

**Report of the
Committee to Review Generic Requirements
on its Assessment of the
U.S. Nuclear Regulatory Commission's
Implementation of
Backfitting and Issue Finality
Requirements and Guidance**

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EXECUTIVE SUMMARY

Between June 2016 and June 2017, the U.S. Nuclear Regulatory Commission (NRC) Committee to Review Generic Requirements (CRGR, or the committee) assessed the agency's implementation of backfitting and issue finality requirements and guidance as directed by the NRC Executive Director for Operations (EDO). The CRGR comprehensively assessed the adequacy and effectiveness of the NRC's existing requirements and guidance, training, and knowledge management tools. The CRGR also applied lessons learned from the review of Exelon Corporation's appeal to the EDO of a compliance backfit of Byron Station, Units 1 and 2 (Byron) and Braidwood Station, Units 1 and 2 (Braidwood). Finally, the CRGR was mindful of new Commission direction to the staff about taking costs into consideration when assessing the compliance exception to the backfit rule and using the General Design Criteria to justify compliance exceptions to the backfit rule.

This report provides the committee's response to the EDO. It details the scope and methodology of the committee's assessment and documents the committee's findings, the corrective actions that are currently underway, and the committee's recommended actions.

External stakeholders representing industry told the CRGR that they are concerned about inappropriate use of the compliance exception by NRC staff to justify facility-specific backfits, as well as the potential for NRC inspection and oversight activities to result in inappropriate backfits. Except for the compliance backfit for Byron and Braidwood, which was overturned by the EDO on appeal, the CRGR did not identify any inappropriate backfits. However, based on industry feedback and the totality of its assessment, the committee concluded that opportunities exist to improve backfitting practices. The corrective actions that are currently underway and recommended will improve oversight by NRC senior managers and first-line supervisors; will enhance engagement and oversight by the CRGR; will improve staff knowledge, skills, and abilities associated with backfitting and generic requirements; and will result in more consistent identification and treatment of potential backfitting issues. The committee expects that broad communication of the new Commission direction, increased management involvement, and improved training and developmental activities will yield the greatest improvements in NRC staff performance and consistency.

The committee recommends three near term actions:

1. Make this report publicly available.
2. Issue interim guidance on the new Commission direction on backfitting to be used by the staff pending publication of the in-process updates of NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection," and NUREG-1409, "Backfitting Guidelines."
3. Require NRC managers and staff with backfitting and issue finality responsibilities to attend initial backfit "reset" training.

In the mid-term, the CRGR will update its charter to reflect fact of life changes, enhance the committee's role in certain backfitting activities, and add rigor to the committee's annual and periodic assessments of agency backfitting. The CRGR will continue to lead development of a comprehensive, role-based backfit training program. In the long-term, the CRGR recommended an effectiveness review of the corrective actions taken in response to this CRGR assessment as part of the CRGR's next periodic assessment of facility-specific and generic backfitting.

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1 INTRODUCTION

In June 2016, the U.S. Nuclear Regulatory Commission (NRC) Executive Director for Operations (EDO) tasked the NRC's Committee to Review Generic Requirements (CRGR, or the committee) with assessing the agency's implementation of backfitting and issue finality requirements and guidance as applied across agency programs, including the adequacy and effectiveness of existing NRC requirements, guidance, training, and knowledge management (KM).¹

Later, in December 2016, the EDO directed the CRGR to also consider agency actions and direction issued since the original tasking, such that the CRGR's assessment would comprehensively address all currently understood challenges and opportunities regarding backfitting and issue finality.² Two notable actions fell within the scope of the supplemental tasking:

1. The EDO's decision to reverse, under appeal from Exelon Corporation (Exelon), a compliance backfit of Byron Station, Units 1 and 2 (Byron) and Braidwood Station, Units 1 and 2 (Braidwood).³
2. Commission direction in SRM-COMSECY-2016-0020 that the staff be "familiar with and operate in a manner consistent with" an Office of the General Counsel (OGC) analysis about consideration of costs when considering exceptions to the backfit rule (Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.109, "Backfitting"), and the use of the compliance exception to mandate consistency with General Design Criteria (GDCs).⁴ This direction is summarized in a publicly available memorandum to the CRGR from the NRC Solicitor.⁵

In the supplemental tasking, the EDO also directed the CRGR to review its charter⁶ against the results of its assessment, and determine if any scope or process changes are warranted.

This report is the CRGR's response to the EDO's tasking. It documents the CRGR's assessment of the agency's implementation of backfitting and issue finality requirements and guidance as applied across agency programs, as well as the committee's findings, the corrective actions that are currently underway, and the committee's recommendations for further action.

¹ NRC 2016c (Appendix B provides a list of all references, with hyperlinks where available.)

² NRC 2016j

³ NRC 2016f

⁴ NRC 2016i

⁵ NRC 2016k

⁶ NRC 2011

2 SUMMARY OF KEY CRGR FINDINGS

For the reasons provided in Section 4 of this report, the CRGR reached the following key findings.

