluntary request to change its licensing basis is like an applicant for a new facility to the extent that the affected entity's request creates unique or first-of-a-kind issues. Accordingly, the NRC agrees that forward fitting should be limited to those instances when the affected entity's voluntary request creates unique safety or security issues, as explained in the NRC Response to Comment 4.3.4. The NRC revised the draft NUREG consistent with this response.

Comment 4.3.4
Several comments stated that the definitions of "direct nexus" and "essential" need to be clarified and that the example of a "direct nexus" is not helpful. One comment noted that those terms in the context of forward fitting are related but different: a change can only be essential if it is directly related to the issues being evaluated. At the same time, a change would likely only be directly related to a licensee's request if its consideration is essential to the NRC's review. Some comments claimed that a "direct nexus" must involve a unique safety or security issue that would not exist but for the licensee's requested change, and the purpose of the proposed forward fit must be to address that unique issue. It is not enough for the proposed forward fit to be generally related to the subject of the licensee's request. There must be something about the request itself that raises the issue. For implementing the "essentiality" criterion for forward fitting, these comments suggested applying "well-established principles of adequate protection and legal compliance already associated with the Backfit Rule." (NEI-27, NEI-28, EGC-04, FPL-03, FPL-04)

NRC Response
The NRC agrees, in part, with these comments. The NRC agrees that its definitions of "direct nexus" and "essential" and examples were not specific enough to provide sufficient guidance. However, the NRC does not fully agree with the definitions suggested by these comments.

The NRC revised the draft NUREG to define a "direct nexus" between the affected entity's request and the NRC condition to mean that (1) the affected entity's requested change would create (a) a safety or security issue, or (b) a noncompliance with a requirement that is already in the affected entity's licensing basis or with 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 (2) the NRC condition would address that issue or noncompliance. The first element specifies the types of issues identified during the NRC's review of the license's request that could be the subject of a forward fit. If the affected entity's requested change would not create the issue or noncompliance if approved by the NRC without a condition, then the issue or noncompliance existed before the affected entity submitted its request, and the NRC should take the applicable regulatory action to address the issue or noncompliance. If the issue or

noncompliance can be addressed by an existing requirement or staff position within the affected entity's licensing basis, then the NRC's condition of its approval based on an existing requirement or staff position would not meet the definition of a "forward fit" in MD 8.4 (i.e., "the imposition of a new or modified requirement or regulatory staff interpretation of a requirement"). The second element establishes the "direct" relationship between the affected entity's request and the NRC's condition.

The NRC revised the draft NUREG to define "essential" to mean that the forward fit would be necessary for the NRC staff to make the safety or security finding to support the NRC's approval of the affected entity's request. A forward fit that is "necessary to make the safety or security finding" will likely be necessary for adequate protection or continued compliance with all applicable requirements, but the NRC is not explicitly limiting the definition to only adequate protection or compliance because the standards for the NRC findings differ depending on the licensing action. The NRC's use of the term "compliance" in a forward fitting context is not the same as use of the term "compliance" in a compliance exception under the Backfit Rule. In the forward fitting context, "compliance" looks ahead to ensure the affected entity would continue to comply with all applicable requirements following the NRC's review and approval of the request. In contrast, "compliance," when used in the context of compliance exception backfits, looks backward to the time of a previous NRC approval.

The NRC revised the draft NUREG to include these revised definitions. The NRC also added supporting guidance to demonstrate how these definitions would be applied in a license amendment request.

Comment 4.3.5
What is the difference between a "new or modified requirement or a regulatory staff position" that is developed before a licensee's request, and one that is developed after a licensee's request? (SM-10)

NRC Response
If the NRC intends to impose a "new or modified requirement or a regulatory staff position" that is developed before an affected entity's request, then the NRC would need to perform a backfitting assessment for its proposed imposition. If the NRC intends to impose a "new or modified requirement or a regulatory staff position" that is developed after an affected entity submits a request for a licensing action, and that imposition would meet the definition of a "forward fit" (see NRC Response to Comment 4.3.4), then such an imposition on that affected entity would need to be assessed for forward fitting. If the latter imposition would not meet the definition of a "forward fit," then the NRC would need to subject the proposed imposition to a backfitting assessment.

The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.6
"Essential" means absolutely necessary, but NUREG-1409 can be read such that "essential" means "worthwhile." Essential should mean that the forward fit is necessary to ensure or redefine adequate protection or ensure compliance. (NEI-28)

NRC Response
The NRC agrees, in part, with this comment. Even if the draft NUREG could be read to interpret "essential" to mean "worthwhile," the NRC's licensing action approval standards in its regulations would not allow the NRC staff to determine that a forward fit would be "worthwhile"

and, based on that finding alone, essential to the NRC staff's determination of the acceptability of the affected entity's request. The NRC agrees that the term "essential" needed a better definition and revised the draft NUREG in response to this comment and others.

Comment 4.3.7
A new or different requirement or interpretation that doesn't meet the direct nexus or essential elements should be evaluated as backfitting. Furthermore, the identification of this type of issue should not impede the review of the licensing request in accordance with 10 CFR 50.109(d). (NEI-29)

NRC Response
The NRC agrees with this comment. The comment can be illustrated as follows. If the NRC identifies an issue with a license amendment request that could be addressed by a currently acceptable method within the licensee's licensing basis (e.g., Regulatory Guide X, Revision 1) that the licensee has proposed to use, and the NRC wants that licensee to use a later version of the same guidance (e.g., Regulatory Guide X, Revision 2), then there would be no direct nexus associated with this issue. To have a direct nexus to the licensee's request, the NRC condition that the licensee use the later version of the regulatory guide must address a safety or security issue or noncompliance that cannot be addressed by an existing requirement or staff position (e.g., a guidance document) within the licensee's licensing basis. In this example, the issue could be addressed by a method currently within the licensee's licensing basis. Furthermore, use of the later version of the regulatory guide is not essential to the NRC's approval of the licensing request because the use of Regulatory Guide X, Revision 1, is sufficient to satisfy the NRC's approval standard. If the NRC's approval of the license amendment request without the condition that the licensee use the later version of the regulatory guide is considered the staff's position, then the NRC's condition of the approval would be imposing a staff position that is different than the previously applicable staff position. Accordingly, imposition of the later regulatory guide version would meet the definition of "backfitting."

The NRC also agrees that the review of the license amendment request should proceed independent of the staff's efforts to impose the later version of the regulatory guide (in accordance with the example above) consistent with the requirements of 10 CFR 50.109(d). Whether the license amendment could be finalized in a proceeding separate from the backfitting assessment would be a fact-specific decision. The backfitting assessment could affect the staff's determination of the license amendment request. This would be consistent with the 1985 Backfit Rule SOC, in which the Commission said that the staff's review of the requested licensing action should proceed until the backfitting review is concluded: "[U]ntil a backfit analysis is complete, licensing action should continue along a course consistent with normal practice." 50 FR at 38103–104. If the staff determines that the potential backfitting action could be pursued independent of the licensing action, then the staff should not delay processing the licensing action. The NRC revised the draft NUREG consistent with this response.

Comment 4.3.8
Issuance of new or revised staff position, where the previous staff position is no longer available for use, independent of any voluntary request to change the licensing basis of the facility, would likely result in backfitting. In this case, the regulatory analysis supporting the issuance of the new guidance should include a backfit analysis. (NEI-30)

NRC Response
The NRC agrees with this comment. If the issuance of new guidance (e.g., a new version of a regulatory guide) is associated with a restriction on the use of the previous guidance (e.g., the

earlier version of the same regulatory guide is no longer available for use, or its use is limited), then the issuance of the new guidance would likely constitute backfitting, independent of any voluntary request to change the licensing basis of the facility. The NRC revised the draft NUREG in response to this comment.

Comment 4.3.9
One comment describes a regulatory analysis supporting a forward fit. The comment concludes that a forward fit must be essential and, as such, necessary for adequate protection. As a result, a regulatory analysis (i.e., cost estimate) would focus on situations where there is more than one way to address the forward fit to enable the most cost-effective approach to be chosen. Otherwise, if there is only one way, then cost would not be part of the decision and not estimated.

Another similar comment states that if the "direct nexus" and "essentiality" criteria are satisfied, then the staff should proceed with a site-specific regulatory analysis of the proposed forward fit. Because "essentiality" necessitates either ensuring/redefining adequate protection or ensuring compliance with a legal requirement, there should be two types of a regulatory analysis performed for forward fits. In cases where the proposed forward fitting involves adequate protection, the regulatory analysis would not evaluate cost except to compare the cost of multiple methods of implementing the forward fit (and the least costly alternative should be selected). If the forward fit involves a matter of compliance, then the regulatory analysis would evaluate the incremental cost of the forward fit (if there is only one means of satisfying the forward fit) or compare the cost of alternatives (again, the least costly alternative should be chosen). In both cases, the NRC need not cost-justify the forward fit; rather, the agency simply must ensure that the forward fit criteria are satisfied and a sufficient regulatory analysis (including evaluation of costs, as appropriate) has been performed. The NRC should request input from the licensee on costs for these regulatory analyses.

Another comment states that guidance does not makes sense where it states that if the forward fit cannot be cost-justified, then the staff may have to deny the request. The comment indicates that this could yield undesirable and illogical outcomes. The potential that the NRC may have to deny a request because it could not cost-justify a compliance-related forward fit does not serve the purpose of the backfit rule or the forward fitting concept. (NEI-33, NEI-34, EGC-05, EGC-06, JJS-03)

NRC Response
The NRC agrees, in part, with these comments. The NRC agrees that forward fits must be essential, but, as noted in the NRC Response to Comment 4.3.4, while this will likely be necessary for adequate protection or continued compliance with all applicable requirements, the NRC is not explicitly limiting the definition to only adequate protection or compliance because the standards for the NRC findings differ depending on the licensing action. If there are multiple ways to proceed, then the cost consideration, which could be a regulatory analysis, can provide estimates of the different approaches to support choosing the most effective approach. The NRC also notes that for compliance-related issues, although the NRC could support a proposed forward fit with a cost estimate, an affected entity is more likely to choose the least costly approach to proceed. In this situation, the affected entity would be expected to choose the best path forward for its needs: accept a forward fit imposition, seek an exemption, revise the request, or withdraw the request. The NRC revised the draft NUREG consistent with this response.

Comment 4.3.10
Can a licensee compel the NRC staff to approve an unacceptable request, unconditionally, if the NRC staff cannot meet the MD 8.4 forward fit analysis requirements? Licensees have often withdrawn requests that seemed unlikely to win the staff's unconditional approval. The draft NUREG doesn't mention this alternative. A licensing action initiated voluntarily by a licensee can be withdrawn voluntarily. Unlike backfitting, a licensee is not required to comply with forward fits or conditions that are attached to its voluntarily initiated licensing actions. (SM-11)

NRC Response
A licensee cannot compel the NRC staff to approve an unacceptable request. If the NRC determines that a submittal is unacceptable, then the agency has options, including denying the request (e.g., if a forward fit cannot be justified). The NRC staff cannot "force" a licensee to withdraw a request; that is the licensee's decision. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.11
The NRC should explain how it will distinguish (and what standard would be applied) between forward fits with low safety benefits that may still be imposed and those with very low safety benefits that may not. (FPL-02)

NRC Response
The NRC disagrees with this comment. As a result of the NRC's revisions to the draft NUREG's definitions of "direct nexus" and "essential," the NRC will not need to distinguish the safety benefits of forward fits as this comment suggests. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.12
Section 3.3 of the draft NUREG indicates that forward fitting applies to relief requests, proposed alternatives, exemptions, license amendments, and other requests. The draft NUREG also states that the NRC's denial of a request for a licensing action may allow the licensee to seek redress of the denial of the licensing action through a demand for hearing. The NRC should clearly identify the subset of licensing actions for which a demand for hearing would be applicable under 10 CFR Part 2 and acknowledge that some licensing actions may not carry hearing rights. (FPL-06, EGC-18)

NRC Response
The NRC agrees, in part, with these comments. The AEA and the NRC's regulations do not allow for a demand for hearing of denials for all licensing actions. Whether a licensee can demand a hearing or seek judicial relief from an NRC denial of a licensing action is beyond the scope of the draft NUREG. The NRC revised the draft NUREG in response to these comments by removing the sentence, "The NRC's denial of the request may allow the licensee to seek redress of the denial through a demand for hearing."

Comment 4.3.13
The draft NUREG lacks clarity on those "essential" forward fits in the middle—those not considered necessary for adequate protection and not of so low a safety benefit as to be abandoned. The guidance suggests that the NRC is applying a cost-benefit test but, in reality, the NUREG would just prescribe the pretense of a cost-benefit analysis that would have the same result regardless of its outcome. For an essential forward fit that can be cost-justified, the NRC would impose the forward fit and approve the license amendment request. For an essential forward fit that cannot be cost-justified, the NRC would deny the license amendment

request. In either case, the licensee's license amendment request would not be approved without the forward fit. If the NRC staff deems a forward fit "essential" and "directly related," economic cost would be no factor, unless the benefit is very low or negligible. Presumably, the Supreme Court in *Michigan v. EPA* and the Commission in approving MD 8.4 did not want the agency to consider costs as a pretense, but instead wanted it to meaningfully influence agency decision-making. By agreeing that compliance requirements can be disregarded for forward fits of "very low or negligible" safety benefits, the NRC has agreed in principle that essential requirements can be disregarded based on cost. The draft NUREG has not clearly explained why all compliance issues that cannot be cost-justified should not be treated in the same manner. (FPL-07)

NRC Response
The NRC disagrees with this comment. Forward fitting does not require cost justification. As set forth in MD 8.4, the NRC must consider the costs of forward fits. This is consistent with the *Michigan v. EPA* decision. So, the NRC would *not* have to deny a license amendment because its "essential forward fit" cannot be cost justified. Further, as explained in the NRC Response to Comment 4.3.11, as a result of the NRC's revisions to the draft NUREG's definition of "direct nexus" and "essential," the NRC will not need to distinguish the safety benefits of forward fits as this comment suggests. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.14
The forward fit guidance should only be applied if the requirements and staff positions within the current licensing basis that the NRC proposes to revise are already applicable to the proposed licensing action. For example, if a licensee proposes to use a methodology, currently in its licensing basis, to support its licensing action request, but the NRC wants to condition its approval on the use of a different methodology, then that condition would be a forward fit. However, if the licensee's proposed methodology is not applicable to the license amendment request (e.g., the methodology was never approved for this purpose), then the NRC staff should not use the forward fitting guidance when conditioning the approval. (ANSM-04)

NRC Response
The NRC disagrees with this comment. Given the NRC's revised definitions of "direct nexus" and "essential," whether the NRC's condition of its approval to use a different methodology constitutes forward fitting would depend on whether the NRC identifies a safety or security issue or noncompliance with a requirement that is already in the affected entity's licensing basis or with a new requirement the affected entity proposed in its requested change that would not exist but for the requested licensing action, the NRC condition would address that issue or noncompliance, and the condition would be necessary to make the safety or security finding to support the NRC's approval of the affected entity's request. These determinations are fact specific, and the examples in the comment do not provide enough details to properly assess the scenarios. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.15
There are many interactions among safety criteria that make the forward fitting policy impossible to implement. (RC-03)

NRC Response
The NRC agrees that addressing the technical issues associated with a requested licensing action that involves a forward fit can be very complex. However, the revised forward fitting guidance, and particularly the revised definitions of "direct nexus" and "essential," are expected to simplify the implementation of the forward fitting policy. Additionally, the NRC revised the

draft NUREG to provide scenarios to describe how these criteria would be applied in different situations. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.16
The forward fitting policy and guidance requires the NRC staff to either accept the licensee's request, exactly as submitted, or deny it, exactly as written. The staff cannot even enter into a dialogue with a licensee about how the request could be revised to address staff concerns, without the staff performing an "analysis" of effects of any staff suggestions to modify the initial proposal. (RC-02)

NRC Response
The NRC agrees, in part, with this comment. The NRC does not need to accept the affected entity's request, exactly as submitted, or deny it, exactly as written. The forward fit process provides an approach for the NRC to condition its approval of an affected entity's licensing action. Also, the NRC can use the request for additional information (RAI) process to request information to support the NRC staff's review of the licensing request. However, the NRC revised the draft NUREG to enable the sharing of forward fitting screening information with affected entities to improve the efficiency of the review process. This will ensure that both sides understand the nature of the issues and the relationship to the NRC's approval. This communication must not convey forward fits or backfits and instead should be conducted in a manner that provides the affected entity the full flexibility on how to proceed with the licensing request. The NRC revised the draft NUREG in response to this comment.

