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**Subject:** Industry Comments on Draft Revision 1 to Regulatory Guide 1409, "Backfitting Guidelines;"  
Docket ID NRC-2018-0142

**Project Number: 689**

On behalf of its members, the Nuclear Energy Institute (NEI)<sup>1</sup> appreciates the opportunity to review and comment on Draft Revision 1 to NUREG-1409, "Backfitting Guidelines" (Draft Rev. 1). NUREG-1409 has served as a foundational guidance document in the area of backfitting for three decades, and Draft Rev. 1 represents a substantial revision to the document.

We appreciate the substantial effort put forth by the NRC staff to revise NUREG-1409 and its intent to revise this NUREG in a way that captures the progress achieved in this area in recent years. We also appreciate the NRC's willingness to extend the comment period on Draft Rev. 1.<sup>2</sup> Given the demands placed upon NEI's members by the COVID-19 public health emergency, development of these comments would simply not have been possible without that extension of time.

Our comments reflect NEI members' interest in ensuring that the Commission's backfitting requirements continue to be faithfully implemented. Over the past four years, the agency has taken several important actions to improve implementation of the agency's backfitting requirements.<sup>3</sup> We

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<sup>1</sup> NEI is responsible for establishing unified policy on behalf of its members relating to matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect and engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations involved in the nuclear energy industry.

<sup>2</sup> "Draft NUREG; request for comment; extension of comment period," 85 Fed. Reg. 29358 (May 15, 2020).

<sup>3</sup> See, e.g., "Tasking Related to Implementation of Agency Backfitting and Issue Finality Guidance," June 9, 2016 (citing recent interactions with stakeholders, including NEI, and directing the Committee to Review Generic Requirements to assess the agency's backfitting requirements, guidance, and criteria; backfitting training; and knowledge management); Letter from V.M. McCree (NRC) to A.R. Pietrangelo (NEI),

view the revision of NUREG-1409, along with the Commission’s revisions to Management Directive 8.4 and the staff’s ongoing efforts to revise NUREG/BR-0058, as the capstones of those actions.

As aptly stated in Draft Rev. 1, “[b]ackfitting is an integral part of the regulatory process” and “ensures discipline, predictability, and optimal use of NRC and licensee resources.”<sup>4</sup> The backfitting requirements have been part of the NRC’s regulatory framework for over 50 years,<sup>5</sup> with the current iteration of those requirements having their genesis in the Commission’s 1985<sup>6</sup> and 1988<sup>7</sup> rulemakings. While the Commission’s backfitting requirements are uniquely tailored to the NRC’s mission of regulating nuclear licensees to ensure adequate protection of the public health and safety, and the common defense and security, the backfitting concept is also consistent with broader, long-standing efforts undertaken by the Federal Government to improve regulatory decision-making.<sup>8</sup>

The publication of Draft Rev. 1 represents NEI’s first opportunity to formally comment on many important concepts included in the revisions to Management Directive 8.4, such as the Commission’s articulation of the agency’s forward fitting policy.<sup>9</sup> Our substantive comments on Draft Rev. 1 are

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“Response to Nuclear Energy Institute Comments in Support of Exelon Generation Company Second-Level Appeal” (describing the EDO’s decision to grant Exelon’s second-level appeal challenging use of the compliance exception to justify a backfit involving pressurizer safety valve performance); Memorandum from A.P. Averbach (Solicitor, NRC) to E.M. Hackett (Chairman, CRGR), “Summary of COMSECY-16-0020 Recommendation on Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception to Backfit Rule,” Dec. 20, 2016 (providing revised guidance on implementation of the compliance exception and the need to consider costs when imposing compliance backfits); “Staff Requirements – SECY-18-0049 – Management Directive and Handbook 8.4, ‘Management of Backfitting, Issue Finality, and Information Collection,’ May 29, 2019 (approving a revision to Management Directive 8.4 and its companion Directive Handbook, subject to significant revisions).

<sup>4</sup> Draft Revision 1, “NUREG-1409, Backfitting Guidelines,” at p. iii (Draft Rev. 1).

<sup>5</sup> “Backfitting of Production and Utilization Facilities; Construction Permits and Operating Licenses,” 35 Fed. Reg. 5317 (March 31, 1970).

<sup>6</sup> “Revision of Backfitting Process for Power Reactors,” 50 Fed. Reg. 38097 (Sept. 20, 1985).

<sup>7</sup> “Revision of Backfitting Process for Power Reactors,” 53 Fed. Reg. 20603 (June 6, 1988).

<sup>8</sup> *See, e.g.*, Executive Order 12291, “Federal Regulation,” Feb. 17, 1981, 46 Fed. Reg. 13193 (Feb. 19, 1981) (issued by President Reagan and, in part, stressing the need for regulations to result in and maximize net benefits, identification of least-cost alternatives, and requiring Regulatory Impact Analyses); Executive Order 12866, “Regulatory Planning and Review,” Sept. 30, 1993, 58 Fed. Reg. 51735 (Oct. 4, 1993) (issued by President Clinton and, in part, stressing problem identification, identification of alternatives to direct regulation, cost-effectiveness, and the use of cost-benefit analysis); Executive Order 13563, “Improving Regulation and Regulatory Review,” Jan. 18, 2011, 76 Fed. Reg. 3821 (Jan. 21, 2011) (Issued by President Obama and, in part, reaffirming use of cost-benefit analysis, as provided in EO 12866); Executive Order 13579, “Regulation and Independent Agencies,” July 11, 2011, 76 Fed. Reg. 41587 (July 14, 2011) (Issued by President Obama and, in part, urging independent agencies to conform to EO 13563); “Remarks of Commissioner Stephen G. Burns,” 29<sup>th</sup> Annual Regulatory Information Conference, March 15, 2017 (analogizing the restrictions contained in the Commission’s backfitting rules to the broader restrictions placed upon the Federal Government by the U.S. Constitution).

<sup>9</sup> Revisions to Management Directive 8.4 were sent to the Commission for approval on April 18, 2018. *See* “Management Directive and Handbook 8.4 ‘Management of Backfitting, Issue Finality, and Information Collection’,” SECY-18-0049, April 18, 2018. Public comment was not solicited on these revisions. The

presented in five attachments to this letter. Those attachments offer specific comments on each of the five main chapters of Draft Rev. 1, which include:

- Chapter 1: Overview of Backfitting and Forward Fitting
- Chapter 2: Screening and Justifying Backfitting Actions and Changes Affecting Issue Finality
- Chapter 3: Forward Fitting
- Chapter 4: Backfitting and Forward Fitting Appeals
- Chapter 5: Relationship of Backfitting and Forward Fitting to Other Processes

Our comments include a combination of recommendations to reorganize the NUREG, remove certain concepts and text, add new text, and edit existing text. Summaries of our comments on each of the five chapters of Draft Rev. 1 are provided below:

*Attachment 1 – NEI Comments on Chapter 1 “Overview of Backfitting and Forward Fitting”*

Chapter 1 of Draft Rev. 1 provides an introduction and overview of NUREG-1409. Our comments in this section focus on providing context for the discussion of terminology, so that it is clear to the reader how the terminology relates to the evaluation of potential backfits and forward fits. In addition, our comments recommend that the discussion of the so-called “administrative exemption” be removed from NUREG-1409. As discussed in Attachment 1, the history of the “administrative exemption” indicates that it was intended to be used within the narrow context of rulemakings, where the Commission’s decision not to comply with the backfitting requirements was subject to notice and comment. In addition, the “administrative exemption” is an extra-regulatory creation and has no basis in the backfitting regulations promulgated through the required notice and comment rulemaking process. No specific criteria supporting a decision to invoke the “administrative exemption” have been articulated, thus the NRC staff has no criteria upon which to make disciplined, transparent, and predictable recommendations or decisions regarding use of the “exemption.” Thus, we recommend that the discussion of the exemption be removed from NUREG-1409.

*Attachment 2 – NEI Comments on Chapter 2 “Screening and Justifying Backfitting Actions and Changes Affecting Issue Finality”*

Chapter 2 is the foundation of NUREG-1409. Our comments propose a reorganization of this chapter to clearly focus on two fundamental concepts: (1) identifying backfits, which is an exercise in the application of the regulatory definition of backfitting, and (2) justifying backfits, which involves proper use of the exceptions to the analytical requirements of the backfitting rules, as well as implementation of those analytical requirements where the exceptions codified in the regulations do not apply. We believe this reorganization will allow users of NUREG-1409 to put the concepts discussed in Chapter 2 into the appropriate context.

Our comments stress that the identification of backfitting should focus primarily on the application of the relevant regulatory definitions of backfitting, and that the NRC staff should avoid categorically excluding broad classes of agency actions from the backfitting requirements without evaluating whether those actions meet the regulatory definitions. In addition, we recommend that Draft Rev. 1 clearly

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Commission approved a substantially rewritten Management Directive 8.4 on May 29, 2019. See “Staff Requirements – SECY-18-0049 – Management Directive and Handbook 8.4, ‘Management of Backfitting, Issue Finality, and Information Collection’,” May 29, 2019.

articulate that, as used in the definition of backfitting, the term “imposition” is *not* limited to imposition of backfits via legally binding requirements. As described in Attachment 2, this reading of the definition of backfitting is consistent with the Commission’s long-standing position on this issue.

With respect to justifying backfitting, our comments recommend a clear articulation of the relationship between adequate protection and compliance so that questions of compliance are resolved, even in situations where the underlying issue raises adequate protection concerns. We also offer edits to the discussion of the compliance exception and, as noted above, strongly recommend removal of the discussion of the so-called “administrative exemption” from this Chapter of the NUREG.

Attachment 3 – NEI Comments on Chapter 3 “Forward Fitting”

Chapter 3 of Draft Rev. 1 represents an important opportunity to provide guidance on implementation of the Commission’s forward fitting policy articulated in Management Directive 8.4. Our comments on Chapter 3 were written with the objective of developing guidance that is consistent with the text of 10 CFR 50.109, as well as the associated regulatory history. Further, our recommendations regarding application of the “direct nexus” and “essentiality” criteria—which is the lynchpin of meaningful implementation of the forward fitting concept—attempt to balance both the interests of the NRC staff and licensee in situations where the licensee is voluntarily seeking approval to modify its licensing basis.

Specifically, our approach would allow the staff to address unique safety or security issues that arise as a direct result of a licensing basis change being requested by the licensee, without meeting the requirements of the backfitting rule, in situations where those unique issues rise to the level of adequate protection or compliance. Consistent with the Commission’s direction in Management Directive 8.4, this approach appropriately limits the forward fitting concept to situations where: (1) there is a *direct nexus* between the proposed new or modified regulatory staff position and the licensee’s request, and (2) the imposition of the new or modified regulatory staff position is *essential* to the NRC staff’s determination of the acceptability of the licensee’s request.

Our recommended approach also appropriately recognizes that a licensee who voluntarily requests changes to its licensing basis stands in the shoes of a pure applicant (*i.e.*, an applicant applying for a license to construct and operate a new facility) only to the extent that the requested changes create unique adequate protection or compliance issues that must be addressed via the proposed forward fit. Outside of that limited situation, the licensee should be able to continue to rely on the facility’s licensing basis and the NRC staff should adhere to the backfitting requirements prior to imposing changes to the licensing basis.

The forward fitting concept is not mentioned in any of the agency’s backfitting regulations. Further, the staff requirements memorandum directing the staff to incorporate the Commission’s description of forward fitting into Management Directive 8.4 did not provide any direction or indication that the Commission was altering any of the important direction provided by prior Commissions regarding implementation of the backfitting requirements. Thus, it is important that the forward fitting guidance provided in NUREG-1409 implement forward fitting in a manner that is consistent with the existing backfitting requirements and the associated regulatory history. The approach we recommend in Attachment 3 preserves the NRC staff’s ability to address unique and significant safety and security issues that arise as a direct result of a licensee’s request to change its licensing basis, while also ensuring adherence to the long-standing backfitting requirements codified in Parts 50, 70, 72, and 76.

Attachment 4 – NEI Comments on Chapter 4 “Backfitting and Forward Fitting Appeals”

Our comments on Chapter 4 focus on clarifying the initiation of the appeals process and ensuring that all communications relevant to appeals are transparent. Our comments regarding initiation of the appeals process focus on licensee appeals alleging a failure of the staff to properly identify backfitting. As explained in Attachment 4, in order to avoid situations where a licensee is essentially forced to appeal staff silence on a potential backfit, NUREG-1409 should not limit a licensee’s ability to raise backfitting concerns during the inspection and enforcement processes. As mentioned in Section 2.5.2.1 of Draft Rev. 1, the concepts of compliance and backfitting are interrelated because a determination of whether a licensee is in compliance with the existing regulations is also a significant factor in determining whether the proposed staff action meets the definition of backfitting (*i.e.*, is the staff simply enforcing the existing requirements, or is the staff attempting to impose an interpretation that is either new or different from a previously applicable staff position?). Thus, discussions about compliance questions and the backfitting implications of an inspection finding or enforcement action are often two sides of the same coin. Given this reality, the staff should be obligated to disclose to the licensee its position regarding whether a proposed inspection finding or enforcement action constitutes backfitting, thereby allowing the licensee to make an informed decision on filing an appeal.

With respect to communications on specific backfitting appeals, we strongly recommend removing the guidance in Draft Rev. 1 that requires or encourages decision-makers (*e.g.*, appeal boards) to have non-public discussions with the staff that are advancing a disputed backfit. We do not believe these types of discussions are conducive to developing a clear picture of the facts relevant to specific appeals and present a basic fairness issue to the appellant/licensee. Instead, all substantive conversations between a backfitting appeals panel and the NRC staff should take place in a forum where stakeholders, including the appellant/licensee, are able to observe the interactions.

Attachment 5 – NEI Comments on Chapter 5 “Relationship of Backfitting and Forward Fitting to Other Processes”

Chapter 5 of Draft Rev. 1 provides important information explaining the relationship between backfitting and several other agency processes, as well as providing additional detail on several concepts covered in other sections of the NUREG. Like our comments on Chapter 2, we recommend that the information provided in Chapter 5 be reorganized around several major themes, including: (1) “previously applicable staff positions;” (2) the significance of backfitting in the inspection and enforcement processes; and (3) other processes and concepts (*e.g.*, “clarifications,” and initial licensing). We also offer substantive comments on the concepts in Chapter 5, with a particular focus on encouraging engagement between the staff and licensee on backfitting during the inspection and enforcement processes. This approach will help to improve the appeals process (as described above), and will sharpen both the licensee and staff’s understanding of compliance at the facility in question.

NEI also reviewed the information provided in the appendices. Although we do not provide detailed comments on those documents in the attachments to this letter, we point out that if our recommendations are adopted some conforming changes to these appendices may be necessary, but that the changes would be fairly straight-forward depending upon which, if any, of our recommendations are incorporated into the final version of Revision 1.

We reiterate our appreciation of the NRC staff’s work on Draft Rev. 1 and for the opportunity to provide our views on the document. We would welcome the opportunity to discuss both our comments and the

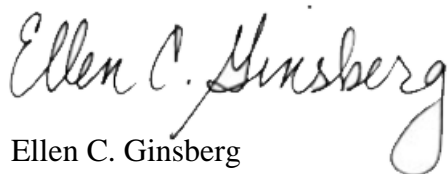
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staff's plans to finalize NUREG-1409 via a public meeting, and encourage the NRC staff to build such interactions into its plans to finalize NUREG-1409.

If you have any questions or require additional information, please contact Jerry Bonanno at 202-739-8147 or [jxb@nei.org](mailto:jxb@nei.org).

Sincerely,

A handwritten signature in cursive script that reads "Ellen C. Ginsberg". The signature is written in dark ink and is positioned above the printed name.

Ellen C. Ginsberg

cc:     Howard Benowitz, U.S. NRC  
         Audrey Klett, U.S. NRC  
         Ho Nieh, U.S. NRC  
         Timothy Reed, U.S. NRC  
         Marian Zobler, U.S. NRC

## I. INTRODUCTION

The Executive Summary and Chapter 1 “Overview of Backfitting and Forward Fitting” of Draft Revision 1 to NUREG-1409 (Draft Rev. 1) introduce many important concepts. With the exception of our comments on the “administrative exemption,” our comments on this chapter are primarily focused on offering specific revisions that we believe will provide additional context for the concepts introduced in this chapter. These concepts are often discussed in greater detail in other portions of Draft Rev. 1, and we have attempted to cross-reference our comments in this chapter as much as possible.

## II. SPECIFIC RECOMMENDED CHANGES

Executive Summary, p. xi, lines 17–28

Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.109, “Backfitting” (the Backfit Rule), provides backfitting provisions for commercial or industrial production and utilization facilities. ~~nuclear power reactor licensees.~~ It is the NRC’s policy that non-commercial or non-industrial ~~power~~ production or utilization facilities licensed under 10 CFR 50.21, “Class 104 licensees; for medical therapy and research and development facilities,” paragraphs (a) or (c), ~~or 10 CFR 50.22, “Class 103 licensees; for commercial and industrial facilities,”~~ are not within the scope of the backfitting provisions. Facilities licensed pursuant to 10 CFR 50.21 are known as “class 104 licensees” (i.e., the underlying statutory authority for licensing such facilities resides in section 104 of the Atomic Energy Act). In turn, section 104 directs the Commission to impose a “minimum amount” of regulation necessary to achieve the Commission’s statutory obligation to protect public health and safety, and the common defense and security. Given this statutory direction to minimize the regulatory burden imposed on such facilities, application of the backfitting requirements contained in 10 CFR 50.109 is unnecessary. As a result, the NRC has not applied 10 CFR 50.109 to research reactors, testing facilities, and other non-commercial or non-industrial facilities licensed under 10 CFR Part 50.

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Backfitting provisions for select nuclear material licensees are contained in 10 CFR 70.76, “Backfitting,” 72.62, “Backfitting,” and 76.76, “Backfitting.” Each of these provisions, as with the issue finality provisions in 10 CFR Part 52, requires that the NRC follow a formal, systematic process before imposing new or changed regulatory requirements or staff positions interpreting requirements on entities that are the subject of these regulations. This process ensures discipline, predictability, and optimal use of NRC and licensee resources.

### Explanation of Proposed Changes

As stressed in our comments on Chapter 2 of Draft Rev. 1,<sup>1</sup> applicability of the NRC’s backfitting requirements should be driven primarily by the regulatory definition of backfitting. The regulations in 10 CFR 50.109 provide a definition of backfitting and also explain when those requirements become applicable. These “timing provisions” are provided in 10 CFR 50.109(a)(1)(i)–(vii) and specify that the applicability of the backfitting rule in Part 50 is tied to the issuance of construction permits, operating licenses, design approvals, manufacturing licenses, and combined licenses.

<sup>1</sup> See Attachment 2 to NEI’s Comments on Draft Revision 1 to NUREG-1409, at Proposed Subsection 2.1.1.1: 10 CFR Part 50 Licensees.

There is nothing in the text of section 50.109 that limits applicability to “nuclear power reactor licensees.” That said, we understand that the Commission has historically taken the position that the requirements of 10 CFR 50.109 will not be applied to non-commercial or non-industrial facilities licensed pursuant to Section 104 of the Atomic Energy Act largely because, by its own terms, Section 104 directs the Commission to impose the “minimum amount” of regulation necessary to meet its obligations under the Act. Given this statutory direction, which is not included in Section 103 of the Act, our understanding is that the Commission has chosen not to apply the backfitting requirements to these facilities. We recommend incorporation of the revisions provided above to ensure that applicability of the backfitting requirements contained in 10 CFR 50.109 is not inappropriately limited in a manner that is not consistent with the rule text and not otherwise supported by underlying statutory considerations. We also recommend any conforming changes necessary in other portions of Chapter 1 where this topic is discussed.

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#### Chapter 1, Subsection 1.2.2 Terminology

Although we agree that the information provided in this subsection is useful, the comments below are intended to provide additional context, in order to more explicitly describe how these topics are germane to implementation of the agency’s backfitting requirements.

##### 1.2.2.1 Legally Binding Requirements, pp. 1-4–1-5:

In Directive Handbook Section I.A.4 of MD 8.4, the Commission ~~clarified~~ explained that, although 10 CFR 50.109(a)(1) refers to only regulations, backfitting can result from the imposition of new or changed requirements—beyond regulations—via regulations (see 10 CFR 50.109(a)(1)) or orders (see 2 CFR 2.202(e)), or the communication of new or changed regulatory staff positions interpreting those requirements. For backfitting and forward fitting purposes, the following sources contain the legally binding requirements that legally bind on a licensee:

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

In order to properly identify instances of backfitting and forward-fitting, it is important for the NRC staff to understand the legally binding requirements that apply to the licensee or licensees in question. As discussed in Chapters 2 and 5 of this NUREG, distinguishing situations where the agency is seeking to ensure compliance with existing legally binding requirements from situations where the staff is seeking to impose new or amended requirements or interpretations is vital to both: (1) identifying backfitting, and (2) evaluating the applicability of the compliance exception to the backfitting requirements.

#### Explanation of Proposed Changes

As written, this subsection could give readers the impression that the Commission extended the



applicability of the backfitting requirements to orders in Management Directive 8.4. This is not the case, as the backfitting rule is explicitly made applicable to certain orders in 10 CFR 2.202(e). The recommended changes to the opening paragraph above are intended to provide this clarification. The remaining changes are intended to provide context for why a clear understanding of the legally binding requirements applicable to a licensee or class of licensees is vital to proper implementation of the backfitting requirements.

#### Chapter 1, Subsection 1.2.2.2 “Previously Applicable Staff Positions”

##### *1.2.2.2 Staff Positions*

10 CFR parts 50, 70, and 76 define backfitting in terms of “cause”—e.g., a “new or amended provision in the Commission’s regulations or the imposition of a regulatory staff position interpreting the Commission’s regulations that is either new or different from a previously applicable staff position”—and “effect”—e.g., “modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility.”<sup>2</sup>

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The causal element of the definition of backfitting can involve either: (1) new or amended regulations or orders (see discussion of subsection 1.2.2 above), or (2) imposition of an interpretation of the Commission’s regulations that is either new or different from a previously applicable staff position. Proper application of this second aspect of the causal element of the definition of backfitting requires that the NRC staff understand where “previously applicable staff positions” are typically documented.

As currently provided in NUREG-1409, previously applicable staff positions may come from several sources, such as:

- legal requirements, as in explicit regulations, orders, and plant licenses and in amendments, conditions, and technical specifications;
- written licensee commitments such as those contained in the final safety analysis report, licensee event reports, and docketed correspondence, including responses to NRC bulletins, generic letters, inspection reports, or notices of violation and confirmatory action letters;
- NRC staff positions that are documented explicit interpretations of more general regulations and are contained in documents such as the Standard Review Plan, branch technical positions, regulatory guides, generic letters, and bulletins.<sup>3</sup>

~~For backfitting and forward fitting purposes, Previously applicable~~ staff positions are those documented interpretations of the Commission’s regulations applicable to a licensee or “class” of licensees at the time ~~of the identification of the proposed backfitting or forward fitting~~ a potential backfit is identified. ~~These~~ staff positions can be facility-specific or generic.

The NRC may ~~establishes~~ facility-specific staff positions through licensing actions (*i.e.*, NRC approvals), ~~or~~ NRC-issued facility-specific correspondence discussing the NRC’s regulatory

<sup>2</sup> See 50 Fed. Reg. 38,101; 10 CFR §§ 50.109(a)(1), 70.76(a)(1), 76.76(a)(1).

<sup>3</sup> NUREG-1409, “Backfitting Guidelines,” (July 1990), at p. 3.

bases for its decisions (e.g., inspection reports ~~(see caution below)~~, or safety evaluations, which may or may not be related to a requested licensing action).

Staff positions in safety evaluations are not requirements; rather, they are the NRC’s regulatory bases for its decisions or interpretations. Safety evaluations (or safety evaluation reports) provide the staff position on whether a licensee’s proposed means for implementing or complying with a governing requirement is acceptable and results in compliance with the requirement. The safety evaluation is generally not part of the licensing basis unless specifically incorporated by the licensee or required as a condition of approval by the staff. The NRR Office Instruction LIC-100 states that NRC staff safety evaluations are not part of a plant’s licensing basis. However, this does not obviate the fact that changes to staff positions established in safety evaluations (and other correspondence) are subject to the backfitting and forward fitting provisions and policy. 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.

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

Additional discussion of both Safety Evaluation Reports and inspections are provided in Chapter 5 of this NUREG.

The staff’s response to a technical assistance request is not a staff position. The response could become a staff position if it is used as the documented basis for further staff action. Until or unless it is used for that purpose, it is an internal agency communication. In general, internal agency communications are not staff positions. Section 5.21 of this NUREG provides more information about the technical assistance request process.

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Generic staff positions may be contained in documents such as regulatory guides, standard review plans, NUREGs, interim staff guidance, branch technical positions, and NRC endorsed-industry topical reports. Licensees may rely upon the staff positions provided in these documents. If the staff decides to reinterpret a requirement and supersedes or withdraws generic positions previously communicated in these types of documents, then new or different communications issued to licensees during that process may constitute backfitting. However, it is important to keep in mind that these generic staff positions ~~do are not apply to~~ legally binding on individual licensees until or unless the licensee incorporates them into its licensing basis—as a means for meeting or complying with a governing requirement, the NRC imposes generic positions on specific licensees through orders or rulemakings, or the NRC approves licensing

actions involving the generic positions. Chapter 5 of this NUREG has additional guidance on the relationship between backfitting and generic communications.