- The CRGR did not find many instances where licensees or NEI expressed backfitting concerns about generic issues that the staff handled through a formal agency process, such as rulemaking, or that were reviewed by the CRGR.
- Reactor licensees and NEI are concerned about inappropriate use of the compliance exception to justify facility-specific backfits, as well as the potential for NRC inspection and oversight activities to result in inappropriate backfits.
- Except for the compliance backfit for Byron and Braidwood, which was overturned on appeal, the CRGR did not identify any instance of inappropriate backfits. However, based on industry feedback and the totality of its experience and assessment, the committee concluded that opportunities exist to improve backfitting practices.
- In the near-term, the EDO should issue interim guidance on the new Commission direction on backfitting to be used by the staff pending publication of the in-process updates of Management Directive (MD) 8.4, "Management of Facility-Specific Backfitting and Information Collection,"⁷ and NUREG-1409, "Backfitting Guidelines."⁸ The staff should use this interim guidance for issues currently under review.
- In the near term, as an interim measure, pending completion of the recommended comprehensive training program, the EDO should require NRC managers and staff with backfitting and issue finality responsibilities to attend initial "reset" training on backfitting.
- Agency knowledge and performance can and should be improved through investments in updated and improved guidance, procedures and training, and new KM tools. Training should yield the greatest overall improvement.
- The CRGR charter should be revised to reflect organizational changes, to incorporate the new rulemaking review decision-making criteria, and to add enhancements that could strengthen and support CRGR activities and overall agency performance on future issues that involve both generic and facility-specific backfitting and issue finality issues.
- The corrective actions that are currently underway and recommended will improve oversight by NRC senior managers and first-line supervisors; will enhance engagement and oversight by CRGR; will improve staff knowledge, skills, and abilities associated with backfitting and generic requirements; and will result in more consistency in identifying and resolving potential backfitting issues.
- Of the in-process actions and recommendations, the committee expects that broad communication of the new Commission direction, increased management involvement, and improved training and developmental activities will yield the greatest improvements in performance and consistency.

⁷ NRC 2013b

⁸ NRC 1990

- An effectiveness review of the corrective actions taken in response to this assessment should be completed at the appropriate time.

3 BACKGROUND

3.1 Scope and Methodology of Current Review

Throughout the assessment documented in this report, the CRGR was guided by the NRC Principles of Good Regulation (independence, openness, efficiency, clarity, and reliability) and the Project Aim principle of seeking opportunities to increase agility, effectiveness, and efficiency.

The scope of the CRGR review included the agency's implementation of backfitting and issue finality requirements and guidance, for both facility-specific and generic issues, as applied across agency programs by the Office of the Executive Director for Operations (OEDO), and the offices with backfitting responsibilities. These are the Office of Nuclear Material Safety and Safeguards (NMSS), the Office of New Reactors (NRO), the Office of Nuclear Reactor Regulation (NRR), the Office of Nuclear Security and Incident Response (NSIR), OGC, the Office of Nuclear Regulatory Research (RES), and the four NRC regional offices. The review included the adequacy and effectiveness of existing NRC requirements, agency guidance, office implementing procedures; internal training for licensing, inspection, and legal managers and staff; and agency KM tools and activities. In addition, the CRGR assessed the facility-specific and generic lessons learned from the Exelon backfit appeal, as well as the recent Commission direction concerning consideration of cost and the applicability of the compliance exception to the backfit rule, to determine if either matter warranted any changes to agency backfitting or issue finality processes, guidance, procedures, or training. Finally, the CRGR reviewed its charter to determine if any scope or process changes are warranted.

The CRGR met with staff and managers of the offices with backfitting responsibilities and reviewed NRC requirements and guidance (e.g., qualification processes, office implementing procedures), training, and KM associated with backfitting and issue finality. The committee solicited external stakeholder perspectives and input at well-attended public meetings on September 13, 2016, and February 28, 2017.⁹ The committee also considered written comments and presentations provided by external stakeholders in support of these meetings,¹⁰ as well as four related letters from the Nuclear Energy Institute.¹¹

3.2 The Role of the CRGR

The CRGR's primary responsibilities are to recommend to the EDO either approval or disapproval of staff proposals that involve new or revised generic requirement or staff positions, and backfitting and issue finality. The CRGR reviews selected regulatory requirements, generic correspondence, regulatory guidance, and NRC staff guidance related to licensing, inspection, and enforcement that could impose a generic backfit. The committee also provides guidance and assistance to the offices with backfitting responsibilities to help them appropriately implement the backfit and issue finality requirements and guidance. The CRGR helps ensure that proposed generic backfits to be imposed on NRC-licensed power reactors, new reactors,

⁹ Meeting transcripts: NRC 2016e and NRC 2017a. Meeting summaries: NRC 2016h and 2017d. Summary of public feedback from meetings: NRC 2017e.