Comment 4.3.17
Requiring the NRC staff to use the forward fit process will result in more staff hours, longer reviews, and greater costs to applicants when the NRC staff considers it necessary to condition a licensing action. In some cases, the costs associated with the forward fit review process may greatly exceed the cost of the forward fit. For example, a delay in an approval that impacts a refueling outage can substantially impact a licensee's revenue. (ANSM-21)

NRC Response
The NRC agrees with this comment. A full forward fit analysis could involve a significant expenditure of staff resources and, in turn, could also impact the affected entity. The NRC also notes that it does not have to proceed with a forward fit; rather, it can, for example, discuss the request at a public meeting or deny the request, or the affected entity can decide to withdraw the request. The NRC also expects that the revised forward fit guidance should help to mitigate the resource expenditures because the revision will result in a smaller scope of NRC actions that meet the definition of a "forward fit." Even for NRC actions that meet the definition of a "forward fit," the revised guidance allows for communication between the NRC and the affected entity that enables an understanding of the forward fit screening and justification (i.e., why the NRC cannot approve the application). This would help the affected entity take the actions that best suit its needs. The NRC revised the draft NUREG's discussion of forward fitting in response to other comments.

Comment 4.3.18
When the NRC staff is considering the imposition of a condition for a licensing action, the current practice is for the NRC staff to provide the proposed condition to the licensee and allow the licensee to comment on the proposed condition. This process ensures the condition is understood by both parties and allows the licensee the opportunity to propose an alternative which may satisfy both parties. It is not clear that the forward fitting guidance will permit this practice.

The NRC staff should continue this practice for forward fitting. The licensee should be notified of the proposed condition and be provided the opportunity to voluntarily agree to the condition, propose alternatives to the condition, and provide input regarding the cost. This should occur before the NRC staff expends resources to fully develop the forward fitting justification. This can avoid unnecessary costs to the licensee when the proposed condition is acceptable to the licensee or if the licensee can propose an alternative to the proposed condition that is acceptable to the staff. (ANSM-22)

NRC Response
The NRC agrees, in part, with this comment. Consistent with MD 8.4, the NRC staff's practice of sharing a proposed license condition could result in backfitting or forward fitting, especially if the interaction with the affected entity does not provide the affected entity flexibility on how to address the issues covered by the proposed license condition. However, when the NRC determines that it cannot approve a request without imposing a condition, communication with the affected entity supports the interests of the NRC, the affected entity, and the public. Communication with the affected entity can prevent unintended consequences, save time, and avert unnecessary costs. The NRC can communicate its issue with the request to the affected entity and provide the affected entity full flexibility to decide on its own how it wants to proceed (including alternatives to the license condition). This approach should avoid backfitting and forward fitting communication issues and ensure alignment with MD 8.4. The NRC revised the draft NUREG to clarify the staff's communication with affected entities.

Comment 4.3.19
The forward fit criteria require the NRC staff to perform some sort of cost analysis of any initiative that the staff believes should be taken in order to approve a proposed license amendment. The staff is not able to perform such analyses. The staff does not have access to all the detailed engineering details or costs to the licensee associated with making engineering changes. It would have to speculate about those costs, and even technical details, in order to perform the "analysis" that is required. The staff would therefore be placed in the situation of either accepting the proposal, as-is, or denying it. (RC-04)

NRC Response
The NRC disagrees with this comment. The NRC has considerable experience performing cost estimates to support regulatory actions, including those that may be required for forward fit assessments. These estimates would reflect the incremental costs to implement the forward fit based on the affected entity's request and supporting information, as well as any additional cost information collected during interactions following the request (e.g., interactions to share the forward fit screening and justification). The NRC forward fit assessment would include a credible documented estimate of the associated incremental costs consistent with the data collected, modeling assumptions, and estimate constraints. The estimate would reflect the considerable experience of performing cost estimates for activities such as rulemaking. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.20
Forward fitting will destroy the license amendment process. It is unworkable and needs to be abandoned. Alternatively, if NRC management thinks that it is really needed, it should proceed with a formal rulemaking, rather than imposing this "guidance" on the staff by way of a Management Directive. (RC-05)

NRC Response
The NRC disagrees with this comment. As explained in the NRC responses to other comments in Section 4.3 of this document, the revised forward fitting guidance aligns with MD 8.4 and previous NRC policy concerning backfitting in response to licensing requests and will enable the NRC staff to implement the forward fitting policy within the existing licensing framework. Further, as explained in the NRC Response to Comment 4.1.3, the forward fitting policy is not a legally binding requirement, so rulemaking is not required to establish a forward fitting process. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.21
For a forward fit, it is not clear what the NRC staff will use as the baseline to determine if a new NRC requirement will result in a modification of the facility. It is not clear if the NRC staff will consider the current state of the facility, the state of the facility following implementation of the licensing action, the state of the facility once all related modifications are completed, or all possible future states allowed under the current licensing basis. If a licensee changes its facility under 10 CFR 50.59 without prior NRC approval and requests a license amendment to change the technical specifications to reflect the change made under 10 CFR 50.59, then imposing a condition on the license amendment could affect the change made under 10 CFR 50.59.

Also, the licensee may already be in compliance with the new NRC requirement. For example, facility procedures may have operational limitations that are consistent with the new NRC requirement. The draft NUREG does not explain how the NRC staff will be able to make this determination. Thus, to determine if a new NRC requirement needs to be evaluated as a forward fit, the NRC staff may need to request more information than what the regulations require. This request would likely have to comply with 10 CFR 50.54(f) since the information needed to make a forward fit determination in this situation is outside the scope of the regulations. (ANSM-05, ANSM-06)

NRC Response
The NRC disagrees with this comment. The baseline for the review will be the licensing basis as it exists at the time of the request. The licensee's request is a request to change the licensing basis, and so the NRC must understand the full nature and extent of the requested change. This can, and likely would, involve information concerning any related facility modifications (and associated impact on the key functional requirements that are changing) that support the request. If the request does not contain this information, then the staff would likely issue RAIs to obtain it. Because an RAI would be related to a licensing request, 10 CFR 50.54(f) would not be applicable. Additionally, the licensee is seeking prior review and approval to change its licensing basis, so whether it is already satisfying the new licensing basis (i.e., the licensing basis including the forward fit) is not relevant. The licensee is assuming the licensing risk and must ensure it is in compliance with the licensing basis that exists prior to the request. This comment also asks, if the licensee revises its facility under 10 CFR 50.59 and then submits a related license amendment request to change its technical specifications, whether imposition of a license condition would be a forward fit. If the licensee has properly followed 10 CFR 50.59 to change its facility licensing basis as described, then the license condition could be backfitting or forward fitting, depending on the facts and circumstances of the request, if the condition affects the change made under 10 CFR 50.59. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.22
There are no criteria that the NRC staff can use to determine whether forward fitting requirements are adequately satisfied. (SM-29)

NRC Response
The NRC disagrees with this comment. Forward fitting is a policy captured in MD 8.4 and is not a requirement. The policy in MD 8.4 and the guidance in NUREG-1409, Revision 1, contain sufficient criteria to support proper and consistent implementation such that forward fitting occurs only when properly justified. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.23
In section 3.2 of the draft NUREG, instead of evaluating statements 3 and 4, the NRC staff should ask the following questions:

1. Has the NRC staff determined that it needs to impose a condition on the approval? a. Yes—continue to next question; b. No—not a forward fit.
2. Does the condition deny part of the request? a. Yes—not a forward fit; b. No—continue to the next question.
3. Does the condition merely limit the scope of the approval? a. Yes—not a forward fit (could be a partial denial if the limit was narrower than the scope of the request); b. No—continue to next question.
4. Does the request indicate that the condition will be met? a. Yes—not a forward fit; b. No—continue to next question.
5. Is the current requirement in the licensing basis applicable to the proposed change? For example, an older Regulatory Guide on instruments may not be applicable to digital instruments. a. Yes—continue to next question in Section 3.2; b. No—not a forward fit.

Each part of the proposed condition should be considered separately. For example, if the NRC staff required a licensee to update to a new version of a Regulatory Guide, the staff would only consider the aspects of the new version that are different when answering these questions. (ANSM-07)

NRC Response
The NRC disagrees with this comment. The comment suggests (through the use of five questions) that to determine whether a proposed NRC action would be a forward fit, the NRC should ignore whether the proposed action would be an imposition of a new or changed requirement or staff interpretation of a requirement, and whether that imposition would result in a modification or addition to the licensee's SSCs, design, or procedures or organizations required for designing, constructing, or operating its facility (i.e., none of the five questions asks whether these two criteria are met). Those two questions are part of the MD 8.4 definition of "forward fitting," so they cannot be ignored. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.24
A regulatory commitment is a written statement made by a licensee to take a particular action. Thus, by making the regulatory commitment, the licensee has proposed to voluntarily comply with the proposed action. The act of changing a commitment to an obligation does not result in a change to the facility, since the applicant has already committed to make such changes. Escalation of regulatory commitments into obligations should not be included within the scope of NUREG-1409 if they are provided as part of a requested licensing action. This process is already addressed in other NRC documents (e.g., NRR LIC-101). Escalation of commitments made under other processes (e.g., in response to generic communications) should be within the scope of NUREG-1409. Requiring the NRC staff to use the forward fit process to escalate

regulatory commitments into obligations will result in more staff hours, longer reviews, and greater costs to applicants with no clear benefit. (ANSM-14)

NRC Response
The NRC agrees, in part, with this comment. The comment claims that the act of changing a licensee's commitment into an obligation does not result in a change to the licensee's facility. Although a licensee may be able to change commitments in accordance with its commitment management program without prior NRC approval, the licensee cannot change obligations (requirements) without prior NRC approval. The NRC agrees that escalating commitments might not change the physical equipment in a plant; however, such an escalation can result in changes to procedures for the design or operation of a facility.

The NRC disagrees that the scope of NUREG-1409 should not include the escalation of regulatory commitments into requirements if the commitments are provided as part of a requested licensing action. A licensee that includes commitments in a requested licensing action is only voluntarily offering to comply with the proposed action. By escalating the commitment into a requirement, the NRC would be imposing a requirement that the licensee did not request. The draft NUREG includes screening such escalations for backfitting and forward fitting for this reason. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.25
On the whole, the NRC must ensure that its implementation of forward fit does not disincentivize licensees from submitting voluntary licensing actions. Licensees should not have to weigh the benefits of submitting a licensing action, which may improve safety, operations, or efficiency, against the potential downsides of inappropriate forward fits. Any such result would have perverse effect on the backfit regulatory construct. (EGC-07)

NRC Response
The NRC agrees with this comment. Implementation of the forward fit policy and guidance should not disincentivize voluntary licensing actions. However, that is a risk each licensee takes when it submits a licensing request. The revisions to the draft NUREG provide a more defined and predictable process that has the appropriate level of process discipline to avoid the condition contemplated in this comment. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.26
The narrow redefinition of the term "forward fit" is confusing in that this phrase has long been used in a more general sense within the industry. Now that this Commission has unilaterally appropriated the term to mean a mere slice of what it used to, what term will this Commission use in instances where a new regulatory position may eventually be applied in a forward-looking manner, whether or not it is directly conditioned to the approval of a licensing action (for example, the issuance of a new revision of a regulatory guide that licensees are not required or committed to follow)? (JJS-01)

NRC Response
The NRC disagrees with this comment. The Commission's definition of "forward fit," as explained in the draft NUREG, is the only definition of that term. Any previous definitions of a "forward fit" should not be used in the future, including when the NRC issues regulatory guides to reflect new or revised guidance. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.27
According to the new forward fit policy, a licensee's voluntary request may apparently be granted without adopting the new regulatory position the regulatory staff deems essential to support implementation of the request. In the case of this Commission's new forward fit policy, there is no fig-leaf presumption of safety derived from a historical finding of regulatory compliance; rather, according to this Commission, the request may be granted under some circumstances, despite full knowledge that the request would lead to a plant configuration that is inadequate to demonstrate regulatory compliance according to the regulatory staff's best judgment using the best available technical knowledge and, hence, inadequate to protect the public health and safety. The new forward fit policy clearly places licensees' profit margins above the public health and safety. The policy permits licensees to cherry-pick favorable regulatory positions, regardless of their technical validity, meanwhile allowing them to ignore those they find burdensome, even those burdensome positions the regulatory staff finds necessary to implement the voluntary licensing request in accordance with the Commission's regulations. (JJS-04, JJS-05)

NRC Response
The NRC disagrees with this comment. As stated in Section 3.3 of the draft NUREG, the NRC does not have to accept an affected entity's voluntary request and instead can deny the request if the request does not satisfy the standards necessary to grant approval. In this circumstance, the NRC would likely interact with the affected entity to ensure a full understanding of the request and the issues involved that prevent approval, prior to a denial. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.28
On page 3-4 of the draft NUREG, in the paragraph beginning on line 17, a distinction is being made with the previous paragraph that does not come across clearly. When, on line 19, the text states that "the existing regulatory staff position is available for current licensees to use and applicable to the licensing action," what is meant (e.g., regulatory guide, standard review plan, interim staff guidance)? Does this Commission intend to include among "available" regulatory positions that another licensee somewhere in the United States maintains an alternative position that was once approved in the past (and has not been backfitted) but which is no longer acceptable to the regulatory staff? If this latter interpretation is correct, then how does this Commission intend to ferret out all the differences in licensing basis that may make the regulatory positions in the licensing basis of one plant appropriate for it, but not necessarily for other plants? (JJS-06)

NRC Response
The "existing regulatory staff position" in the statement cited in the comment refers to generic NRC staff positions that licensees can choose to adopt (e.g., regulatory guides). "Available" regulatory staff positions in that context are not facility-specific positions, which typically are staff positions adapted and applicable to only a specific licensee or facility and therefore not available to be adopted by another licensee or facility. The NRC revised the draft NUREG to provide this clarification.