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

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

### Explanation of Proposed Changes

The text we recommend adding as the first two paragraphs of this section provides much needed context explaining how identification of “previously applicable staff positions” fits in the context of backfitting identification. The text added as the third paragraph at the beginning of this section provides examples of “previously applicable staff positions” that is taken directly from NUREG-1409. We believe this long-standing guidance remains useful and should be preserved.

The text added to the sixth paragraph above on safety evaluation reports is taken directly from footnote 8 in Chapter 1 of Draft Rev. 1. These two sentences make an important point about the status of safety evaluation reports with respect to backfitting.

The paragraph on generic staff positions seemed to be making two distinct points: (1) the documents listed may contain generic “previously applicable staff positions,” which would be important from a backfitting identification standpoint, and (2) while this is true, these generic documents do not typically contain legally binding requirements. This is an important distinction.

For example, a generic guidance document may communicate a method of compliance that the staff finds acceptable to meet an underlying legally binding requirement. A licensee may rely upon that method and, for example, design a required program based upon that reliance. This is important from a backfitting perspective because if the staff were to subsequently conclude that the method of compliance provided in that guidance document were no longer acceptable, that change in position may constitute a new or different interpretation, thus satisfying the “causal” element of the definition of backfitting. At the same time, while important from a backfitting standpoint, methods of compliance described in guidance are not typically considered legally binding on licensees because, generally, those methods represent merely one acceptable means to achieve compliance, rather than the sole means.

### Chapter 1, Subsection 1.2.4 Administrative Exemption

As explained in Draft Rev. 1, the Commission first articulated the concept of an “administrative exemption” to the backfitting requirements in a 1993 staff requirements memorandum.<sup>4</sup> The “exemption” is applied in situations where the proposed regulatory action meets the regulatory definition of backfitting and does not qualify for any of the exceptions that are codified in the regulations (*e.g.*, the compliance or adequate protection exceptions), but the Commission nonetheless wishes to forgo compliance with the agency’s backfitting requirements. The Commission has only used

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<sup>4</sup> “Staff Requirements Memorandum, SECY-93-086 – Backfit Considerations,” June 30, 1993 (SRM-SECY-93-086).

the exemption twice since 1993.<sup>5</sup> In both instances, the Commission stressed that use of the exemption is “a highly exceptional action.”<sup>6</sup> We appreciate the Commission’s restraint in its use of the exemption.

That said, the “administrative exemption” is an extra-regulatory creation and has no basis in the backfitting regulations promulgated through the required notice and comment rulemaking process. No specific criteria supporting a decision to invoke the “administrative exception” have been articulated, thus the NRC staff has no criteria upon which to make disciplined, transparent, and predictable recommendations or decisions regarding use of the “exemption.” Further, it creates an inherent conflict of interest for the staff to have the option to recommend that the agency simply forgo application of the backfitting requirements, when there is no basis in the regulations for doing so.

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Thus, use of the so-called “administrative exemption” should not be part of the NRC staff’s rubric for determining whether a particular instance of backfitting is justified. For proposed backfits that must be sent to the Commission for approval, the Commission may determine whether the circumstances surrounding the proposed backfit warrant the “highly exceptional action” of invoking the administrative exemption.

The issue being addressed in the 1993 notation vote paper that was the subject of the staff requirements memorandum cited in Draft Rev. 1 was:

Whether the backfit provisions of 10 CFR 50.109 should be revised to address difficulties encountered in situations where a seemingly worthwhile change to the regulations cannot be adopted because of difficulties in demonstrating that the change represents a “substantial increase in the overall protection of the public health and safety or the common defense and security” as required by 10 CFR 50.109.<sup>7</sup>

The options presented to the Commission in SECY-93-086 were: (1) amend the backfitting rule so that it was no longer applicable to agency rulemakings; (2) amend the backfitting rule to revise or supplement the “substantial increase” standard to address rulemakings that are worthwhile, but do not meet the standard; and (3) clarify through a policy statement that the Commission intends to use the exemption provisions of 10 CFR 50.12(a) to exempt particular rulemakings from the backfitting rule after determining that the benefits of such rulemakings were worthwhile and justified, despite the fact that the requirements of the backfitting rule were not satisfied.<sup>8</sup> The staff recommended that the Commission approve the third option—*i.e.*, use the specific exemption provision in section 50.12 to exempt certain rulemakings from the backfitting requirements, noting that such exemptions should be rare.<sup>9</sup>

Notably, the Office of the General Counsel (OGC) disagreed with Option 3. Specifically, SECY-93-086 explains:

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<sup>5</sup> “Consideration of Aircraft Impacts for New Nuclear Power Reactors,” Final Rule, 74 Fed. Reg. 28112, 28144 (June 12, 2009); “In the Matter of All Power Reactor Licensees and Holders of Construction Permits in Active or Deferred Status: Order Modifying Licenses with Regard to Reliable Spend Fuel Pool Instrumentation (Effective Immediately),” 77 Fed. Reg. 16082, 16084 (March 19, 2012).

<sup>6</sup> *Id.*

<sup>7</sup> “Backfit Considerations,” SECY-93-086, April 1 1993, at p. 1. (SECY-93-086).

<sup>8</sup> *Id.* at pp. 4-6.

<sup>9</sup> *Id.* at p. 7.

OGC disagrees with Option 3 and prefers either Option 1 or 2 if rule changes are to be considered. OGC does not believe that Option 3 will be workable, since practice to date suggests that rules which are candidates for exemptions will be difficult to distinguish from other rules to which the backfit rule will still apply, and yet such distinctions will be necessary to avoid the exercise of exemption power from appearing arbitrary. Moreover, it is the judgement of the General Counsel that an exemption by exemption approach is not a sound regulatory approach to achieve a regulatory policy objective which is inconsistent with an existing regulation. The regulation should be changed to cover the objective. This is also consistent with the regulatory position the Commission has previously expressed in connection with frequently invoked exemptions for operating licenses (*e.g.*, for leak rates and criticality monitoring).<sup>10</sup>

So, it seems that OGC was concerned that use of the even the existing provision in section 50.12 for issuing specific exemptions could appear arbitrary.

In its staff requirements memorandum, the Commission declined to amend the backfitting regulations, finding that the existing “substantial increase” standard provided the agency with sufficient flexibility. Despite this flexibility, the Commission believed that there may still be proposed rules that do not meet the backfitting standards, but should be “promulgated mainly for nonsafety reasons.”<sup>11</sup> Thus the Commission concluded:

As in the past, the Commission remains willing to consider, on a case-by-case basis, whether such rules should be promulgated as exceptions to the Backfit Rule. However, it is the judgement of the General Counsel that using 10 CFR 50.12 to promulgate such exceptions is not a sound regulatory approach. 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.<sup>12</sup>

Again, as indicated in the passage from SECY-93-086 quoted above, it appears that OGC’s primary concern with use of 10 CFR 50.12 was that it would be difficult for the Commission to meaningfully distinguish situations where the exemption was appropriately used from situations where the agency continued to adhere to the backfitting requirements. Thus, it would be difficult “to avoid the exercise of exemption power from appearing arbitrary.” The Commission understood and seemingly heeded the General Counsel’s advice by specifying that exemptions from the backfitting requirements would only be taken in situations involving rulemaking where the decision not to apply the backfitting requirements were subject to notice and comment. This caveat is extremely important. If concerns about the Commission’s use of the exemption provisions included in its duly promulgated regulations—*i.e.*, the requirements in section 50.12—raised concerns about such exemptions being viewed as arbitrary and capricious, then such concerns would intensify significantly in a situation where the Commission is exercising an exemption power that is completely extra-regulatory (*i.e.*, not in accordance with section 50.12 or the exceptions included in section 50.109). Unfortunately, this seems to be precisely the concept being implemented under the current rubric of the “administrative exemption.”

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<sup>10</sup> *Id.* at p. 8.

<sup>11</sup> SRM-SECY-93-086, at p. 2.

<sup>12</sup> *Id.* (emphasis added).

Thus, we strongly recommend that subsection 1.2.4 be removed from NUREG-1409 and that the Commission consider limiting its future use of the “administrative exemption” to support rulemakings where there is an opportunity for notice and comment on the Commission’s proposal not to apply the backfitting requirements to the specific proposed rule in question. This is consistent with the Commission’s original intent, as articulated in SRM-SECY-93-086.<sup>13</sup>

Chapter 1, Subsection 1.2.6 Issue Finality

NEI-5

We recommend that the information provided in subsection 1.2.6 be relocated to Chapter 2. *See our comments on proposed Section 2.3 “Issue Finality.”*

Chapter 1, Subsection 1.2.7 Independent Spent Fuel Storage Installations

NEI-6

We recommend that the information provided in subsection 1.2.7 be relocated to Chapter 2. *See our comments on proposed subsection 2.1.1.5 “10 CFR Part 72 Licensees.”*

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<sup>13</sup> To be clear, we believe that the ability of a regulator to grant exemptions from generally applicable regulations is a valid and necessary component of any coherent regulatory framework. To that end, the Commission has included provisions for the issuance of specific exemptions in 10 CFR §§ 50.12, 70.17, 72.7, and 76.23. Further, in the context of backfitting, the Commission has built additional exceptions into the backfitting requirements themselves, which provide relief from the analytical requirements of those rules. These exemption provisions and exceptions have been promulgated via notice and comment rulemakings that comply with the requirements of the Administrative Procedure Act.

## I. INTRODUCTION

Chapter 2 of Draft Revision 1 to NUREG-1409 (Draft Rev. 1) addresses “Screening and Justifying Backfitting Actions and Changes Affecting Issue Finality.” Our comments on this chapter of Draft Rev. 1 are structured as follows. First, we propose that Chapter 2 be reorganized to focus more clearly on two key topics: (1) identifying and (2) justifying backfitting. While we agree with much of the information presented in Chapter 2 of Draft Rev. 1, we believe that the reorganization recommended below would make the information presented in this chapter easier for both the NRC staff and public stakeholders to understand and use. Second, we discuss several concepts that we believe should be removed from Chapter 2. Finally, we step through each section of our revised table of contents presented below in Figure 2. In this final section, we suggest incorporating much of the existing language in Draft Rev. 2, recommend edits to some of the existing language, and recommend replacement language where appropriate.

Although it is vitally important that this chapter be clear and well organized, we strongly encourage the NRC not to over-proceduralize this material. NUREG-1409 should not be viewed as an agency procedure. Instead, NUREG-1409 should continue to serve as an important policy document providing guidance to the NRC staff and stakeholders on the principles that undergird the agency’s implementation of the backfitting and issue finality requirements, as well as the NRC’s “forward fitting” policy. That said, if additional, more granular procedures are necessary to ensure consistent application of the policy principles articulated in this NUREG, we encourage the staff to develop and seek stakeholder input on those documents (inspection guidance, office procedures, *etc.*).

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## II. ORGANIZATION AND STRUCTURE OF CHAPTER 2

As mentioned above, Chapter 2 covers two foundational concepts regarding implementation of the Commission’s backfitting requirements: (1) identifying backfitting (*i.e.*, applying the definition of backfitting), and (2) justifying backfitting (*i.e.*, understanding the exceptions and analytical requirements of the backfitting regulations). We recommend that the chapter be reorganized around those foundational themes. Specifically, as proposed, Chapter 2 of Draft Rev. 1 is organized to address the following six questions:

**Figure 1.**

<b>Structure Proposed in Chapter 2, Draft Rev. 1 NUREG-1409</b>	
1.	Is the proposed action excluded from backfitting and issue finality provisions?
2.	Would the proposed action affect any entity that is within the scope of a backfitting or issue finality provision?
3.	Would the proposed action constitute backfitting or affect issue finality?
4.	Do any of the exceptions to the requirement of preparing a backfit analysis apply to the proposed backfitting?
a.	Do one or both of the adequate protection exceptions to the requirement of preparing a backfit analysis apply?
b.	Does the compliance exception to the requirement of preparing a backfit analysis apply?



5. Does the proposed backfitting action constitute a cost-justified substantial increase in the overall protection of public health and safety or the common defense and security, or does the change affecting issue finality in the proposed action satisfy an issue finality criterion?
6. Should the NRC take an action to avoid the effect of the backfitting or issue finality provision on the proposed action by invoking an administrative exemption from the backfitting or issue finality provision?

We recommend that Chapter 2 be reorganized to address these topics, as follows:

NEI-8

**Figure 2.**

<b>NEI’s Proposed Table of Contents for Chapter 2, Rev. 1 NUREG-1409</b>	
2.	Identifying and Justifying Backfitting and Issues Affecting Issue Finality
2.1:	Identifying Backfits
2.1.1:	Question 1: Would the proposed action affect any entity that is within the scope of a backfitting or issue finality provision?
2.1.1.1:	10 CFR Part 50 Licensees
2.1.1.2:	10 CFR Part 52 Licensees
2.1.1.3:	10 CFR Part 54 License Renewal
2.1.1.4:	10 CFR Part 70 Licensees
2.1.1.5:	10 CFR Part 72 Licensees
2.1.1.6:	Part 76 Certificate Holders – Gaseous Diffusion Plants
2.1.1.7:	Other Materials Licensees
2.1.1.8:	Regulatory Actions that Affect Both Entities Within the Scope of Backfitting Requirements and Entities that are not Within the Scope of Backfitting Requirements
2.1.2:	Question 2: Does the proposed action meet the definition of backfitting in the relevant backfitting regulation ( <i>i.e.</i> , 10 CFR §§ 50.109, 70.76, 72.62, or 76.76)?
2.1.2.1:	A new or changed ( <i>e.g.</i> , amended, revised, or modified) NRC requirement ( <i>e.g.</i> , a regulation or order)
2.1.2.2:	Imposition of a regulatory staff position interpreting the Commission’s regulations that is either new or different from a previously applicable staff position
2.1.2.2.1:	New Interpretations
2.1.2.2.2:	Interpretations that are Different from Previously Applicable Staff Positions
2.1.2.2.3:	“Imposition”
2.1.2.3:	Timing provisions

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cont'



2.2: Justifying Backfits	
2.2.1: Question 1: Do any of the exceptions to the requirement of preparing a backfit analysis apply to the proposed backfitting?	
2.2.1.1: Adequate Protection Exceptions	
2.2.1.1.1: Background	
2.2.1.1.2: Adequate Protection Determinations	
2.2.1.1.3: Documenting Adequate Protection Evaluations	
2.2.1.2: Compliance Exception	
2.2.1.2.1: Background	
2.2.1.2.2: Compliance Exception Determinations	
2.2.1.2.3: Consideration of Costs	
2.2.1.2.4: Documenting Compliance Exception Evaluations	
2.2.2: Substantial Increase in Safety or Security that is Justified by Costs	
2.2.2.1: Background	
2.2.2.2: Cost-Justified, Substantial Increase in Overall Protection Determinations	
2.2.2.3: Documenting a Backfit Analysis	
2.3: Issue Finality	

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cont'

We believe this organizational structure improves upon the structure provided in Draft Rev. 1 for several reasons. First, when discussing backfitting it is helpful to draw a distinction between issues relevant to identifying backfitting, which is an exercise in application of the regulatory definition of backfitting, and justifying specific instances of backfitting once the definitions have been applied, which is an exercise in application of the exceptions and analytical requirements of the backfitting regulations. Thus, two of the three main sections of the reorganized structure—proposed sections 2.1 and 2.2—are explicitly devoted to these topics. This revised organization allows readers to easily place the material they are reviewing into the appropriate context. For example, by simply referring back to the table of contents, a reader would be able to discern that the discussion on “previously applicable staff positions” is relevant to the “causal” portion of the definition of backfitting, which, in turn, is relevant to backfitting identification.

Further, while the issue finality requirements in Part 52 are an important part of the regulatory framework, they are structured differently than the backfitting requirements. Thus, we believe that they should be addressed in a separate section (2.3), with any discrete connections to the backfitting requirements discussed in that section (as opposed to being scattered throughout the discussion of backfitting).

The remainder of our comments provided below are structured to address: (1) concepts that we suggest deleting from Chapter 2 altogether; and (2) comments regarding the specific sections that are outlined in the NEI Proposed Table of Contents provided above.

### III. CONCEPTS THAT SHOULD BE REMOVED FROM Chapter 2

#### A. Question 1: “Is the proposed action excluded from backfitting and issue finality provisions?”

This question should be removed from the rubric for assessing the applicability of the backfitting or issue finality requirements. The primary consideration when determining whether the proposed action constitutes backfitting is whether the proposed action meets the definition of backfitting provided in the relevant part of 10 CFR. Generally, the NRC staff should not make assumptions regarding whether a proposed action meets the definition of backfitting based upon the broad category within which the proposed actions falls (reporting requirements, *etc.*). The reason that certain categories of actions are *typically* not considered backfitting is because they *typically* do not meet the definition of backfitting provided in the relevant regulations. The NRC staff should not start with the presumption that entire categories of proposed regulatory actions<sup>1</sup> are “excluded” from the backfitting provisions. This approach to the backfitting requirements often results in a lack of fidelity to the actual regulatory definitions of backfitting provided in 10 CFR Parts 50, 70, 72, and 76.

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Instead, we strongly recommend that this topic be briefly covered under the discussion of the question of whether the proposed regulatory action meets the definition of backfitting provided in the relevant regulation (*i.e.*, 10 CFR §§ 50.109, 70.76, 72.62, or 76.76). While lists of such actions (like the one provided by the Commission in Management Directive 8.4) may prove helpful, all NRC staff conclusions regarding the applicability of the backfitting requirements to a proposed regulatory action should be based upon, and explained in the context of, application of the regulatory definitions of backfitting. This topic is included under subsection 2.1.2 of the NEI Proposed Table of Contents and is discussed further below in our comments on that subsection.

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

This question is included in Chapter 2 of Draft Revision 1, but it is not discussed further in Chapter 2. Instead, this topic is discussed in subsection 1.2.4. This question should not be part of the NRC staff’s rubric for determining whether backfitting is justifiable. First, no specific criteria supporting a decision to invoke the “administrative exception” have been articulated by the NRC. Thus, the NRC staff has no criteria upon which to make disciplined, transparent, and predictable recommendations regarding use of the “exemption.” Decisions to forgo compliance with a requirement applicable to the agency staff, despite the fact that the backfit in question does not meet any of the exceptions included in the regulations, should be made by the Commission. It creates an inherent conflict for the staff to have the option to recommend that the agency forgo application of the backfitting requirements, when there is no basis in the regulations for doing so. We have included additional substantive comments on use of the “administrative exemption” in our comments on subsection 1.2.4 of Draft Revision 1.

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<sup>1</sup> As used in these comments the term “proposed regulatory action” would include both the imposition of new or amended legally binding requirements, as well as new or different interpretations of unchanged legally binding requirements.

#### IV. COMMENTS ON SPECIFIC SECTIONS OUTLINED IN NEI’S PROPOSED TABLE OF CONTENTS

##### A. Proposed Section 2.1: “Identifying Backfits”

When reviewing whether proposed regulatory actions meet the definition of backfitting, the NRC staff should ask the following questions:

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

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2. Does the proposed action meet the definition of backfitting in the relevant backfitting regulation (*i.e.*, 10 CFR §§ 50.109, 70.76, 72.62, or 76.76)?

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##### 1. Proposed Subsection 2.1.1: Question 1: Would the proposed action affect any entity that is within the scope of a backfitting or issue finality provision?

In addressing Question 1, the staff must determine whether the proposed action would affect in some way, either directly or indirectly, an entity that is within the scope of the backfitting regulations contained in 10 CFR Parts 50, 70, 72, or 76. Table 1-1, “NRC Backfitting and Issue Finality Requirements,” in Draft Rev. 1 lists the regulations that contain backfitting provisions/requirements. If an affected entity is not within the scope of the backfitting regulations, then the backfitting requirements do not apply with respect to that entity, and the staff can exit the backfitting process and issue the proposed action or staff position under an appropriate agency process. It should be noted, however, that changes to some parts of the Commission’s regulations without backfitting provisions (*e.g.*, Part 55 requirements for operator training and plant-reference simulators) can indirectly affect Part 50 licensees who are covered by the backfitting rule in 10 CFR 50.109. Because a “new or amended provision in the Commission’s regulations” under Part 55 could cause changes in the procedures or organization required to operate a Part 50 facility, such an action should be treated as a backfit.

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NEI-12

If the entity is within the scope of the backfitting regulations, the staff should continue with the backfitting process. Subsections 2.1.1.1–2.1.1.6 of NEI’s Proposed Table of Contents lists each of the types of entities to which the backfitting requirements apply. We recommend that Revision 1 to NUREG-1409 contain brief descriptions of the entities covered under each of these subsections. In our view, the following *italicized text* would be appropriate for these subsections.

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##### Proposed Subsection 2.1.1.1: 10 CFR Part 50 Licensees

*The backfitting requirements in 10 CFR 50.109 apply to the following power reactor licensees and permit holders:*

- *holder of a limited work authorization (10 CFR 50.10, “License required; limited work authorization”)*
- *holder of a construction permit (10 CFR 50.50, “Issuance of licenses and construction permits”)*
- *applicant for an initial operating license (10 CFR 50.50)*
- *holder of an initial operating license (10 CFR 50.56, “Conversion of construction permit to license; or amendment of license,” and 50.57, “Issuance of operating license”)*

- *applicant for a renewed operating license (10 CFR Part 54) (There are no backfitting provisions in Part 54. However, the regulatory structure of Part 54 bounds what the staff can review in these applications, as described in Section 5.16 of this NUREG.)*
- *holder of a renewed operating license (10 CFR Part 54)<sup>2</sup>*

NEI-10(a)

*As described above, the Backfit Rule applies to a holder of a power reactor construction permit (including “partial” construction permits—e.g., limited work authorizations) or operating license issued under 10 CFR Part 50. This means that the NRC would need to meet the requirements of 10 CFR 50.109 prior to issuing positions that meet the definition of backfitting provided in section 50.109(a) to these licensees, permit holders, and applicants.*

*The NRC’s policy is not to apply the backfitting provisions to non-commercial or industrial production and utilization facilities, including radioisotope production facilities, research reactors, and testing facilities, licensed under 10 CFR Part 50.21. Historically, the NRC expressed the regulatory basis for 10 CFR 50.109 solely in terms of commercial or industrial production and utilization facilities. For example, the NRC’s Advanced Notice of Proposed Rulemaking, Policy Statement, Proposed Rule, and Final Rule for the 1985 revision of 10 CFR 50.109 focused on commercial and industrial production and utilization facilities. Further, facilities licensed pursuant to 10 CFR 50.21 are known as “class 104 licensees” (i.e., the underlying statutory authority for licensing such facilities resides in section 104 of the Atomic Energy Act). In turn, Section 104 directs the Commission to impose a “minimum amount” of regulation necessary to achieve the Commission’s statutory obligation to protect public health and safety, and the common defense and security.<sup>3</sup> Given this statutory direction to minimize the regulatory burden imposed on such facilities, application of the backfitting requirements contained in 10 CFR 50.109 is unnecessary. As a result, the NRC has not applied 10 CFR 50.109 to research reactors, testing facilities, and other non-commercial or non-industrial facilities licensed under 10 CFR Part 50.<sup>4</sup>*

Part of  
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Proposed Subsection 2.1.1.2: 10 CFR Part 52 Licensees

NEI-10(b)

*The backfitting requirements in 10 CFR 50.109 apply to holders of combined licenses issued pursuant to 10 CFR Part 52. See 10 CFR 52.98, “Finality of combined licenses; information requests). Part 52 also*

<sup>2</sup> This text is taken largely from Draft Rev. 1 at p. 2-3, lines 12–26.

<sup>3</sup> See Atomic Energy Act of 1954, at §§ 104(a)(“In issuing such licenses the Commission is directed to permit the widest amount of effective medical therapy possible with the amount of special nuclear material available for such purposes and to impose the minimum amount of regulation consistent with its obligations under this Act to promote the common defense and security and to protect the health and safety of the public.”); 104(b)(“In issuing licenses under this subsection, the Commission shall impose the minimum amount of such regulations and terms of license as will permit the Commission to fulfill its obligations under this Act.”) (footnote omitted); 104(c)(“The Commission is directed to impose only such minimum amount of regulation of the licensee as the Commission finds will permit the Commission to fulfill its obligations under this Act to promote the common defense and security and to protect the health and safety of the public and will permit the conduct of widespread and diverse research and development.”).

<sup>4</sup> For example, “Limiting the Use of Highly Enriched Uranium in Domestically Licensed Research and Test Reactors; Final Rule” (51 Fed. Reg. 6514; March 27, 1986), and “Clarification of Physical Protection Requirements at Fixed Sites; Final Rule” (58 Fed. Reg. 13699; March 15, 1993). For additional discussion of this topic, see Attachment 1 to this comment letter.