¹⁰ Duke 2016, Exelon 2016b, Miranda 2017, NEI 2016d, and UCS 2016

¹¹ NEI 2016a – 2016c and 2016e

and certain nuclear materials facilities are appropriately justified based on the backfit or issue finality provisions of the applicable NRC regulations, and the guidance contained in the Commission's backfit and issue finality policies.

The CRGR charter states that the “CRGR will not consider plant-specific regulatory actions.” For this reason, historically, CRGR involvement in facility-specific actions has been limited. However, to leverage their technical and backfitting expertise, individual CRGR members have been called upon to work on facility-specific backfitting issues. As an example, as suggested in MD 8.4, the EDO appointed a CRGR member to serve on the panel that reviewed Exelon’s appeal to the EDO of a compliance backfit of Byron and Braidwood. The CRGR discusses this backfit appeal and its relevance to its assessment, as documented in Section 3.4.4 of this report.

The key NRC guidance documents related to backfitting and issue finality are:

- MD 8.4,
- NUREG-1409,
- NUREG/BR-0058, “Regulatory Analysis Guidelines,”¹² and
- NUREG/BR-0184, “Regulatory Analysis Technical Evaluation Handbook.”¹³

The CRGR members are NRC senior executives at the deputy or associate office director or deputy regional administrator level, drawn from NMSS, NRO, NRR, NSIR, OGC, RES, and one of the four regional offices selected on a rotating basis (currently, Region II). The CRGR reports to the EDO, who appoints the chairman and members. The committee conducts its activities in accordance with Revision 8 of the CRGR charter, dated March 2011.¹⁴ RES provides technical and administrative support to the committee. A brief history of the CRGR is provided in the CRGR Charter, Appendix B, “Procedures to Control Proposed New or Revised Generic Requirements and Staff Positions,” Section A.

3.3 Backfitting and Issue Finality

The NRC originally promulgated the backfit rule in 1970, and revised it in 1985 and 1988.¹⁵ In its current form, the backfit rule defines backfitting for a nuclear power reactor as “the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission’s regulations that is either new or different from a previously applicable staff position.”

To implement backfitting requirements for selected materials licensees, the NRC subsequently revised 10 CFR Part 76 in 1994, 10 CFR Part 72 in 1999, and 10 CFR Part 70 in 2000. In August 2007, the NRC updated the issue finality requirements of 10 CFR Part 52 for new power

¹² NRC 2004

¹³ NRC 1997

¹⁴ NRC 2011

¹⁵ AEC 1970, NRC 1985, NRC 1988

reactor licensees, design certification applicants, and holders of related NRC approvals. For new reactors, the term “issue finality” is used rather than “backfit” or “backfitting.”

The following table summarizes the regulated entities that are subject to backfitting or issue finality and the specific regulations that apply to each entity.

Limited work authorizations – nuclear power reactors	10 CFR 50.10(f), 10 CFR 50.109
Construction permit holders – nuclear power reactors	10 CFR 50.109
Operating license holders – nuclear power reactors	10 CFR 50.109
Renewed operating license holders – nuclear power reactors	10 CFR 54.30 (limits scope of renewal review), 10 CFR 54.33, 10 CFR 50.109 See also 10 CFR 51.91(c) and 10 CFR Part 51, Appendix B for limited scope of environmental review at license renewal
Early site permit holders – nuclear power reactors	10 CFR 52.39 See also 10 CFR 51.50(c)(1)
Early site permit with limited work authorization authority	10 CFR 52.39 10 CFR 50.10(f) See also 10 CFR 51.50(c)(1)
Final design certification rules – nuclear power reactor	10 CFR 52.63 10 CFR 50.109
Individual design certification rule applicants* – nuclear power reactors ABWR System 80+ (Note: No longer in effect.) AP600 (Note: No longer in effect.) AP1000 ESBWR	10 CFR Part 52, Appendices A through E: Section VI. Issue Resolution Section VIII. Processes for Changes and Departures
* there are no “holders” of a design certification rule	
Combined license applicants referencing an early site permit or design certification rule – nuclear power reactors	10 CFR 52.83 10 CFR 50.109
Combined license holders – nuclear power reactors	10 CFR 52.98(a), (b) 10 CFR 50.109
Design approval holders – nuclear power reactors	10 CFR 52.145 10 CFR 50.109
Manufacturing license holders – nuclear power reactors	10 CFR 52.171 10 CFR 50.109
Non-power production and utilization facilities licensed under 10 CFR Part 50	No formal backfit protection, but “minimum regulation” standard in Atomic Energy Act applies for facilities licensed under Section 104 of the Act. (Note: The “minimum regulation” standard applies only to facilities licensed under Section 104 of the Act and not to non-power production and utilization facilities licensed under Section 103 of the Act.)
Fuel cycle facilities (authorized to possess critical amounts of special nuclear material)	10 CFR 70.76
Licensees who package, transport, or deliver to a common carrier for transport, radioactive material	10 CFR 71.65

Holders of both general and specific independent spent fuel storage installation licenses	10 CFR 72.62 (Note: A Certificate of Compliance holder does not have backfitting protection.)
Gaseous diffusion plants	10 CFR 76.76

Appendix A to this report provides additional detail about backfitting, including a history of the backfit rule and details on application of the compliance exception for power reactors.