Comment 4.3.29
On page 3-4 of the draft NUREG, when the "availability" of regulatory staff positions is being discussed, it is not clear how earlier revisions of documents are regarded. Earlier revisions of documents, while no longer considered acceptable on a technical basis for new applications according to the NRC staff's current standards, have never been withdrawn or otherwise formally disavowed for future applications. Preventing future applications of the antiquated

guidance is a separate and distinct act (i.e., neither a backfit nor a forward fit) from removing an antiquated guidance document from the licensing basis of individual plants previously approved to use it (i.e., a backfit). Do the regulatory positions represented by such earlier revisions of approved documents, which in general have not been explicitly repudiated, remain "available" or not? Does this Commission plan to direct the NRC staff to review any such superseded, but non-repudiated, documents that it would deem as containing so-called "available" regulatory positions to ensure that they remain technically valid and justifiable, or does this Commission intend to require the regulatory staff to accept, carte blanche, licensees' use of outdated regulatory positions that obviously lack technical justification for voluntary design changes to their plants? (JJS-07, JJS-08, JJS-12)

NRC Response
If the NRC has issued more than one version of a guidance document and has not withdrawn any of those versions, then all versions remain available for use by licensees. If an earlier version of guidance is removed, or its use restricted in some way (including if the NRC staff determines that use of this guidance would not demonstrate compliance with the applicable requirement), and this version of the guidance is within existing licensees' approved licensing bases, then that action to restrict its use is subject to backfitting. If the various versions of the regulatory guidance all fully address the technical issues associated with a voluntary licensing request, then the staff attempt to require the affected entity to adopt a version of the guidance that the affected entity did not propose to use in its licensing request is subject to backfitting. The NRC staff may explore technical issues associated with any request and to ensure proper application of guidance (i.e., the affected entity's use of the guidance is technically valid and justifiable). The NRC does not plan to systematically review guidance to determine whether it is outdated. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.30
What are the standards or criteria for consideration of costs for forward fitting? Are they the same as backfitting? The policy is utterly amorphous and unsuitable for practical implementation and will cause inconsistency in the regulatory staff's determinations. This would not appear logical or appropriate since, versus backfitting, the decision to implement licensing requests ultimately remains voluntary (i.e., the licensee may withdraw the request), the request has not previously been approved, and plant design modifications associated with the request do not necessarily represent a sunk cost.

It would be inappropriate to consider costs associated with preparing and submitting a licensing application in a regulatory cost-benefit balance. Should these costs be brought into explicit consideration, it could spell the end of the regulatory staff's capability to perform credible, independent technical assessments of licensees' engineering analyses. For example, a licensee might argue it has already signed contracts or spent multi-millions to analyze and purchase a new fuel design. In this example, according to the licensee's (unapproved) probabilistic risk assessment models, changing fuel designs may result in no change in plant risk. Therefore, the licensee might argue, not only is it unreasonable for the staff to forward fit, but there also may be no justification to pose RAIs. How does this Commission intend to treat this point? (JJS-09, JJS-10)

NRC Response
The NRC disagrees with these comments. The standards for considering costs are different for forward fitting and backfitting. In backfitting, the NRC must show that the proposed agency action would be cost justified. For a forward fit, the NRC must only consider the costs of the proposed agency action.

The cost estimates to support a potential forward fitting would be performed to inform the decision whether to approve the request with the condition or to enable the most cost-effective approach to be chosen. This comment is correct in that an affected entity would still have the choice to revise its request, withdraw its request, or accept the NRC's forward fit. If the affected entity has already incurred sunk costs associated with the request, then the affected entity assumes that licensing risk, including any costs incurred to support responses to RAIs. The cost estimated for the forward fit would exclude those sunk costs. The NRC revised the draft NUREG regarding cost estimates supporting forward fits consistent with this comment.

Comment 4.3.31
The new forward fitting policy pressures the regulatory staff to accept unacceptable technical positions it has already found to be outdated and inadequate. A further consequence of the new policy is that by forcing such low standards onto the regulatory staff, it suppresses a healthy safety-conscious work environment. (JJS-11)

NRC Response
The NRC disagrees with this comment. The NRC staff can perform a backfit or forward fit assessment depending on the circumstances to determine whether new requirements can be imposed on an affected entity. If an affected entity proposes inadequate technical approaches or positions, then the NRC may deny the application. The new forward fit policy provides additional discipline to NRC reviews. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.32
Can the staff penalize a licensee who has done the proper thing (i.e., using a new version of guidance that it is not already part of its licensing basis) by asking questions or challenging anything in its evaluation? For, in fact, the minimum acceptable standard, as determined by this Commission, after scraping away the artifice of its euphemisms, would be the technically invalid previous version of the standard that's already part of the licensing basis. (JJS-13)

NRC Response
The NRC disagrees with this comment. The comment implies that the NRC might "penalize" a licensee that has proposed in a licensing request to adopt new guidance by asking questions and challenging the request. Although the NRC certainly welcomes the use of newer guidance that increases safety, its reviews are based on the technical merit of the licensee's proposal. The NRC may use the RAI process, audits, and public meetings to ensure it fully understands the proposal such that it has sufficient information and basis to approve or deny the request. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.33
The new forward fitting policy, in addition to the pressure caused by Nuclear Energy Innovation and Modernization Act (NEIMA) and economics, unduly shifts the burden of proof onto the regulatory staff to complete its reviews in a timely manner and with little burden to the licensee. When licensees choose technically invalid but "available" positions to support licensing requests, NRC staff now must prove there is a risk-significant adequate protection safety problem with the request. However, NRC staff frequently lacks the tools and information to perform such analyses in the limited amount of time it has available to process licensing requests. The new policy provides a superficial appearance of containing minimal checks and balances (i.e., adequate protection). However, because of the burden of proof, lack of available information, challenges associated with posing questions to licensees, and the schedule

pressures facing the NRC staff's review effort, even these minimal checks and balances appear largely ineffectual. (JJS-14)

NRC Response
The NRC disagrees with this comment. As discussed in response to other comments, the new policy provides greater discipline to ensure that new requirements are imposed on affected entities only when properly justified by safety or security reasons. Contrary to the statements in this comment, the NRC has the tools it needs to implement these processes and policy. These processes, when implemented properly, provide a holistic approach of considering risk insights, deterministic information, and, depending on the circumstances, costs. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.34
This guidance does not consider the possibility of an inconsistent application of forward fitting policy (e.g., asking one licensee to meet a new licensee condition but not another licensee, which may have, or have had a similar licensing request under review). (SM-26b)

NRC Response
The NRC disagrees with this comment. The purpose of NUREG-1409, Revision 1, is to provide the NRC staff with updated backfitting, forward fitting, and issue finality guidance. Proper and consistent implementation of this guidance is addressed through training and management oversight. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.3.35
The implication that the forward fitting guidance applies to anything the licensee did not request is too broad. Limitations on the scope of the NRC staff's approval should be excluded from a forward fitting review. For example, the NRC may need to condition its approval of a licensee's change to its technical specifications on the completion of a plant modification. The draft NUREG suggests that if the NRC were to impose such a condition, it would need to evaluate the condition as a forward fit. (ANSM-03)

NRC Response
The NRC disagrees with this comment. The issue described by the example in the comment can be addressed through RAIs that, as the basis for the question, cite the regulatory requirement that the NRC must have reasonable assurance of the licensee's continued compliance with applicable requirements. The NRC staff can also hold a public meeting to explain to the licensee its basis for not approving the requested action before potentially entering the forward fit process. The licensee could voluntarily respond, for example, with proposed changes to address the staff's concerns. The NRC staff does not have to enter the forward fit process (e.g., it can deny the application). The NRC did not revise the draft NUREG in response to this comment.

4.4 Comments on Chapter 4 of the Draft NUREG

Comment 4.4.1
On page 4-1 of the draft NUREG, the NRC states that "[l]icensees can discuss the applicability of backfitting regulations and the forward fitting policy with the applicable U.S. Nuclear Regulatory Commission (NRC) staff *whenever* the licensees have a concern." (emphasis added) However, the draft NUREG provides no further clarification about this process, whether it is intended to be something different than a formal appeal, how staff would disposition a

licensee's backfitting/forward fitting "concern," and how the staff's position should be communicated to the licensee. (EGC-11)

NRC Response
The NRC agrees, in part, with this comment. Although the draft NUREG describes how the staff would disposition the affected entity's concern (e.g., determine whether the proposed staff action would constitute backfitting or forward fitting and take the appropriate next steps), the NRC agrees that it does not explain how the staff would communicate its response, if any, to the affected entity.

The NRC revised the draft NUREG in response to this comment to provide guidance for the NRC staff on how to communicate with affected entities about backfitting concerns raised by affected entities that are not submitted as backfit appeals under Chapter 4 of the NUREG. The NRC staff should discuss the concern with the affected entity to ensure mutual understanding of the issue. The staff must ensure that its division-level management is informed of an affected entity's concern and must evaluate the points raised by the affected entity before taking a proposed staff action (e.g., issuing a violation or license amendment). The staff's evaluation of the affected entity's concern is not intended to be exhaustive but should appropriately consider the affected entity's concern within the established schedule for issuing the NRC action (e.g., an inspection report following the exit meeting). The staff should orally discuss its understanding of the licensing basis without conveying an expectation of action by the affected entity prior to taking an action.

The NRC also revised the NUREG by relocating this guidance from Chapter 4 to Chapter 1 of the NUREG.

Comment 4.4.2
On page 4-1 of the draft NUREG, the NRC states that "[t]he NRC provides a process by which licensees may appeal staff actions on the basis that the licensee concludes the staff did not properly follow the backfitting or forward fitting *process*" (emphasis added). As written, this seems to further narrow the scope of an appeal to only "process" concerns. This is too narrow and inconsistent with the remainder of the appeal section, which allows for challenging both a process concern as well as a concern with the staff's technical basis for the backfit/forward fit. (EGC-14)

NRC Response
The NRC agrees, in part, with this comment. Following the backfitting or forward fitting process includes properly justifying the staff determination. To make this point explicit, the NRC revised the sentence referenced in the comment by changing "follow the backfitting or forward fitting process" to "perform a backfitting or forward fitting assessment." As explained in the draft NUREG, a backfitting or forward fitting assessment includes the screening, justification, and any cost considerations for the backfitting or forward fitting action.

Comment 4.4.3
In the context of a license amendment request, the licensee arguably would have to accept the staff position and obtain approval of the license amendment request before it could appeal the decision because the staff position would not be "imposed" on the licensee until the legally binding license amendment is issued. This creates an absurd result that we do not believe is consistent with the Commission's intent in its revisions to Management Directive 8.4. This is also inconsistent with other statements found in the draft NUREG that clearly suggest that the licensee does not have to wait until a legally binding position is "imposed" on them prior to

appealing the staff's position. Page 4-4 of the draft NUREG indicates that an NRC position regarding forward fits expressed during the pendency of the staff's review of a licensing action request would trigger the beginning of the 30-day clock for filing an appeal. But this seems inconsistent with the text on page 3-3 (lines 43–48) of the draft NUREG indicating that the NRC would not clearly explain the forward fit to the licensee during the licensing review. In this case, the NRC should send formal correspondence to the licensee regarding the forward fit determination, together with the appeal instructions, in order to make clear what the issue is and that the clock would begin to run. (FPL-08, EGC-10)

NRC Response
The NRC agrees with these comments. The NRC revised the draft NUREG to clarify that the NRC will provide affected entities an opportunity to submit MD 8.4 appeals (including first-level and second-level appeals) on proposed backfitting or forward fitting actions before issuance of the staff's licensing action and on issued backfitting or forward fitting actions. If the affected entity chooses to appeal the proposed backfitting or forward fitting action, then it cannot file another MD 8.4 appeal after the NRC issues the licensing action as long as the NRC did not substantially change the proposed backfitting or forward fitting action. If NRC does substantially change the proposed backfitting or forward fitting action, then the affected entity will have another opportunity to appeal the revised proposed backfitting or forward fitting action.

If the affected entity does not appeal the proposed backfitting or forward fitting action, then it may submit an MD 8.4 appeal after issuance of the licensing action. Following the issuance of NUREG-1409, Revision 1, the staff will update office implementing procedures to address appeals of issued licensing actions and staff actions to take upon conclusion of the appeal process (e.g., rescinding or modifying the licensing action). The NRC also added guidance to Chapter 5 (Section 5.1.4) of the NUREG to describe how it would communicate proposed backfitting or forward fitting actions to the affected entity within the context of processing a licensing action.

Comment 4.4.4
In the draft NUREG, the NRC states on page 4-1 that "[i]f the NRC initiated a staff action using an order, the appeal process described in this section does not apply. After the NRC issues an order, appeals are governed by the provisions of 10 CFR Part 2…." While true that the proper process for challenging an order is a request for hearing under Part 2, this does not account for the requirement at 10 CFR 2.202(e)(1) that "[i]f the order involves the modification of a Part 50 license and is a backfit, the requirements of § 50.109 of this chapter shall be followed." Section 2.202(e)(1) does not explain what it means to "follow" § 50.109 in the context of an order. We recommend that the NRC clarify this relationship, particularly the agency's obligations under § 2.202(e)(1). (EGC-15)

NRC Response
The NRC agrees with this comment. The NRC revised the draft NUREG to note that the regulation at 10 CFR 2.202(e)(1) states, in part, that if an order involves the modification of a 10 CFR Part 50 license and is a backfit, then the requirements of 10 CFR 50.109 shall be followed unless the licensee has consented to the action required. Therefore, if the NRC proposes to issue an order that would constitute backfitting for a 10 CFR Part 50 licensee, then the NRC must subject the proposed order to a backfitting assessment before issuing the order unless the order is needed to address an imminent threat to public health and safety or the licensee consents to the requirements of the order. The NRC typically provides the licensee the

opportunity to submit a backfitting appeal on a proposed facility-specific nonenforcement order if time permits.

Regarding the comment's example of appealing a backfit order, the NRC staff revised the NUREG to state that if the affected entity chooses to request a hearing on an issued order, then the MD 8.4 appeal process does not apply. Rather, the provisions of 10 CFR Part 2, Subpart B, "Procedure for Imposing Requirements by Order, or for Modification, Suspension, or Revocation of a License, or for Imposing Civil Penalties," would apply, as specified in MD 8.4. Any backfitting issues would be raised within the 10 CFR Part 2 proceeding. If an Atomic Safety and Licensing Board (ASLB) grants a hearing request, then the ASLB would be responsible for the resolution of the hearing, including any backfitting concerns raised by an affected entity or intervenor. An affected entity or intervenor can also appeal (under 10 CFR Part 2) the ASLB's decision to the Commission. In this instance, the ASLB and Commission replace the MD 8.4 first-level and second-level appeals, respectively. If the affected entity does not pursue an adjudicatory hearing, then it may submit an MD 8.4 appeal only if the affected entity did not already submit an MD 8.4 appeal of the proposed order and the issued order is not substantively different from the proposed order.

The staff notes that 10 CFR 2.202(e)(2) and (e)(3) contain similar requirements for orders involving combined licenses and early site permits. However, 10 CFR 50.109; 10 CFR 52.98, "Finality of combined licenses; information requests"; and 10 CFR 52.39, "Finality of early site permit determinations," do not contain requirements for appealing or requesting a hearing on backfitting orders. Therefore, the requirements in 10 CFR 2.202(a)(3) would be used to request a hearing. In part, 10 CFR 2.202(a)(3) states that the Commission may issue an order that will inform the licensee or any other person to whom the order was issued of their right, within 20 days of the date of the order, or such other time as may be specified in the order, to demand a hearing on all or part of the order except if the licensee or other person has consented in writing to the order.