*contains issue finality requirements applicable to several of the approvals issued pursuant to that part.* NEI-10(b)  
*The issue finality provisions are discussed below in section 2.3.* cont'

Proposed Subsection 2.1.1.3: 10 CFR Part 54 License Renewal

*Backfitting ordinarily does not apply to the renewal of an operating license under 10 CFR Part 54. However, similar to the constraints of the staff's review of a license amendment request, if the NRC proposes to address safety or security issues outside the scope of Part 54 (i.e., other than issues related to time-limited aging analyses and aging management of long-lived, passive SSCs), then any actions necessary to address such out-of-scope safety or security issues are subject to the Backfit Rule. Once the NRC issues a renewed license, the Backfit Rule applies to the renewed license. Renewal of a COL under 10 CFR Part 54 would be similar to renewal of an operating license, except that Section VI.B of the DC appendices in 10 CFR Part 52 provides issue resolution in proceedings to renew a COL.<sup>5</sup>* NEI-10(c)

Proposed Subsection 2.1.1.4: 10 CFR Part 70 Licensees

*The backfitting requirement in 10 CFR 70.76 apply to entities licensed pursuant to Part 70. As stated in section 70.76(a), the backfitting rule applies to the requirements of Subpart H of Part 70 upon NRC approval of the licensee's Integrated Safety Analysis (ISA) Summary pursuant to 10 CFR 70.66. For requirements other than those in subpart H, the requirements of section 70.76 apply regardless of the status of the approval of the licensee's ISA Summary.* NEI-10(d)

Proposed Subsection 2.1.1.5: 10 CFR Part 72 Licensees

*The backfitting requirement in 10 CFR 72.62 apply to holders of general or specific licenses for independent spent fuel storage installations, and holders of licenses for monitored retrievable storage installations.* NEI-10(e)

In addition, much of the discussion of Part 72 licensees provided in subsection 1.2.7 of Draft Rev.1 could be moved to this subsection.

Proposed Subsection 2.1.1.6: Part 76 Certificate Holders – Gaseous Diffusion Plants

*The backfitting requirement in 10 CFR 76.76 applies to holders of certificates of compliance issued pursuant to part 76. Because no gaseous diffusion plants are currently operating, and the NRC does not expect to license any such plants in the foreseeable future, this NUREG does not provide specific guidance for implementation of 10 CFR 76.76.* NEI-10(f)

Subsections 2.1.1.7 and 2.1.1.8 in NEI's Proposed Table of Contents are intended to address the material that is discussed on pages 2-5 through 2-7 of Draft Revision 1, specifically (1) materials licensees that are not licensed pursuant to parts of Title 10 containing backfitting provisions, and (2) situations where a proposed backfit will affect both licensees that are subject to backfitting provisions and those that are not. Each topic and proposed text are discussed below.

Proposed Subsection 2.1.1.7: Other Materials Licensees

Although not called out as such, the language on page 2-5, lines 14–31 of Draft Rev. 1 addresses the idea that the Commission has decided not to extend the backfitting provisions to certain materials

<sup>5</sup> This text is taken largely from Draft Rev. 1 at p. 2-4, lines 39–47.



licensees. While this discussion was generally accurate, additional clarity could be provided by adding language specifically identifying those licensees licensed pursuant to parts of 10 CFR that do not include backfitting provisions. We recommend the *italicized text* provided below: NEI-10(g)

*The NRC issued backfitting provisions for independent spent fuel storage installation licensees in 1988 and gaseous diffusion plants in 1994. In SECY-95-061, “Need for a Backfit Rule for Materials Licensees,” dated March 14, 1995, the NRC staff recommended to the Commission that the NRC not extend backfitting provisions to all other materials licensees. The staff determined that extending the Backfit Rule to all other materials licensees would create technical problems (e.g., the challenge of developing a consistent definition of “substantial” and the uncertainties in quantifying risk) and potentially significant resource burdens for the staff. The staff also determined that regulatory analysis requirements, already applicable to NRC actions involving materials licensees, were similar to the Backfit Rule in preventing the imposition of generic requirements having marginal overall safety benefit or costs not commensurate with the benefits. The Commission approved the staff’s recommendation in the Staff Requirements Memorandum (SRM) to SECY-95-061, dated June 29, 1995, and instructed the staff to “consider the applicability of a backfit provision to particular classes of licensees.” Subsequently, the NRC added a backfitting provision to Part 70. However, the backfitting provision in Part 70 is only applicable to Part 70 licensees authorized to engage in specific activities and possess greater than a critical mass of special nuclear material. The Part 72 backfitting provision applies to Part 72 licensees but not to holders of a Part 72 certificate of compliance.<sup>6</sup>*

*There are currently no backfitting provisions applicable to entities licensed pursuant to the following parts of Title 10:*

- *Byproduct Materials Licensees licensed pursuant to Parts 30, 31, 32, 33, and 35*
- *Industrial radiography licensees licensed pursuant to Part 34*
- *Irradiator licensees licensed pursuant to Part 36*
- *Well logging licensees licensed pursuant to Part 39*
- *Source materials licensees licensed pursuant to Part 40*
- *High level waste repository licensees licensed pursuant to Parts 60 or 63*
- *LLRW disposal facilities licensed pursuant to Part 61*

NEI-10(g)  
cont'

*Although there are not backfitting requirements applicable to entities licensed pursuant to these parts, the Commission has directed the staff to ensure that regulatory requirements applied to such facilities “are well-founded in protection of public health and safety without being overly burdensome.”<sup>7</sup>*

<sup>6</sup> This text is taken largely from Draft Rev. 1 at p. 2-5, lines 14–31.

<sup>7</sup> Staff Requirements Memorandum, “SECY-95-061 – Need for a Backfit Rule for Materials Licensees,” June 29, 1995.

Proposed Subsection 2.1.1.8: Regulatory Actions that Affect Both Entities within the Scope of Backfitting Requirements and Entities that Are Not within the Scope of Backfitting Requirements NEI-10(h)

Subsection 2.1.1.8 in NEI’s Proposed Table of Contents is intended to address the discussion that begins on page 2-5, line 33 of Draft Rev. 1 and continues through page 2-7, line 4. This discussion in Draft Rev. 1 addresses the following scenarios: (1) a proposed regulatory action affects entities not licensed pursuant to a part of Title 10 containing a backfitting provision;<sup>8</sup> (2) a proposed regulatory action affects an entity that is licensed pursuant to a part of Title 10 containing a backfitting provision, but the proposed regulatory action does not involve amendment or changing interpretations of a part of 10 CFR containing a backfitting provision (*e.g.*, changes to 10 CFR Part 40 affecting a Part 70 licensee);<sup>9</sup> and (3) a proposed regulatory action applies to power reactor licensees and other materials licensees that are not licensed pursuant to a part of 10 CFR containing a backfitting provision (*e.g.*, regulatory action affects commercial power reactors and Part 30 by-product material licensees).<sup>10</sup>

With respect to scenario 1, Draft Revision 1 concludes that further consideration of the backfitting implications of the proposed regulatory action is not required. We agree with this conclusion. We do not, however, agree with the discussion of scenarios 2 and 3 in Draft Rev. 1.

Specifically, the discussion of scenario 2 in Draft Rev. 1 seems to be addressing situations where a materials licensee is licensed pursuant to a part of Title 10 containing a backfitting provision (*e.g.*, a Part 70 licensee), but is also authorized to conduct activities pursuant to a part of Title 10 that does not contain a backfitting provision (*e.g.*, Part 40). In this scenario, Draft Rev. 1 states that the backfitting provisions applicable to the Part 70 licensee would not apply to changes to the Part 40 requirements (and presumably any interpretation of the Part 40 requirements) applicable to that licensee.

This position is inconsistent with the definition of backfitting, as well as the NRC’s past practice in such situations. 10 CFR parts 50, 70, 72, and 76 define backfitting in terms of “cause”—*e.g.*, a “new or amended provision in the Commission’s regulations or the imposition of a regulatory staff position interpreting the Commission’s regulations that is either new or different from a previously applicable staff position”—and “effect”—*e.g.*, “modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility.”<sup>11</sup> The “causal” element of these definitions is not limited to changes to specific regulations (or interpretations of those regulations). And, as discussed above, the various backfitting provisions apply to holders of licenses, permits, and certificates under those provisions. Further, we are not aware of any instance where the NRC has justified changes to Part 40, which is used as an example in Draft Rev. 1, using this rationale. For example, in the 2013 rulemaking on distribution of source material to exempt persons and general licensees, the NRC provided this explanation for not performing a backfitting analysis:

NEI-10(h)  
cont'

The NRC’s backfit provisions are found in the regulations at §§ 50.109, 52.39, 52.63, 52.83, 52.98, 52.145, 52.171, 70.76, 72.62, and 76.76. The requirements contained in this final rule do not involve any provisions that impose backfits on nuclear power plant

<sup>8</sup> Draft Revision 1, at p. 2-6, lines 9–12.

<sup>9</sup> Draft Revision 1, at p. 2-6, lines 17–30.

<sup>10</sup> Draft Revision 1, at p. 2-6, line 34–p. 2-7, line 13.

<sup>11</sup> See 50 Fed. Reg. 38097, 38101 (Sept. 20, 1985).

licensees as defined in 10 CFR parts 50 or 52, or on licensees for gaseous diffusion plants, independent spent fuel storage installations or special nuclear material as defined in 10 CFR parts 70, 72, and 76, respectively, and as such a backfit analysis is not required. Therefore, a backfit analysis need not be prepared for this final rule to address these classes of entities. With respect to 10 CFR part 40 licensees, there are no provisions for backfit in 10 CFR part 40. Therefore, a backfit analysis has not been prepared for this final rule to address 10 CFR part 40 licensees.<sup>12</sup>

NEI-10(h)  
cont'

Here, the NRC’s clearly recognized that the backfitting provisions in Parts 50, 52, 70, 72, and 76 applied to entities licensed pursuant to those Parts, but concluded that Part 40 requirements contained in the final rule did not impose backfits on those licensees. Contrary to the position articulated in Draft Rev. 1, the Commission did not conclude that the changes to Part 40 did not involve backfitting with respect to Part 50, 52, 70 licensees and gaseous diffusion plans because Part 40 does not contain a backfitting provision. The only class of licensees which were excluded from backfitting consideration due to the lack of a backfitting provision in Part 40 were Part 40 licensees. The guidance should recognize that changes to some parts of the Commission’s regulations without backfitting provisions (e.g., Part 40) can indirectly affect Part 50 or Part 70 licensees who are covered by the backfitting provisions of 10 CFR 50.109 or 10 CFR 70.76.

NEI-10(h)  
cont'

The discussion of scenario 3 in Draft Rev. 1 is also problematic. For power reactor licensees, Draft Rev. 1 appears to state that a new or amended provision of the Commission’s regulations, and new or different interpretations would be considered backfits only if the potential backfit:

NEI-10(h)  
cont'

- Would uniformly apply to all applicable non-nuclear power reactor licensees, and at least one of these non-nuclear power reactor licensees is within the scope of a backfitting provision; or
- Is directed only at nuclear power reactor licensees; or
- Seeks a level of performance for nuclear power reactor licensees that is higher than the level of performance sought from non-nuclear power plant licensees.

As with scenario 2, we are unaware of any instance where the Commission has explicitly justified the backfitting of reactor licensees using the rationale provided in Draft Rev. 1. To the contrary, the Commission has applied the backfitting requirements to power reactor licensees when changes were made to 10 CFR Part 20, which is generally applicable to materials and commercial power reactor licensees.<sup>13</sup> The rationale for the position take in Draft Rev. 1 seems to be “equity.” Specifically, Draft Rev. 1 states:

In this case, the NRC would be imposing the proposed action on nuclear power reactor licensees in a manner that is equal to the manner that the NRC would impose the proposed action on non-nuclear power plant licensees. In other words, nuclear power reactor licensees would receive equal treatment as materials licensees because the proposed action would be imposed on the nuclear power reactor licensees in their capacities as material licensees. Therefore, to ensure equal backfitting treatment, no backfitting provision should

<sup>12</sup> 78 Fed. Reg. 32309, 32337 (May 29, 2013).

<sup>13</sup> See 56 Fed. Reg. 23360, 23389 (May 21, 1991).



apply to the nuclear power reactor licensees in this instance because, in this case, no backfitting provision applies to the non-nuclear power licensees.<sup>14</sup>

But as explained earlier in this same section of Draft Rev. 1, and as discussed above in subsection 2.1.1.7 of the NEI Proposed Table of Contents, the Commission made a deliberate decision not extend backfitting protection to all classes of materials licensees in SRM-SECY-95-061.<sup>15</sup> Thus, the push for “equity” in this area, which would result the backfitting provisions that actually apply to reactor licensees being read out of the rule in these situations, is misguided.

Given the discussion above, we suggest the following, simplified *italicized text* for subsection 2.1.1.8 of the NEI Proposed Table of Contents, which would replace the discussion beginning on line 33 of page 2-5 and running through line 13 on page 2-7:

*In certain circumstances, a proposed action may affect entities that are within the scope of backfitting and entities that are not within the scope of backfitting. A proposed action may also affect entities authorized to conduct certain activities under multiple parts of the NRC’s regulatory framework (e.g., nuclear power reactor licensees that are authorized to receive, possess, and use source, byproduct, and special nuclear material under Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material,” Part 40, “Domestic Licensing of Source Material,” Part 50, and Part 70). In these scenarios, the staff needs to determine whether any backfitting provisions apply and, if so, to which licensees the provisions apply. Generally, the staff can make that determination by ascertaining how the proposed action would affect the licensee. To help make that determination, the staff should follow these steps:*

NEI-10(h)  
cont'

1. *Identify all the NRC-regulated entities affected by the proposed action.*
2. *Identify all the NRC-regulated entities affected by the proposed action that are within the scope of a backfitting requirement.*
  - a. *For those NRC-regulated entities that are not within the scope of a backfitting or issue finality provision, the staff can exit the backfitting process. The NRC can still consider taking the proposed action (e.g., through conducting a regulatory analysis), but the staff does not need to consider the backfitting implications of the proposed action for these entities.*
  - b. *For those entities that are within the scope of a backfitting or issue finality requirement (see discussion in subsections 2.1.1.1–2.1.1.7 above), the staff should comply with the backfitting requirement applicable to those entities. In such cases, application of the backfitting requirement would be limited to examining the safety and security implications, as well as costs (where appropriate), applicable to those affected entities licensed, permitted, or certified pursuant to a regulation containing a backfitting provision. In these situations, it is likely that the staff will be performing a regulatory analysis to support the proposed regulatory action. To maximize efficiency, the limited backfitting analysis described in this paragraph should be included as part of any broader regulatory analysis prepared to support the proposed action.*

<sup>14</sup> Draft Rev. 1, at pp. 2-6–2-7.

<sup>15</sup> See Draft Rev. 1, at p. 2-5.

**2. Proposed Subsection 2.1.2: Question 2: Does the proposed action meet the definition of backfitting in the relevant backfitting regulation (*i.e.*, 10 CFR §§ 50.109, 70.76, 72.62, or 76.76)?**

NEI-11

In answering question 2, the NRC staff determines whether the proposed action constitutes backfitting. To determine whether the proposed action constitutes backfitting, the answer to each of the following three questions must be “YES”:

1. Does the issue involve either—
  - a. a new or changed (*e.g.*, amended, revised, or modified) NRC requirement (*e.g.*, a regulation or order), or
  - b. imposition of a regulatory staff position interpreting the Commission’s regulations that is either new or different from a previously applicable staff position?
2. Will the new or changed NRC requirement or interpretation result in a modification or addition to—
  - a. SSCs of the entity’s facility;
  - b. design (including but not limited to a DC, SDA, or ML) of the entity’s facility; or
  - c. procedures or organization for designing, constructing, or operating the entity’s facility?
3. Will the imposition of the new or changed NRC requirement or interpretation occur after the point that the applicable backfitting provision begins to apply (*see, e.g.*, as specified in 10 CFR 50.109(a)(1)(i) through (vii))?

NEI-11

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

As discussed above in section II.A., the primary consideration when determining whether the proposed action constitutes backfitting is whether the proposed action meets the definition of backfitting provided in the relevant part of Title 10. Generally, the NRC staff should not make assumptions regarding whether a proposed action meets the definition of backfitting based upon the broad category within which the proposed actions falls (reporting requirements, *etc.*). That said, the Commission has provided a “non-exhaustive list of regulatory actions that generally do not meet the definition of backfitting” in Management Directive 8.4.<sup>16</sup>

part of  
NEI-9

As stated above in Section II.A, we recommend that section 2.2 of Draft Rev. 1 (“Question 1: Is the proposed action excluded from the backfitting and issue finality provisions?”) be removed from the document. As discussed in Section II.A, NEI’s view is that the only valid test of whether the backfitting requirements apply to a proposed regulatory action is to apply the definition of backfitting provided in the relevant regulations. Backfitting is a regulatory construct, with specific exceptions to the analytical requirements built into the rule itself. Unless there is a regulatory basis for doing so, it is inappropriate

part of  
NEI-9

<sup>16</sup> Management Directive 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,” Sept. 20, 2019, at DH pp. 10–11.

for the NRC staff to make the *a priori* assumption that an entire category of staff actions is outside the scope of the backfitting requirements, without actually applying the definition of backfitting.

For example, the discussion on lines 4-8 of page 2-2 of Draft Rev. 1 state:

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

NEI-9  
cont'

But this is an overstatement. Although there may be situations where statutory requirements require the NRC to impose specific regulatory requirements with little or no discretion or without regard to cost, these situations are very rare. To the contrary, even in situations where the NRC is statutorily required to impose some type of requirement, the agency typically has wide latitude to determine exactly what to impose and how to do so, and to consider cost impacts as part of the analysis.

For example, the Energy Policy Act of 2005 added Section 170E to the Atomic Energy Act of 1954, requiring that the NRC initiate a rulemaking to revise the Design Basis Threat (DBT). Section 170E also required the NRC to consider 12 factors in the course of the DBT rulemaking. Notwithstanding the statutory mandate to conduct the DBT rulemaking and consider certain factors, the NRC still addressed the backfitting implications of the rule. The agency ultimately concluded that the rule met the adequate protection exception in 10 CFR 50.109(a)(4)(iii) and 10 CFR 70.76(a)(4)(iv), and therefore, a backfit analysis was not required.<sup>17</sup> Thus, simply because the NRC is implementing a mandatory statutory requirement does not automatically exclude the action from the purview of the backfitting regulations.

Any discussion of categories of regulatory actions that do not generally fall within the definition of backfitting should be limited to the examples provided by the Commission in Management Directive 8.4. While consideration of whether a proposed action falls within one of these categories can be helpful, the staff should not elevate form over substance. A determination that a proposed action does not constitute backfitting should always be based upon a clearly articulated analysis of whether the proposed action meets the regulatory definition of backfitting.

In the preamble to the 1985 final backfitting rule, the Commission explained that there are both “cause” and “effect” elements to the definition of backfitting. Specifically, the Commission stated:

Section 50.109(a) sets out the definition of backfitting, the analysis requirement, the standard to be used in determining whether a backfit should be imposed and the exceptions to the rule. The definition focuses on modifications to systems, structures, components, designs, procedures or organization which may be caused by new or modified Commission rules or orders or staff interpretations of Commission rules or orders. Thus, this definition includes both cause and effect of backfitting. It may also be noted that “cause” includes not only Commission rules and orders, but staff interpretations of those rules and orders. This is not to say that staff interpretations of rules are viewed by the Commission as being legal requirements. Clearly, they are not. Nevertheless, staff interpretations of broadly

NEI-13

<sup>17</sup> “Design Basis Threat,” Final Rule, 52 Fed. Reg. 12705, 12726 (March 19, 2007).

stated rules are often necessary to give a rule effect and in some instances may be a causal factor in initiating a backfit.<sup>18</sup>

Additional guidance on implementation of the “causal” elements of the definition of backfitting is provided under subsections 2.1.2.1, 2.1.2.2, and 2.1.2.3 of the NEI Proposed Table of Contents. Questions often arise regarding these “causal” elements of the backfitting definition, therefore additional guidance would be helpful. Most of the text suggested below is provided in Draft Rev. 1; however, we believe it could be reorganized and supplemented, as suggested below.

Proposed Subsection 2.1.2.1: A New or Changed (e.g., Amended, Revised, or Modified) NRC Requirement (e.g., a Regulation or Order)

NEI-11(a)

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

- the license, which ensures compliance with and operation within applicable NRC requirements and the facility-specific design bases as well as all modifications and additions over the life of the facility that are docketed and in effect, including any NRC-approved license amendments, license renewals, license conditions, and license appendices such as technical specifications and an environmental protection plan;
- the regulations as they apply to the licensee; and
- orders.<sup>19</sup>

It is important to note that *new or amended* legally binding requirements meet the “causal” element of the definition of backfitting. This includes imposition of new legally binding requirements regulating areas that the NRC has not previously regulated, as well as amendments to existing legally binding requirements. If the proposed action comes in the form of a new or amended regulation or an order, the “causal” element of the definition of backfitting is met and the staff should proceed to an examination of the “effect” element described above (*i.e.*, modification or addition to the SSCs of the entity’s facility; the design of the facility; or the procedures or organization for designing, constructing, or operating the entity’s facility).

Proposed Subsection 2.1.2.2: Imposition of a Regulatory Staff Position Interpreting the Commission’s Regulations that Is Either New or Different from a Previously Applicable Staff Position

NEI-11(b)

The second “causal” element of the definition of backfitting involves imposition of new interpretations of unchanged legally binding requirements, or interpretations that are different from previously

<sup>18</sup> “Revision of Backfitting Process for Power Reactors,” Final Rule, 50 Fed. Reg. 38102.

<sup>19</sup> This language is taken from section 1.2.2.1 of draft Rev. 1.

applicable interpretations of unchanged legally binding requirements (*i.e.*, “previously applicable staff positions”).

Proposed Subsection 2.1.2.2.1: New Interpretations

As with the first “causal” element of the definition of backfitting described above in subsection 2.2.1, the second “causal” element includes “new” positions taken by the agency that come in the form of “a regulatory staff position interpreting the Commission’s regulations that is . . . new.” For backfitting purposes, new interpretations could involve situations where the agency is seeking to impose a prescriptive interpretation of an unchanged broadly worded or performance-based legally binding requirement on a licensee or class of licensees for the first time. New interpretations could also arise due to the discovery of design vulnerabilities that were not adequately identified and evaluated at the time a facility was licensed. NEI-11(c)

Given the Commission’s current policy of issuing implementing guidance simultaneously with rulemakings, any new interpretations that arise during the rulemaking context should be addressed as part of the backfitting analysis associated with the relevant rulemaking proceeding. If the proposed action comes in the form of a new interpretation of an unchanged underlying legally binding requirement, the “causal” element of the definition of backfitting is met and the staff should proceed to an examination of the “effect” element described above in subsection 2.1.2.

Proposed Subsection 2.1.2.2.2: Interpretations that Are Different from  
Previously Applicable Staff Positions

NEI-11(d)

This portion of the causal element of the definition of backfitting is often the subject of questions and discussion between the industry and the NRC. The discussion provided in subsection 1.2.2.2 of Draft Rev. 1 should be moved to this section.

Proposed Subsection 2.1.2.2.3: “Imposition”

It has been the Commission’s long-standing position that the backfitting process is defined on the principle that new positions or requirements are to meet the standards of the backfitting rules *before they are issued to the licensee(s)*. New generic positions in documents, such as generic letters, bulletins, and regulatory guides, as well as plant-specific positions, are to be considered and justified as backfits *before they are issued*. Therefore, application of the backfitting process is not always contingent upon imposition of a new or different interpretation via a legally binding requirement. NEI-11(e):

For example, in its 1985 Final Rule amending 10 CFR § 50.109, the Commission stated:

Because there must be safety reasons for the agency to impose any changes to a regulatory requirement or a staff position, applicable to the licensee, because the safe consequences are unknown until analyzed, and because the Commission should fully understand the effects of a proposed backfit before its imposition, it is of little consequence how a backfit is imposed. Safety and sound management require that analysis precede imposition of a new or modified regulatory requirement or staff position. It follows that those backfits imposed by rulemaking should undergo the same scrutiny as proposed by other means. It also follows that changes in regulatory requirements or staff positions for procedures and organization should also be analyzed before implementation to determine, *inter alia*, the safety significance of any such proposed change. The final rule reflects this position.

Many of the most important changes in plant design, construction, operation, organization, and training have been put in place at a level of detail that is expressed in staff guidance documents which interpret the intent of broad, generally worked regulations. The NRC has determined that the correct focus for backfit regulation is the establishment of effective management controls on existing staff processes for the interpretation of regulations that are known to result in valuable upgrades in industry safety performance. Thus, the Commission opts to adopt a management process not only for the promulgation of regulations as backfit instruments, but also for the lower tier staff review and inspection processes known to result in reactor plant changes.<sup>20</sup>

This passage acknowledges the practical, action-forcing nature of NRC’s interpretive guidance. Given that guidance often spurs changes at facilities subject to the agency’s backfitting requirements, the Commission determined that the agency’s process for managing backfits should focus not only on regulations, which “impose” agency positions via legally binding requirements, but also on “lower-tier” processes that result in plant changes.