3.4 Previous Backfitting Assessments

As discussed below, a number of assessments of both CRGR and staff activities associated with generic and facility-specific backfitting have been completed by CRGR and other entities over the years.

3.4.1 Annual CRGR Assessments

Since 1997, the CRGR has annually evaluated its activities and provided its results in an annual report to the Commission. The annual reports, which are required by the CRGR charter, summarize the backfit reviews that the committee performed during the assessment period and provide the results of the committee’s annual self-assessment. For its self-assessments, the committee solicits feedback from the offices with backfitting responsibilities that it had interacted with during the assessment period, and uses its own insights to assess its effectiveness in fulfilling the primary areas of responsibility associated with generic backfits, as specified in the CRGR charter, as well as its impact on staff activities.

As part of its response to the EDO’s tasking, the CRGR reviewed the self-assessments documented in its annual reports to the Commission from 2012 through 2016.¹⁶ Overall, the reports indicate that the CRGR performed its reviews and evaluations related to generic backfits in an efficient and effective manner, added value to the regulatory process, and contributed to staff and industry awareness of backfitting.

3.4.2 Periodic Assessments of Administrative Controls for Facility-Specific Backfits

MD 8.4 states that the CRGR will “periodically [conduct] audits, typically every 5 years, to assess the effectiveness of the NRC’s administrative controls for facility-specific backfitting as part of its regulatory effectiveness responsibility.” Including the CRGR assessment documented in this report, the committee has conducted four periodic assessments.

The CRGR conducted its first periodic assessment between August 2002 and August 2003. At the request of the EDO, the CRGR reviewed the agency’s backfitting processes to determine if the backfitting procedures used by the offices and regions were adequate, if the backfitting training was adequate, and if the applicable staff guidance was clear and comprehensive. The CRGR also addressed concerns raised by industry about the adequacy of NRC’s controls for the facility-specific backfit process, including appeals of imposed backfits. While the CRGR focused at that time on the facility-specific backfitting process, because of commonality, it also considered some aspects of the generic backfit process.

The EDO provided the results of this CRGR review to the Commissioners in September 2003.¹⁷ Based on this review, the CRGR found that the offices requiring backfitting controls had

¹⁶ NRC 2012, NRC 2013a, NRC 2014a, NRC 2015a, NRC 2016g

¹⁷ NRC 2003

procedures in place that were generally consistent with MD 8.4. However, the CRGR also had several findings:

- MD 8.4 did not reflect changes in organizational responsibilities, did not address important elements for ensuring effective management of backfits, and did not provide guidance on backfitting in the physical security or safeguards areas under 10 CFR Part 73.
- The decision process for facility-specific backfits was not clearly described in office procedures and was not readily available to licensees.
- The NRC backfit training program was not clearly defined.
- The RES functions associated with the regulatory analysis guidelines were not clearly established in the backfitting procedures.

The CRGR provided recommendations to address each of its findings, which resulted in corrective actions including guidance and procedure changes and agency-wide introduction to backfitting training.

The CRGR conducted its second periodic assessment of administrative controls for facility-specific backfitting between June 2007 and May 2008.¹⁸ The CRGR focused on efforts to develop the backfit training that the CRGR had recommended because of its previous periodic assessment. The CRGR noted that it was drafting web-based backfit training to be used agency-wide and summarized next steps. The CRGR conducted its third periodic assessment between June 2013 and May 2014, concluding that the offices with backfitting responsibilities had implementing procedures and some offices indicated that they had adequate training.¹⁹ The CRGR again summarized its efforts to develop a web-based training backfit training program for all staff. Later, in its annual report for the period of June 2015 through May 2016, the CRGR informed the Commission that it had completed the Web-based backfitting training and that the NRC Office of the Chief Human Capital Officer (OCHCO) had made the training available agency-wide in September 2015.²⁰

This report documents the results of the CRGR's fourth periodic assessment. Unlike CRGR's previous assessments, which addressed facility-specific backfitting, as directed by the EDO, this fourth assessment considers both facility-specific and generic backfitting. The CRGR believes this current effort constitutes the most comprehensive agency assessment of backfitting to date. As documented in Section 4 of this report, the CRGR found gaps and is either leading corrective actions or making recommendations for action by other organizations.

3.4.3 Office of Inspector General Audit of the CRGR

In response to NRC Commission interest, between May 2008 and August 2008, the NRC's Office of the Inspector General (OIG) audited the CRGR. The audit objectives were to determine if the CRGR added value for EDO decision-making and whether the committee's function was still needed.