Comment 4.4.5
The draft NUREG does not consider whether the NRC staff is justified in conducting its own research that goes beyond facts of the appeal (i.e., to conduct a purposive investigation, which would include information that is not presented by the appellant), or whether it should limit itself to the information that is available in the appeal, and within the NRC. If an independent review is authorized, then it is necessary to allocate time and budget resources, to some specified limit. It is also necessary to apply quality controls, to avoid biased methods, and prevent reaching prescribed conclusions. (SM-32)

NRC Response
The NRC disagrees with this comment. MD 8.4 specifies that the NRR and NMSS Office Directors decide first-level appeals within their respective program office's area of responsibility, and the EDO decides second-level appeals. The draft NUREG already specifies that a reviewing panel established by an office director must consist of "individuals who are independent from the initial action or position at issue," and a panel established by the EDO must consist of managers and an attorney "who have not previously participated in the initial action or staff position nor first-level appeal." MD 8.4 specifies that a second-level appeal panel "must consider all supporting staff analyses, submitted licensee analyses, and supplemented staff analyses, as well as any other information that is relevant and material to the appeal." The draft NUREG provides this guidance for first-level appeal panels: "The panel must consider all supporting staff analyses, licensee-submitted analyses, and any other information that is relevant and material to the appeal." This guidance also applies to the office directors and

EDO. Each appeal is different, so the NUREG cannot set generic limits on staff resources to be expended during an appeal. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.4.6
The draft NUREG expects each individual member of an appeal panel (e.g., the attorney) to have the "appropriate technical…expertise and experience to thoroughly evaluate the action or position at issue." Then the guidance relaxes the required individual qualifications of each member (including the attorney) to a single, collective qualification. Which is it? (SM-36)

NRC Response
The NRC disagrees with this comment. The qualifications for the first- and second-level appeal panels are the same (although NRC staff below the level of Deputy Division Director cannot be members of the second-level appeal panel). Section 4.3.a of the draft NUREG provides the qualifications of the members of a first-level appeal panel: "A manager at the deputy division director level or higher should chair the panel, and membership should include an attorney from OGC and staff or management with the appropriate technical and regulatory expertise and experience to thoroughly evaluate the action or position at issue" (emphasis added). Section 4.6.a of the draft NUREG provides the qualifications of the members of a second-level appeal panel: "The panel should consist of managers at the deputy division director level or higher and an attorney from OGC, each with the appropriate technical and regulatory expertise and experience to thoroughly evaluate the action or position at issue" (emphasis added). To clarify that the qualifications are the same, the NRC revised the draft NUREG by removing ", each" from the qualifications of the members of a second-level appeal panel.

Comment 4.4.7
In the draft NUREG, the NRC states on page 4-4 regarding a first-level appeal that "[i]f the licensee fails to appeal the decision within 30 calendar days or implement the required action by the agreed-upon date, then the NRC will resolve the issue through the enforcement program." This statement is both vague and too narrow. Not all denied appeals are resolved "through the enforcement program." For instance, if the licensee were to appeal a forward fit imposed as part of a license amendment request, then the issue would not be resolved "through the enforcement program." We recommend this statement be clarified. This comment also applies to the same statement in the context of second-level appeals found on page 4-6. (EGC-17)

NRC Response
The NRC agrees, in part, with this comment. The NRC modified the NUREG to account for the appeals of proposed actions and, thus, modified the statements on the appropriate steps for the NRC to take after an appeal. If the NRC has already taken an action and an affected entity does not timely appeal the backfit or forward fit or, after the appeals process results in the backfit or forward fit being upheld, implement the backfit or forward fit by the required implementation date, then the NRC can take enforcement action against the affected entity for being out of compliance with its license (e.g., not implementing the issued amendment containing a forward fit). However, the NRC did clarify the statements in the draft NUREG about how the NRC would respond to the noncompliance: "If, after the appeal decision upholding an NRC-issued action, the affected entity either does not submit a second-level appeal within the timeframe specified in the first-level appeal response letter or does not implement the required action, then the NRC may take appropriate action to address the affected entity's noncompliance."

Comment 4.4.8
The rulemaking process should be used to eliminate the second-level appeal. Its existence gives the EDO an opportunity to overrule his expert staff. If the second-level appeal decision overturns the first-level appeal decision, then the competence of the staff is rightly questioned. It also implies that the EDO is in possession of information or expertise that is not available amongst members of the NRC staff. The second-level appeal also gives appellants and their representatives an opportunity to exert undue influence upon the EDO's appeal evaluations and decision. (SM-63b)

NRC Response
The NRC disagrees with this comment. The NRC would not use the rulemaking process to eliminate second-level appeals when MD 8.4 and NUREG-1409 and not the regulations address the overall appeals process for backfitting and forward fitting actions. Regarding the EDO's overturning a first-level appeal decision, it is the EDO's responsibility and prerogative to make such a decision on a second-level appeal, as specified by the Commission in its policy captured in MD 8.4. The NRC disagrees that a decision to overturn a first-level appeal calls into question the competence of the staff. Rather, it may reveal the need for the agency to update its training and procedures to capture lessons learned. Also, the EDO's decision to overturn the first-level appeal does not imply that "the EDO is in possession of information or expertise that is not available amongst members of the NRC staff." It means that the EDO reached a different conclusion than the staff. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.4.9
The draft NUREG does not specify criteria by which the NRC staff can judge whether the appeal's information is relevant or sufficient. If the first-level appeal must include sufficient documentation to justify the licensee's basis for the appeal, and that appeal is denied, it can be concluded that its information is irrelevant or insufficient. What additional information would be required for a second-level appeal? (SM-31)

NRC Response
The NRC disagrees with this comment. Whether a staff action constitutes backfitting or forward fitting is a fact-specific determination, so the NRC cannot provide generic guidance on whether information to support a backfitting or forward fitting appeal is "relevant or sufficient." The affected entity must decide what information to provide to justify its appeal. Second-level appeal information could depend on the basis for the first-level appeal denial.

Further, the fact that a first-level appeal is denied does not mean that the information submitted to support that appeal was "irrelevant or insufficient." The multiple levels of appeal provide opportunities to address mistakes, oversights, or misunderstandings made at the lower levels of the NRC staff (i.e., with the imposition of the backfit or forward fit, or at the first-level appeal). This is analogous to the U.S. system of justice, in which court decisions can be appealed based on various reasons, such as perceived errors in process or application of law. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.4.10
The draft NUREG should define and limit the content of a second-level appeal to the "outcome" of the first-level appeal. A second-level appeal addresses flaws in the first-level appeal outcome (i.e., in the facts and/or logic of the evaluation, in the review process, or in the credentials and/or eligibility of the appeal evaluators). A second-level appeal could not be solely

a repeat of the first-level appeal. A second-level appeal would be expected to contain facts that were not presented in the first-level appeal. (SM-35)

NRC Response
The NRC agrees, in part, with this comment. The second-level appeal is an appeal of the first-level decision (outcome) and not of the initial backfitting or forward fitting determination; however, the second-level appeal could make findings different than the initial backfitting or forward fitting action. The second-level appeal could find, in some cases, other issues associated with the backfit or forward fit and the first-level appeal that may not have been apparent during the first-level appeal review. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.4.11
The draft NUREG blurs the lines of responsibility and accountability between the EDO and his/her appointed panel. The guidance should clearly state that the responsibility and accountability belong to the EDO, regardless of the presence of a panel's recommendations, right or wrong. (SM-37)

NRC Response
The NRC agrees, in part, with this comment. The NRC disagrees that the draft NUREG blurs the line of responsibility on appeals. The NRC agrees, and already states in Section 4.7 of the draft NUREG, that the EDO is ultimately responsible for the second-level appeal: "The EDO will evaluate the information and recommendation provided by the panel and make a decision on the appeal. The EDO will draft a response letter to the licensee that comprehensively documents the basis for the EDO's decision and submit the draft response letter to OGC for its review. … To the extent practical, the EDO should transmit the response letter to the licensee within 90 calendar days of receipt of the appeal." The NRC did not revise the draft NUREG in response to this comment.

Comment 4.4.12
The draft NUREG does not recognize the possibility that a stakeholder, other than a licensee or other regulated entity, can be affected by a backfit order and can file an appeal. For example, a backfit order that has the effect of exempting a licensee from complying with certain regulations or design criteria could impede the NRC's ability to protect the health and safety of persons (i.e., public stakeholders) who live in the vicinity of the licensee's plant. NUREG-1409 should help the NRC staff process appeals received from public stakeholders. (SM-22)

NRC Response
The NRC agrees, in part, with this comment. Backfitting imposes new or changed requirements based on criteria intended to result in an increase in safety, security, or both. As a result, the public is typically a beneficiary of the agency action, and the affected entity is typically the impacted entity. The NRC uses the backfitting and forward fitting appeal process to determine whether to take a backfitting or forward fitting action. The section of MD 8.4 on appeals does not provide for non-affected entities filing backfitting or forward fitting appeals. However, stakeholders could participate in the actual agency action that implements the result of the forward fitting or backfitting action (e.g., through the filing of a hearing request related to a license amendment, assuming the stakeholders can show standing and proffer an admissible contention, as appropriate for the regulatory mechanism used to modify the license). For issued backfitting orders, a member of the public could use the appropriate process from 10 CFR Part 2 (i.e., either request a hearing related to the order or a 10 CFR 2.206 petition rather than file a backfitting appeal) or general correspondence to raise concerns with the

agency's action. If a member of the public can show standing and meet the contention requirements with respect to an issued backfitting order, that member may be granted a hearing. The ASLB would be responsible for the hearing process and resolution, including any backfitting issues. An intervenor can also appeal an ASLB's decision to the Commission.

Although the opportunity to appeal will continue to be afforded only to the entity affected by the proposed backfitting or forward fitting action, the NRC revised the draft NUREG to state that external stakeholders (e.g., members of the public) would continue to have the ability to participate in proceedings that change a facility's license (e.g., through the filing of a hearing request related to a license amendment, a petition request under 10 CFR 2.206, "Requests for action under this subpart," that the NRC issue an order, or general correspondence).

Comment 4.4.13
Several comments involved a request for increased transparency or public participation during a backfit or forward fit appeal. These comments include:

- Appeal panel meetings with NRC staff should at least allow the licensee to attend the meeting, otherwise it seems to be patently unfair to the licensee. The licensee, the NRC staff, and interested stakeholders should all be able to at least observe all substantive conversations between the decision maker, the relevant NRC staff including the appeal panel, and the licensee. If a meeting is not made public, then a transcript of the meeting should be made publicly available promptly after the meeting. (NEI-41, EGC-16)

- The NRC should convene a public meeting when it receives a backfitting or forward fitting appeal. Also, zero-sum regulation should solicit and carefully consider input from affected public stakeholders. Relaxation of requirements for the licensee can establish an "alternative approach" that decreases safety. That decrease in safety would have to be borne by the public. A decrease in safety can cause health problems or a drop in property values. The licensee's gain would be achieved at the expense of the public stakeholders. It seems fair that such zero-sum regulation would have to solicit and carefully consider input from affected public stakeholders. The draft NUREG specifies the offer of a public meeting during an appeal, but this offer is made only to the licensee. Failure to convene a public meeting, when considering a backfit (or forward fit) appeal, shuts out public stakeholders' participation in regulatory matters that concern them. This could erode the public's confidence in the NRC. It is also possible that other information (e.g., analyses) could be available from other sources (e.g., public stakeholders). NUREG-1409 should include a call for such information at the time that information is being collected from the staff and licensee. This is inconsistent with the NRC's strategic plan (ADAMS Accession No. ML18032A561). The draft NUREG does not specify how the NRC staff should include summaries of the closed meetings, described as "drop in" visits by MD 3.5, in its summaries of all the appeal meetings with the licensee. (SM-30, 34, 38, 48)

- The rulemaking process should be used to require the NRC staff appeal panel to convene at least one public meeting during its deliberations and prohibit all closed meetings between NRC staff appeal panel and appellants and/or their representatives during the panel's deliberations. (SM-63b)

NRC Response
The NRC agrees, in part, with these comments. The NRC revised the NUREG to recommend that an affected entity state whether it requests the NRC to hold a public meeting with the

NRC's applicable office director (or the EDO) or an appeal panel when it files its appeal. The NRC will issue a publicly available acknowledgement letter to the affected entity informing the affected entity that the NRC received its appeal and is processing it in accordance with MD 8.4 and NUREG-1409, Revision 1.

The NRC revised the NUREG to have the Office Director (or the EDO) or an appeal panel provide a public meeting for the appeal decisionmaker to discuss the facts associated with the appealed action and the NRC staff responsible for the appealed backfitting or forward fitting action, if the decisionmaker wants such a meeting. However, this does not preclude the appeal panel or decisionmaker from holding nonpublic (internal) meetings to discuss the issue with the NRC staff. The NRC will notice a public meeting with the NRC staff and any appeal meetings with the affected entity as Category 1 public meetings and allow an opportunity for members of the public to speak and ask questions of the appeal panel members or decisionmaker and the NRC staff. The appeal panel or decisionmaker has the flexibility to determine how many public meetings it will hold (e.g., whether to hold separate meetings with the staff and affected entity if the affected entity chooses to participate, or to combine the meetings), the style of information exchange, and the roles of meeting attendees. The appeal decisionmaker should clarify this information in the meeting notice. The NRC staff will refrain from making any decisions on the appeal at the public meeting(s).

Discussions involving sensitive (e.g., proprietary or security-related) information with the staff and affected entity will be closed in accordance with other NRC processes; however, the NRC staff would notice the meetings and issue a written (redacted) meeting summary in accordance with Section IV.C.2 of the handbook for MD 3.5, "Attendance at NRC Staff-Sponsored Meetings." If the licensee declines its opportunity for a public meeting, and if the Office Director, EDO, or appeal panel decides not to meet with the NRC staff responsible for the appealed action, then the NRC will not hold a public meeting.

The NRC disagrees with the comment about using the rulemaking process to establish requirements for backfit or forward fit appeals process public meetings because it determined that rulemaking is not necessary for the staff to follow the MD policy and the guidance in the NUREG (see NRC Response to Comments 4.1.3 and 4.3.20).

In addition, the NRC staff revised the NUREG to state that the Office Director, EDO, or appeal panel members must not have substantive discussions (i.e., beyond a simple status of the process and scheduling logistics) about the appeal with the affected entity or its representatives during any closed drop-in visits, in accordance with MD 3.5. Closed drop-in visits are not part of the appeal process described in NUREG-1409. Under MD 3.5 Handbook, Section III.E.2, drop-ins are exempt from the requirement to provide summaries of closed meetings.

The NRC disagrees with the zero-sum regulation comment. To justify a backfitting action, the NRC must show that the action would either be (1) necessary for adequate protection or compliance, which would not involve a decrease in safety or security, or (2) a substantial increase in safety or security. A forward fit must be essential to the NRC staff's determination of the acceptability of the affected entity's request, which means that the forward fit would be necessary to make the safety or security finding to support approving the request. Therefore, a backfitting or forward fitting action would not result in a decrease in safety that "would have to be borne by the public."