This principle was carried forward in the previous iteration of NUREG-1409, which recognized that the NRC has issued a number of guidance documents that were considered backfits. A footnote expanding upon this recognition explains:

As a legal matter, the backfit rule does not strictly apply until the point at which a backfit is required by, for example, a rule or an order. However, for the purpose of this discussion, that legal distinction is not important. The NRC backfit process, including the CRGR Charter and NRC Manual Chapter 0514, is defined on the principle that new positions or requirements are to meet the standards of the rule before they are issued to licensee(s). New generic positions in documents, such as generic letters, bulletins, and regulatory guides, as well as plant-specific positions, are to be considered and justified as backfits before they are issued. For this reason, they often are discussed in the same way as legally required backfits.<sup>21</sup>

The NRC’s General Counsel has subsequently explained that the backfitting requirements should be applied to interpretive guidance where:

- The NRC staff’s expectation that licensees “voluntarily” adopt the “guidance” constitutes the basis, or part of the bases, for resolution of a safety or regulatory issue;
- The NRC staff intends the positions presented in the proposed interpretive guidance to become legally binding on the licensee through further NRC action; or
- The NRC staff issues a “recommendation” that a license adopt the proposed guidance, and the recommendation is accompanied by a request for information as to whether the licensee intends to adopt the NRC staff’s “recommendation.”<sup>22</sup>

In Management Directive 8.4, the Commission further clarified that:

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<sup>20</sup> “Revision of Backfitting Process for Power Reactors: Final Rule,” 50 Fed. Reg. 38101.

<sup>21</sup> “Backfitting Guidelines,” NUREG-1409, at p. 3 (July 1990).

<sup>22</sup> See Letter from S.G. Burns to E.C. Ginsberg, July 14, 2010.



If the NRC staff conveys an expectation that licensees change programs, processes, procedures, or the physical plant by using or committing to use voluntary guidance (*e.g.*, Regulatory Guides or NRC-endorsed industry topical reports) that is not already within the LB for the identified purpose, then the staff’s communication of that expectation is considered backfitting or forward fitting. As discussed in Section I.B of this DH, forward fits do not constitute backfits but must meet additional specified criteria and are subject to the backfit appeals process.<sup>23</sup>

Thus, for purposes of implementing the agency’s backfitting requirements, the “imposition” element of the definition of backfitting should be considered to be met upon issuance of interpretive guidance that meets the following criteria:

1. The NRC staff expects that licensees will voluntarily adopt the guidance to resolve, or partially resolve, a safety or regulatory issue; *or*
2. The NRC staff conveys an expectation that licensees change programs, processes, procedures, or the physical plant by using or committing to use guidance that is not already included within the facility’s licensing basis; *or*
3. The NRC staff intends the positions presented in the proposed interpretive guidance to become legally binding on the licensee through further NRC action; *or*
4. The NRC staff issues a “recommendation” that a license adopt the proposed guidance, and the recommendation is accompanied by a request for information as to whether the licensee intends to adopt the NRC staff’s “recommendation;” *and*
5. One or more of the above criteria would apply to a licensee that is not voluntarily seeking approval of a licensing action that would modify the facility’s licensing basis (*see* Chapter 3 Forward Fitting).

In situations where any one of criteria 1-4 and criteria 5 are met, a backfitting analysis or documented evaluation should be prepared prior to issuance of the guidance and published with the proposed interpretive guidance document.

#### Proposed Subsection 2.1.2.3: Timing Provisions

NEI-14

The staff should also be aware that many of the backfitting requirements (*e.g.*, 10 CFR 50.109, 70.76, and 72.62) contain timing provisions explaining when the backfitting provisions become applicable to entities licensed pursuant to those parts.

### **B. Proposed Section 2.2: Justifying Backfits**

If the NRC staff determines that its proposed action would constitute backfitting it must justify the proposed action. The default method for justifying a proposed backfitting action is a backfit analysis. However, the Commission has directed the staff to first determine whether the proposed action satisfies the criteria for one (or more) of three exceptions to the requirement to prepare a backfit analysis. Furthermore, the staff must consider whether the backfitting action involves the adequate protection

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<sup>23</sup> “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,” Management Directive 8.4, Directive Handbook, at p. 10 (Sept. 20, 2019).

exception before considering justification by the compliance exception.<sup>24</sup>

At this stage of its analysis, the staff should address the following questions:

1. Do any of the exceptions to the requirement of preparing a backfit analysis apply to the proposed backfitting?
  - a. Do one or both of the adequate protection exceptions to the requirement of preparing a backfit analysis apply?
  - b. Does the compliance exception to the requirement of preparing a backfit analysis apply?
2. Does the proposed backfitting action constitute a cost-justified substantial increase in the overall protection of public health and safety or the common defense and security?

Proposed Subsection 2.2.1: Do Any of the Exceptions to the Requirement of Preparing a Backfit Analysis Apply to the Proposed Backfitting?

Proposed Subsection 2.2.1.2: Adequate Protection Exceptions

This subsection of the NEI Proposed Table of Contents corresponds to subsection 2.5.1 of Draft Rev. 1. The material in that subsection is not reproduced here, but we provide specific comments on the text below.

Proposed Subsection 2.2.1.2.1: Background

This subsection corresponds with subsection 2.5.1.1 in Draft Rev. 1. This subsection should clearly state that if a backfitting action involves an issue of adequate protection, then the backfitting justification must be *reviewed and approved* by the Commission. Further, if the issue involves an imminent adequate protection issue, the staff may proceed with the backfit (*see* 10 CFR 50.109(a)(6)), but should complete and provide its documented evaluation to the Commission for information as soon as practicable after imposition of the backfit.

NEI-15

Proposed 2.2.1.2.2: Adequate Protection Determinations

This subsection corresponds with section 2.5.1.2 in Draft Rev 1. This subsection should clearly state that the staff must inform and obtain Commission approval when considering any generically applicable adequate protection backfitting actions. The NRC staff should inform the Executive Director for Operations (EDO) when the staff is considering any facility-specific adequate protection backfitting actions. Such notifications should occur once the staff has determined that the adequate protection exception may apply and the staff has begun developing a documented evaluation for the adequate protection exception, not when the staff first considers adequate protection. Unless the backfit is required to address an imminent adequate protection issue, the staff should provide documented evaluations justifying facility-specific adequate protection backfits to the Commission for approval prior to issuing the backfit to the licensee.

NEI-16

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<sup>24</sup> See “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,” Management Directive 8.4 (Sept. 20, 2019), at Directive Handbook, p. 5.



Further, in several places Draft Rev. 1 directs that the staff must first determine whether a backfit involves the adequate protection exception before considering the compliance exception or other justifications. While this framework is inherently logical in that the NRC’s fundamental mission is to ensure reasonable assurance of adequate protection of public health and safety and common defense and security, the blanket statements in Draft Rev. 1 are overly-broad and do not acknowledge nuanced situations that may also involve compliance questions and the compliance exception. NEI-17

As written, the Draft Rev. 1 could be read to suggest that adequate protection and compliance are mutually exclusive such that the staff would never consider a compliance question (or even reach the compliance exception test) if the issue in any way “involves” adequate protection. (*See, e.g.*, Draft NUREG-1409, Rev. 1, p. 2-8, lines 49–50, “Furthermore, the staff must consider whether the backfitting action involves the adequate protection exception before considering justification by the compliance exception.”) However, this direction is not consistent with the construct of the backfit rule or its exceptions. NEI-17 cont'

Consider a scenario in which the dispute is whether a licensee is following a requirement that was promulgated on the basis of adequate protection. The Draft Rev. 1 could be read to mean that because the requirement at issue was originally determined to be necessary for adequate protection, the present-day condition necessarily represents an adequate protection issue and therefore, no further analysis is warranted. If so, the staff could simply rely on the original adequate protection determination and never reach the compliance question (effectively circumventing the compliance exception test). The real question, however, 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. Therefore, the NRC cannot solely rely on the fact that a regulation might have originally been promulgated under an adequate protection basis to conclude that it continues to be required for adequate protection in the present time. The Commission has stated repeatedly that “adequate protection is presumptively assured by compliance with the regulations and other license requirements,” clearly indicating that the two concepts are inextricably intertwined.<sup>25</sup> NEI-17 Cont'

That said, if the NRC’s intent is that there must be an imminent adequate protection issue with the plant as it currently exists (as opposed to a “historical” adequate protection issue or an adequate protection issue that will not arise in the near future), then the NUREG should state that explicitly. All documented evaluations for adequate protection should address whether the issue is imminent. NRC should not allow a non-imminent or historical adequate protection issue to bypass a compliance question altogether, thereby rendering the compliance exception meaningless. NEI-18

Moreover, it may also be the case that the issue involves a dispute over the method of complying with an adequate protection requirement. In that scenario, the question is not whether an action is necessary for adequate protection, but rather, how to comply with that requirement. 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. NEI-17 cont'

<sup>25</sup> See Final Rule, Revision of Backfitting Process for Power Reactors, 53 Fed. Reg. 20603, 20606 (June 6, 1988).

At bottom, the NUREG should make clear that the initial consideration of adequate protection should not be used to bypass the compliance exception test if the backfit fundamentally rests on a question of compliance and there is no imminent adequate protection issue.

NEI-17  
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Proposed Subsection 2.2.1.2.3: Documenting Adequate Protection Evaluations

This subsection corresponds to subsection 2.5.3.1 in Draft Rev. 1.

Proposed Subsection 2.2.1.3: Compliance Exception

This subsection of the NEI Proposed Table of Contents corresponds to subsection 2.5.2 of Draft Rev. 1. The material in that subsection is not reproduced here, but we provide specific comments on the text in this section below.

Proposed Subsection 2.2.1.3.1: Background

This section corresponds to subsection 2.5.2.1 of Draft Rev. 1.

Proposed Subsection 2.2.1.3.2: Compliance Exception Determinations

This subsection corresponds to subsection 2.5.2.2 of Draft Rev. 1. The opening paragraph of the text in subsection 2.5.2.2 should be modified to stress the importance of distinguishing situations where a licensee has failed to meet a known and established standard due to an omission or mistake of fact, from situations where the NRC is seeking to impose a new or modified interpretation on the licensee. In addition, the text of this subsection should be modified to ensure that the substitution of terms like “error” for “mistake of fact” do not create confusion.

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We recommend the following specific edits to this subsection:

In the 1985 Backfit Rule SOC, the Commission stated, “The compliance exception is intended to address situations in which the licensee has failed to meet known and established standards of the Commission because of omission or mistake of fact. It should be noted that new or modified interpretations of what constitutes compliance would not fall within the exception and would require a backfit analysis and application of the standard.” Distinguishing situations where the licensee has failed to meet a known and established standard due to an omission or mistake of fact from situations where the NRC is seeking to impose a new or modified interpretation of what constitutes compliance is vital to appropriate application of the compliance exception. As approved by the Commission in SRM-COMSECY-16-0020, dated November 29, 2016, and as further explained in the NRC Solicitor’s 2016 memorandum to the chairman of the Committee to Review Generic Requirements, the staff should determine that an omission or mistake of fact exists within the scope of the exception under 10 CFR 50.109(a)(4)(i), 10 CFR 70.76(a)(4)(i) or (ii), 10 CFR 72.62(b), or 10 CFR 76.76(a)(4)(i) only when all of the following three conditions exist:

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

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incorrectly perceived facts,

performed or failed to recognize flawed analyses, or

failed to draw inferences from those facts or analyses.

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2. The staff’s ~~error~~ mistake of fact is deemed a ~~error~~ mistake as judged by the standards and practices that were prevailing among professionals or experts in the relevant area at the time of the determination in question.
3. The facts, analyses, or inferences have now been properly perceived, performed, or drawn.

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

1. The NRC approved or found acceptable a licensee’s method of compliance with a requirement.
2. The staff determines that the licensee’s method of compliance does not meet the requirement because of an ~~error~~ mistake of fact or omission related to the NRC’s approval (as described above).
3. If the NRC had known about the error or omission at the time it issued the approval, the NRC would not have approved the licensee’s method of compliance.

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

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

- provide information to the NRC (or other necessary Federal agency the NRC relies upon in its approval decision) that should have been submitted in connection with obtaining the NRC approval at issue;
- consider or address information that the NRC requires to be considered or addressed in connection with obtaining an NRC approval (e.g., development of an application or preparation of an applicant response to an NRC request for additional information); or
- consider or address information that the NRC requires be addressed through a legal obligation (e.g., for nuclear power plant licensees, the change control provisions of 10 CFR 50.59, “Changes, tests, and experiments”).

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

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The applicant’s, licensee’s, or third party’s ~~error~~ mistake of fact or omission must be relevant and material to the NRC’s approval that is now regarded as incorrect. An omission or ~~error~~ mistake of fact—even those now acknowledged by the applicant or licensee as having

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occurred—cannot be the basis for invocation of the compliance exception if that ~~error~~ mistake of fact or omission, had it been known to the NRC at that time, would not have affected the NRC’s approval.

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\* \* \* \* \*

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

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#### Proposed Subsection 2.2.1.3.3: Consideration of Costs

This subsection corresponds to the description provided on page 2-15 starting at line 30 and running through line 34 on page 2-16 in Draft Rev. 1.

#### Proposed Subsection 2.2.1.3.4: Documenting Compliance Exception Evaluations

This subsection corresponds to subsection 2.5.2.3 in Draft Rev. 1.

#### Proposed Subsection 2.2.2: Does the Proposed Backfitting Action Constitute a Cost-Justified Substantial Increase in the Overall Protection of Public Health and Safety or the Common Defense and Security?

This subsection corresponds to subsection 2.6.2 of Draft Rev. 1. We have no specific comments on this subsection. This topic is covered primarily in NUREG/BR-0058 and we recommend that the NRC not attempt to reproduce that material here. Unnecessarily redundant discussion of the topic in NUREG-1409 could lead to unintentional inconsistencies and confusion. Therefore, we recommend that overlap be minimized and that this subsection be kept as brief as possible.

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#### Proposed Subsection 2.2.2.3: Documenting a Backfit Analysis

This subsection corresponds to subsection 2.6.3 of Draft Rev. 1.

### **C. Proposed Section 2.3: Issue Finality**

This would be a new section. This section should be populated with the material contained in section 1.2.6 of Draft Rev. 1, as well as the explanation the runs from line 28 on page 2-3 through line 5 on page 2-4.

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relocate info

The following comments on Chapter 3, “Forward Fitting,” were written with the objective of developing guidance on the forward fitting policy articulated in MD 8.4 in a manner consistent with 10 CFR 50.109 and other relevant regulatory history. NEI appreciates that MD 8.4 established parameters on the forward fit concept. The discussion below attempts to reconcile those parameters with the original intent of the backfit rule and set forth a simplified and workable process for addressing forward fit issues.

## **I. THE COMMISSION’S LONG-STANDING POSITION IS THAT THE BACKFITTING REQUIREMENTS APPLY TO THE LICENSE AMENDMENT PROCESS**

The issue of whether and, if so, how the backfitting process should apply to the issuance of license amendments was explored during the rulemaking that culminated in the issuance of the 1985 Final Backfit Rule. Describing responses to the NRC’s invitation to comment on this very issue, the Commission stated:

The Commission also expressed a concern over whether preparation of a backfitting analysis should be required as a condition precedent to the issuance of a license amendment. NUBARG stated that “unless requested by a licensee, the staff should not be requested to prepare a backfitting analysis as a condition precedent to issuance of a license amendment if the licensee requests an amendment pursuant to 10 CFR § 50.90.” NUBARG points out that application for significant amendments requires a description of the proposed modification and the preparation of a safety analysis report by the licensee. Since the licensee presumably will have subjected the amendment to an internal cost effectiveness review, a backfitting analysis by the NRC would appear to be neither necessary nor appropriate. AIF was in general agreement with this position and stated further that the option to allow a licensee to request a backfitting analysis should be retained. AIF suggested that there are instances when licensees are under informal but intense regulatory pressure to submit an amendment request. In this circumstance, backfitting analysis should precede the issuance of a license amendment according to AIF. General comments from other members of the industry tend to support the NUBARG and AIF positions.<sup>1</sup>

In response to the comments described above, the Commission stated:

The Commission agrees with those who suggest that the Staff should not be required to prepare a backfitting analysis as a condition precedent to issuance of a license amendment if the licensee requested the amendment pursuant to 10 CFR 50.90. 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. It is unnecessary to amend the rule in this regard since mention of the point here provides adequate direction to the Staff and licensees.<sup>2</sup>

These passages in the 1985 Final Backfit Rule indicate that—while at the time Industry groups did not feel that requiring a backfit analysis as a condition precedent to issuance of a license amendment was

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<sup>1</sup> *Revision of the Backfitting Process for Power Reactors*, 50 Fed. Reg. 38097, 38101 (Sept. 20, 1985) (emphasis added).

<sup>2</sup> 50 Fed. Reg. 38101 (emphasis added).

necessary—the Commission recognized that such an analysis would be performed at the request of the licensee.

There is no indication that the Commission contemplated that issuance of license amendments—voluntary or not—would be categorically excluded from backfit consideration by being characterized as so-called “forward fitting” —a term that is not used in the 1985 or 1988 backfitting rulemakings, or in the version of NUREG-1409 that has been in place since 1990. In fact, the Commission expressly dismissed the suggestion that the backfitting rule needed to be modified to explicitly allow licensees to request backfitting analyses of license amendments because—according to the Commission—its “mention of the point” in the Supplementary Information “provid[ed] adequate direction to the Staff and licensees.”<sup>3</sup> Thus, in our view, the rulemaking record for the 1985 Final Backfitting Rule makes it clear that the Commission’s long-held view has been the requirements of 10 CFR 50.109 apply to backfits imposed via the license amendment process. NEI-23

This view is also supported by the express language of section 50.109 itself. Specifically, paragraph 50.109(d) provides: “No licensing action will be withheld during the pendency of backfit analyses required by the Commission’s rules.” Explaining this requirement, the Commission stated:

During internal review of the rule, a question was raised as to whether licensing action should be withheld during backfit review. The answer is that the rule never contemplated such a withholding. To the contrary, until a backfit analysis is complete, licensing action should continue along a course consistent with normal practice. For clarification of the point § 50.109(d) was added to the final rule.<sup>4</sup>

In addition, other provisions of section 50.109 expressly mention applicants, as well as licensees.<sup>5</sup> An argument could be made that the “applicants” referred to in these portions of the backfitting regulations are applicants for operating licenses with construction permits issued prior to 1985 (*see* 10 CFR 50.109(a)(1)(ii)). But there is no indication that the references to applicants in the rule were limited to that class of applicants. In addition, the language in 50.109(d) references “licensing actions” generally, and the discussion in the 1985 rulemaking record quoted above was clearly addressing licensees requesting license amendments, not applicants for operating licenses.

This view is also verified by the Commission’s 1993 “Final Policy Statement on Technical Specification Improvements for Nuclear Power Reactors.”<sup>6</sup> In the STS Policy Statement, the Commission established guidance on which requirements and operating restrictions should be included in the technical

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<sup>3</sup> *Id.* at 38100.

<sup>4</sup> *Id.* at 38103–38104.

<sup>5</sup> *See*, 10 CFR 50.109(a)(7)(“If there are two or more ways to achieve compliance with a license or the rules or orders of the Commission, or with written licensee commitments, or there are two or more ways to reach a level of protection which is adequate, then ordinarily the applicant or licensee is free to choose the way which best suits its purposes.”)(emphasis added); 10 CFR 50.109(c)(2)(in determining how backfits should be scheduled in light of other activities, the staff may consider, among other factors, a “[g]eneral description of the activity that would be required by the licensee or applicant in order to complete the backfit.”)(emphasis added).

<sup>6</sup> “Final Policy Statement on Technical Specification Improvements for Nuclear Power Reactors,” 58 Fed. Reg. 39132 (July 22, 1993) (“STS Policy Statement”).



specifications and “encouraged licensees to implement a voluntary program to update their Technical Specifications to be consistent with improved . . . Standard Technical Specifications issued by the NRC in September 1992.”<sup>7</sup> These voluntary licensee requests to incorporate the Standard Technical Specifications (STS) would come to the NRC in the form of license amendment requests.<sup>8</sup>

In discussing the processing of voluntary licensee requests (*i.e.*, license amendment requests) to adopt the STS, the Commission stated:

The Commission encourages licensees to use the improved STS as the basis for plant-specific Technical Specifications. During individual Technical Specification conversions, the nonvoluntary addition of new requirements from the improved STS to individual plant Technical Specifications will be evaluated in accordance with the Commission regulations on backfitting (10 CFR 50.109) unless the staff suggested additional changes are needed to make the licensee requested changes acceptable from the standpoint of adequate protection or compliance with NRC regulations, in which case § 50.109 does not apply and the request may be denied without the additional items.<sup>9</sup>

The Commission’s position on the applicability of the backfitting rule to implementation of its STS Policy Statement is consistent with its description of how the backfitting rule would be applied to voluntary license amendment requests in the 1985 final backfitting rule. Specifically, the STS Policy Statement confirmed that backfitting analyses would not be required as a condition precedent to the staff’s approval of changes that a licensee voluntarily requested, while also describing the conditions where the backfitting requirements would be applied—*i.e.*, situations where the staff was seeking to impose new or different requirements not requested by the licensee through the amendment approval process. Reasonably, the Commission applied the existing adequate protection and compliance exceptions to the backfitting rules to bound application of the backfitting requirements in these situations. As discussed in more detail below, we believe that this approach should be carried forward into Revision 1 of NUREG-1409.

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## II. THE EVOLUTION OF NRC’S CURRENT POSITION ON “FORWARD FITS”

In June of 2010, NEI sent a letter<sup>10</sup> to the NRC expressing concern that the agency was not adhering to the backfitting process when issuing interpretive agency guidance—despite the Commission’s statements to the contrary in the preamble to the 1985 backfitting rule,<sup>11</sup> as well as the guidance

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<sup>7</sup> *Id.*

<sup>8</sup> *Id.* at 39136.

<sup>9</sup> *Id.*

<sup>10</sup> Letter from E.C. Ginsberg (NEI) to S.G. Burns (NRC), June 4, 2010 (Ginsberg Letter).

<sup>11</sup> See “Revision of Backfitting Process for Power Reactors: Final Rule,” 50 Fed. Reg. 38101 (Sept. 20, 1985) (“Many of the most important changes in plant design, construction, operation, organization, and training have been put in place at a level of detail that is expressed in staff guidance documents which interpret the intent of broad, generally worked regulations. The NRC has determined that the correct focus for backfit regulation is the establishment of effective management controls on existing staff processes for the interpretation of regulations that are known to result in valuable upgrades in industry safety performance. Thus, the Commission opts to adopt a management process not only for the promulgation of regulations as backfit

provided in NUREG-1409.<sup>12</sup> NEI’s specific concern was that the NRC staff seemed to be taking the position that the backfitting process would not be applied until new or different interpretations provided in agency interpretive guidance were imposed on a licensee via a legally binding requirement (*e.g.*, by regulation or order).<sup>13</sup>

The NRC promptly responded to the Ginsberg Letter in July 2010.<sup>14</sup> In the Burns Letter, the NRC agreed with NEI that “as a general matter” certain staff guidance must be subject to the requirements of the backfitting rule. Specifically, the Burns Letter stated:

NRC staff guidance must be subject to the Backfit Rule if either: (i) the NRC staff intends the positions presented in the proposed interpretive guidance become (through further NRC action) legally binding upon a licensee; or (ii) the NRC staff’s expectation that licensees voluntarily adopt the guidance constitutes the basis (or a part of the bases) for resolution of a safety or regulatory issue.

\* \* \* \* \*

This also includes situations where the staff issues a recommendation that a licensee adopt the proposed guidance, and the recommendation is accompanied by a request for information (for example, under the auspices of 10 CFR 50.54(f)) as to whether the licensee intends to adopt the NRC staff’s recommendation. In this situation, the NRC recognizes the implicit coercive effect of the guidance.<sup>15</sup>

But the Burns Letter also included an important caveat to the position stated above, which distinguished so-called “forward-fits” from backfitting, as defined in 10 CFR 50.109(a), stating:

By contrast, there are guidance documents which the NRC staff intends only to be “forward fit,” that is, the guidance will be applied only to: (i) future applicants; and (ii) applications from existing licensees for license amendments, requests for exemptions, and other requests for dispensation from compliance with otherwise-applicable legally binding requirements. . . . In these circumstances, the NRC does not consider the issuance of “forward fit” interpretive guidance to constitute “backfitting.” As the NRC has stated in several different contexts, the Backfit Rule does not protect the expectations of future applicants (including licensees seeking NRC permission to conduct licensed activities in a

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instruments, but also for the lower tier staff review and inspection processes known to result in reactor plant changes.”).

<sup>12</sup> See, *e.g.*, “Backfitting Guidelines,” NUREG-1409 (July 1990), at p. 3. (“As a legal matter, the backfit rule does not strictly apply until the point at which a backfit is required by, for example, a rule or an order. However, for the purpose of this discussion, that legal distinction is not important. The NRC backfit process, including the CRGR Charter and NRC Manual Chapter 0514, is defined on the principle that new positions or requirements are to meet the standards of the rule before they are issued to licensee(s). New generic positions in documents, such as generic letters, bulletins, and regulatory guides, as well as plant-specific positions, are to be considered and justified as backfits before they are issued. For this reason, they often are discussed in the same way as legally required backfits.”)(emphasis added).

<sup>13</sup> See Ginsberg Letter, at p. 4.

<sup>14</sup> Letter from S.G. Burns to E.C. Ginsberg, July 14, 2010 (Burns Letter).