¹⁸ NRC 2009b

¹⁹ NRC 2014a

²⁰ NRC 2016g

In a February 2009 report, the OIG recommended that the NRC improve its process for reviewing backfit issues and clarify the role of the CRGR.²¹ The committee's action plan²² for resolving the OIG recommendations included implementing an overarching agency backfit program by updating the CRGR charter and MD 8.4, updating the office implementing procedures for backfitting, and completing the agency-wide backfit training program discussed in Section 3.4.2 of this report.

In response to the OIG audit, the EDO revised the CRGR charter, the staff revised MD 8.4, and the offices with backfitting responsibilities updated their implementing procedures, as appropriate, to address the revised MD 8.4. Specific to the training program, as summarized in Section 3.4.2 of this report, the CRGR, working with OGC and OCHCO, developed Web-based introductory backfitting and issue finality training for all staff. OCHCO made the training available agency-wide in September 2015. The training covers the backfitting and issue finality processes, including the basics of the applicable regulatory requirements and guidance.²³

3.4.4 Exelon (Byron and Braidwood) Backfit Appeal Review Panel Insights

In June 2016, Exelon appealed to the EDO the staff's determination that a backfit was necessary at Byron and Braidwood, as well as the staff's application of the compliance backfit exception provided in 10 CFR 50.109.²⁴ Based on its review of the appeal, the backfit appeal review panel chartered by the EDO concluded that the positions the staff used to support its compliance backfit finding represented new and different staff views and did not provide a basis for a compliance backfit.²⁵ Furthermore, the panel concluded that its findings supported Exelon's backfit appeal and recommended, therefore, that the EDO reverse the staff's imposition of a backfit. In September 2016, the EDO reversed the compliance backfit of Byron and Braidwood imposed by the staff.²⁶

The panel's review was not in and of itself a review of agency backfitting process and practices. Nevertheless, by its nature it presented a unique opportunity for the panel to conduct an in-depth historical review of a facility-specific licensing basis issue while at the same time observing, almost in real time, how the staff approached the issue while applying its knowledge of backfitting. Thus, the panel gleaned first-hand insights into the difficulties associated with in-depth technical and regulatory reviews of facility-specific licensing bases and associated staff positions, as well as a staff application of the compliance exception to the backfit rule, and the staff's overall knowledge of and experience with the backfit rule and backfitting.

Based on its review of the panel's report and discussions with panel members, the CRGR considered insights regarding the generic issue process, the potential for facility-specific issues to have generic applicability, the level of review and documentation needed to justify staff positions associated with backfits, and the generic issues processes, the justification for and documentation of facility-specific backfits that are based on the compliance exception, CRGR involvement in facility backfitting issues, and staff training on backfitting and issue finality. The

²¹ NRC 2009a

²² NRC 2010a

²³ Current agency backfit training predates SRM-COMSECY-16-0020, and will be updated as described in Section 4.3 of this report.

²⁴ Exelon 2016a

²⁵ NRC 2016d

²⁶ NRC 2016f

CRGR's assessment and planned actions associated with the insights from the panel are provided in Section 4.1 of this report.

4 DISCUSSION

4.1 Requirements, Guidance, and Criteria

CRGR FINDINGS:

- MD 8.4 should be updated to be inclusive of all types of backfitting.
- Interrelated backfitting guidance documents such as NUREG-1409, NUREG/BR-0058, and NUREG/BR-0184 should be better aligned.
- Consistency and standardization of office-level guidance should be improved.
- Lessons learned from the Byron and Braidwood backfit appeal and the new Commission direction regarding the compliance exception to the backfit rule need to be incorporated into NRC's guidance documents and implementing procedures.

CRGR-LED ACTIONS:

- Update MD 8.4, NUREG-1409, NUREG/BR-0058 (with Commission approval)
- Update office-level implementing guidance.

CRGR RECOMMENDATIONS:

- Review and update the NRC Enforcement Manual to ensure that it includes guidance for addressing potential backfitting issues and how to address those issues that do not warrant imposition of a backfit.
- Evaluate whether additional processes used by the staff and industry (e.g., frequently asked questions) should receive more formal backfit reviews.

4.1.1 Review Activities and Results

The EDO's June 2016 tasking asked the CRGR to consider the following questions regarding existing NRC requirements, guidance, criteria, and procedures for backfitting:

- Are the guidance, procedures, and responsibilities still effective, clear, and current?
- Should there be separate sets of guidance for generic versus facility-specific backfits?
- How consistently are they being implemented across the agency?
- Based on the review of NUREG-1409 and MD 8.4, are the office implementing procedures adequate, needed, and consistent with agency-wide guidance?
- Are our backfit assessments providing the appropriate level of rigor and the appropriate clarity and consistency as defined in the Principles of Good Regulation?

The CRGR surveyed the offices with backfitting responsibilities for feedback on office- and region-specific procedures and the agency-level guidance documents on backfitting. The agency-level documents reviewed for this effort were MD 8.4, NUREG-1409, NUREG/BR-0058, and NUREG/BR-0184.