Comment 4.4.14
Licensees should be able to raise backfitting concerns (but not a formal backfitting appeal) when the NRC identifies an apparent violation, including an apparent "minor violation," but the licensee thinks it is following applicable requirements. This is to avoid initiating a separate process to address issues that are at the heart of the enforcement action, which is whether the licensee is in compliance with a legally binding requirement. (NEI-38, NEI-39)

NRC Response
The NRC agrees with this comment. The NRC Response to Comment 4.4.1 discusses the NRC response to licensee claims of backfitting outside of the appeal process. In response to this comment and Comments 4.4.1 and 4.4.16, the NRC clarified Chapters 1, 4, and 5 of the NUREG to explain how NRC inspectors should respond to licensee oral claims of a backfit outside of the backfitting appeals process.

Comment 4.4.15
The NRC received multiple comments whether licensee can both deny a violation and file a backfit appeal:

- In 2019, Exelon disputed a Notice of Violation (NOV), claiming that the alleged violation was actually outside the licensing basis. Because the NRC had not taken a position on the licensing basis question, there would have been no definitive NRC backfitting position to appeal. Nevertheless, the NRC initially interpreted Exelon's statements in our October 16, 2019, response letter as a backfit appeal even though it would not have met the filing requirements of MD 8.4. NRC staff and Exelon spent additional time and effort to clarify Exelon's position that we were merely requesting that the staff take a position with respect to the licensing basis. This experience reinforces the need for NUREG-1409 to establish a clear, predictable process for raising and receiving clarity on backfitting issues that arise in the context of inspection and enforcement proceedings. (EGC-09)

- Licensees should be able to appeal a backfit while also denying a violation, or the licensee may present backfitting-related arguments when replying to the NOV or NCV. (NEI-74)

NRC Response
The NRC agrees, in part, with these comments. Regarding the situation described in Comment EGC-09, the licensee used available processes to dispute the violation based on unjustified backfitting. The NRC revised the draft NUREG to include guidance in Chapter 4 of the NUREG on how the NRC can address the possible combinations of the 10 CFR Part 2 dispute process and the MD 8.4 appeal process that a licensee may use (i.e., the licensee submits a 10 CFR Part 2 dispute, an MD 8.4 appeal, or both, and the timing of those submittals). The NRC also revised the draft NUREG to indicate that licensees should be explicit in their correspondence that they are denying or disputing a violation in accordance with 10 CFR Part 2, submitting an MD 8.4 appeal, or both.

Comment 4.4.16
The NRC received multiple comments that the NRC should share backfitting screening determinations before taking actions:

- The staff should share its backfitting determinations with the licensee before imposition so that the licensee can appeal. It is difficult to appeal an NRC determination that its

proposed action is not backfitting (i.e., during inspection when the NRC concludes the issue is within the licensing basis and the licensee does not agree) when the licensee does not understand the basis for the NRC's determination. This could arise due to a verbal suggestion that the licensee would not ignore, but the licensee would not be able to formulate an appeal of the NRC's determination without some reasonable articulation supporting the NRC's determination. Additionally, the NRC's "silence" in this situation shifts the burden for identifying backfits to the licensee and creates a disincentive to expend the resources for identifying any backfits. It also leads to an overreliance on the appeals process, which is not efficient and can lead to challenges during the first-level appeal. (NEI-35, NEI -36, NEI-37)

- If a licensee believes that the NRC inspection finding constitutes backfitting, then the staff must directly address the licensee's claim. The staff's position should be documented in the preliminary and/or final exit meeting discussion and documented in the associated inspection report. Provide opportunities for licensees to address forward fit or BF challenges, such as during an inspection, by using the NRC's existing process for addressing Very Low Safety Significant Issues. A recent contested violation experience demonstrates the inefficiencies of the current BF processes as they apply to inspection and enforcement scenarios, and also reinforces the need for further refinements to both Chapters 4 and 5 of draft NUREG-1409. By challenging inspectors on the licensing basis question during the inspection process, Exelon expected that, under MD 8.4, the NRC would have assessed the BF implications of its position and informed the licensee of the staff's conclusions. Had the NRC agreed to assess the licensing basis question prior to issuing the NOV, the current processes in MD 8.4, current NUREG-1409, and the draft revision to NUREG-1409 would have provided no guidance to either the staff or the licensee on how Exelon's BF claim should have been dispositioned. Consistent with NEI's comments on Chapter 5, the NRC should establish clearer process expectations for raising BF concerns during inspections. Section 5.4 of the draft NUREG states that "the staff should first identify and resolve any differing views about the licensing basis (e.g., through the technical assistance request process discussed in Section 5.21 of this NUREG) and ensure that the licensing basis is understood before beginning a BF or forward fit assessment or pursuing enforcement." While Exelon appreciates this acknowledgment, the draft NUREG still does not provide clarity on how those issues would be resolved. (STARS-07, EGC-08, NEI-72)

- Consistent with our comments on Chapter 4, a process prior to "imposition" of a staff position (similar to the VLSSIR process described in IMC 612, Appendix B) is needed. Arguably, the VLSSIR process already provides this opportunity since it is focused on the question of resolving licensing basis questions that arise during inspections. The primary distinction with BF, however, is that the level of effort in resolving a licensing basis issue is not necessarily relevant from a licensee's perspective if the NRC persists in pursuing enforcement action. In contrast, if the VSSLIR process results in the staff discontinuing an enforcement action notwithstanding the lack of resolution of the licensing basis question, Exelon would agree that the VSSLIR process is appropriate. However, the staff's final decision must be documented to guard against unnecessarily reopening the issue sometime in the future. (EGC-19, STARS-07)

NRC Response
The NRC agrees, in part, with these comments. The NRC agrees that the NRC and the affected entity should communicate on the issue to mitigate any misunderstandings concerning an issue or disagreements about the issue's standing within the licensing basis. The NRC also

agrees that it has the burden and responsibility for identifying and justifying backfitting and forward fitting; these requirements and policies are imposed on the NRC. The NRC staff revised Chapter 4 of the NUREG to acknowledge the MD 8.4 provision that allows affected entities to submit appeals on proposed and issued actions. However, the NRC faces practical limitations to providing written predecisional information to affected entities, and affected entities submitting MD 8.4 appeals on such information may not result in an efficient use of resources. For example, proposed violations discussed at exit meetings are subject to subsequent NRC management approval or denial before the NRC issues of the inspection report or violation. After an exit meeting, the NRC inspector may continue to review supporting documentation and consult with other NRC staff to ensure proper disposition of the issue of concern. The affected entity may not be aware of the latest status of the proposed violation after the exit meeting until or unless the NRC communicates a change in the proposed violation's status to the affected entity, and the proposed violation may change or not be issued at all. Although the affected entity may file an MD 8.4 appeal before the NRC issues the inspection report, the proposed action may still change or not be issued at all; thus, NRC and affected entity resources spent on such an appeal may be unproductive.

Recent changes to NRC guidance (e.g., Reactor Oversight Process Inspection Manual Chapter 0611, "Power Reactor Inspection Reports," dated January 7, 2020, and Chapter 0612, "Issue Screening," dated January 1, 2020, and NRR Office Instruction COM-106, "Technical Assistance Request (TAR) Process," dated August 24, 2020) reflect the agency view that NRC resources should not be inappropriately spent on licensing basis determinations for issues having very low safety significance. These processes acknowledge that unresolved licensing basis determinations for issues having very low safety significance may go unresolved unless further information supports a resource-appropriate disposition. These processes also provide for resolving licensing basis interpretations that arise during inspections. Therefore, the NRC did not revise the draft NUREG to require the NRC staff to resolve all licensing basis determination issues prior to issuing inspection reports because this issue is outside the backfitting process.

However, the NRC revised Chapters 4 and 5 of the draft NUREG to provide guidance for increased communications on proposed actions and appealing proposed and issued agency actions.

Comment 4.4.17
Licensee should be able to appeal a backfitting decision made by the NRC staff and not have to wait until issuance of an enforcement action or an inspection report. (NEI-40)

NRC Response
The NRC agrees, in part, with this comment. MD 8.4 states that affected entities can appeal proposed staff actions, including proposed inspection results orally communicated at inspection exit meetings. As discussed in the NRC Response to Comment 4.4.16, because much of the inspection deliberations are predecisional and subject to change until an inspection report is issued, backfit appeals on proposed inspection results may not result in an efficient use of NRC and affected entity resources. The NRC revised the NUREG to acknowledge the MD 8.4 provision that allows affected entities to submit appeals on proposed and issued actions, which includes proposed inspection results orally communicated at inspection exit meetings. The NRC also revised the NUREG to provide the NRC staff with options on how to respond to appeals submitted on proposed actions.

Comment 4.4.18
Licensees who object to forward fitting requirements have nothing but MD 8.4, and NUREG-1409 to support their right to file an appeal. Likewise, the NRC staff has only MD 8.4 and NUREG-1409 to guide it through an appeal, if it decides to consider it. (SM-28)

NRC Response
The NRC agrees with this comment. Affected entities are subject to the requirements imposed on them by a forward fit and can appeal a forward fit under the process described in MD 8.4 and Chapter 4 of NUREG-1409, Revision 1. The NRC will process appeals consistent with MD 8.4 and NUREG-1409, Revision 1. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.4.19
The appeals section assumes that a licensee would be appealing an NRC staff decision that an action does not constitute forward fitting. If the NRC staff decides not to pursue a forward fit, then the licensee would not appeal that decision. The guidance should be revised to remove this statement. A proposed imposition on the licensee's request that does not meet the direct nexus and essentiality criteria to be a forward fit should be treated as backfitting. (NEI-43)

NRC Response
The NRC disagrees with this comment. If the NRC staff imposes a condition that the NRC staff concludes does not meet the definition of "forward fitting," then MD 8.4 provides the affected entity an opportunity to appeal that imposition if the affected entity determines that the NRC's imposition is unjustified forward fitting. An NRC-proposed imposition on a licensee's request should be screened for backfitting if it is not justified forward fitting. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.4.20
Part 52 applicants relying on NUREG-0800 can submit forward fitting appeals if the staff changes a position in NUREG-0800 vis a vis that applicant. (NEI-44)

NRC Response
The NRC agrees with this comment. As stated in MD 8.4, forward fitting would generally not apply to an applicant for an initial licensing action for a new facility. However, that same part of MD 8.4 also states that applicants can reasonably rely on the applicable sections of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition" (SRP), and that any change in staff positions from the version of the SRP interpreting the Commission's regulations should follow the same reasoned decisionmaking process as a forward fit. Accordingly, if an applicant finds that the NRC staff has not followed such a reasoned process for revising an applicable SRP section, then that applicant can submit an MD 8.4 appeal. The NRC revised the draft NUREG to add this clarification in response to this comment.

Comment 4.4.21
The NRC received several comments about the timing of issuing forward fitting actions and filing forward fitting appeals:

- Once the staff finds that the proposed forward fit meets the direct nexus and essential elements, the staff should provide its evaluation to the licensee. The licensee should be able to appeal the NRC's direct nexus and essentiality determinations. Chapter 4 of the draft NUREG should include a separate section on forward fit appeals. This section

should describe how the NRC shares the direct nexus and essentiality determination with the licensee, which can initiate a forward fit appeal, and the options available to both the staff and licensees at the initiation and conclusion of the appeals process. This would enable a streamlined process in which the licensee is not required to accept the staff position prior to issuing an appeal. (NEI-31, NEI-32, NEI-42, FPL-05, STARS-06)

- The NRC must complete a regulatory analysis after winning a forward fitting appeal but before issuing the forward fit. A licensee should be able to appeal not only direct nexus and essential findings but also regulatory analyses that support forward fits. (NEI-45, NEI-46)

- In the context of a license amendment request, the licensee arguably would have to accept the staff position and obtain approval of the license amendment request before it could appeal the decision because the staff position would not be "imposed" on the licensee until the legally binding license amendment is issued. This creates an absurd result that we do not believe is consistent with the Commission's intent in its revisions to Management Directive 8.4. This is also inconsistent with other statements found in the draft NUREG that clearly suggest that the licensee does not have to wait until a legally binding position is "imposed" on them prior to appealing the staff's position. Page 4-4 of the draft NUREG indicates that an NRC position regarding forward fits expressed during the pendency of the staff's review of a licensing action request would trigger the beginning of the 30-day clock for filing an appeal. But this seems inconsistent with the text on page 3-3 (lines 43–48) of the draft NUREG indicating that the NRC would not clearly explain the forward fit to the licensee during the licensing review. In this case, the NRC should send formal correspondence to the licensee regarding the forward fit determination, together with the appeal instructions, in order to make clear what the issue is and that the clock would begin to run. (FPL-08, EGC-10)

- On page 4-1 of the draft NUREG, the NRC states that closely connected to the triggering of an opportunity for appeal are appeal filing deadlines. On page 4-2, lines 23–25, the draft NUREG states that "[l]icensees should submit written appeals within 90 days of receiving the NRC's written action or staff position or 30 days after the NRC issues its decision on a directly related disputed violation." However, it remains unclear when the 90-day deadline would be triggered for a forward fitting scenario (e.g., issuance of the license amendment or at some point before then). (EGC-13)

NRC Response
The NRC agrees, in part, with these comments. The NRC agrees that the draft NUREG needed additional guidance for allowing licensees to submit MD 8.4 appeals on proposed actions. The NRC also agrees that waiting to inform the affected entity of the forward fit until issuance of the licensing action can result in inefficiencies and unintended consequences. The NRC revised the NUREG by adding guidance in Chapters 4 and 5 on how the NRC staff can initiate discussions with an affected entity when the NRC identifies a concern with a requested licensing action and how to provide an affected entity an opportunity to appeal a proposed backfit or forward fit. Because licensing actions are fact specific, especially in regard to issuance, effective, and implementation dates, the NRC does not specify specific due dates for filing appeals in this NUREG. Office-level implementation procedures can specify guidance for establishing those dates depending on the details of the licensing action.

4.5 Comments on Chapter 5 of the Draft NUREG

Generic Comments on Chapter 5

Comment 4.5.1
Restructure Chapter 5 into three topics: Previously Applicable Staff Position, Inspection and Enforcement, and Other Processes to make Chapter 5 a much more practical tool to assist the NRC staff in implementing the agency's backfitting and forward fitting procedures. (NEI-47)

NRC Response
The NRC agrees, in part, with this comment. The NRC agrees that rearranging the content in Chapter 5 by grouping closely related processes would provide a more fluent narrative on how backfitting and forward fitting apply to various NRC processes. The NRC revised Chapter 5 by grouping processes into the categories of licensing, generic processes, inspection, and enforcement. This resulted in renumbering all subsections.

Comment 4.5.2
Align section 1.2.2.2. in the draft NUREG, including NEI's comments on that section, with NEI's suggested changes to the discussion of "applicable staff position" in the draft NUREG's Chapter 5. (NEI-48)

NRC Response
The NRC agrees, in part, with this comment. The NRC verified the consistency of the discussion of "staff positions" throughout the draft NUREG; however, as stated in the NRC Response to Comment 4.2.12, the NRC did not incorporate the comment on "previously applicable staff positions." The NRC did not revise the draft NUREG in response to this comment.