<sup>15</sup> Burns Letter, at 1. (internal quotation marks omitted).



manner different than what the NRC previously approved) regarding the regulatory requirements that they must meet to obtain NRC approval.<sup>16</sup>

Several points in the language quoted above are vital to understanding the position that was being communicated in the Burns Letter. First, it is clear that the actions identified as “forward-fitting” in the Burns Letter were not considered to meet the definition of “backfitting” provided in 10 CFR 50.109. This is an important foundational concept that must be carried forward in implementing the Commission’s definition of forward-fitting provided in Management Directive 8.4. Specifically, since the Commission has not modified the definition of backfitting in any of the relevant regulations, nor expressly changed its position on the applicability of backfitting to the license amendment process, the term forward-fit necessarily describes a concept that the agency believes falls outside of the regulatory definition of backfitting. NEI-24

Consistent with this concept, the second important distinction drawn in the Burns Letter between “forward-fitting” and “backfitting” was based upon the status of the regulated entity as an applicant, as opposed to a licensee. Although the Burns Letter did not provide any specific support for the statement that the backfitting rule “does not protect the expectations of future applicants,” that concept is arguably rooted in the definition of backfitting and, particularly in the timing provisions contained in 10 CFR 50.109(a)(1)(i)-(vii). These provisions are clear that, in most cases, the backfitting requirements contained in section 50.109 become effective upon issuance of construction permits and various licenses to applicants.

In our view, the step change in agency policy articulated in the Burns Letter was that a licensee seeking permission from the NRC to change its current licensing basis would—for the purposes of backfitting—be treated the same as an applicant seeking a license to construct or operate a new facility. If not appropriately limited, this position would turn the backfitting requirements on their head by allowing the imposition of unanalyzed backfits whenever a licensee otherwise subject to one of the agency’s backfitting requirements sought permission to modify (and potentially improve) the facility’s licensing basis. This outcome would not only subvert the Commission’s backfitting requirements, but would clearly contradict the Commission’s express statement regarding the applicability of the backfitting requirements to the license amendment process in its 1985 backfitting rulemaking. In addition, from a policy standpoint, such an outcome would provide a perverse incentive for licensees to “leave well enough alone” and potentially forgo otherwise desirable, innovative changes to their facilities and procedures that require prior NRC approval out of concern regarding the imposition of “forward fits” that they may face as part of the process. NEI-25

Although it does not expressly recognize these concerns, the Burns Letter provides an important limitation on the application of the forward fit concept to licensees (as opposed to pure applicants), stating:

If a licensee voluntarily seeks to change its licensing basis (*i.e.*, the change is initiated by the licensee to take advantage of a voluntary alternative afforded in the NRC’s regulations, such as the adoption of NFPA 805 under 10 CFR 50.48(c), and is not compelled by a new or amended regulation), then the NRC may condition its approval of the proposed change upon a licensee agreement to adopt new or revised guidance. Such action will not be deemed to be backfitting if: (i) the new or revised guidance relates directly to the licensee’s

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<sup>16</sup> *Id.* at p. 2 (emphasis added).

voluntary request; and (ii) the specific subject matter of the new or revised guidance is an essential consideration in the NRC staff’s determination of the acceptability of the licensee’s voluntary request.<sup>17</sup>

The “direct nexus” and “essentiality” tests articulated in the Burns Letter are carried forward in the Commission’s most recent revision to Management Directive 8.4. We believe that proper articulation and application of these tests are vital to distinguishing backfitting from “forward fitting” in a manner that does not undermine the integrity of the definitions provided in the Commission’s backfitting rules, conflict with the Commission’s previous statements regarding how the backfitting process should apply in the context of license amendments, or result in unintended outcomes, such as licensees avoiding otherwise beneficial changes to the licensing bases of their facilities.

Having articulated what we believe is the proper regulatory construct for forward fitting, we now turn to implementing that construct. The following sections will discuss how the “direct nexus” and “essentiality” tests should be applied and the process for evaluating and justifying forward fits.

### III. IMPLEMENTATION OF “DIRECT NEXUS” AND “ESSENTIALITY” TESTS

The “direct nexus” and “essentiality” tests should be implemented in a manner that limits forward fitting 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). As explained below, in our view 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. Further, as stated in Management Directive 8.4, the backfitting rules and policies are intended to provide stability, reasoned, and informed decision-making, and transparency.<sup>18</sup> We believe these worthwhile goals are best accomplished by modeling implementation of the Commission’s forward fitting policy after the approach taken in the 1993 STS Policy Statement.

NEI-26

Forward fitting, as applied to licensees,<sup>19</sup> typically involves a situation where the NRC is attempting to condition approval of voluntary licensee request to change its licensing basis through imposition of a staff interpretation that is either new or different from the staff positions that are currently applicable to the facility.<sup>20</sup> More specifically, forward fitting covers situations where the NRC staff would not be seeking to impose the new or different interpretation or requirement if the licensee had not sought to modify its licensing basis.

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<sup>17</sup> Burns Letter, at FN 2 (emphasis added). We are unaware of this “test” being specifically articulated in any document prior to issuance of the Burns Letter in 2010.

<sup>18</sup> Management Directive 8.4, at p. 3.

<sup>19</sup> This discussion focuses on the application of the term forward fitting to current licensees, as opposed to applicants seeking NRC approval of designs for new facilities, or authorization to construct and operate new facilities.

<sup>20</sup> See “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,” Management Directive 8.4, Directive Handbook at p. 6. (Sept. 20, 2019).

Given the discussion provided above, we recommend the following approach to implementation of the “direct nexus” and “essentiality” tests articulated in both the Burns Memo and Management Directive 8.4.

### A. Direct Nexus

The “direct nexus” criteria is articulated most completely in the Burns Letter, which states that the forward fit (*i.e.*, the new or revised guidance in the parlance of the Burns Letter) must relate directly to the licensee’s request.<sup>21</sup> Draft Revision 1 of NUREG-1409 states that direct nexus “means that the requirement or staff position must related directly to the specific subject matter of all or part of the licensee’s request for NRC approval.”<sup>22</sup> Draft Revision 1 goes on to state:

For example, if the licensee’s license amendment request concerns the emergency diesel generators, then the new or modified requirement or regulatory staff position that the staff wants to impose on the licensee cannot involve the height of the fence surrounding the protected area. If the staff wished to impose a proposed action that does not have a direct nexus to the licensee’s request, then it would have to perform a backfitting assessment.<sup>23</sup>

While this example is accurate, it is too simplistic. The “direct nexus” criteria must be more than a requirement that the proposed forward fit be generally relevant to the licensee’s voluntary request. More specifically, the example quoted above could give the impression that so long as the forward fit had something to do with emergency diesel generators, then the “direct nexus” requirement would be satisfied. This cannot be the case. If it were, then the staff could impose new or different positions dealing with any aspect of the design, operation, or maintenance of emergency diesel generators, regardless of whether the licensee’s request raised a unique safety or security issue that was directly related to the new or different interpretation that the staff wished to impose.

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Instead, if the Burns Letter and Management Directive 8.4 are to be read consistently with the language of section 50.109, the position taken by the Commission in the 1985 rulemaking, and, subsequently, the Commission’s approach in the STS Policy Statement, then the direct nexus criterion needs to require a close tie between the change being requested by the licensee and the new or different interpretation or requirement that the staff wishes to impose. Specifically, in order to meet the “direct nexus” criterion, there must be a unique safety or security issue that would not exist but for the change being requested by the licensee, and the purpose of the proposed forward fit must be to address that unique safety or security issue.

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This position is consistent with the basis for applying the forward fit concept to licensees put forward in the Burns Letter, which was that “the Backfit Rule does not protect the expectations of future applicants (including licensees seeking NRC permission to conduct licensed activities in a manner different than what the NRC previously approved) regarding the regulatory requirements that they must meet to obtain

<sup>21</sup> Burns Letter, at FN 2. Management Directive 8.4 simply states: “The NRC may condition its approval of such a licensing action on the use of a new or modified regulatory staff position only if: (1) there is a direct nexus to the licensee’s request. . . .” Management Directive 8.4, Directive Handbook at p. 6.

<sup>22</sup> Draft Revision 1 NUREG-1409, at p. 3-3.

<sup>23</sup> *Id.*

NRC approval.”<sup>24</sup> A licensee who voluntarily requests changes to its licensing basis stands in the shoes of an applicant only to the extent that the requested changes create unique safety or security issues that must be addressed via the proposed forward fit. Imposition of a new or different requirement or interpretation to address a safety or security issue that is not caused by the licensing basis changes requested by the licensee is indistinguishable from backfitting and should be treated as such.

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## B. Essentiality

The Burns Letter also describes the criterion of “essentiality” stating that, in addition to meeting the “direct nexus” criterion, in order to avoid treatment as backfitting “the specific subject matter of the new or revised guidance [must be] an essential consideration in the NRC staff’s determination of the acceptability of the licensee’s voluntary request.”<sup>25</sup> This concept is not further explained in the Burns Letter or Management Directive 8.4. Taking the concepts at face value, the “direct nexus” criteria measures the closeness of the relationship between the licensing basis changes being requested by the licensee and the forward fit being proposed by the staff, while the “essentiality” criteria measures how important imposition of the forward fit is to the staff’s decision to grant the licensee’s request. The dictionary defines essential as “absolutely necessary; indispensable.”<sup>26</sup> Using this plain language definition, the “essentiality” criterion requires that the proposed forward fit must be “absolutely necessary” to address the unique safety or security issue identified under the “direct nexus” criterion.

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In explaining the “essentiality criterion” Draft Rev. 1 to NUREG-1409 states “[w]hat is essential . . . will vary depending on the type of request.” More specifically, Draft Rev. 1 suggests that the approval standards for the type of voluntary request the licensee has submitted (license amendment request, relief request, etc.) be used to evaluate “essentiality.” While this approach seems reasonable, we do not believe it is specific enough to be useful. This type of standard could easily devolve into a general question of whether the NRC staff reviewing the licensee’s requests thinks that imposition of the forward fit would be a worthwhile safety or security enhancement. But “essentiality” requires more.

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Although it was not described using the current terminology, we believe the Commission addressed this issue in its 1993 STS Policy Statement. In that case, the Commission was clear that nonvoluntary imposition of requirements during the review of voluntary requests to implement the STS would be evaluated as backfitting, “unless the staff suggested additional changes are needed to make the licensee requested changes acceptable from the standpoint of adequate protection or compliance with NRC regulations, in which case § 50.109 does not apply and the request may be denied without the additional items.”<sup>27</sup> Use of the adequate protection and compliance exceptions to implement the “essentiality criterion” will provide a coherent approach that is consistent with the NRC’s backfitting requirements. The adequate protection and compliance exceptions to the backfitting rules are well understood, and the additional guidance on the exceptions provided in Draft Rev 1. will improve implementation even

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<sup>24</sup> Burns Letter, at 2.

<sup>25</sup> Burns Letter, at FN 2. The description of this criteria in Management Directive 8.4 is essentially identical to the description provided in the Burns Letter.

<sup>26</sup> <https://www.dictionary.com/browse/essential?s=t> (last viewed June 1, 2020).

<sup>27</sup> STS Policy Statement, at p. 39,136.

further.<sup>28</sup> Thus, we recommend that in order to meet the “essentiality criteria,” the forward fit must be necessary to either ensure or redefine adequate protection of the public health and safety or the common defense and security, or be necessary to ensure continued compliance with a legally binding requirement—given the unique safety or security issue identified and articulated in the staff’s “direct nexus” analysis.

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In summary, a “direct nexus” must present a unique safety or security issue that would not exist but for the licensee’s requested change and the proposed forward fit would address that unique issue, and an “essential” forward fit action is one that is necessary for adequate protection or compliance.

### C. Consistency with Management Directive 8.4

As the Commission points out in Management Directive 8.4, adequate protection forward fits should be relatively rare:

In establishing or modifying the requirement or regulatory staff position interpreting the requirement, the NRC staff had the opportunity to consider whether the resulting position should be imposed as a backfit on existing facilities. Under the mandatory backfitting provisions of 10 CFR 50.109(a)(5), 70.76(a)(5), and 76.76(a)(5), and the portions of 10 CFR 72.62(b) regarding backfitting necessary to assure adequate protection of public health and safety, if such a change were necessary to ensure adequate protection of public health and safety when the new or modified requirement or regulatory staff position was made, the NRC would have been required to impose it as a backfit. Because such a backfit has not been imposed for cases where a forward fit is being considered, it is unlikely that a change could be justified to be necessary to ensure adequate protection of public health and safety.<sup>29</sup>

Our proposal regarding application of the “direct nexus” test described above is entirely consistent with the Commission’s observation. By appropriately limiting forward fits to new or different positions that are required to address safety or security issues that would not have arisen but for the licensee’s request, the staff would only be evaluating the adequate protection implications (*i.e.*, “essentiality”) of issues that would not otherwise raise concerns about continued operation of the facility. As the Commission aptly points out, a proposed adequate protection forward fit that addresses an issue that affects a facility whether or not the requested licensing basis change is approved would likely have been imposed as a backfit at the time the new or different position (*e.g.*, a revision to existing guidance) was developed.

If the new or different requirement or interpretation does not satisfy both the “direct nexus” and “essentiality” criterion, then it should be considered backfitting and evaluated under the requirements of the relevant backfitting rule. As noted above, this approach recognizes that a licensee requesting changes to their approved licensing bases stands in the shoes of an “applicant” only to the extent that their requested changes raise significant safety or security issues that are new or different from the issues relevant to continued operation of the facility before the change was requested.

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<sup>28</sup> In addition, the adequate protection and compliance exceptions to the backfitting rules closely approximate, if not duplicate, the standard for approval or license amendment requests provided on page 3-3 of Draft Rev. 1.

<sup>29</sup> Management Directive 8.4, Directive Handbook at p. 7.



## D. Justifying Forward Fits

If the new or different requirements or interpretation meets the definition of forward fitting and satisfies the “direct nexus” and “essentiality” tests, then Management Directive 8.4 requires either a generic or facility-specific regulatory analysis, depending on the nature of the forward-fit.

### 1. Regulatory Analyses Required by Management Directive 8.4

Management Directive 8.4 states:

If the agency issues a new or modified regulatory staff position (*e.g.*, a revision to regulatory guidance), and the prior regulatory staff position is no longer available for use by current licensees, then the new or modified regulatory staff position should include a regulatory analysis.<sup>30</sup>

This paragraph seems to be describing a scenario where the prior regulatory staff position, typically memorialized in an agency guidance document (*e.g.*, Regulatory Guide), is superseded and replaced by a new or different position in a subsequent revision to that agency guidance document. In this scenario, if the prior position is no longer available for use by current licensees to address an issue that is applicable to licensed facilities, independent of any voluntary request to change the licensing basis of the facility, then issuance of the new or different position would likely meet the definition of backfitting.<sup>31</sup> In that case, the regulatory analysis referenced in Management Directive 8.4 should be performed upon issuance of the revised generic guidance document and should include a backfitting analysis.<sup>32</sup> NEI-30

Management Directive 8.4 goes on to state:

If the staff imposes a new or modified regulatory staff position as part of the approval of a licensing action for a current licensee, and the prior regulatory staff position is available for use by current licensees and applicable to the licensing action under review, then the staff should perform a site-specific regulatory analysis.

This paragraph covers a more common forward fitting scenario, where an existing position, typically memorialized in an agency guidance document (*e.g.*, Regulatory Guide), is updated or modified in a subsequent revision to that agency guidance document. In this scenario, both revisions to agency guidance are acceptable for use by current licensees. In other words, in this scenario the staff has decided not to impose the new or different position in the revised guidance on current licensees as a backfit. Here, Management Directive 8.4 directs the NRC staff to perform a site-specific regulatory analysis to justify imposition of any forward fits.

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<sup>30</sup> *Id.*

<sup>31</sup> To meet the definition of backfitting provided in section 50.109, the new or different position would need to result in “modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility.”

<sup>32</sup> Generic backfitting analyses are typically incorporated into broader Regulatory Analyses. *See* NUREG/BR-0058.



## 2. Staff and Licensee Alternatives in Evaluating Forward Fits

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As discussed above, if the proposed forward fit does not meet the “direct nexus” or “essentiality” criteria, then it should be evaluated as backfitting—*i.e.*, a cost-justified, substantial increase analysis should be undertaken if the staff wishes to pursue imposition of the backfit. Evaluation of such backfits should not impede processing of the associated licensing action, consistent with the requirement in section 50.109(d).

If the proposed forward fit meets the “direct nexus” and “essentiality” criteria, then Management Directive 8.4 requires a site-specific regulatory analysis be undertaken prior to imposition of the forward fit. In order to ensure efficient use of both staff and licensee resources, at this point in the process, it is vital that the staff provide its evaluation demonstrating that the proposed forward fit meets the “direct nexus” and “essentiality” criteria to the licensee. At this point, the licensee has the following options: NEI-31

- Appeal the staff’s conclusion that the proposed forward fit meets the criteria (see our comments on Chapter 4);
- Withdraw the request/application (this would be an option at any point in the process);
- Amend the request/application to address the staff’s concern (either by voluntarily adopting the forward fit or an acceptable alternative); or
- Take no action.

If the licensee takes no action, the NRC staff could either deny the licensee’s request/application, or prepare a site-specific regulatory analysis supporting imposition of the proposed forward fit (or the most cost-effective alternative) as a condition of approving the request.

As indicated above, the licensee should have the opportunity to appeal the staff’s conclusion that the proposed forward fit meets the “direct nexus” and “essentiality” criteria. If the licensee successfully appeals the staff’s determination, then the staff would have the option to discontinue pursuit of the issue, or direct the issue into the appropriate process (*e.g.*, backfitting). If the staff prevails in such an appeal, the licensee would have the option to: NEI-32

- Withdraw the request/application (this would be an option at any point in the process);
- Amend the request/application to address the staff’s concern (either by voluntarily adopting the forward fit or an acceptable alternative); or
- Take no action.

Again, if the licensee chose to take no action in response to losing an appeal, the staff could either deny the licensee’s request/application, or prepare a site-specific regulatory analysis supporting imposition of the proposed forward fit (or the most cost-effective alternative) as a condition of approving the request.

General guidance on development of regulatory analyses is provided in NUREG/BR-0058. More detailed guidance on the performance of site-specific forward fitting regulatory analyses should be provided in the planned “phase 2” revisions to that NUREG. That said, our recommendations for general guidelines regarding the performance of site-specific, forward fit regulatory analyses are provided below.

#### **a. Site-Specific Regulatory Analysis for Adequate Protection Forward Fits**

In the case of a forward fit that meets both the “direct nexus” and “essentiality” criteria because it is necessary to address an adequate protection issue raised by the requested licensing basis change, the site-specific regulatory analysis should focus on:<sup>33</sup>

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- Describing the nature of the adequate protection issue created by the licensee’s requested licensing basis change. The staff should use the guidance provided on developing documented evaluations supporting use of the adequate protection exceptions to the backfitting rules to develop this portion of the regulatory analysis.
- Describing alternatives to imposition of the forward fit, if any, that would sufficiently redefine or ensure adequate protection.
- If no alternatives to imposition of the specific, proposed forward fit being considered are identified, which should be rare in this context, then the regulatory analysis would conclude without the consideration of cost.
- If at least one alternative, other than the status quo (*i.e.*, denying the application, which would leave the facility in its current configuration), is identified that would sufficiently redefine or ensure adequate protection, then a cost-effectiveness evaluation should be part of the regulatory analysis. This cost-effectiveness evaluation would compare the relative costs of each viable alternative, consistent with 10 CFR 50.109(a)(7). The most cost-effective alternative should be chosen as the preferred alternative by the NRC staff. In preparing this type of regulatory analysis, the staff should provide the licensee an opportunity to comment on, or provide, information related to the implementation costs associated with each option. These types of regulatory analyses should be provided for Commission approval prior to being issued in final form to the licensee.

#### **b. Compliance Forward Fits**

In the case of a forward fit that meets both the “direct nexus” and “essentiality” criteria because it is necessary to address a compliance issue raised by the licensee’s requested licensing basis change, the site-specific regulatory analysis should focus on:

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- Describing the nature of the compliance issue created by the licensee’s requested licensing basis change. The staff should use the guidance provided on developing documented evaluations supporting use of the compliance exception to the backfitting rule to develop this portion of the regulatory analysis.
- Describing alternatives to imposition of the forward fit, if any, that would sufficiently ensure compliance.
- Describing the possibility of issuing an exemption to the legally binding requirements at issue.

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<sup>33</sup> Unlike in the backfitting scenario, in this scenario there would be no need for an imminence evaluation because the staff is evaluating a proposed change to the facility’s licensing basis that could not be implemented before NRC approval is granted. The presumption is that any adequate protection issues arising from continued operation of the facility pursuant to its current licensing basis would be addressed via the backfitting process.

- If no alternatives to imposition of the specific, proposed forward fit being considered are identified, which should be rare in this context, then the regulatory analysis would include a brief consideration of the costs associated with imposition of the forward fit.
- If at least one alternative is identified that would sufficiently address the compliance issue in question, then a cost-effectiveness evaluation should be part of the regulatory analysis. This cost-effectiveness evaluation would compare the relative costs of each viable alternative, consistent with 10 CFR 50.109(a)(7). The most cost-effective alternative should be chosen as the preferred alternative by the NRC staff. In preparing this type of regulatory analysis, the staff should provide the licensee an opportunity to comment on, or provide, information related to the implementation costs associated with each option.

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Section 3.3 of Draft Rev. 1 should be revised to incorporate the concepts of “direct nexus” and “essentiality” described above. As written, the draft NUREG’s explanation of the critical “direct nexus” and “essentiality” tests are too vague. To provide clear guidance and facilitate implementation, the NUREG must contain the level of specificity and explanation set forth above.

Section 3.3 should also be revised to reflect the framework for evaluating forward fits set forth in the above paragraphs (Section 2 “Staff and Licensee Alternatives in Evaluating Forward Fits”). The section should be reframed to first describe the pathways that the staff and licensees can pursue when a forward fit situation has been identified. It should then describe the purpose, scope, and content of any regulatory analysis performed for a forward fit action.

## I. INTRODUCTION

Chapter 4 of Draft Rev. 1 discusses the process available to licensees to appeal facility-specific backfitting and forward fitting decisions, as well as guidance on how the NRC staff should process and disposition such appeals. We believe the appeals process plays an important role in effectively implementing the agency’s backfitting requirements. That said, the process could be improved and clarified to increase the ability of licensees to understand and appropriately utilize the process. Further, although the backfitting and forward fitting concepts are related, we believe that forward fitting appeals warrant additional attention in this chapter.

Our comments on Chapter 4 focus on three areas: (1) initiation of the backfitting and forward fitting appeals processes; (2) communications during the appeal process; and (3) guidance specific to forward fitting.

## II. INITIATION OF THE APPEALS PROCESS

Chapter 4 of Draft Rev. 1 begins by stating:

Licensees can discuss the applicability of backfitting regulations and the forward fitting policy with the applicable U.S. Nuclear Regulatory Commission (NRC) staff whenever the licensees have a concern. The staff should ensure that its management is informed of a licensee’s concern and should consider the points raised by the licensee before proceeding to issue a proposed staff action (*e.g.*, a finding, violation, or license amendment).<sup>1</sup>

We agree. Licensees should discuss backfitting concerns with the NRC staff as issues arise. These conversations are often most fruitful early in the lifecycle of an issue. Backfitting discussions should not be perceived as a “taboo”—backfitting is a vital and longstanding element of the NRC’s regulations and regulatory philosophy, and should be actively used to inform and effectively communicate agency decision making.

But as recognized repeatedly in NUREG-1409 and elsewhere, the responsibility for identifying and justifying backfitting (and now forward fitting) rests with the NRC staff.<sup>2</sup> Further, as aptly stated in NUREG-1409, “[t]he NRC backfit process . . . is defined on the principle that new positions or requirements are to meet the standards of the rule before they are issued to the licensee(s).”<sup>3</sup> It is important to keep these foundational principles in mind when considering the appeals process.

As explained in Draft Rev. 1, licensees may use the appeals process only in situations where:

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<sup>1</sup> Draft Rev. 1, at p. 4-1.

<sup>2</sup> *See, e.g.*, NUREG-1409, at p. 3 (“The NRC staff is responsible for identifying plant specific and generic backfits and for determining if proposed new or revised positions would constitute a backfit.”); *Id.*, at p. 1 (“The NRC staff, at all levels, is responsible for identifying plant specific backfits.”); *Id.* at p. 3 (“Staff positions are not communicated to licensees unless the NRC official communicating that position determines whether the position is a backfit.”).

<sup>3</sup> *Id.* at p. 3.

- The NRC staff imposed an applicable staff position on the licensee that the staff determined was not backfitting . . . but that the licensee believes is backfitting. . . .
- The NRC staff imposed an applicable staff position on the licensee that the staff determined was backfitting . . . but that the licensee believes was not properly justified. This includes an appeal to modify or withdraw a backfitting action for which the staff conducted a backfitting analysis or an appeal that a backfitting action justified by the adequate protection or compliance exception in fact must be justified through a backfit analysis.