The review of NRC's guidance documents was initially undertaken prior to the Byron and Braidwood backfit appeal. The assessment that follows also considers both the EDO's decision regarding the Byron and Braidwood backfit appeal,²⁷ and the Commission's subsequent decisions regarding application of the compliance exception to the backfit rule and the appropriate consideration of the GDCs in assessment of potential backfit.²⁸

At the time of the NRC review of the Byron and Braidwood backfit appeal, the Nuclear Energy Institute (NEI) provided its views regarding imposition of a compliance backfit.²⁹ The letter included the following "proposed solution":

To ensure proper application of the compliance exception, every documented evaluation prepared to justify the use of the compliance exception must—at a minimum—provide a clear and thorough description of:

1. The "known and established standards" at issue;
2. The prior NRC staff approval(s) of the licensee's method of compliance with such "known and established standards;"
3. The specific omission or mistake of fact that undermines the prior NRC staff approval(s);³⁰
4. An evaluation explaining that, but-for the identified omission or mistake of fact, the NRC staff would not have issued the prior approval; and
5. A description of how the NRC has interpreted the "known and established standards" at issue (with respect to the specific licensee in the case of a facility-specific backfit, or generically in the case of a generic backfit)."

The NRR response to NEI referenced the agency's response on the Byron and Braidwood matter and stated that the points raised by NEI had been considered in the agency's response to the licensee.³¹ As noted above, the decision on Exelon's appeal to the EDO re-evaluated the staff's application of the compliance backfit and reversed the backfit. Additional direction on application of the compliance backfit was subsequently provided by the Commission in SRM-COMSECY-16-0020, as described in Section 4.2 of this report.

During the CRGR's public meeting on September 13, 2016, representatives from NEI, NRC licensees, State government, and non-governmental organizations raised a variety of comments and questions that pertain to the agency procedures and guidance. The CRGR concluded that

²⁷ NRC 2016f

²⁸ NRC 2016i, based on OGC recommendations summarized in NRC 2016k

²⁹ NEI 2016a

³⁰ *Note 22 from NEI's letter: NEI provided a detailed description of how the terms "mistake of fact" and "omission" should be interpreted when invoking the compliance exception.* [Reference included in this report as NEI 2015.]

³¹ NRC 2016a

the staff should consider the input captured in the meeting summary during its efforts to improve the agency's backfitting process and guidance documents. The CRGR members identified common recommendations in their review of the external stakeholder comments and suggestions:

- Unify guidance for facility-specific backfits and generic backfits.
- Engage industry early on inspection issues before entering the backfit process.
- Improve the transparency and predictability of the backfit process.
- Make backfit training materials publicly available.
- Ensure facility-specific backfits are not generic issues.
- Consider management panels or automatic CRGR reviews for facility-specific backfit appeals.
- Allow licensees to provide formal input on facility-specific or generic backfits.
- Allow stakeholder participation, including State or local community representatives.
- Compile and use examples of appropriate and inappropriate backfits to illustrate guidance for clarity and consistency.
- Conduct a CRGR spot-check of facility-specific backfits.

In its review and consideration of the Exelon backfit appeal review panel's report and discussions with a panel member, the CRGR also noted harmony with the external stakeholder comments. The panel's insights included:

- Engage industry early on inspection issues before entering the backfit process.
- Unify guidance for facility-specific backfits and generic backfits.

In assessing the adequacy of existing NRC requirements, guidance, criteria, and procedures, the CRGR identified that, in general, these documents are still effective and clear for the topics they cover. However, the documents could be improved by including more up-to-date information. As examples, MD 8.4 provides NRC policy for facility-specific backfitting, but no NRC policy document exists for generic requirements or backfitting. MD 8.4 should be updated to be inclusive of any type of backfitting. Moreover, improved alignment between the various interrelated backfitting guidance documents, such as NUREG-1409, NUREG/BR-0058, and NUREG/BR-0184 is needed.

Regarding the implementing procedures for the offices with backfitting responsibilities, the CRGR found that those offices responsible for implementing backfitting controls have applicable procedures and that these procedures are generally consistent with the existing agency guidance and MD 8.4. However, some offices told the CRGR that guidance for non-rulemaking backfit assessments should be clarified, and the consistency of the implementing procedures across the agency could also be improved. The CRGR noted that the consistency of the guidance across offices could also be better, as well as the alignment of the procedures with MD 8.4. A more standardized approach and procedure for the four NRC regional offices would

also help bring consistency to the application of the NRC backfitting requirements and guidance during oversight activities. Moreover, the implementing procedures do not sufficiently discuss backfitting for non-rulemaking activities that involve materials licensees.

The CRGR found that the lessons learned from the Byron and Braidwood backfit appeal and the new Commission direction regarding the compliance exception to the backfit rule should also be incorporated into the appropriate guidance documents and implementing procedures. Enhanced guidance in these areas will support rigorous staff reviews and appropriate application of the compliance exception.