Comment 4.5.3
NUREG-1409, Revision 1, should contain a section on FSARs based on language in the current NUREG-1409. (NEI-56)

NRC Response
The NRC agrees, in part, with this comment. The NRC revised Chapter 5 of the draft NUREG to discuss mandated licensing basis documents, which include the updated FSAR. In Section 3.3(15) of the 1990 version of NUREG-1409, the NRC states, "Where the staff previously accepted the licensee's program as adequate, any staff-specified change in the program would be classified as a backfit." The draft NUREG addresses this point in Section 1.2.2.2:

> Safety evaluations (or safety evaluation reports) provide the staff position on whether a licensee's proposed means for implementing or complying with a governing requirement is acceptable and results in compliance with the requirement. ... If the NRC subsequently decides that a staff position in a safety evaluation is incorrect, then agency actions related to that decision are subject to backfitting assessment.[8]

Footnote 8 reinforces this: "[C]hanges to staff positions established in safety evaluations (and other correspondence) are subject to the backfitting and forward fitting provisions and policy." Statements throughout the draft NUREG speak to "staff-specified" changes to a licensee's

program (e.g., page 5-4, line 1-2: "If the [staff-]imposed action is beyond what is required under the licensee's licensing basis, then the action would be backfitting").

The NRC revised the draft NUREG in response to this comment by adding a new section to Chapter 5 on mandated licensing basis documents, which discusses the requirements for their content, change control, and reporting, and the relationship between mandated licensing basis documents and staff positions.

Comment 4.5.4
Approval of exemptions can create applicable staff positions if the NRC includes conditions (either proposed by the licensee or initiated by the NRC) in the approval. (NEI-59)

NRC Response
The NRC agrees, in part, with this comment. The NRC's basis for concluding that an exemption request is acceptable is documented in its approval of the request and is a facility-specific staff position. Any conditions specified in the exemption are requirements. The NRC revised the draft NUREG discussion on staff positions in Section 1.2.2.2 and Chapter 5 to address this comment.

Comments on Section 5.1, "Change Control Processes"

Comment 4.5.5
Section 5.1, "Change Control Processes," of the draft NUREG should be clarified that a change under a change control process establishes an applicable staff position (because NRC-imposed revisions to the changed position would be subject to backfitting). (NEI-55)

NRC Response
The NRC agrees with this comment. Changes that licensees make to their licensing bases in accordance with applicable change control processes (e.g., 10 CFR 50.59) and any other applicable requirements can be considered "staff positions" for purposes of backfitting. The establishment of the regulations and requirements for the change control programs provided the NRC position that changes made in compliance with such regulations and requirements are acceptable to the NRC staff. The NRC revised the draft NUREG to add this explanation to Section 5.1.

Comments on Section 5.2, "Clarifications"

Comment 4.5.6
As stated in Section 5.2, "Clarifications," even clarifications must be evaluated for backfitting. (NEI-77)

NRC Response
The NRC agrees with this comment. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.5.7
A clarification that does not impose a burden upon the licensee (e.g., a staff position that revokes a previous staff position or positions that the licensee has not implemented) is not backfitting. The draft NUREG does not explain why a backfitting assessment would be necessary for such a clarification. (SM-40)

NRC Response
The NRC disagrees with this comment. Whether a staff action "imposes a burden" on a licensee is not the test of whether the staff action constitutes backfitting. Backfitting occurs when the NRC issues a new or revised requirement or staff position that, in general, results in certain changes to an affected entity's SSCs or design of its facility or its procedures or organization required to design, construct, or operate its facility. The draft NUREG explains that "proposed clarifications have the potential to impose new or additional requirements or staff positions (e.g., revoking previous staff positions) …. If the original staff position allowed for multiple interpretations, and the staff is now trying to limit licensees to one interpretation, then that limitation would be a new staff position and, if imposed on a licensee, would require a backfitting or forward fitting justification." The NRC did not revise the draft NUREG as a result of this comment.

Comments on Section 5.3, "Commitments"

Comment 4.5.8
Section 5.3, "Commitments," should include a discussion of how an applicable staff position could be created through commitments, including staff engagement with a licensee regarding a commitment. The 1990 version of the NUREG provides for this (e.g., licensee commitments in FSAR, licensee event reports, and docketed correspondence). (NEI-58)

NRC Response
The NRC agrees, in part, with this comment. As stated in the draft NUREG, MD 8.4 provides that, in the backfitting context, a written commitment is a commitment that has been submitted to the NRC on the docket, has been incorporated into the license, and directly relates to how the licensee complies with a requirement. When a commitment has been incorporated into the license, it ceases being a commitment and becomes a requirement. Therefore, licensee commitments are not legally binding requirements nor enforceable unless the commitment was escalated into a requirement.

Communications guidance throughout the draft NUREG cautions the NRC staff against verbally conveying new requirements or new staff positions to affected entities because the verbal communication can constitute backfitting (e.g., the NRC staff should not be involved with the licensee's creation of a commitment it makes to the NRC). Therefore, the staff would need to conduct any engagement with an affected entity about a commitment in accordance with the communications policy in MD 8.4. If the NRC issued a document about a commitment's acceptability or adequacy, then the NRC's document would establish a staff position about the commitment.

The NRC recognized the need to add guidance for certain commitments. If the staff directs a licensee to place a commitment in a mandated licensing basis document (e.g., updated FSAR), then the commitment ceases being a commitment managed by the licensee's commitment management program and would be subject to other change control processes (e.g., 10 CFR 50.59). This NRC action could be subject to a backfitting or forward fitting assessment. The NRC revised the draft NUREG to contain this clarification.

Comment 4.5.9
Page 5-10, lines 12–14, of the draft NUREG state, "Therefore, for nuclear power reactor licensees, the staff would need to take a backfit or forward fit action to escalate a regulatory commitment into a requirement if the licensee did not voluntarily do so." The "if the licensee did

not voluntarily do so" part of the statement is unclear. A licensee cannot make a commitment an obligation. Only the NRC can make something an obligation. (ANSM-15)

NRC Response
The NRC agrees with this comment. Licensees can request the NRC's escalation of a commitment into an obligation (requirement) rather than make a commitment a requirement. The NRC revised the draft NUREG to make the following clarification: "Therefore, for nuclear power reactor licensees, the staff may need to take a backfitting or forward fitting action to escalate a regulatory commitment into a requirement if the licensee did not voluntarily ask the NRC to do so."

Comments on Section 5.4, "Differing Views of a Licensing Basis"

Comment 4.5.10
NUREG-1409 does not need a section on differing views when the NRC has processes for addressing differing internal views. (NEI-50)

NRC Response
The NRC agrees, in part, with this comment. Section 5.4 in the draft NUREG covers differing views of a licensing basis and reminds the staff that it must develop its interpretation of the licensing basis before beginning the backfitting or forward fitting process. However, that section contained some redundant and unnecessary statements. The NRC revised the draft NUREG to replace the text, "Therefore, the staff should first identify and resolve any differing views about the licensing basis (e.g., through the technical assistance request process discussed in Section 5.21 of this NUREG) and ensure that the licensing basis is understood before beginning a backfitting or forward fitting assessment or pursuing enforcement," with the following text: "Therefore, before beginning a backfitting, issue finality, or forward fitting assessment, the NRC must verify the licensing basis using informal or formal processes internal to the NRC (e.g., routine staff interactions or technical assistance requests)." Although members of the NRC staff may have differing views of the licensing basis, processes outside the backfitting and forward fitting process will address these issues.

Comment 4.5.11
One issue that causes confusion is when a licensee's non-conservative Technical Specification (TS) is identified during an inspection. The confusion concerns whether this issue is an enforcement issue or a potential backfit issue. The draft NUREG should provide sufficient clarifications concerning enforcement issues and enforcement matters that are outside the scope of the backfitting process. (RM-06)

NRC Response
The NRC disagrees, in part, with this comment. The determination of whether an issue of concern should be addressed through enforcement or backfitting depends on whether the issue is part of the existing licensing basis. NUREG-1409 is not a guidance document for determining what is in the licensing basis, but it does reference other documents and processes that are intended to address that determination, such as the addition to the draft NUREG stated in the NRC's Response to Comment 4.5.10. The NRC did not revise the draft NUREG in response to this comment.

Comments on Section 5.5, "Enforcement"

Comment 4.5.12
In Section 5.5.2, "Violations," of the draft NUREG, provide more substance, including an explanation for each of the example violations regarding backfitting applicability. (NEI-73)

NRC Response
The NRC agrees with this comment. The NRC revised the draft NUREG in response to this comment by explaining the basis for the applicability of backfitting to the scenarios discussed in Section 5.5.2 of the draft NUREG.

Comment 4.5.13
Section 5.5.1, "Confirmatory Action Letters," of the draft NUREG should be revised to state that a confirmatory action letter (CAL) can be an applicable staff position if the NRC ultimately requires the licensee to do something more or different from those obligations or commitments. (NEI-54)

NRC Response
The NRC disagrees with this comment. The NRC's enforcement policy (ADAMS Accession No. ML19352E921) defines a CAL as a letter confirming a licensee's, contractor's, or nonlicensee's (subject to NRC jurisdiction) voluntary agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment. A CAL does not require a licensee to perform the actions that the licensee commits to perform as described in the CAL, so the fact that a CAL describes a licensee commitment does not create a staff position. Although the purpose of a CAL is not to create a staff position, the staff could inadvertently do so. The NRC has revised the draft NUREG-1409 to explain that the NRC should avoid creating staff positions in CALs by (1) stating that the staff understands that the licensee intends to take certain actions and (2) not using language suggesting that the licensee's actions are acceptable or would restore compliance. Furthermore, if the NRC requires the licensee to do something more or different from the actions described in the CAL that the licensee is not already required to do under its licensing basis, then the imposition of the new requirement would constitute backfitting because the causal aspect of the backfit would be a change to the licensing basis, not a change to the commitments or requirements in the CAL.

Comments on Section 5.6, "General Design Criteria"

Comment 4.5.14
By the time a licensee receives an operating license, its PDC are approved and filed away with the plant's Preliminary Safety Analysis Report. Since "the design basis of the plant, as reflected in the PDC, meets or exceeds the minimum criteria in the GDC," it follows that any design that doesn't meet GDC requirements cannot possibly meet PDC requirements. Therefore, a plant design fails to comply with GDC requirements must be remedied, possibly via a compliance-based backfit order. No reference to PDC requirements is necessary. GDCs are design requirements, which are more than just performance standards. Performance standards are entered into technical specifications; and they're derived from the results of analyses and evaluations of plant designs that are developed in accordance with the GDCs. The results of said analyses and evaluations are reported in Chapter 15 of the FSAR. The consequent technical specifications follow in Chapter 16. Therefore, technical specifications come after the GDCs are implemented, not before. Technical specifications assure that the plant is operated

within the performance standards set by the results of analyses and evaluations reported in Chapter 15 of the FSAR. (SM-42, -43)

NRC Response
The NRC disagrees with these comments. As explained in the draft NUREG, for purposes of the compliance exception, the NRC should consider the technical specifications, other licensee requirements derived from the GDC, and the PDC before considering the GDC. If those requirements do not address the matter in question and the GDC is prescriptive in nature, then the GDC can be considered as the relevant requirement. Also, many licensees were licensed prior to the establishment of the current GDC and, therefore, the current GDC do not apply to those licensees (some exceptions apply in facility-specific circumstances). The NRC did not revise the draft NUREG as a result of this comment.

Comments on Section 5.7, "Generic Communications"

Comment 4.5.15
Section 5.7, "Generic Communications," should be revised to state that although generic communications cannot be used to establish a new requirement or impose a staff position that is new or different from a previously applicable staff position, each generic communication must be assessed for any backfitting implications prior to publication. For example, the boilerplate language in a RIS does not demonstrate that the staff performed a backfitting assessment. (NEI-67)

NRC Response
The NRC agrees, in part, with this comment. Generic communications are not intended to establish new requirements or impose staff positions. That does not mean that the NRC could never issue a generic communication that inadvertently meets the definition of "backfitting." For this reason, the NRC should subject each generic communication to a backfitting assessment before issuing the generic communication. The NRC revised the draft NUREG in response to this comment.

Comments on Section 5.8, "Guidance Documents"

Comment 4.5.16
Section 5.8, "Guidance Documents," should reflect discussions of "impositions" in Chapter 2 and voluntary submissions in Chapter 3 and expressly state that guidance documents can establish applicable staff positions. (NEI-62)

NRC Response
The NRC agrees, in part, with this comment. The discussion of guidance documents in Section 5.8 should be consistent with and reflect discussions in the rest of the draft NUREG. Applicants and licensees are treated differently in the context of applications, and NUREG-1409, Revision 1, should reflect this distinction, too. The NRC revised the draft NUREG to clarify the discussion of licensees and applicants. The staff also corrected page 5-5, line 45, in the draft NUREG because licensees do not submit applications for initial licenses. Sections 1.2.2.2 and 5.8 of the draft NUREG state that guidance documents can establish staff positions, and Section 1.2.2.2 describes when guidance documents and generic staff positions apply to a specific licensee. The staff included a reference to Section 1.2.2.2 in the "Guidance Documents" section in Chapter 5 of the NUREG.

Comment 4.5.17
Licensees should be able to continue to rely on guidance that has been superseded even if they voluntarily choose to amend a provision of their license relative to that guidance. Also, the NRC should merge Sections 5.8.3, "Withdrawing Guidance," and 5.8.4, "Superseding Guidance." The comment included proposed clarifying edits to the draft NUREG's section about withdrawing guidance documents. (NEI-64, NEI-65, NEI-66)

NRC Response
The NRC agrees with this comment. Section 5.8.4 of the draft NUREG contains a statement that the NRC would limit the ability of a licensee to continue using guidance that the NRC supersedes with new guidance: "Superseding prior guidance could have backfitting and forward fitting effects. To prevent backfitting, the NRC allows a licensee already using the prior version of the guidance to continue using that version as long as the licensee does not change its licensing basis relative to that guidance document." The NRC recognizes that this statement is incorrect. For the NRC to allow a licensee to continue using the superseded guidance, the NRC must conclude that use of the guidance would continue to enable the licensee to comply with applicable requirements. The licensee should be able to make a change to its licensing basis relative to that guidance document as long as it properly follows the applicable change control process. This is consistent with the underlying premise of regulatory stability established within the backfitting regulations and the NRC's Principles of Good Regulation.

Further, if licensees can continue to use "superseded" guidance, then the guidance is not actually superseded. If the NRC wants licensees not to use a guidance document, then the NRC needs to withdraw that guidance document in accordance with existing procedures and the guidance withdrawal section of NUREG-1409, Revision 1. The NRC revised the draft NUREG by removing Section 5.8.4 in response to this comment.

Comment 4.5.18
Last year, the NRC withdrew a Regulatory Issue Summary that concerned what is described in the draft NUREG as "forward fitting." The NRC also withdrew a draft revision to the Regulatory Issue Summary. The draft NUREG does not explain how the withdrawal of a "clarification" would be consistent with the guidance. (SM-39)

NRC Response
The NRC disagrees with this comment. The draft NUREG includes guidance on the withdrawal of guidance documents in Chapter 5. Regarding the specific example cited in the comment, in the "Withdrawal of Regulatory Issue Summary 2005-29 and Draft Revision 1, 'Anticipated Transients That Could Develop Into More Serious Events,'" dated May 15, 2019 (ADAMS Accession No. ML19121A534), the NRC explained that it was withdrawing those documents because "the information in RIS 2005-29 and draft Revision 1, is not consistent with current staff positions." The NRC did not revise the draft NUREG as a result of this comment.