Our comments here focus primarily on the first appeal scenario, which describes a situation where the licensee is challenging the staff’s alleged failure to properly identify backfitting. With respect to this appeal scenario, Draft Rev. 1 states, “[i]f the staff determines that the proposed staff action is not backfitting or forward fitting, then the staff should proceed with the proposed staff action.”<sup>4</sup>

But it is unclear whether and, if so, how the staff will communicate its determination that a position it intends to impose upon the licensee does not meet the definition of backfitting.<sup>5</sup> If the staff has not issued its determination to the licensee, preferably in writing, it is very difficult for the licensee to “appeal” that “determination.” For example, the staff’s backfitting may take the form of a “suggestion” offered verbally during an inspection, which a licensee certainly would not ignore, especially if that suggestion is linked to avoiding potential enforcement action. In order to formulate an appeal, the licensee must have a decision or determination from the staff that has been articulated in a reasonable amount of detail. It is not effective or efficient to set up a process where licensees are forced to appeal the staff’s silence on why it believes imposition of a perceived new or different position does not constitute backfitting. As noted above, this arises most often in the inspection and enforcement context, as most generic documents (*e.g.*, rulemaking, guidance, generic communications) contain text specifically addressing backfitting.<sup>6</sup> NEI-35

This ambiguity has the potential to inadvertently shift the burden of identifying backfitting from the NRC staff to the licensee. Specifically, from a policy standpoint, overreliance on the appeals process to challenge the NRC staff’s silence on whether or not taking a specific regulatory action meets the definition of backfitting can create a disincentive for the staff to apply resources to identify backfits before issuing positions to licensees. NEI-36

Such burden shifting undermines the effectiveness of the agency’s backfitting requirements and program because licensees must balance multiple considerations when deciding whether to appeal or argue against agency positions—many of which have little to do with maintaining the integrity of the agency’s backfitting program. Instead, the primary responsibility for identifying and communicating its positions regarding backfitting must continue to rest with the NRC staff. The appeals process should not NEI-37

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<sup>4</sup> Draft Rev. 1, at p. 4-1.

<sup>5</sup> This concern is not as prevalent with staff positions justifying backfitting that has been properly identified because in those cases the staff will be producing either a documented evaluation (supporting use of an exception), or a cost-justified, substantial increase analysis.

<sup>6</sup> Although not an issue in the context of appeals, we note that while generic documents typically expressly address backfitting, lackadaisical use of boilerplate backfitting language in those documents can lead to problems as well.

inadvertently encourage a situation where the backfitting requirements are only meaningfully considered if a licensee raises a backfitting appeal.<sup>7</sup>

In addition to the burden shifting described above, the ambiguity with respect to whether and, if so, how the staff will document and communicate its determinations on whether a proposed action meets the definition of backfitting also creates inefficiencies in the appeals process. For example, if the staff has not clearly articulated its basis for concluding that a proposed action does not meet the definition of backfitting, then the appellant is left to create a strawman argument, and knock that strawman down in its appeal. This, in turn, results in an agency response to the licensee’s first-level appeal that—for the first time—articulates the staff’s position, which subsequently prompts a second-level appeals that—for the first time—actually addresses the staff’s position. This type inefficiency should be avoided.

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#### A. Maintain Flexibility for Licensee Response to Apparent Violations

We believe that maintaining flexibility for the licensee to raise backfitting concerns in responding to apparent violations would help to avoid the challenges described above. As explained in our comments on Section 5.5, we recommend that Draft Rev. 1 clarify that a licensee may raise backfitting concerns in situations where the NRC staff identifies an apparent violation, but the licensee believes it is following the applicable requirements, regardless of whether a formal appeal is filed. This approach avoids the need for the licensee to submit a formal backfitting appeal and initiate that separate process, in order to address issues that are at the heart of the enforcement issue—*i.e.*, whether or not the licensee is, in fact, in compliance with the relevant legally binding requirement. In addition, this approach allows the licensee to formally communicate the basis for its position to the staff, and to have the benefit of a staff response in the form of a detailed, written articulation of its position on the matter. This provides a record or basis upon which the licensee can decide whether to file a first-level appeal, or accept that staff’s response. This approach is particularly important in cases where the licensee determines that the inspection report or other communication of the apparent violation is not detailed enough to support a backfitting appeal at the outset.

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Another area that is often overlooked in the context of backfitting are so-called “minor violations.” Although these violations are not typically documented in inspection reports and do not typically prompt formal enforcement actions by the NRC (*e.g.*, issuance of NOVs, NCVs), they do represent agency determinations that the licensee is not in compliance with a legally binding requirement and it is clear that the NRC expects licensees to correct such violations.<sup>8</sup> Thus, although the minor violation may not be documented, it may represent a new or different interpretation of unchanged requirements that results in a modification to procedures or the organization required to operate a facility. We recommend that Rev. 1 to NUREG-1409 include guidance indicating that a licensee may raise backfitting concerns arising from a minor violation (*i.e.*, that the licensee believes it is following its licensing basis and, thus, no

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<sup>7</sup> We recognize that the Commission and NRC staff have made great strides, through training and the revision of agency guidance and policies, to improve implementation of the backfitting requirements. We continue to applaud those efforts. These comments are aimed primarily at avoiding the unintentional creation of incentives that run counter the Commission’s long-standing position that backfitting identification is, first and foremost, a staff responsibility.

<sup>8</sup> NRC Inspection Manual Chapter 0612, Appendix E “Examples of Minor Issues.” (January 1, 2020) states: “While licensees must correct minor violations, minor violations or other minor findings do not normally warrant documentation in inspection reports and do not warrant enforcement action.” *Id.* at p. 1 (emphasis added).



violation has occurred) and that the staff’s response should concisely state its position on the relevant compliance issue, including any information that the licensee has submitted. As in the case of inspection findings associated with more formal enforcement actions, upon receiving the staff’s response the licensee may either further pursue a backfitting appeal, or accept the staff’s compliance determination.

In order to ensure this flexibility, the following changes should be made on page 4-2:

Section 5.5 of this NUREG addresses situations where the licensee raises a backfitting claim, concern, or appeal while also disputing a violation. As explained in Section 5.5, a licensee may formally submit a backfitting appeal in accordance with this chapter in conjunction with denying a violation in response to an enforcement action, typically an NOV or NCV. Alternatively, the licensee may raise backfitting concerns or arguments that are germane to disputing the enforcement action in its denial, without filing a formal backfitting appeal.

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-38, and -39

If the licensee chooses to submit a formal backfitting appeal in conjunction with its denial of the proposed enforcement action, the NRC staff will not respond to the disputed violation until the agency has reviewed the formal backfitting appeal and made a final decision on the validity of the claim. If the NRC denies the licensee’s backfitting appeal, then the NRC will continue the enforcement process and ultimately either uphold or withdraw the violation. If the NRC grants the licensee’s backfitting appeal, then the NRC will withdraw the violation.

Alternatively, if the licensee raises a backfitting claim or concern to the NRC in conjunction with a disputed violation in reply to an NOV or NCV, but the licensee has not formally submitted a backfitting appeal, then the NRC staff should consider the backfitting arguments as part of the evaluation of the disputed violation. As the draft NUREG recognizes in subsection 2.5.2.1, compliance and backfitting issues are two sides of the same coin – that is, a backfit is typically the imposition of a staff position that goes beyond what is necessary for compliance with an existing requirement. If the NRC staff identifies an apparent violation, but the licensee believes it is following the relevant requirement, and that the staff is enforcing a position that reflects a new or modified requirement or staff position, then the licensee may make that argument in its response to the apparent violation, without filing a formal backfitting appeal. In this scenario, if the NRC staff agrees with the licensee’s argument and withdraws the violation, then there would be no need for a subsequent backfitting appeal. If, on the other hand, the NRC staff disagrees with the licensee and upholds the violation, then the licensee may file a backfitting appeal.

In the case of undocumented minor violations, if the licensee believes that it is complying with the relevant requirement, then the licensee may communicate its basis for that position to the NRC in writing. The NRC staff should reply to the licensee in writing providing a concise explanation of the basis for its conclusion. If the staff maintains its position that the licensee is not in compliance and that corrective actions are required, then the licensee may file a backfitting appeal or accept the staff’s position.

## **B. Maintain Flexibility Regarding When a Licensee May File a First-Level Appeal**

In addition to the issue described above, Draft Rev.1 states that forward fitting appeals are appropriate only in situations where the staff has “imposed” an applicable staff position on the licensee.<sup>9</sup> As discussed on our comments on Chapter 2, it has been the Commission’s long-standing position that the

<sup>9</sup> Draft Rev. 1, at p. 4-1.

backfitting process is defined on the principle that new positions or requirements are to meet the standards of the backfitting rules before they are issued to the licensee(s). Thus, application of the backfitting process is not always contingent upon imposition of a new or different interpretation via a legally binding requirement.

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This principle should carry forward into this chapter on backfitting appeals. Specifically, the ability of a licensee to appeal a facility-specific backfit should not be contingent upon the NRC “imposing” a new or different requirement or interpretation upon the licensee via a legally binding requirement (regulation, order, license condition, *etc.*). Instead, a licensee should be able to appeal a backfitting decision as soon as the decision is formally issued to the licensee.

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For example, in the case of an appeal challenging the NRC’s justification for a backfit, the licensee should be able to appeal the NRC’s decision once the staff has issued the licensee either a documented evaluation justifying use of an exception, or the analysis required under 50.109(a)(3). In the case of an appeal challenging the NRC’s alleged failure to properly identify backfitting, the licensee would be able to appeal once the staff has issued its inspection report along with any proposed enforcement action (*e.g.*, NOV, NCV), or upon the staff issuing a response to a licensee’s denial of a proposed enforcement action (see discussion above in Section II.A).

This more flexible and efficient approach avoids putting licensees in a position where they have to “force the NRC’s hand” by waiting until a proposed backfit is “imposed” via a legally binding requirement in order to utilize the appeals process.

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In order to ensure this flexibility, the following simple changes should be made on page 4-1:

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

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- The NRC staff ~~imposed~~ issued an applicable staff position ~~on to~~ the licensee that the staff determined was not backfitting or forward fitting, but that the licensee believes is backfitting or forward fitting.
- The NRC staff ~~imposed~~ issued an applicable staff position ~~on to~~ the licensee that the staff determined was backfitting or forward fitting, but that the licensee believes was not properly justified. This includes an appeal to modify or withdraw a backfitting action for which the staff conducted a backfit analysis or an appeal that a backfitting action justified by the adequate protection or compliance exception in fact must be justified through a backfit analysis.

### III. COMMUNICATIONS DURING THE APPEAL PROCESS

On pages 4-3 and 4-5 Draft Rev. 1 requires the first and second-level appeals panels to “offer a non-public internal meeting” to the NRC staff responsible for the action being appealed, and the second-level appeal panel to offer such a meeting to both the staff responsible for the action being appealed and the first-level appeal panel. (emphasis added). These requirements should be removed from NUREG-1409.

First, a requirement that the arbiter of an appeal of any kind must have meetings with the NRC staff responsible for the action being appealed or first-level appeal panel responsible for the decision that is being challenged via a second-level appeal, without the licensee at least having the opportunity to be

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present, is patently unfair to the licensee. Draft Rev. 1 offers no such opportunity to the licensee. Further, it is unclear what the purpose of such meetings would be and why that purpose would be undermined by making those discussions transparent to the licensee and other stakeholders.

It appears that this requirement was taken from Sections III.F.6 and 7 of the Handbook for Management Directive 8.4, which address first-level and second-level appeals, respectively. With respect to first-level appeals, paragraphs III.F.6. (b) and (c) state:

(b) During the review process, the OD may designate a panel to consider the appeal. A public meeting must be offered at which the licensee may discuss the appeal to ensure the NRC has a full understanding of the appeal. No determinations will be made at this public meeting.

(c) During the review process and following any public meeting with the licensee, a meeting with the originating staff must be offered to discuss the backfitting action and supporting documentation to ensure a full understanding of the initial action in question.

With respect to second-level appeals, paragraphs III.F.7. (b) and (c) state:

(b) The EDO may designate a panel to consider the Second-Level Appeal. A public meeting with the licensee must be offered to discuss the licensee’s appeal and allow for a full understanding of the licensee’s position.

(c) The EDO’s designated 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. Meetings with the staff involved in the original action in question and those involved in the First-Level Appeal must be offered to allow a full understanding of the staff position.

But the Commission did not require that the meetings with responsible staff be “non-public” or “internal.” Rather, it appears that the Commission was simply attempting to ensure that the decision maker in both a first and second-level appeal had the opportunity to hear from both the responsible NRC staff and the licensee. There is no indication that the Commission’s intent was for the public, including the licensee, to be shut out of any conversations with the relevant NRC staff.

Fairness concerns aside, we do not believe that requiring (or even encouraging) such meetings will help the decision maker to understand the underlying facts. In our view, the NRC staff, licensee, and other stakeholders should be permitted to observe all substantive conversations between the decision maker and the relevant staff (including the first-level appeal panel) or the licensee. Any worthwhile appeals process must be transparent to both parties—i.e., those standing in the shoes of both the appellant and appellee.

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Given the discussion above, we suggest the following revisions to the text on pages 4-3 and 4-5 of Draft Rev.1:

*Page 4-3*

During the review process and following any public meeting with the licensee, the panel must offer a ~~non-public internal~~ meeting to the NRC staff who originated the contested action or position and may meet with other NRC staff who have expertise in the area. The licensee and other interested members of the public will be allowed to observe these meetings.

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Page 4-5

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

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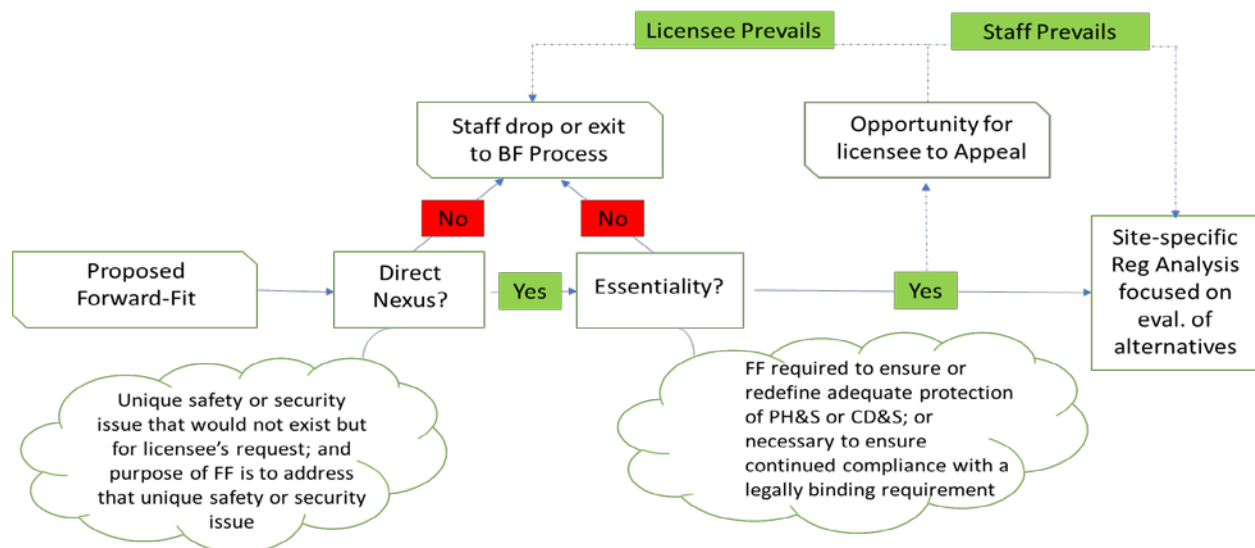
The panel ~~must~~will offer a ~~non-public internal~~ meeting to the originating staff of the NRC action. The licensee and other members of the public will be allowed to observe these meetings.

The panel ~~must~~will offer a ~~non-public internal~~ meeting to the first-level appeal panel to discuss both the licensee’s first- and second-level appeal documentation. The licensee and other members of the public will be allowed to observe these meetings.

#### IV. FORWARD FITTING

Our comments on implementation of the Commission’s forward fitting policy are included in Attachment 3. In our view, Attachment 3 provides a coherent and meaningful approach to implementing the Commission’s forward fitting policy that is consistent with the text of the backfitting rule in 10 CFR 50.109, the Commission’s statements in the preamble to the 1985 final backfitting rule, the Commission’s approach to managing licensee requests for voluntary licensing basis changes via the license amendment process, the 2010 Burns Letter, and the direction provided in Management Directive 8.4.

The lynchpin to the approach provided in Attachment 3 is distinguishing forward fitting from backfitting through careful application of the “direct nexus” and “essentiality” criteria. If these criteria are applied using the methodology provided in Attachment 3, then we believe that the NRC staff’s determination on these two criteria should be the primary focus of so-called forward fitting appeals. Specifically, the figure below provides our input on how the forward fitting appeal process could fit into the overall process for evaluating forward fits.



The process described in this figure begins with the staff proposing a forward fit that meets the first part of the definition provided in Management Directive 8.4.<sup>10</sup> This portion of forward fitting is proceduralized on pages 4-1 and 4-2 of Draft. Rev. 1. Next, the staff must determine whether the proposed forward fit meets the “direct nexus” and “essentiality” criteria. If the proposed forward fit does not meet both of these criteria, then it does not qualify for treatment as forward fitting.

As provided in the Burns Letter and discussed in Attachment 3, the staff’s attempt to impose a new or revised interpretation or position on a licensee as a condition of approving a voluntary licensee request to modify its licensing basis: “will not be deemed to be backfitting if: (i) the new or revised guidance relates directly to the licensee’s voluntary request; and (ii) the specific subject matter of the new or revised guidance is an essential consideration in the NRC staff’s determination of the acceptability of the licensee’s voluntary request.”<sup>11</sup> Thus, if the proposed forward fit fails to meet these criteria, it should be evaluated as backfitting. At that point, the staff could also decline to pursue the issue further, rather than performing a backfitting analysis. NEI-29

If the staff concludes that the proposed forward fit meets the direct nexus and essentiality criteria, the staff should provide its analysis to the licensee along with a notice that the licensee may appeal those conclusions. This is a vital step in the forward fitting process both because it is necessary for the licensee to understand the basis for the staff’s conclusions, and because it serves as a trigger for the appeals process. NEI-31

As discussed in Attachment 3, at this point the licensee will have several options:

- Appeal the staff’s conclusion that the proposed forward fit meets the criteria;
- Withdraw the request/application (this would be an option at any point in the process);
- Amend the request/application to address the staff’s concern (either by voluntarily adopting the forward fit or an acceptable alternative); or
- Take no action.

If the licensee successfully appeals the staff’s determination, then the staff would have the option to discontinue pursuit of the issue, or direct the issue into the appropriate process (*i.e.*, backfitting). If the staff prevails in such an appeal, the licensee would have the option to:

- Withdraw the request/application (this would be an option at any point in the process);
- Amend the request/application to address the staff’s concern (either by voluntarily adopting the forward fit or an acceptable alternative); or
- Take no action.

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<sup>10</sup> “A forward fit is defined as the imposition of a new or modified requirement or regulatory staff interpretation of a requirement that results in the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility as a condition of approval by the NRC of a licensee-initiated request for a licensing action when the underlying request did not propose to comply with the new or revised requirement or interpretation.” Management Directive 8.4, at Directive Handbook, p. 6.

<sup>11</sup> Burns Letter, at FN 2 (emphasis added).



Again, if the licensee chose to take no action in response to losing an appeal, the staff could either deny the licensee’s request/application, or prepare a site-specific regulatory analysis supporting imposition of the proposed forward fit (or the most cost-effective alternative) as a condition of approving the request. It is important to note that the approach to forward fitting provided in Attachment 3 would increase efficiency by requiring resolution of challenges to the staff’s “direct nexus” and “essentiality” findings before the staff devotes resources to undertaking a site-specific cost or regulatory analysis. Under our proposed approach, such an analysis would only be necessary in situations where the staff has determined that the proposed forward fit addresses a unique safety or security issue created by the licensee’s voluntary request to change its licensing basis, and that the proposed forward fit is necessary to address either an adequate protection or compliance issue associated with that unique safety or security issue.

Further, while these comments do not provide a detailed redline of Chapter 4, we believe that the points discussed above should be incorporated into a separate section of Chapter 4. This section could follow section 4.7, and would provide additional information specific to the forward fitting appeal process. Consistent with the comments provided above, this section should address:

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- The importance of the staff’s consideration of the “direct nexus” and “essentiality” criteria, including the need for the staff to provide the licensee with its analysis and conclusions regarding whether the proposed forward fit satisfies these criteria.
- The trigger for initiation of a forward fit appeal, which would be issuance of the “direct nexus” and “essentiality” determinations to the licensee. These determinations should also be made publicly available consistent with any restrictions under 10 CFR 2.390 to protect the confidentiality of the licensee’s proprietary information.
- The options available to both the licensee and the NRC staff—both upon issuance of the staff’s “direct nexus” and “essentiality” determinations, and upon the conclusion of the appeals process.

Incorporation of this new section in Chapter 4 may require conforming changes to the remainder of Chapter 4 because the terms backfitting and forward fitting are generally paired throughout the rest of the document. Recommendations for several such changes are provided below.

Page 4-1 lines 38–44 and page 4-2 lines 1–2 of Draft Rev. 1 should be revised as follows:

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

- The NRC staff ~~imposed~~ issued an applicable staff position ~~on to~~ the licensee that the staff determined was not backfitting ~~or forward fitting~~, but that the licensee believes is backfitting ~~or forward fitting~~.
- The NRC staff issued a determination to the licensee that a proposed new or modified requirement or interpretation of a requirement meets the definition of forward fitting provided in Management Directive 8.4 and that the proposed forward fit meets the “direct nexus” and “essentiality” criteria provided in Management Directive 8.4 and explained in Chapter 3 of this NUREG.
- The NRC staff imposed an applicable staff position on the licensee that the staff determined was backfitting ~~or forward fitting~~, but that the licensee believes was not properly justified.

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NEI-43



This includes an appeal to modify or withdraw a backfitting action for which the staff conducted a backfit analysis or an appeal that a backfitting action justified by the adequate protection or compliance exception in fact must be justified through a backfit analysis.

As written, this language seems to assume that licensees would be appealing a staff determination that a proposed action does not constitute forward fitting. This is not how we understand the concept articulated in the Burns Letter and expanded upon in Management Directive 8.4. Specifically, as discussed above, the concept of forward fitting described in the Burns Letter was that so-called forward fits were a specific category of staff actions that would escape treatment as backfits only if they met the “direct nexus” and “essentiality” criterion. As discussed in Chapter 3, we do not read the Commission’s description of forward fitting in Management Directive 8.4 as altering that concept. Based on this understanding of forward fitting, we believe licensees would actually be challenging the staff’s decision to treat a proposed action as a forward fit, rather than a staff decision that a proposed action did not constitute forward fitting (and thus, according to the Burns Letter, would result in the issue being treated as backfitting).

NEI-43

Page 4-2, lines 19–26 should be revised as follows:

The NRC will accept appeals from only those licensees for which the NRC action constitutes a backfit or forward fit and only if they are subject to the backfitting provisions in 10 CFR Chapter I. The only exception is for applicants for light-water reactor facilities that are relying upon a version of NUREG-0800, “Standard Review Plan [SRP] for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,” that is specifically incorporated into the relevant section of 10 CFR Part 52. For this class of applicants, the Commission has directed that any change from the regulatory staff positions established in NUREG-0800 “should follow the same reasoned decision-making process as forward fits.”<sup>12</sup> Thus, such applicants may appeal the imposition of forward fits using the procedures provided in the chapter. The NRC will not accept appeals from NRC staff who disagree with an agency action or position. Licensees should submit written appeals within 90 days of receiving the NRC’s written action or staff position or 30 days after the NRC issues its decision on a directly related disputed violation.

NEI-44

This change is recommended to ensure that Chapter 4 conforms to the Commission’s direction in Management Directive 8.4, as well as the similar statements in Section 3.1 of Draft Rev. 1.

Page 4-4, lines 25–33 should be revised as follows:

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

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<sup>12</sup> [Management Directive 8.4, at Directive Handbook, p. 8.](#)

Page 4-6, lines 27–34 should be revised as follows:

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

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## **V. CONCLUDING CAVEAT**

The approach discussed above assumes that our recommendations regarding forward fitting in Attachment 3 to our comments are incorporated into NUREG-1409. If the recommendations put forward in Attachment 3 are not accepted, then, at the very least, we recommend that the licensee’s opportunity to appeal should be expanded to include not only the staff’s conclusions on the direct nexus and essentiality criteria, but also any cost and regulatory analyses that are performed to justify a proposed forward fit.

NEI-46

## I. INTRODUCTION

In our view, Chapter 5 should serve as a guide for practical application of backfitting and forward fitting by describing how these concepts relate to other NRC processes. While it is useful for the Draft Revision 1 to NUREG-1409 (Draft Rev. 1) to address the relationship of multiple different processes to backfitting, simply listing these other processes without an overarching organizational structure is problematic. For example, many of the topics covered in Chapter 5 are interrelated, and if those relationships are not adequately explained, Chapter 5 may unintentionally create additional ambiguities and inconsistencies. This is particularly true for a group of sections that all are related to inspection and enforcement (*i.e.*, current Sections 5.5 (Enforcement), 5.5.2 (Violation), and 5.11 (Inspections)), and also those sections that related to the licensing basis (*i.e.*, current sections 5.4 (Differing Views of Licensing Basis), 5.12 (Licensing Basis), and 5.21 (Technical Assistance Requests)).

## II. ORGANIZATION AND STRUCTURE OF CHAPTER 5

NEI recommends that Chapter 5 be realigned to address three general topics. The first topic is whether a particular process can establish a “previously applicable staff position” for purposes of backfitting (including the composition of the current licensing basis). All of the issues discussed under this general topic relate to applying the “causation” element of the definition of backfitting—*i.e.*, identifying “a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a *previously applicable staff position*.” The second topic addresses the significance of backfitting in the inspection and enforcement processes. The third topic covers other processes that don't fit cleanly into the first two categories. This reorganization would make Chapter 5 a much more practical tool to assist the NRC staff in implementing the agency's backfitting and forward fitting procedures.