In reviewing the input from the offices with backfitting responsibilities and from external stakeholders, the CRGR identified areas where enhancements to NRC's guidance documents and implementing procedures should be made during the current round of document updates. The specific enhancements, in addition to those noted above, should:

1. Streamline the guidance and remove redundant or unnecessary material.
2. Include guidance for both generic and facility-specific backfitting in MD 8.4.
3. Clarify roles, responsibilities, and processes, including the CRGR, for handling backfitting issues.
4. Improve the openness and transparency of agency backfitting processes and reviews, including appropriate opportunities for external stakeholder feedback.
5. Address NEI's proposal that NRC staff evaluations prepared to justify invocation of the compliance exception should provide a clear and thorough description of each of the following criteria:
 - a. The "known and established standards" at issue.
 - b. The prior NRC staff approval(s) of the licensee's method of compliance with such "known and established standards."
 - c. The specific omission or mistake of fact that undermines the prior NRC staff approval(s).
 - d. An evaluation explaining that, but for the identified omission or mistake of fact, the NRC staff would not have issued the prior approval.
 - e. A clear description of how the NRC has interpreted the "known and established standards" at issue, with technical and regulatory bases.
6. Require a test of all potential or proposed facility-specific backfits for generic applicability, including those revealed through TIAs (and similar processes), inspections, and enforcement actions. If there is generic applicability, require application of the appropriate generic process.
7. Identify the specific regulatory requirements for backfitting and issue finality for each type of regulated entity as shown in Section 3.3 of this report.
8. Describe the applicability of the backfit rule to research and test (nonpower) reactors.

9. Describe the applicability of the backfit rule to such NRC interpretive guidance as regulatory guides.³²
10. Develop new guidance for the appropriate guidance documents and implementing procedures to address situations in which the staff, in implementing the Commission direction in SRM-COMSECY-16-0020, decides not to pursue a potential compliance issue through a backfit (e.g., because the costs are not justified).
11. Consider requiring a lessons-learned or root-cause evaluation, with an appropriate feedback loop, for any future inadvertent or inappropriate backfits.

4.1.2 Actions and Recommendations

The staff is currently revising MD 8.4, NUREG-1409, and NUREG/BR-0058 to bring them up to date and ensure consistent application of the backfitting rules and updated backfitting policy and practices. The staff will also develop and incorporate new guidance to implement the new Commission direction in SRM-COMSECY-16-0020, as described in Section 4.2 of this report. At a high level, this new guidance will address the need for the staff to first consider adequate protection as a threshold matter, as well as the need for the staff to apply some level of cost consideration when using the compliance exception. The new guidance will also clarify the scope of the compliance exception, and clarify the use of the GDC as bases for using the compliance exception. The staff is following the following framework and principles to complete the in-process updates to these agency guidance documents:

- Up-to-date agency backfitting policy and guidance for both generic and facility-specific backfits will be documented in the revised MD 8.4.
- Up-to-date agency implementing guidance will be included in the revised NUREG-1409.
- The revisions to both MD 8.4 and NUREG-1409 will refer users to up-to-date cost guidance in the revision to NUREG/BR-0058.
- The office implementing procedures will be revised to reflect the new and updated guidance in the revised agency guidance documents.
- The offices with backfitting responsibilities will work together to develop office implementing procedures that are consistent and standardized to the extent practicable.
- The CRGR will review and approve all revised guidance and procedures associated with facility specific and generic backfitting before they are published and implemented. The staff shall coordinate the review required by the CRGR with the CRGR staff in advance and allow enough time for either an informal or formal review at the CRGR's discretion.

4.1.2.1 MD 8.4 Update

The staff is currently working on a revision to MD 8.4 and has sought CRGR comments on early draft revisions. Once a draft revision of MD 8.4 is developed that incorporates the changes described in this report, the staff plans to solicit internal stakeholder feedback through additional CRGR review and inter-office review and concurrence, following agency procedures for

³² NRC 2010b

updating management directives. The staff will also coordinate the review required by the CRGR with the CRGR staff in advance and will allow enough time for either an informal or formal review at the CRGR's discretion.

The staff is currently committed to "provide the revised guidance concerning application of the backfit rule to the Commission for approval," consistent with SRM-COMSECY-16-0020, in April 2018.

4.1.2.2 NUREG-1409 Update

The staff is currently working on an update to NUREG-1409 and has sought CRGR comments on early draft revisions. Once a draft revision of NUREG-1409 is developed that incorporates the changes described in this report, the staff will solicit internal stakeholder feedback through additional CRGR review and inter-office review and concurrence. The staff will also solicit external feedback by publishing the draft revision to NUREG-1409 in the *Federal Register* for public comment. If necessary, the staff will hold public meetings to address external feedback. The staff will finalize the updated NUREG report in accordance with its procedures for NUREG revisions. The staff will also coordinate the review required by the CRGR with the CRGR staff in advance and will allow enough time for either an informal or formal review at the CRGR's discretion.

The staff is currently committed to "provide the revised guidance concerning application of the backfit rule to the Commission for approval," consistent with SRM-COMSECY-16-0020, in April 2018.