Comment 4.5.19
The staff can impose a guidance document provision on a licensee only if it's part of a backfitting, based upon a regulation (e.g., 10 CFR 50.109). The staff cannot impose a guidance document provision as part of a forward fitting, since there is no regulation pertaining to forward fitting. The staff cannot impose a guidance document provision without a regulatory basis. "Draft guidance does not constitute a staff position, so the staff should not use it in licensing decisions" (page 5-6, ln 1). (SM-45)

NRC Response
The NRC agrees, in part, with this comment. The NRC agrees that the staff cannot impose a guidance document provision without a regulatory basis. However, the staff does not need a regulation to take a forward fitting action, as discussed in the NRC Response to Comment 4.1.3. Also, 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. The NRC revised the draft NUREG to clarify the statement about draft guidance.

Comments on Section 5.11, "Inspections"

Comment 4.5.20
On page 5-9 of the draft NUREG, the NRC states that "[a]n inspector's suggestions to consider an applicable guidance document or NRC-endorsed topical report to resolve the findings are not backfitting as long as the inspector does not convey an expectation that the licensee must use the guidance document or topical report." While we agree that inspector "suggestions" typically would not constitute backfitting, the NRC should not categorically exclude the possibility that an inspector's suggestion could never result in a backfit. Rather than categorically excluding certain regulatory interactions, NUREG-1409 should make clear that even a suggestion might intentionally or unintentionally constitute backfitting, and that these scenarios must be reviewed on a case-by-case basis to understand the full context of the inspector's suggestion and how it is perceived by the licensee. (EGC-20)

NRC Response
The NRC disagrees with this comment. The NRC cannot subject every conversation between an inspector and an affected entity to a backfitting assessment. The draft NUREG only states the importance of ensuring that any interactions with the affected entity comply with MD 8.4 and, as such, are not conducted in a manner that conveys an expectation to the affected entity. The NRC cannot preclude an affected entity from perceiving this communication as an expectation even when properly conducted, and the NRC should not expend resources addressing such scenarios. As stated in Section 1.5 of the draft NUREG, "Suggestions for consideration do not constitute backfitting, and licensees may consider the suggestions and choose whether to implement them…. A licensee is not obligated to conform to staff suggestions; however, if it chooses to do so, the licensee should understand that it is doing this voluntarily and that the suggestion does not constitute the imposition of a requirement" (emphasis added). The NRC did not revise the draft NUREG as a result of this comment.

Comment 4.5.21
The draft NUREG's discussion of inspections should be separated from the discussion of violations. (NEI-69)

NRC Response
The NRC agrees, in part, with this comment. In response to Comment 4.5.1, the NRC reorganized Chapter 5, and the discussion of violations is now under a section on enforcement. However, violations are also discussed in the inspection section so far as they relate to inspection activities.

Comment 4.5.22
The draft NUREG should explicitly state that if an inspector does identify a concern with the adequacy of the current licensing basis (i.e., an issue beyond the requirements in the licensing basis), then that concern should be dispositioned in accordance with the backfitting process and

not through the inspection or enforcement process. Also, the phrase “exceed a governing requirement” in Section 5.11 is vague. (NEI-70)

NRC Response
The NRC agrees, in part, with this comment. The NRC states on page 5-9 of the draft NUREG, lines 26–29, “If an inspection identifies a potential safety or security issue that is beyond the requirements in the licensing basis, then the staff must follow the backfitting process to define the backfitting action, determine whether backfitting actions should be pursued, and develop the necessary justification.” This statement essentially restates the comment. However, the NRC determined that other statements in Section 5.11 of the draft NUREG could be clarified to state that if an NRC inspector identifies a concern with the adequacy of the current licensing basis, then that concern must be dispositioned in accordance with the backfitting process discussed in the NUREG. Any backfitting actions resulting from such concerns will be coordinated by NRR or NMSS, as appropriate. The NRC revised the draft NUREG in response to this comment.

Comments on Section 5.12, “Licensing Basis”

Comment 4.5.23
Section 5.12, “Licensing basis,” should combine the draft NUREG’s Sections 5.4, “Differing views of licensing basis,” 5.12, “Licensing Basis,” and 5.21, “Technical Assistance Requests,” to ensure consistency in discussion of these issues and also provide additional emphasis on the importance of establishing the licensing basis early in any licensing and enforcement process. (NEI-49)

NRC Response
The NRC agrees, in part, with this comment. In response to Comment 4.5.1 and this comment, the NRC reorganized Chapter 5 and grouped the sections on differing views and technical assistance requests under a new section, “Licensing Basis Verifications.” The NRC revised the draft NUREG in response to this comment.

Comments on Section 5.13, “Orders”

Comment 4.5.24
Section 5.13, “Orders,” of the draft NUREG should define an “imminent threat analysis” because it seems to be unique to backfitting, and it is not clear how an order citing an imminent threat analysis is different from an immediately effective order under 10 CFR 2.202(a). Also, Section 5.5.1, “Confirmatory Orders,” of the draft NUREG should be merged with Section 5.13, “Orders.” (NEI-53)

NRC Response
The NRC agrees with this comment. The staff revised the draft NUREG to provide clarification for the meaning of an imminent threat analysis within the context of the NUREG and its relation to immediately effective orders. In response to Comment 4.5.1 and this comment, the NRC reorganized Chapter 5 and grouped the topics of orders, imminent threat analyses, and confirmatory orders. The NRC also included a brief discussion on enforcement orders in the new enforcement section of Chapter 5 of the NUREG.

Comment 4.5.25
A regulatory action, such as issuing an order, would have to be based upon a regulation (e.g., 10 CFR 50.109), not NUREG-1409 or MD 8.4. (SM-44)

NRC Response
The NRC agrees, in part, with this comment. The NRC agrees that regulatory actions cannot be based on NUREG-1409 or MD 8.4. In addition, the NRC does not consider 10 CFR 50.109 as the basis for taking regulatory actions, such as issuing orders. NUREG-1409, MD 8.4, 10 CFR 50.109 concern the backfitting and forward fitting processes that the NRC must follow when developing its regulatory actions. The NRC did not revise the draft NUREG as a result of this comment.

Comments on Section 5.14, "Policy Statements"

Comment 4.5.26
If a policy statement constitutes "a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position," then the policy statement should be evaluated for both backfitting and forward fitting implications. Section 5.14 of the draft NUREG should discuss this and the significance of policy statements with respect to establishing an applicable agency position that licensees should be able to rely upon for purposes of backfitting. (NEI-75)

NRC Response
The NRC disagrees with this comment. The definition of "backfitting" in 10 CFR 50.109 does not include "agency" positions; rather, that definition includes "staff" positions. An NRC policy statement is the policy of the Commission; therefore, a Commission policy statement cannot be a regulatory staff position interpreting the Commission's regulations. As explained in Section 5.14 of the draft NUREG, the NRC would take an additional action to enforce a policy statement in a specific case. Likewise, to make a policy statement a requirement for a licensee, the NRC staff would issue a facility-specific licensing action (e.g., a safety or security order) involving the policy statement to create a facility-specific staff position. Such an action would be subject to a backfitting or forward fitting assessment. The NRC can also make a policy statement generically applicable by conducting a rulemaking that creates or amends regulations that implement the principles described in the policy statement. The NRC revised the draft NUREG to add this clarification.

Comments on Section 5.15, "Regulatory Analysis"

Comment 4.5.27
One commenter suggested edits to Section 5.15, Regulatory Analysis," of the draft NUREG. (NEI-76)

NRC Response
The NRC agrees with this comment. The suggested edits provide additional information to distinguish a regulatory analysis from a backfit analysis. These two different types of analyses are similar enough to be confusing and warrant additional clarification in NUREG-1409, Revision 1. The NRC revised the draft NUREG in response to this comment.

Comments on Section 5.16, "Requested Licensing Actions"

Comment 4.5.28
A discussion of requested licensing activities is not necessary in Chapter 5 of the draft NUREG because the subject is covered at length in Chapter 3, "Forward Fitting." The discussion on license renewals in Section 5.16, "Requested Licensing Actions," of the draft NUREG should be moved to Chapter 3 in the context of forward fitting. (NEI-78)

NRC Response
The NRC agrees, in part, with this comment. Section 5.16 of the draft NUREG provides guidance on voluntary licensee requests, the scope of the NRC's review of requested licensing actions in the context of backfitting, and license renewal applications under 10 CFR Part 54 in the context of backfitting and forward fitting. Chapter 2 of the draft NUREG already has a section on license renewals, so the NRC moved that Section 5.16 discussion to Chapter 2. The NRC revised the draft NUREG in response to this comment.

Comment 4.5.29
Section 5.16, "Requested Licensing Actions," contains these sentences: "The backfitting provisions do not apply to voluntary licensee requests for changes to its licensing basis. 'Voluntary' is considered to be any action or request to the NRC by the licensee that was made of the licensee's own accord, without the force of a legally binding requirement or an NRC representation of further licensing or enforcement action." It is not clear what is meant by "without the force of a legally binding requirement or an NRC representation of further licensing or enforcement action." If the NRC requires a licensee to submit a licensing action by order, then the backfitting implications should be considered at the time of the order and not with the licensing action. Additionally, 10 CFR 50.59 (for example) requires licensees to submit amendments if certain conditions are met. The NRC should consider such actions to be voluntary even though there is a legally binding requirement. Typically, licensees can decide what to request even if they are obligated to make the request by rule, license condition, or order. Licensing requests where the licensee has a choice regarding the proposed change should all be considered voluntary. (ANSM-16)

NRC Response
The NRC agrees, in part, with this comment. The NRC agrees that if the NRC requires (e.g., by order) a licensee to submit a license amendment request, then the NRC would assess the order for backfitting implications. Such a license amendment request would not be considered to have been submitted voluntarily because the NRC required the submittal. The NRC also could introduce backfitting issues during its review of the license amendment request, and the NRC would need to subject its approval of the license amendment to a backfitting assessment. Within the request itself, the licensee has flexibility to develop the amendment to fit its needs and the specifics of its facility, provided the amendment also implements the imposed requirements. In this context, "force" means to directly cause the licensee to submit the request.

The NRC agrees that 10 CFR 50.59 provides a regulatory structure and associated authority for a power reactor licensee to make changes to its facility or procedures on its own volition. The NRC does not force the licensee to propose or make these modifications, even when that same structure defines when those changes must be submitted to the NRC for prior review and approval. The NRC determined that Chapters 1, 2, and 3 of the draft NUREG address licensee submittals, and Chapter 5 already has a discussion on change control processes. Therefore, the NRC revised the draft NUREG in response to this comment to delete this guidance from Chapter 5 and to explain "voluntary" in a footnote in Chapter 1.

Comment 4.5.30
Nuclear plants are licensed to operate for a period of 40 years. In their licensing bases, "infrequent incidents" are described as incidents that "may occur during the life of the particular plant" (e.g., once in 40 years). Therefore, if a plant's operating license is renewed (i.e., authorized to operate for an additional 20 years), then the plant design must be modified to

enable the plant to deal with more than one infrequent incident during its new design lifetime of 60 years. Subsequent license renewals (SLRs) could extend plants' design lifetime to 80 years. License renewals have been approved without a review of such design modifications, since they're not part of aging management programs. The draft NUREG does not address how the NRC staff might apply 10 CFR 50.109 during operation under a renewed license to compel a licensee to modify its plant design in order to comply with its plant's original design requirement (i.e., one infrequent event in 40 years). (SM-52)

NRC Response
The NRC disagrees with this comment. The commenter appears to take issue with the 10 CFR Part 54 licensing process and specifically with whether the scope of that review is adequate regarding the frequency of licensing basis events. That issue is beyond the scope of this NUREG. However, as stated on pages 2-4 and 5-11 of the draft NUREG, the matters that fall outside of the scope of the 10 CFR Part 54 review (i.e., the portion not subject to the 10 CFR Part 54 aging management review) fall within the provisions of the backfitting regulation. The NRC did not revise the draft NUREG as a result of this comment.

Comments on Section 5.17, "Rulemakings and Guidance"

Comment 4.5.31
Section 5.17, "Rulemaking and Guidance," should be retitled, "Regulations," and focus on how regulations and statements of consideration (SOCs) can establish staff positions. (NEI-51)

NRC Response
The NRC agrees, in part, with this comment. The definition of "backfitting" in 10 CFR 50.109 distinguishes regulations from staff positions. Regulations are the Commission's positions, not the staff's positions. An SOC provides the Commission's position on the meaning and intent of a regulation and, accordingly, is very important to understanding the regulation. The Commission writes an SOC, which is included as part of the FRN for a final rule, and the Commission can change an SOC, typically through rulemaking or a notice of interpretation. The staff cannot change an SOC.

The NRC reorganized Chapter 5 of the NUREG and created two sections, "Regulations," and "Statements of Considerations." The NRC clarified that SOCs provide the Commission's position on the meaning and intent of the regulation and, accordingly, are: (1) very important to backfitting, forward fitting, and inspection because they support understanding of the meaning of the regulations, and (2) not a position that the staff can change (i.e., the Commission would have to change it, typically through rulemaking or a notice of interpretation).

Comment 4.5.32
Include more information on how backfitting relates to rulemaking (e.g., describe preliminary backfit analyses for rulemaking plans). (NEI-52)

NRC Response
The NRC agrees with this comment. The NRC revised the draft NUREG by adding a new section, "Rulemaking Process," to Chapter 5. This section provides guidance on developing backfitting discussions for rulemaking plans, regulatory bases, proposed rules, and final rules.

Comment 4.5.33
The draft NUREG should explain how rulemakings cannot apply to a licensee request. (SM-53)

NRC Response
The NRC agrees, in part, with this comment. Section 5.17 of the draft NUREG states, "Because rulemakings are not regulatory actions associated with a licensee request, it is not possible for rulemakings to involve forward fits." The NRC agrees that this statement should be clarified because a rulemaking could be initiated by a licensee request in the form of a petition for rulemaking under 10 CFR 2.802, "Petition for rulemaking—requirements for filing." However, before the NRC would begin the rulemaking based on that petition, the NRC would close the docket for the petition under 10 CFR 2.802(h)(2), thereby ending the petition proceeding. Thus, even if the petition requests that the NRC amend its regulations in order to amend one or more licenses and could be considered a "requested licensing action," the rulemaking would not be a licensing action because the petition process (i.e., the licensee's "requested licensing action") would have ended. In response to this comment, the NRC revised the sentence in the draft NUREG to read, "Because rulemakings are not requests for licensing actions submitted by an affected entity, rulemakings do not involve forward fitting."

Comments on Section 5.18, "Safety Evaluations (or Safety Evaluation Reports)"

Comment 4.5.34
Section 5.18, "Safety Evaluation Reports," should include text from Section 1.2.2.2 that, although safety evaluations generally are not part of the licensing basis and generally do not contain legally binding requirements, they do contain staff positions. (NEI-61)

NRC Response
The NRC agrees, in part, with this comment. The discussion of safety evaluations in Section 5.18 should note that safety evaluations can constitute staff positions. The NRC revised the draft NUREG to include in the section on safety evaluations a reference to the discussion in Section 1.2.2.2.