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NEI's proposed reorganization of Chapter 5 is described below, followed by specific, substantive comments on the text in Chapter 5. Please note that the comments are organized by NEI's proposed reorganization, but we have included cross-references to NRC's original proposed organization for clarity.

NEI's Proposed Table of Contents for Chapter 5, Rev. 1 NUREG-1409	
5.1: Previously Applicable Staff Positions	
5.1.1: Current Licensing Basis [Current Section 5.12]	
[This section would also include the discussions of Differing views (Current Section 5.1) and Technical Assistance Requests (Current Section 5.21)]	
5.1.1.1: Regulations [Current Section 5.17 (retitled)]	
5.1.1.2: Orders [Current Section 5.13 – This section would also include Confirmatory Orders (Current Subsection 5.5.1)]	
5.1.1.3: Confirmatory Action Letters [Current Subsection 5.5.1]	
5.1.1.4: Change to the License through Change Control Processes [Current Section 5.1]	
5.1.1.5: Final Safety Analysis Report [New Subsection – Not addressed in the draft]	
5.1.1.6: General Design Criteria [Current Section 5.6]	

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5.1.1.7: Commitments [Current Section 5.3]

5.1.1.8: Specific Exemptions [New Subsection – Not addressed in the draft]

5.1.1.9: Section 50.55a Relief or Alternatives [Current Section 5.19]

5.1.2: Safety Evaluation Reports [Current Section 5.18]

5.1.3: Voluntary Consensus Standards [Current Section 5.23]

5.1.4: Guidance Documents [Current Section 5.8]

5.1.4.1: Regulatory Guides [Current Subsection 5.8.1]

5.1.4.2: Interim Staff Guidance [Current Subsection 5.8.2]

5.1.4.3: Standard Review Plan [Current Section 5.20]

5.1.4.4: Withdrawing and Superseding Guidance Documents [Current Subsections 5.8.3 and 5.8.4]

5.1.5: Generic Communications [Current Section 5.7]

5.1.6: Topical Reports [Current Section 5.22]

5.2: Inspection and Enforcement

5.2.1: Inspection [Current Section 5.11]

5.2.2: Enforcement [Current Section 5.5]

[The discussion of Violations in 5.5.2 would be subsumed into this discussion]

5.3: Information Requests [Current Section 5.9]

5.4: Initial Licensing [Current Section 5.10]

5.5: Policy Statements [Current Section 5.14]

5.6: Regulatory Analysis [Current Section 5.15]

5.7: Clarifications [Current Section 5.2]

5.8: Requested Licensing Actions [Current Section 5.16 – Recommend Deletion]

### III. SPECIFIC COMMENTS ON CHAPTER 5

The following sections provide industry’s specific comments on the proposed language in Chapter 5 of Draft Rev. 1.

#### A. 5.1: Previously Applicable Staff Positions

As noted above, the “causal element” of the definitions of backfitting provided in the NRC’s regulations include “imposition of a regulatory staff position interpreting the Commission’s regulations that is either new or different from a previously applicable staff position.” In evaluating whether a proposed interpretation of the Commission’s regulations is either “new” or “different,” the NRC staff must

understand any “previously applicable staff positions” that may exist. The sources of staff positions can be found both within documentation constituting a facility’s licensing basis, as well as from other documents that are outside of the facility’s licensing basis. The 1990 version of NUREG-1409 specifically discusses applicable regulatory staff positions and provides a number of examples. Many of our comments below reflect the NRC’s current policy on applicable staff positions that were not captured in Draft Rev. 1.

Current subsection 1.2.2.2 discusses “staff positions” as they apply to backfitting. NEI has offered comments on subsection 1.2.2.2 in Attachment 1 and recommends that that section be aligned with the discussion of “applicable staff positions” here.

NEI-48

### 1. 5.1.1: Current Licensing Basis [Current Section 5.12]

As noted by former Executive Director for Operations in 2016, “foundational understanding of [the licensing and design bases] is essential.”<sup>1</sup> However, it is often the case, particularly in inspection and enforcement activities, that such understanding and alignment are not achieved early in the process and in some cases, never. In many of these examples, the failure to directly address the licensing basis question leads to unnecessary confusion and wasted effort. We have several recent examples during which a significant expenditure of time is made only to have the staff withdraw a finding or notice of violation.<sup>2</sup> It would be far more efficient and effective if, early on in an inspection activity, the NRC and licensee align on whether a potential finding or violation is consistent with the licensing basis. In fact, current NRC efforts to establish procedures associated with Very Low-Level Safety Significance Issue Resolution (VLLSIR) have acknowledged the importance of establishing clarity on the licensing basis as a matter of first order and could be given consideration as a process to resolve licensing basis conflicts for backfitting purposes.

Therefore, NEI strongly agrees with the statement in Section 5.4 that “the staff should first identify and resolve any differing views about the licensing basis . . . and ensure that the licensing basis is understood before beginning a backfitting or forward fitting assessment or pursuing enforcement.” We also agree with the statement in Section 5.12 that “Not all information that constitutes licensing basis information is within the scope of the backfitting and forward fitting provisions (*e.g.*, regulatory commitments that were not escalated into requirements should not be used as the basis for invoking the compliance exception). Likewise, some staff positions applicable to a facility may be within the scope of the backfitting and forward fitting provisions but do not constitute licensing basis information (*e.g.*, safety evaluations).”

NEI recommends that material from current Sections 5.4, 5.12, and 5.21 be merged 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 does not believe that a separate discussion of “differing views” is necessary, particularly with respect to internal differing views (for which the NRC has separate processes).

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<sup>1</sup> Memorandum from Victor M. McCree, Executive Director for Operations, *Tasking in Response to Committee to Review Generic Requirements Report on the U.S. Nuclear Regulatory Commission’s Implementation of Backfitting and Issue Finality Requirements*, July 19, 2017 (ML17198C141).

<sup>2</sup> Of note, several of these examples arose after the EDO-directed “reset” training on backfitting and issue finality.

Recommended Changes to Subsection 5.1.1

We recommend that the following text be used to populate proposed subsection 5.1.1 and replace the text current in section 5.12.

An important task in assessing potential backfitting for any facility is to identify and review NRC records and interact with licensees to understand the prevailing issue within the context of the licensing basis. The processes discussed in this NUREG assume that backfitting or forward fitting assessments of proposed staff actions begin with a correct understanding of the existing licensing basis. Therefore, the staff should first identify and resolve any differing views about the licensing basis and ensure that the licensing basis is understood before beginning a backfitting or forward fitting assessment or pursuing enforcement.

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NEI-49

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

In resolving questions about the licensing basis, the NRC staff should use the Technical Assistance Request (TAR) process, which is designed to support NRC offices and regions in answering questions that arise from regulatory activities. Once the staff submits a TAR to the appropriate NRC office, that office will make a determination on the licensing basis. Of note, if the requesting staff’s concern is whether the licensing basis is adequate, the TAR process will redirect the staff to the backfitting process for consideration of further NRC action. Backfitting and its associated activities (i.e., screening, justifying, and issuing) are outside the scope of the TAR process.

**a. 5.1.1.1: Regulations [Current Section 5.17 (Retitled)]**

This section is titled “Rulemakings and Guidance” in Draft Rev. 1. We recommend that this section be retitled to “Regulations,” and focus on their significance from the perspective of establishing an applicable staff position. As discussed in more detail below, NUREG-1409 should establish a separate section discussing backfitting requirements of rulemaking. There is no debate that an NRC regulation has the force and effect of law and establishes an agency position, so the subject requires little discussion. The regulatory significance of the Statements of Consideration accompanying a proposed or final rule, however, deserves further discussion. NEI recommends that NUREG-1409 provide additional clarity with respect to the significance of the Statements of Consideration as they relate to establishing an applicable staff position. In NEI’s view, Statements of Consideration in a final rule clearly establish an applicable staff position that can be relied on for backfitting purposes and NUREG 1409 should clearly state so.

NEI-51



NEI does believe, however, that the NRC should clearly articulate the backfitting process as it relates to rulemaking. Currently, such requirements are scattered throughout guidance documents and Commission Staff Requirements Memorandum,<sup>3</sup> but the totality of the current backfitting requirements as they relate to rulemaking are not captured. Management Directive 8.4, *Management of Backfitting, Forward Fitting, and Issue Finality, and Information Requests*, provides no detail other than affirming the applicability of backfitting to rulemaking. Similarly, Management Directive 6.3, *The Rulemaking Process*, contains only three short paragraphs on backfitting, and cross references NUREG-1409 for additional details. NUREG/BR-0058, *Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission*, for example, contains only brief mention of backfitting and only discusses backfitting in relation to regulatory analysis. NEI-52

Given the complexity of backfitting and the rulemaking process, NEI recommends that the subject be given greater, and more detailed coverage than what is currently provided in the cursory discussion found in Section 5.17.

#### **b. 5.1.1.2: Orders [Current Section 5.13]**

The language provided in Section 5.13 could create confusion about the applicability of backfitting to orders. The NRC’s regulations at 10 CFR 2.202 unambiguously state that “If 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, unless the licensee has consented to the action required.” Given the clarity of the regulation, a separate description is unnecessary.

Regarding the issuance of immediately effective orders under 10 CFR 2.202(a)(5), while the term “imminent threat analysis” is used throughout Draft Rev. 1, as well as Management Directive 8.4, it is unclear what is intended by an “imminent threat analysis” and how it differs from the criteria in 10 CFR 2.202(a) regarding issuance of an immediately effective order. The term seems to originate in the Commission’s revisions to Management Directive 8.4 (SRM-SECY-18-0049). As revised by the Commission, Management Directive 8.4 states that “If the NRC is considering a backfitting action, it must first consider whether regulatory action is necessary to ensure adequate protection of public health and safety and, if so, whether there is an imminent threat to public health and safety,” however the Commission did not provide any further explanation. Nor is the term referenced in the NRC’s Enforcement Manual or Enforcement Policy, making it seem as if it is a process unique to backfitting. NEI-53

While NEI does not oppose the Commission’s restrictions to issuing an immediately effective order, it notes that 2.202(a)(5) already requires that the Commission find “that the public health and safety or common defense and security interests so require” prior to issuing an immediately effective order. In order for clear and consistent application of the “imminent threat analysis” criterion, further clarification should be provided on this term. NEI-53 cont'

Draft Rev. 1 also does not specify that if the NRC does issue an immediately effective order, this should not relieve it from providing justification after the fact. NUREG 1409 currently explains that “if NEI-15 cont'

<sup>3</sup> For example, SRM-SECY-15-0129, Commission Involvement in Early Stages of Rulemaking, the Commission required the staff to develop a rulemaking plan template for initiating new rulemaking activities, and that the template should include “a section containing a preliminary backfit analysis.” The NRC staff’s proposed language to address this direction was approved by the Commission in SRM-COMSECY-16-0029. However, there is no detailed description in any NRC document, including this draft NUREG, of the “preliminary backfit analysis” required in the rulemaking plan.

immediately effective regulatory action is needed, the required documented evaluation may follow the issuance of the regulatory action.”<sup>4</sup> In addition, the Commission noted in the Statements of Consideration to the 1985 Final Rule that “The rule also provides that a backfit imposed by immediately effective regulatory action shall not relieve the Commission of performing an analysis after the fact to document the safety significance and appropriateness of the action taken.”<sup>5</sup> NEI recommends that this requirement be brought forward into Draft Rev. 1.

NEI-15  
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NEI also recommends that current subsection 5.5.1, Confirmatory Orders and Confirmatory Action Letters, be merged, in part, with proposed subsection 5.1.1.2. 10 CFR 2.202 does not distinguish between different types of “orders” and confirmatory orders are not treated separately in the NRC’s regulations. As such, confirmatory orders should be covered under this section. Confirmatory Action Letters are not orders, and so should be discussed in a separate section.

#### Recommended Changes to Subsection 5.1.1.2

We recommend that the following text be used to populate proposed subsection 5.1.1.2 and replace the text current in section 5.13, as well as the text in subsection 5.5.1 addressing Confirmatory Orders.

Orders are a mechanism through which the NRC can impose legally binding requirements. The requirements of an order have the same force and effect as a regulation, with the primary difference being that the recipient of an order may demand an adjudicatory hearing on the order. However, all orders are subject to backfitting considerations. NRC’s regulations at 10 CFR 2.202 state that “If 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, unless the licensee has consented to the action required.” Orders may also be made immediately effective “if the Commission finds that the public health, safety, or interest so requires.” Such a finding requires immediate implementation by the recipient, notwithstanding a demand for hearing. Determining that it is necessary to issue an immediately effective order, however, does not relieve the NRC from assessing the backfitting implications of the order, even if after the fact. The purpose of conducting a backfitting evaluation after the issuance of such an order is to document the safety significance and appropriateness of the action taken.

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NEI-53

Confirmatory orders are a sub-category of orders that confirm licensee implementation of licensee commitments and make these commitments legally binding. The primary distinction is that the licensee must voluntarily waive its right to an adjudicatory hearing for the NRC to be able to use a confirmatory order. Because confirmatory orders merely make legally binding commitments that the licensee has voluntarily made, they do not meet the definition of backfitting. However, confirmatory orders may nonetheless establish applicable staff positions for purposes of backfitting.

#### **c. 5.1.1.3: Confirmatory Action Letters [Current Subsection 5.5.1]**

NEI agrees with statements on Confirmatory Action Letters (CAL) in Draft Rev. 1. However, we believe that additional clarity is needed regarding the significance of a CAL with respect to establishing an applicable staff position. As stated in the NRC’s Enforcement Manual, the purpose of a CAL is “to

<sup>4</sup> “Backfitting Guidelines,” NUREG-1409, July 1990, at p. 4 (NUREG-1409).

<sup>5</sup> “Revision of Backfitting Process for Power Reactors,” 50 Fed. Reg. 38097, 38103 (Sept. 20, 1985).

emphasize and confirm an agreement to take certain actions in response to specific issues.” Further, the Enforcement Manual states that “CALs should only be issued when there is a sound technical and/or regulatory basis for the desired actions discussed in the CAL.” The Enforcement Manual also discusses the NRC’s ability to review and negotiate with a licensee on the obligations and commitments that are ultimately reflected in the CAL. In other words, the CAL reflects the staff’s position on licensee obligations and commitments and could represent an applicable staff position for purposes of backfitting if the NRC ultimately requires the licensee to do something more or different from those obligations or commitments. NUREG-1409 currently reflects this view.<sup>6</sup> Draft Rev. 1 should make this distinction and NEI has proposed revisions to the language currently in 5.5.1 to reflect this position. NEI-54

#### Recommended Changes to Subsection 5.1.1.3

We recommend that the following text be used to populate proposed subsection 5.1.1.3 and modify the text describing CALs currently in subsection 5.5.1.

A Confirmatory Action Letter is not a requirement and, accordingly, is not enforceable. Licensees voluntarily agree to the actions described in a confirmatory action letter. Thus, the issuance of a Confirmatory Action Letter does not constitute backfitting. In most cases, the licensee would have taken this voluntary action in response to an enforcement action. Attempts by the NRC to require compliance with a confirmatory action letter could constitute backfitting. For instance, the NRC’s Enforcement Manual states that “CALs should only be issued when there is a sound technical and/or regulatory basis for the desired actions discussed in the CAL.” The Enforcement Manual also discusses the NRC’s ability to review and negotiate with a licensee on the obligations and commitments that are ultimately reflected in the CAL. In this context, a CAL could reflect the staff’s position on licensee obligations and commitments and could represent an applicable staff position for purposes of backfitting if the NRC ultimately requires the licensee to do something more or different from those obligations or commitments. If an order is required to impose additional requirements above those reflected in the underlying CAL, the NRC will conduct a backfit analysis using the CAL as the basis for the applicable staff position.

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#### **d. 5.1.1.4: Change to the License through Change Control Processes [Current Section 5.1]**

Section 5.1 states that “If the change processes are used properly, then the licensee can reasonably implement the change *without concern about future enforcement* action and with the assurance that any future NRC-imposed modifications to the changes would be subject to backfitting considerations.” This implies, but does not make clear, that a change made to the licensing basis of a facility under one of these processes is deemed to establish an applicable staff position that would require a backfitting evaluation were the NRC to subsequently demand a change to the revised portion of the facility’s licensing basis. If that is in fact the point that it is being made, then NEI agrees. We offer language below that would improve the clarity of this section.

NEI-55

<sup>6</sup> See NUREG-1409, at pg. 3.

Recommended Changes to Subsection 5.1.1.4

We recommend that the following text be used to populate proposed subsection 5.1.1.4, and modify the text currently in section 5.1.

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

NEI-55  
cont'

e. **5.1.1.5: Final Safety Analysis Report [New Subsection – Not addressed in the Draft]**

NEI-56

Current NUREG-1409 discusses the significance of a licensee’s Final Safety Analysis Report (FSAR) in the context of backfitting, explaining:

Where the staff previously accepted the licensee’s program as adequate, any staff-specified change in the program would be classified as a backfit.

NEI-56  
cont'

For example, in the case of a plant with an operating license, once the SER is issued signifying staff acceptance of the programs described in the safety analysis report (SAR), the licensee should be able to conclude that its commitments in the SAR satisfy the NRC requirements for a particular area. If the staff were to subsequently require that the licensee agree to additional action other than that specified in the SAR for the particular area, such action would constitute a backfit. In the case described in the question, it is likely that the compliance exception in 10 CFR 50.109(a)(4) would apply (*i.e.*, it would be a compliance backfit).<sup>7</sup>

NEI agrees with this statement and believes that it should be included in Draft Rev. 1. A licensee should be able to rely on the staff’s approval as an applicable staff position when future questions regarding the FSAR or licensee programs described in the FSAR arise.

<sup>7</sup> NUREG-1409, p. 18.

**f. 5.1.1.6: General Design Criteria [Current Section 5.6]**

Section 5.6 of Draft Rev. 1 states that General Design Criteria (GDC) can be used to justify application of the compliance exception “only if a GDC provides more than just a performance standard and has not been superseded through the approval of the [principal design criteria] . . . and technical specifications.” It goes on to state that “a GDC can be regarded as a requirement in those circumstances in which the GDC is prescriptive in nature, and the technical specifications, other licensee requirements derived from the GDC, and the [principal design criteria] do not address the matter in question.”

While Draft Rev. 1 attempts to impose boundaries on using GDC to support a compliance exception, NEI questions whether reliance on GDC is ever necessary, appropriate, or consistent with NRC practice. For example, the NRC Enforcement Manual states that “GDC were not intended, in and of themselves, to constitute the controlling parameters for operation of nuclear power plants.” Rather, “[technical specifications] provide the controlling parameters on operation of a nuclear power plant.” (NRC Enforcement Manual, Rev. 11, p. 343.) While the Enforcement Manual contemplates that citations against the GDC are possible, they are expected to be “rare.” NEI expects the same rare outcome here, if at all. NEI-57

Furthermore, and as pointed out in subsection 2.5.2.2 of Draft Rev. 1, the Commission has explained that “[t]he compliance exception is intended to address situations in which the licensee has failed to meet known and established standards of the Commission.” However, it is not clear which GDC would meet the criteria to serve as the “known and established standard” under the compliance exception test. Therefore, the NUREG should provide examples of GDC that would meet these criteria for serving as the basis for a compliance exception justification.

**g. 5.1.1.7: Commitments [Current Section 5.3]**

NEI generally agrees with the discussion of commitments currently in Section 5.3. However, the discussion of commitments in Draft Rev. 1 should cover the agency’s view on the relationship between licensee commitments and applicable staff positions. Depending on the level of staff engagement with a licensee regarding a commitment, it seems that an applicable staff position on a licensee commitment could be established from this record. As such, Draft Rev. 1 should at least include a requirement that the staff should, on a case-by-case basis, consider the possibility that an applicable staff position was established related to a commitment. This would be consistent with current statements in current NUREG-1409 (*see* subsection 2.1.2). NEI-58

**h. 5.1.1.8: Specific Exemptions [New Subsection – Not addressed in the Draft]**

NRC approvals of licensee requests for exemptions could establish an applicable staff position. For instance, while the intent of an exemption request is to seek relief from the NRC’s regulations, the exemption request might include other conditions that the licensee intends to implement in the alternative. The staff must therefore review those other conditions as part of its overall review of the exemption request. Therefore, the staff’s evaluation and approval would represent an applicable staff position with respect to those specific conditions. NEI recommends that Draft Rev. 1 include a specific subsection on specific exemptions to establish that they can establish applicable staff positions. NEI-59



**i. 5.1.1.9: Section 50.55a Relief or Alternatives [Current Section 5.19]**

As with specific exemption requests, relief or alternatives under 10 CFR 50.55a could establish applicable staff positions for purposes of backfitting. In addition, this section correctly states that when a licensee proposes an alternative to ASME code requirements under 10 CFR 50.55a(z), the NRC should subject its own proposed alternative to a backfitting evaluation. However, NEI recommends that, consistent with the overall directive of NUREG-1409 that backfitting analyses should be done prior to imposing a backfit, the language be revised to specify that the NRC should evaluate alternative proposals to a backfitting evaluation upon conveyance, rather than after imposing the requirement. In addition, we note that there is currently an effort underway to examine transformative change with respect to 10 CFR 50.55a. NEI may have additional recommendations with respect to how the backfitting requirements are applied to section 50.55a as part of that process.

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Recommended Changes to Subsection 5.1.1.9

We recommend that the following text be used to populate proposed subsection 5.1.1.9, and modify the text currently in section 5.19.

The provisions of 10 CFR 50.55a allow licensees to request relief from certain requirements in 10 CFR 50.55a and to propose alternative requirements. These provisions for requesting relief and proposing alternative requirements are found in 10 CFR 50.55a(f)(6)(i) and (g)(6)(i). The NRC calls these requests “relief requests.” Under 10 CFR 50.55a(z), licensees can propose alternatives to certain requirements in 10 CFR 50.55a. The NRC calls these requests “proposed alternatives.” As with specific exemption requests, relief or alternatives under 10 CFR 50.55a could establish applicable staff positions for purposes of backfitting.

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cont'

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

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

NEI-60  
cont'



### 2. 5.1.2: Safety Evaluation Reports [Current Section 5.18]

In general, we agree with the information provided in section 5.18 of Draft Rev. 1. That said, we believe that the section should be expanded to include the important discussion of Safety Evaluation Reports provided in subsection 1.2.2.2 of Draft. Rev. 1. Specifically, subsection 1.2.2.2 of Draft. Rev. 1 provides:

Staff positions in safety evaluations are not requirements; rather, they are the NRC’s regulatory bases for its decisions or interpretations. Safety evaluations (or safety evaluation reports) provide the staff position on whether a licensee’s proposed means for implementing or complying with a governing requirement is acceptable and results in compliance with the requirement. The safety evaluation is generally not part of the licensing basis unless specifically incorporated by the licensee or required as a condition of approval by the staff. If the NRC subsequently decides that a staff position in a safety evaluation is incorrect, then agency actions related to that decision are subject to backfitting assessment. (emphasis added)

NEI-61

Further, footnote 8 in subsection 1.2.2 of Draft Rev. 1, which is associated with the last sentence of the passage quoted above, states:

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

These passages provide important context for the discussion of Safety Evaluation Reports, as they relate to the backfitting process. Specifically, although these reports are not generally part of the plant’s licensing basis and generally do not contain legally binding requirements, they do contain staff positions as that term is used in the definition of backfitting. This is an important distinction, and it is often overlooked or misconstrued by both NRC staff and industry personnel. Thus, it is important to clarify the distinction in this subsection, as well as subsection 1.2.2.2. NEI provides additional, detailed comments on subsection 1.2.2.2 in Attachment 1.

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cont'

### 3. 5.1.3: Voluntary Consensus Standards [Current Section 5.23]

We recommend that the text currently contained in section 5.23 be moved to subsection 5.1.3. As noted above, NEI is currently engaging with the staff on its effort to examine transformative change with respect to 10 CFR 50.55a. NEI may have additional recommendations with respect to how the backfitting requirements are applied to section 50.55a as part of that process.

part of  
NEI-47

### 4. 5.1.4: Guidance Documents [Current Section 5.8]

While NEI largely agrees with the discussion in current Section 5.8 and its subsections, regarding the significance of guidance documents, we believe additional clarity is needed. First, NEI provided its views on the notion of “imposition” as part of its comments on Chapter 2 and much of this discussion centered around the relevance of guidance documents. In addition, the discussion of voluntary submittals in this section should be revised to clarify that it applies only to applicants for an initial license. As drafted, this section is inconsistent with the statements made with respect to forward fitting in Chapter 3.

NEI-62

Second, NEI recommends that this section expressly state that guidance documents in general can establish applicable staff positions and should be considered in any discussion of backfitting. This is consistent with statements in the current NUREG-1409 (*See* subsection 2.1.2).

#### Recommended Changes to Subsection 5.1.4

We recommend that the following text be used to populate proposed subsection 5.1.4, and modify the text currently in section 5.8.

If an licensee-applicant voluntarily submits an application for an initial license, ~~an amendment, or license renewal,~~ then the staff must use the staff guidance applicable to that licensee-applicant during the review to ensure that NRC requirements are met. ~~This would not be considered backfitting.~~ If the staff used different guidance than that which was used by the applicant to review the ~~licensee's~~ request, then the staff could be forward fitting that licensee-applicant and would need to meet the forward fitting criteria discussed in Chapter 3 of this NUREG. Draft guidance does not constitute a staff position, so the staff should not use it in licensing decisions.

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cont'

For voluntary license amendment requests submitted by an existing licensee, Chapter 3 of this NUREG discusses the appropriated use of guidance documents to review a licensee's application.

In general, final guidance documents may establish an applicable staff position that is subject to backfitting evaluation if the NRC were to take a new or different position sometime in the future. These instances must be evaluated on a case-by-case basis.

#### **a. 5.1.4.1: Regulatory Guides [Current Section 5.8.1]**

*See* generally our comments above on proposed subsection 5.1.4. In addition, the following proposed revisions are provided for clarification.

#### Recommended Changes to Subsection 5.1.4.1

We recommend that the following text be used to populate proposed subsection 5.1.4.1, and modify the text currently in subsection 5.8.1.

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

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cont'

#### **b. 5.1.4.2: Interim Staff Guidance [Current Subsection 5.8.2]**

*See* generally our comments above on proposed subsection 5.1.4. We recommend moving the language from subsection 5.8.2 to proposed subsection 5.1.4.2.

part of  
NEI-47

**c. 5.1.4.3: Standard Review Plan [Current Section 5.20]**

See generally our comments above on proposed subsection 5.1.4 on guidance documents. NEI also offers several proposed revisions for further clarity. The discussion of the Standard Review Plan should also acknowledge, as the NRC does in current NUREG-1409, that the Standard Review Plan may represent an applicable staff position.

Recommended Changes to Subsection 5.1.4.3

We recommend that the following text be used to populate proposed subsection 5.1.4.3, and modify the text currently in section 5.20.

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

NEI-63

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

**d. 5.1.4.4: Withdrawing and Superseding Guidance Documents  
[Current Subsections 5.8.3 and 5.8.4]**

NEI recommends that the current subsections on withdrawing and superseding guidance documents be merged into one subsection. NEI is also recommending several revisions to increase the clarity of this discussion. NEI does not agree with the caveat to the statement in current subsection 5.8.4, lines 42-43, that if the NRC issues superseding guidance, licensees could only continue using the superseded guidance “as long as the licensee does not change its licensing basis relative to that guidance document.” In our view, if the NRC continues to permit use of the superseded guidance, licensees should be able to continue to rely on that guidance even if they voluntarily choose to amend a provision of the license relative to that guidance. In such a situation, unless the NRC can justify imposition of the revised guidance using the forward fitting criteria described in Attachment 3, the NRC would be obligated to justify the imposition of the superseding guidance as backfitting. The NRC’s decision to permit use of the superseded guidance is presumably based on a finding that reasonable assurance of adequate protection is still provided and a staff position concluding that this is no longer the case (by requiring use of the superseding guidance) would have to be justified accordingly.

NEI-64

NEI-65

Recommended Changes to Subsection 5.1.4.4

We recommend that the following text be used to populate proposed subsection 5.1.4.4, and modify the text currently in subsections 5.8.3 and 5.8.4.

To withdraw a guidance document, the NRC typically must already have the guidance located in other documents, determine that the guidance concerns an aspect of a facility’s design or

operation that is no longer used as a means to meet the governing requirements, or conclude that the guidance could no longer be used to comply with applicable requirements. If the guidance can be found in other locations or is no longer needed, then withdrawing the guidance document ~~has~~ should have no substantive impact on licensees. However, if the NRC determines that the guidance document should be withdrawn because the methods contained are no longer an acceptable means of complying with the applicable requirements, then ~~withdrawing the withdrawal of~~ that guidance document could constitute should be evaluated for backfitting implications for those licensees using the guidance document. If the NRC determines that a backfit is justified, it will use the appropriate regulatory process to impose a modification to the licenses. The backfitting would occur through another regulatory action, such as an order removing the guidance document from the license. That regulatory action would need to justify the backfitting. If the withdrawal of the guidance document requires issuance of a Federal Register notice, then the staff should generically address the backfitting, forward fitting, and issue finality implications of withdrawing the guidance document in the Federal Register notice

NEI-66

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

implements  
NEI-65

### 5. 5.1.5: Generic Communications [Current Section 5.7]

While NEI agrees with the sentiment in Draft Rev. 1 that generic communications cannot establish or impose new requirements, history provides numerous examples where the NRC issued a generic communication that purported to “clarify” existing requirements, but in effect imposed an unanalyzed backfit. For instance, the NRC recently published Draft Regulatory Issue Summary 2020–XX, “Clarification of Personnel Access Authorization Requirements for Non-Immigrant Foreign Nationals Working at Nuclear Power Plants” for comment. The draft RIS purports to “reinforce the existing requirement that prior to granting or reinstating unescorted access (UA), or certifying unescorted access authorization (UAA) to non-immigrant foreign nationals for the purpose of performing work, licensees shall satisfy the requirements in 10 CFR 73.56(d)(3), ‘Verification of true identity.’” However, as industry has argued, this is clearly not the case, and the position taken by the staff in the draft RIS constitutes a new or different interpretation from a previously applicable staff position. Yet this draft RIS contains only a cursory statement that “This RIS does not require any action or written response on the part of any licensee or applicant” and therefore “issuance of this RIS does not represent backfitting.” This draft RIS is only one, recent example of a situation where a generic communication was published

with boilerplate backfitting language, but it does not appear that the staff actually confirmed that the boilerplate was consistent with the content of the generic communication.

In this light, Draft Rev. 1 can be read to mean that generic communications are categorically not backfits, thus relieving the NRC from assessing the impact of a generic communication from a backfitting perspective. This should be revised so that it is clear that 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, but that each generic communication must be assessed for any backfitting implications prior to publication. NEI has proposed revised text to address this concern.

#### Recommended Changes to Subsection 5.1.5

We recommend that the following text be used to populate proposed subsection 5.1.5, and modify the text currently in section 5.7.

~~The issuance of generic communications does not~~ cannot be used to establish new requirements or impose staff positions ~~and, therefore, cannot constitute that would result in backfitting. Section 5.9 of this NUREG contains a discussion of generic communications that request information. However, every generic communication must be evaluated prior to issuance to assess whether the positions described in the communication have backfitting implications. Staff should be cautious not to over rely on generic boilerplate language without evaluating the specific content and effect of the generic communication at issue. The fact that generic communications should not be used to impose backfits does not mean that backfits cannot be imposed through the misuse of generic communications.~~

NEI-67

#### **6. 5.1.6: Topical Reports [Current Section 5.22]**

NEI has no specific concerns with the language in current Section 5.22, but proposes several provisions for clarity.

#### Recommended Changes to Subsection 5.1.6

We recommend that the following text be used to populate proposed subsection 5.1.6, and modify the text currently in section 5.22.

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

NEI-68

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



staff must ensure that its communication does not limit the licensee in choosing how to resolve the issues. Section 3.3 of this NUREG contains more guidance on these situations.

## **B. 5.2: Inspection and Enforcement**

Many backfitting issues arise during the course of an inspection or enforcement proceeding, so additional clarity in this section is critically important. There is, however, little if any clarity in the NRC’s existing procedures for how a licensee is to raise a backfitting issue or how the NRC is to disposition a backfitting claim during inspection and enforcement proceedings. NEI believes that relying on the appeal process alone creates an unnecessary burden on both the NRC and the industry given the level of formality involved in such an appeal. In addition, if the NRC does not take a position on a licensee backfitting claim and does not document its basis for its view that a finding or violation does not constitute backfitting, the burden is then upon the licensee to essentially guess what the NRC’s position is when it files a backfitting appeal. Our comments in Attachment 4 explain this potential burden shifting, and how it can be addressed in the appeals process. Our comments on the appeals process aside, we believe there should be a simpler, more straightforward method to dealing with backfitting claims during the inspection and enforcement processes.

The purpose of NRC inspection is to assess a licensee’s compliance with its current licensing basis. As Draft Rev. 1 implies but does not expressly state, the intent of an inspection is not to assess the adequacy of the current licensing basis. That said, there may be times during which an inspection reveals a deficiency in the current licensing basis that the NRC must explore further, but it must do so through the backfitting process. Moreover, when the NRC takes enforcement action, *i.e.*, issues a finding or notice of violation, that action must be against the current licensing basis as well.

### **1. 5.2.1: Inspection [Current Section 5.11]**

As a general comment, current section 5.11 discusses inspection activities (findings) and enforcement activities (violations) together. But backfitting considerations may be different depending on whether the issue is related to a finding versus a violation. While NEI’s suggested reorganization of Chapter 5 acknowledges the relationship between the two, as it relates to backfitting considerations, inspections and enforcement should be clearly delineated. As such, NEI recommends removing references to violations in the section discussing inspections.

NEI-69

As Draft Rev. 1 points out, “the inspection procedures define those items that the staff should consider in determining whether the licensee is conducting its activities in accordance with the facility’s licensing basis.” As such, inspection findings must be based on the licensee’s current licensing basis. However, the following paragraph in section 5.11, creates ambiguity on this point, stating:

In the normal course of inspections, the inspector may examine and identify findings or violations in specific technical or regulatory areas. Identifying findings or violations usually does not involve backfitting, but it may if the establishment of the NRC’s position can be reasonably understood to exceed the governing requirement or a licensee’s self-imposed standard that is included in the licensing basis.

NEI recommends that this paragraph be revised to clarify that if an inspector does identify a concern with the adequacy of the current licensing basis, then that concern should be dispositioned in accord with the NRC’s backfitting processes, and not through the inspection or enforcement processes as the

NEI-70



section implies. In addition, the phrase “exceed a governing requirement” is vague and requires clarification.

In this light, NEI recommends replacing the above-quoted paragraph with the following:

In the normal course of inspections, the inspector may identify a concern regarding the adequacy of the licensee’s current licensing basis. An inspection should not typically involve backfitting, but it may if the inspector’s regulatory position appears to be inconsistent with previous NRC positions regarding that facility or regarding a generic perspective that is directly applicable to that facility regarding the plant licensing basis. If an inspection identifies a potential safety or security issue that is beyond the requirements in the current 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.

Implements  
NEI-70

NEI recommends revising the paragraph on page 5-9, lines 4-11, as follows:

Inspections may include the review of activities that were previously inspected. Many inspections are done on a sampling basis and the focus areas may differ from one inspector to another. A different inspection conclusion (e.g., one resulting in identified findings versus one that does not—refer to the caution in subsection 1.2.2.2 of this NUREG) may not constitute backfitting because (1) most inspections use a sampling methodology, circumstances surrounding the activity may have changed, (3) the focus of the inspection may be different, (4) the licensing basis may have changed, (5) maintenance that was previously committed to may not have been accomplished, or (6) other factors have been considered. Consistent with these factors, if an inspection report specifically states that an inspector has reviewed an SSC, a licensee program, or the licensing basis associated with an SSC or program, and did not identify a regulatory compliance matter, a licensee may reasonably rely on that specific review to conclude that for those areas assessed by the inspector, no non-compliances exist. It follows that if a subsequent inspector also performs a specific review of the same SSC, program, and/or associated licensing basis and now concludes that a non-compliance exists, the subsequent conclusion could represent a backfit.

NEI-71

On page 5-9, the Draft Rev. 1 states that:

an inspector’s discussion of findings with the licensee is not considered backfitting. During these discussions, the licensee may agree that certain changes are appropriate in response to the inspector’s findings. This would not constitute backfitting if the inspector does not indicate that specific actions are the only way to satisfy the staff when the licensing basis does not require the specific action. An inspector’s suggestions to consider an applicable guidance document or NRC-endorsed topical report to resolve the findings are not backfitting as long as the inspector does not convey an expectation that the licensee must use the guidance document or topical report. Thus, the staff expects that findings or violations documented as part of the NRC’s inspection activities would not involve backfitting.

While NEI does not disagree with the underlying principle that “the staff expects that findings or violations documented as part of the NRC’s inspection activities would not involve backfitting,” we believe that Draft Rev.1 should make it clear that if a licensee believes that the NRC inspection finding constitutes backfitting, NUREG 1409 should set forth an explicit requirement that the staff must directly

NEI-72

address the licensee’s claim. Further, the staff’s position should be documented in the preliminary and/or final exit meeting discussion and documented in the associated inspection report. Otherwise, the alleged finding or violation could be used as evidence of untimely corrective actions for a matter identified by the NRC, which the licensee believes did not require corrective actions due to the backfit.

NEI-72  
cont'

Also, on page 5-9, Draft Rev. 1 states that “if a licensee concludes that a finding or violation in a written NRC inspection report is a new staff position that is not part of the licensing basis, then the licensee can initiate a backfitting appeal as described in Chapter 4 of this NUREG.” This appears to be inconsistent with the procedures laid out in Chapter 4 because it suggests a licensee would challenge or appeal a backfitting determination before the inspection organization has responded to and reached a position on the backfitting claim. If the inspection organization does not take a position with respect to the licensee’s claim, it is unclear what the licensee would appeal. Attachment 4 to these comments discusses the issue of forcing a licensee to appeal the staff’s silence on a backfitting issue in greater detail.

Part of  
NEI-35

Finally, on page 5-9, the NUREG states that:

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

As we have commented through the Inspection and Enforcement sections, NEI agrees that there should be an opportunity for the licensee to raise a backfitting claim during the inspection process and that the NRC should consider the safety significance of the underlying issue. That said, the wording of this section should be clarified to describe the opportunities the licensee has to better understand and possibly challenge the staff’s position.

Part of  
NEI-35

## **2. 5.2.2: Enforcement [Current Section 5.5]**

Section 5.5 of Draft Rev. 1 addresses the relationship between enforcement and backfitting. The relevant enforcement activities include notices of violation (NOVs), non-cited violations (NCVs), confirmatory orders, confirmatory action letters, and other enforcement actions. As an initial matter, it is unclear why Draft Rev. 1 identifies Violations (Current Subsection 5.5.2) as a subsection to Enforcement. We recommend that the discussion of violations be covered under the general enforcement section, rather than a stand-alone subsection. This also makes better sense in view of our recommendation that Confirmatory Orders be covered under Orders generally, and Confirmatory Action Letters be treated separately.

Draft Rev. 1 correctly notes that NRC enforcement action should be based only on “legally binding requirements” that apply to the licensee. NEI agrees with the NRC on this principle and with the further statement that an enforcement action that improperly reflects the imposition of a new or modified requirement or staff position constitutes a backfit. As Draft Rev. 1 states (at page 5-2):

The staff should take extra caution when reviewing regulatory requirements, such as an operating reactor’s licensing basis, cited in an enforcement action to ensure that the

enforcement action is, in fact, citing only legally binding requirements. A citation that improperly reflects a new or modified requirement or staff position constitutes backfitting.

In this situation, Draft Rev. 1 indicates that a licensee may formally submit a backfitting appeal in accordance with Chapter 4 of the NUREG while also denying the violation. Further, it states that the NRC staff will not respond to the disputed violation until the agency reviews the formal backfitting appeal and makes a final decision on the validity of the claim.

NEI appreciates the NRC staff’s clarification that a licensee may invoke the backfitting appeal process to contest a violation that raises backfitting concerns. This is an important clarification; however, we do not believe it is necessary to make the formal backfitting appeal process the exclusive process by which a licensee can raise backfitting concerns in response to a proposed enforcement action. In our view, a licensee should also be able to raise backfitting arguments in response to an identified violation as part of the normal enforcement process if it chooses. In fact, Draft Rev. 1 appears to agree with this position when it states at the beginning of Chapter 4 that “Licensees can discuss the applicability of backfitting regulations and the forward fitting policy with the applicable U.S. Nuclear Regulatory Commission (NRC) staff whenever the licensees have a concern.” In contrast, Chapter 5 of Draft Rev. 1 seeks to constrain this broad statement, stating (at p. 5-3; emphasis added):

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if the licensee raises a backfitting claim or concern to the NRC in conjunction with a disputed violation in reply to an NOV or NCV, but the licensee has not formally submitted a backfitting appeal, then the NRC staff should not consider the backfitting claim. Instead, the enforcement staff should direct the licensee to Chapter 4 of this NUREG.

In our view, a licensee should be able to raise backfitting concerns in response to a potential enforcement matter without going to the lengths of submitting a formal backfitting appeal. As recognized in subsection 2.5.2.1 of Draft Rev. 1, compliance and backfitting issues are two sides of the same coin – that is, a backfit is the imposition of a staff position that goes beyond what is necessary for compliance with an existing requirement. If the NRC staff identifies an apparent violation, but the licensee believes it is complying and that the staff is enforcing a position that reflects a new or modified requirement or staff position, the licensee should be able to show the NRC why that is the case in its response to the apparent violation as part of the enforcement process. This approach would be more efficient since it would avoid the need for the licensee to submit a formal backfitting appeal and initiate that separate process. In fact, whenever a licensee denies a proposed violation, it is effectively saying that it is already in compliance and the citation goes beyond what is required. The language highlighted above from page 5-3 of Draft Rev. 1 could cause confusion in the event a licensee denies a violation on the basis that the violation goes beyond existing requirements reflected in the plant’s licensing basis, since that language suggests that the NRC staff “should not consider” the licensee’s position.

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Some real-world examples illustrate how backfitting concerns can be raised productively during the normal enforcement process without the need to submit formal backfitting appeals:

- The NRC staff identified an apparent violation with respect to whether a PWR licensee’s fire suppression system in the cable spreading room complied with NRC fire protection requirements in 10 CFR Part 50, Appendix R. At the regulatory conference, the licensee presented information showing that the NRC’s Safety Evaluation Report on its fire protection program accepted the design of the fire suppression system in the cable spreading room, which had not changed significantly since that approval. Based on this previous NRC staff position accepting the licensee’s design, the NRC withdrew the apparent violation.

- The NRC staff identified a violation related to the licensee’s commercial grade dedication process for certain equipment items. In its response to the NOV, the licensee denied the violation and presented information showing that previous NRC inspections had accepted its commercial grade dedication practices for the items. As a result, the NRC agreed to withdraw the violation and treat its concerns with commercial grade dedication programs as a generic issue for industry and NRC.
- The NRC staff identified a violation of 10 CFR Part 50, Appendix B, Criterion III, “Design Control,” because the licensee did not design or ensure that in the event of a design-basis earthquake, the emergency diesel generators would not be lost due to an electrical circuit fault in the non-safety related sump pump motor. The licensee contested the violation, arguing that requirement underlying the violation was not part of the licensing basis, and that imposition of the violation would constitute a backfit. The NRC ultimately agreed that the facility was operating consistent with its approved licensing basis and withdrew the NOV.

Regarding Violations (current subsection 5.5.2), as noted above, NEI recommends that this topic be covered under enforcement generally. NEI generally agrees with the discussion contained in current subsection regarding violations. That said, the subject is covered in a very conclusory fashion, without an accompanying rationale. Rather, the subsection largely appears as a list of scenarios, followed by statements regarding whether each scenario constitutes backfitting. NEI recommends that more substance be provided in the discussion of violations to include an explanation for each of the statements regarding backfitting applicability. As we have emphasized throughout our comments, the basis for concluding that a given situation does or does not constitute backfitting should be tied to the definition of backfitting.

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#### Recommended Changes to Subsection 5.5.2

For the above reasons, NEI recommends that the NRC move the text currently in section 5.5 of Draft Rev. 1 to the proposed subsection 5.5.2. Further, we recommend that the NRC revise this text to indicate that, when a licensee believes a proposed violation reflects a backfit, the licensee has the option of either: (1) submitting a formal backfitting appeal in response to the violation in accordance with Chapter 4 of NUREG-1409; or (2) presenting its backfitting-related arguments in its reply to an NOV or NCV or other citation as part of the basis for denying the cited violation. This clarification could be made by revising the first two paragraphs at p. 5-3 of Draft Rev. 1 as follows:

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

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By contrast, if the licensee raises a backfitting claim or concern to the NRC in conjunction with a disputed violation in reply to an NOV or NCV, but the licensee has not formally submitted a backfitting appeal, then the NRC staff should ~~not~~ consider the backfitting arguments claim-as part of the evaluation of the disputed violation. Instead In addition, the enforcement staff may ~~should~~ direct the licensee to Chapter 4 of this NUREG.

In short, enforcement actions involve essentially the same analysis as backfits—namely, what exactly does the legally binding requirement provide? It should be perfectly acceptable for a licensee to challenge a proposed enforcement action or NOV on grounds that are similar to backfitting grounds, without having to submit a formal backfitting appeal. The licensee should be able to raise those issues in the normal process of replying to an NOV or other enforcement context. The licensee should also have the option to submit a backfitting appeal separately if the licensee so chooses. The NRC staff, as indicated in Draft Rev. 1, can always direct the licensee to Chapter 4 of NUREG-1409 if the staff believes the formal backfitting appeal process may be preferable for resolving the issue.

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#### C. 5.4: Initial Licensing [Current Section 5.10]

NEI has no specific comments on the discussion regarding initial licensing in current section 5.10, but we emphasize our agreement with the statement that “if the staff imposes any change in requirements or regulatory staff positions from the applicable version of the SRP, then the staff should follow the same reasoned decision-making process as a forward fit to justify the change.”

#### D. 5.5: Policy Statements [Current Section 5.14]

NEI agrees with the statement in Draft Rev. 1 that policy statements do not establish legally binding requirements. However, NEI believes that policy statements can have backfitting implications in two respects. First, if the 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. Second, NEI recommends that this discussion be expanded to cover the significance of policy statements with respect to establishing an applicable staff position. The issuance of a policy statement can clearly establish an applicable agency position that licensees should be able to rely upon for purposes of backfitting. NEI has proposed revisions to current section 5.14 to reflect these views.

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#### Recommended Changes to Section 5.4

We recommend that the following text be used to populate proposed section 5.4, and modify the text currently in subsection 5.14.

~~As compared to an NRC regulation, a~~ An NRC policy statement ~~does not~~ cannot establish a legally binding requirement. Thus, a policy statement, unlike an NRC regulation, is not directly enforceable. Any action to enforce the Commission’s interpretation or policy in a specific case must be done through a subsequent rule or order subject to the applicable backfitting regulations or forward fitting policy. However, a policy statement that represents a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position could have both backfitting or forward fitting implications. Therefore, proposed policy statements should be evaluated for any potential backfitting or forward fitting implications. In addition, policy statements could establish an applicable staff position for purposes of backfitting, and should be considered in any discussion of a licensee’s current licensing basis.

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### E. 5.6: Regulatory Analysis [Current Section 5.15]

NEI has no specific comments on the discussion of regulatory analyses in current section 5.15. However, we offer some additional language to clarify the distinction between regulatory analyses and backfitting analyses.

#### Recommended Changes to Section 5.5

We recommend that the following text be used to populate proposed section 5.5, and modify the text currently in section 5.15.

Regulatory analyses are different from backfit analyses and are required for almost all regulatory actions. A regulatory analysis measures all the benefits and costs of a proposed action. In contrast, ~~whereas~~ a backfit analysis considers only certain factors as discussed in Section 2.6 of this NUREG and includes an analysis of whether a particular proposed backfit would result in a substantial increase in the overall protection of the public health and safety or the common defense and security, and, if so, whether the direct and indirect costs of implementation for that facility are justified in view of this increased protection. The costs identified in the regulatory analyses can be used, therefore, in determining whether a backfit can be justified. Regulatory analyses help the staff provide adequate justification for the proposed action and document a clear explanation of why the staff recommends the proposed action. The staff provides instructions for performing regulatory analyses in NUREG/BR-0058.

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### F. 5.7: Clarifications [Current Section 5.2]

We agree with the description of clarifications provided in section 5.2 of Draft Rev. 1. Particularly, section 5.2 states:

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However, proposed clarifications have the potential to impose new or additional requirements or staff positions (*e.g.*, revoking previous staff positions); therefore, the staff should subject the proposed clarification to a backfitting assessment to verify that the clarification is not backfitting. If the original staff position allowed for multiple interpretations, and the staff is now trying to limit licensees to one interpretation, then that limitation would be a new staff position and, if imposed on a licensee, would require a backfitting or forward fitting justification.

This guidance is extremely important. Merely characterizing a staff position as a “clarification” does not answer, or even inform, the question of whether that position meets the definition of backfitting. In our view, when the NRC staff is developing a position that “clarifies” an existing position, it should always be evaluating that position against the definition of backfitting provided in the relevant regulations. As stated in section 5.2 of Draft Rev. 1, certain clarifications may not rise to the level of a new or changed requirement or a new or different staff position, thus not meeting the “causal element” of the definition of backfitting. That said, other staff actions characterized as mere “clarifications” may constitute new interpretations of existing requirements (*e.g.*, picking one of several possible interpretations as the only acceptable interpretation), or interpretations that are different from previously applicable staff positions. As stressed in our suggested changes to Chapter 2, application of the definition of backfitting is the determining factor when considering whether a specific proposed regulatory action triggers the requirements of the backfitting regulations. The broad category into which the proposed regulatory action falls—*e.g.*, a “clarification”—is not dispositive.

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**G. 5.8: Requested Licensing Actions [Current Section 5.16 – Recommend Deletion]**

NEI does not believe that a discussion of requested licensing activities is necessary in Chapter 5 since the subject is covered at length in Chapter 3, Forward Fitting. With respect to the discussion on license renewals, this should be moved to Chapter 3 in the context of forward fitting. That discussion should also ensure that the principles that apply to license renewal apply equally to subsequent license renewal. As such, NEI recommends that current section 5.16 be deleted from Chapter 5.

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