Comments on Section 5.19, "Section 50.55a Requests"

Comment 4.5.35
The statement, "10 CFR 50.55a(z) does not permit the NRC to impose alternatives to the requirements" on page 5-12 of the draft NUREG is confusing. One way to read this statement is that the NRC cannot, on its own initiative, impose an alternative under 10 CFR 50.55a(z). However, alternatives approved under 10 CFR 50.55a(z) are always optional since the licensee may continue to comply with current ASME Code requirements. Another way to read this statement is that the NRC cannot condition its approval of a proposed alternative. The last two sentences in the statement appear to contradict each other. One sentence says alternatives cannot be imposed and the next sentence ("Therefore, if the NRC intends to impose an alternative to the requirement, then the NRC would need to subject its proposed alternative to a backfitting or fitting assessment") implies they can. (ANSM-17)

NRC Response
The NRC agrees with this comment. The last two sentences of Section 5.19 in the draft NUREG appear to contradict each other. The NRC revised the draft NUREG to clarify that in contrast to 10 CFR 50.55a(f)(6)(i) and (g)(6)(i), which permit the NRC, on its own initiative, to impose alternative requirements in certain circumstances, 10 CFR 50.55a(z) does not have such a provision. Further, even when the NRC authorizes an alternative under 10 CFR 50.55a(z), the affected entity can continue to comply with current requirements; therefore, it is not possible for the NRC to impose an alternative. The NRC also cannot modify or add to the affected entity's proposed alternative; otherwise, the requirement in 10 CFR

50.55a(z) for an alternative to be submitted and authorized would no longer be met. An affected entity can supplement its submittal of its own volition if the NRC or the affected entity identifies issues with the proposed alternative.

Comment 4.5.36
Approved relief requests and alternatives can establish applicable staff positions. NUREG-1409, Revision 1, should specify that if the NRC conveys an expectation that the licensee propose an alternative other than one the licensee has already proposed, then the NRC should subject its alternative proposal to a backfitting evaluation upon conveyance of the expectation, rather than after imposing the requirement. (NEI-60)

NRC Response
The NRC agrees, in part, with this comment. Approved relief requests and alternatives can establish facility-specific staff positions. The NRC revised the draft NUREG discussion on staff positions to provide this clarification. However, the draft NUREG already explains that NRC staff conveyances of expectations can constitute backfitting.

As explained in NRC Response to Comment 4.5.35, the NRC cannot impose alternatives within the context of 10 CFR 50.55a(z) submittals because authorized alternatives must be submitted by the affected entity (i.e., not imposed by the NRC) and the affected entity has the choice to follow the American Society of Mechanical Engineers (ASME) requirement for which an alternative was authorized.

Furthermore, the draft NUREG states that if "the NRC intends to impose requirements that are not alternatives to the requirements from which the NRC granted the affected entity relief" under 10 CFR 50.55a(f)(6)(i) and (g)(6)(i), then the NRC would need to subject its proposed requirements or alternatives to a backfitting or forward fitting assessment. Such assessment would occur before the imposition of the requirements or alternative. Notwithstanding this explanation in the draft NUREG, the NRC revised the draft NUREG to provide this clarification.

Comments on Section 5.20, "Standard Review Plans"

Comment 4.5.37
Section 5.20, "Standard Review Plan," should reflect that the SRP can establish applicable staff positions. (NEI-63)

NRC Response
The NRC agrees with this comment. Section 5.20 of the draft NUREG already conveys that the SRP may be an applicable staff position: "If the staff uses acceptance criteria that are more stringent than those stated in the applicable SRPs, or if it proposes licensee actions that are more stringent than or in addition to those specified in the applicable SRPs, then these criteria and actions may be considered either forward fitting or backfitting" (emphasis added). Section 5.10 of the draft NUREG, on initial licensing, has similar text in which it also refers to the more stringent criteria as "staff positions." However, the NRC recognized that it could provide additional clarity concerning applicable staff positions and new staff positions in the context of SRPs. The NRC revised the draft NUREG in response to this comment.

Comments on Section 5.22, "Topical Reports"

Comment 4.5.38
Section 5.22, "Topical Reports," of the draft NUREG should explicitly state that NRC approval of an application using a topical report establishes an applicable staff position. (NEI-68)

NRC Response
The NRC agrees, in part, with this comment. NRC approval of a licensing action involving an NRC-approved topical report can establish a facility-specific staff position. This is explicitly described in Section 1.2.2.2 of the draft NUREG. However, the NRC approval can be a generic position if the safety evaluation specifically provides for other licensees to adopt the topical report or approved method consistent with the conditions and limitations specified in the safety evaluation. Therefore, the NRC revised the draft NUREG to provide this clarification.

Further, Section 5.22 of the draft NUREG states that requirements imposed on a licensee by the NRC that are different than those specified in a topical report approved for use by that licensee through the NRC's approval of a licensing action "should be considered as potential backfitting." The requirements would be considered potential backfits because the approved topical report would be a facility-specific staff position for that licensee. Nevertheless, the NRC revised the draft NUREG to provide this clarification.

Comment 4.5.39
Section 5.22 appears to focus only on licensing actions where the licensee adopts a topical report. It does not appear to address the topical report review process itself. Thus, it is not clear if the NRC may impose conditions or limitations on a topical report without consideration of backfitting or forward fitting. It is also not clear if the NUREG requires different treatment of topical reports submitted by operating reactor licensees than reports submitted by vendors. (ANSM-18, -19)

NRC Response
The NRC agrees with these comments. Section 5.22 of the draft NUREG only discusses the use of a topical report in a licensing action and not the process of approving the topical report before any requested licensing action. The NRC revised the draft NUREG in response to this comment.

A topical report submitted by a vendor is not subject to backfitting, issue finality, or forward fitting considerations because the vendor is not a holder of or an applicant for an approval under 10 CFR Part 50, 52, 70, 72, or 76. Therefore, the NRC can impose the constraints needed for the NRC to conclude that affected entities' use of the topical report (within the constraints) will be acceptable without having to perform a backfitting, issue finality, or forward fitting assessment.

If, as justification for its requested licensing action, an operating reactor licensee submits its own topical report or incorporates a vendor's draft topical report as the licensee's topical report, then any NRC conditions of approval would be subject to a backfitting or forward fitting assessment.

Comment 4.5.40
Section 5.22," Topical Reports," in the draft NUREG includes this statement: "If the licensee submits information that the NRC is reviewing for the first time, the NRC has no existing staff position applicable to the licensing action under review, and the staff is considering a forward fit, then the staff needs to perform a site-specific cost consideration." This statement conflicts with

the requirement in the AEA that the NRC cannot consider cost if the action is necessary for adequate protection. Additionally, the NRC staff should be given broad latitude in situations where there is no existing staff position. Such situations have the greatest uncertainty and may require more limitations in order to approve. Thus, NRC conditions in this situation are often necessary for the NRC staff to have reasonable assurance of adequate protection. (ANSM-20)

NRC Response
The NRC agrees, in part, with this comment. The NRC agrees that the AEA requires the NRC to address adequate protection issues without considering the costs of taking such action. However, the NRC does not expect every forward fitting situation to involve adequate protection. Notwithstanding whether the forward fit would involve adequate protection, the NRC would not use cost information to decide not to impose the condition. The NRC would use the cost information only to inform the imposition. The NRC did not revise the draft NUREG as a result of this comment.

Comments on Section 5.24, "Voluntary Relaxations"

Comment 4.5.41
The draft NUREG does not define "very small", as it is to be used when judging the safety impact of an "alternative approach" in Section 5.24, "Voluntary Relaxations." (SM-47)

NRC Response
The NRC agrees with this comment. To address this comment, the staff added "(e.g., NRC Regulatory Guide 1.174 defines 'very small' within the context of changes in core damage or large early release frequency)" after "very small." Regulatory Guide 1.174 provides a full discussion of what constitutes "very small" within the broader context of the Commission's Safety Goal policy and risk-informed decisionmaking that includes the associated need to maintain a small proposed change in risk, defense-in-depth, safety margins, and monitoring strategies; where applicable, it also addresses the need to meet applicable regulations. The NRC revised the draft NUREG in response to this comment.

Comment 4.5.42
The relaxation of regulatory requirements, if taken far enough, can create a new, illegal backfit order. It would be equivalent to an imposition of a regulatory burden upon the public (i.e., the cost of a degradation in safety margin). It would be illegal because the requirements of 10 CFR 50.109 would not be met. The draft NUREG implies that such a backfit by relaxation is possible; but doesn't elaborate. (SM-49)

NRC Response
The NRC disagrees with this comment. The draft NUREG states in Section 5.24, "When the NRC relaxes requirements, the NRC must ensure the new framework provides for the adequate protection of the public health and safety and the common defense and security." Such actions (i.e., approval of voluntary safety relaxations) do not involve backfitting or orders and, as a result, are not discussed in that context within the NUREG. The NRC did not revise the draft NUREG as a result of this comment.

4.6 Comments on Chapter 6 of the Draft NUREG

Comment 4.6.1
The NRC should periodically audit backfitting decisions to ensure that they demonstrate consistency in application. The results of such audits should also be made publicly available. (UUSA-08)

NRC Response
The NRC agrees with this comment. The Roles and Responsibilities section of MD 8.4 already requires the NRC's CRGR to perform such audits, which are publicly available. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.6.2
The draft NUREG does not define "external stakeholders" nor distinguish them from public stakeholders. (SM-54)

NRC Response
The NRC agrees with this comment. The NRC revised the draft NUREG to replace the phrase "external stakeholders" with "the affected entity, the public, or both."

Comment 4.6.3
The draft NUREG does not specify the circumstances that would cause any information concerning backfitting or forward fitting (or the disclosure of the existence of any such information) to be withheld from external stakeholders. The draft NUREG does not help the NRC staff identify the information to be withheld and justify its withholding. It is necessary for the identification criteria and disclosure means to be specified, for the NRC staff, vendors, licensees and members of the public. (SM-55)

NRC Response
The NRC agrees with this comment. However, other NRC requirements, policies, and procedures determine whether certain documentation related to backfitting or forward fitting will be withheld from public disclosure. The NRC did not revise the draft NUREG in response to this comment.

4.7 Comments on the Draft NUREG's References and Appendices

Comment 4.7.1
Not all the references listed in Section 7 of the draft NUREG are explicitly cited in the text. Some are buried in footnotes, without citations. This can be difficult to follow. (SM-57)

NRC Response
The NRC agrees, in part, with this comment. The references in Section 7 of the draft NUREG are cited in the NUREG, are related to documents that are discussed in the NUREG, or helped the staff develop the guidance. The staff listed the references based on the type of document and their chronological order consistent with NRC publication guidance. The NRC did not revise the draft NUREG in response to this comment.

Comment 4.7.2
The checklist in Appendix B of the draft NUREG (page B-12, Step 9) refers to just one error or omission and asks whether it would be sufficient to deny an approval. This checklist does not

advise the reviewer on how he or she must consider the effects of multiple different errors and omissions. There might be no single error and omission that would cause the NRC staff to deny an approval, but the combined effect of several errors and omissions might be serious enough to merit a denial. (SM-59)

NRC Response
The NRC agrees, in part, with this comment. Step 9 of the Compliance Exception checklist directs the NRC staff to review the approval at issue in light of the error or omission identified by the NRC. The comment is correct that more than one error or omission could have occurred and, had the NRC known of them at the time of the approval, could have resulted in a different outcome. The NRC revised the Compliance Exception checklist, the Compliance Exception Documented Evaluation Guide, and the discussion in Section 2.5.2.2 of the draft NUREG in response to this comment.

Comment 4.7.3
The inclusion of checklists in the draft NUREG is troubling because they can restrict reviews to items in the checklists. Furthermore, it's easy to tick boxes in a checklist without understanding the issues or their bases and end the review with a false confidence that it is comprehensive and complete. (SM-61)

NRC Response
The NRC disagrees with this comment. The steps in these checklists require the NRC staff to perform substantive work to understand the regulatory issues and bases. The NRC did not revise the draft NUREG in response to this comment.

4.8 Out-of-Scope Comments

These comments were not applicable to the effort to revise final NUREG-1409.

Comment 4.8.1
Revise Management Directive 3.5, "Attendance at NRC Staff-Sponsored Meetings," to remove the provision that allows licensees private access to the NRC's EDO and other senior officials. The MD 3.5 revision should give licensees and public stakeholders equal access to NRC decision makers in public meetings. (SM-64)

NRC Response
This comment concerns Management Directive 3.5 and is outside the scope of the draft NUREG.

Comment 4.8.2
The NRC could include an attachment as part of its safety evaluations and inspection reports to list findings and conclusions that represent staff positions. (UUSA-01)

NRC Response
This suggestion does not directly pertain to the guidance in NUREG-1409; rather, it pertains to processes associated with inspections and the approval of licensing basis requests (i.e., the development and issuance of safety evaluations). As such, it is beyond the scope of the NUREG. However, the NRC staff may consider this comment during its update of office-level procedures after the NUREG is issued.

Comment 4.8.3
The NRC should publish all backfitting decisions on its website in a central location in searchable form to promote a better understanding of the process and precedents, as well as consistency in implementation. (UUSA-03)

NRC Response
This suggestion does not directly pertain to the guidance in NUREG-1409; rather, it pertains to processes associated with public communication on the NRC's Web site. As such, it is beyond the scope of the NUREG. However, the NRC staff may consider this during its update of office-level procedures after the NUREG is issued.

Comment 4.8.4
The NRC staff respects licensees' Fifth Amendment right to "due process of law" as discussed in section 2.2 of the draft NUREG but not the public's First Amendment right to "petition the Government for a redress of grievances." The NRC staff, each of whose members is sworn to support and defend the Constitution…and faithfully discharge the duties of the office (5 U.S.C. § 3331, "Oath of Office"), has continually denied the public its First Amendment right to "petition the Government for a redress of grievances" by denying every 10 CFR 2.206 petition. (SM-17)

NRC Response
This comment concerns 10 CFR 2.206 and is outside the scope of the draft NUREG.

Comment 4.8.5
It seems that now, the NRC staff regulates on two levels: one for Exelon, and one for everyone else. The NUREG-1409 guidance does not anticipate the establishment of the NRC staff's current, two-tier regulatory regime, and consequently has no advice regarding its implications in backfitting evaluations. (SM-50)

NRC Response
The comment implies that the NRC favors one licensee over other licensees. Although not all stakeholders will agree with every NRC decision, the NRC's regulatory actions are administered fairly across all classes of licensees.

Comment 4.8.6
Together, NUREG-1409 and MD 8.4 seem to be a maneuver to augment the protection against unexpected, possibly unnecessary expenses that is already extended to licensees via 10 CFR 50.109 without the bother of undergoing the rulemaking process. Furthermore, NUREG-1409 aggravates, and "institutionalizes" several errors that have become apparent in the NRC staff's backfitting experience (e.g., avoiding public meetings); but notably absent in the draft NUREG. This maneuver illustrates the need to correct the faults in 10 CFR 50.109 through rulemaking. (SM-63a)

NRC Response
As explained in the NRC Response to Comment 4.1.3, 10 CFR 50.109 is not a legally binding requirement on the public. Neither are MD 8.4 and NUREG-1409. Although rulemaking would be necessary to amend 10 CFR 50.109, rulemaking to amend 10 CFR 50.109 would not be necessary to correct any "faults" or change the Commission's backfitting policies.

Comment 4.8.7
Engineering judgment is just an educated guess that is made by an engineer. Engineering judgment is used as a last resort, when adequate reliable data are not available. The avoidance of engineering judgement, whenever possible, is fundamental to any review, or design, or evaluation. This is not addressed in the draft NUREG. (SM-51)

NRC Response
Whether the staff uses engineering judgment “in any review…or evaluation” is, by its own terms, a generic issue beyond the scope of the NUREG.