The staff will reflect the appropriate changes to NUREG-1409 in MD 8.4 and the office implementing procedures.

4.1.2.3 NUREG/BR-0058 Update

The staff is currently updating NUREG/BR-0058 using the two-phased approach described in SECY-17-0035.³³ Under Phase 1, the staff will focus on the use of qualitative factors, will restructure the guidance to consolidate the agency's cost benefit guidance (primarily NUREG/BR-0058 and NUREG/BR-0184), and will incorporate improved cost estimating methods. The staff published the Phase 1 revision to NUREG/BR-0058 for public comment in April 2017. The staff plans to provide the completed Phase 1 guidance to the Commission for approval in January 2018. Under Phase 2, the staff will develop and incorporate new guidance to implement the new Commission direction in SRM-COMSECY-16-0020, as described above and in Section 4.2 of this report, as well as the CRGR findings and recommendations documented in this report. The staff will coordinate the review of the Phase 1 and Phase 2 reports required by the CRGR with the CRGR staff in advance and will allow enough time for either informal or formal reviews at the CRGR's discretion.

4.1.2.4 Office Implementing Procedure Updates

After it has dispositioned the internal and external stakeholder feedback on MD 8.4, NUREG-1409, and NUREG/BR-0058, including the CRGR feedback and recommendations in this report, the staff will work with the offices with backfitting responsibilities to revise their implementing procedures to address the new and updated guidance in the revisions to MD 8.4

³³ NRC 2017b

and NUREG-1409. The revised implementing procedures will not be implemented until after the Commission approves the revisions to MD 8.4 and NUREG-1409. The CRGR will review and approve the revised procedures before they are published and implemented. The staff shall coordinate the CRGR review with the CRGR technical assistant and allow appropriate time for the CRGR review.

OGC has developed three templates to provide uniformity and structure in preparing documented evaluations for the adequate protection or compliance exceptions, as well as backfit analyses.

4.1.2.5 Additional Recommendations

The CRGR recommends that the NRC Enforcement Manual³⁴ be reviewed and updated to ensure that it includes guidance for addressing potential backfitting issues and how to address those issues that do not warrant imposition of a backfit.

The CRGR also recommends that offices evaluate whether additional processes used by the staff and industry (e.g., frequently asked questions) should receive more formal backfit reviews.

4.2 New Commission Policy Direction

CRGR FINDINGS:

- Adherence to the new Commission policy direction in SRM-COMSECY-16-0020 will provide greater discipline in the staff's exercise of the compliance exception.
- Implementing the new Commission direction with updated guidance and training will also add clarity and consistency to the backfitting process.

CRGR-LED ACTIONS:

- Issue guidance to the staff, e.g., through a Yellow Announcement, to highlight the policy changes reflected in SRM-COMSECY-16-0020 as an interim step before MD 8.4 is updated.

4.2.1 Review Activities and Results

During the summer of 2016, and informed by the EDO's tasking to the CRGR, OGC undertook a review for the Commission concerning the proper application of the compliance exception to backfitting. OGC reexamined the extent to which costs are appropriately considered when the agency imposes a requirement on a licensee that implicates the backfit rule. Included in this reexamination was a review of the application and legal precedent from a Supreme Court case in *Michigan vs. EPA*³⁵ that indicated that an agency's decision-making calculus should include at least some consideration of the cost placed on a licensee to comply with a new regulation.

This examination led OGC to recommend to the Commission that existing guidance concerning consideration of costs and the use of the compliance exception to backfitting be revised. In

³⁴ NRC 2017c

³⁵ https://www.supremecourt.gov/opinions/14pdf/14-46_10n2.pdf

SRM-COMSECY-16-0020,³⁶ the Commission directed the staff to be familiar with and operate in a manner consistent with OGC's conclusion. The Commission also directed the staff to maintain consistency with OGC's analysis in completing the EDO's tasking to the CRGR.

The OGC recommendation to the Commission, summarized in a memorandum to the CRGR,³⁷ focused on two key points associated with the exceptions to the backfit analysis requirements under the backfit rule:

1. When staff has reached a new or changed position with respect to whether a particular requirement has been satisfied, the staff should first consider, as a threshold matter, whether regulatory action is required to achieve adequate protection. The compliance exception should be pursued only in those circumstances where the requirement that the staff seeks to impose exceeds the level necessary to achieve adequate protection.
2. Before the staff invokes the compliance exception to the backfit rule, it must give some consideration to cost.

With respect to the threshold matter that a new requirement or changed staff position is necessary to ensure adequate protection, no further justification is necessary and such a requirement is imposed without consideration of cost (although cost may be considered in selecting among different ways of achieving adequate protection). The Commission direction reflects a clear expectation that the staff first consider whether the requirement involves adequate protection to support the imposition of a particular backfitting.

For purposes of cost consideration associated with the compliance exception, the staff need not develop the robust analysis required by 10 CFR 50.109(a)(3), nor establish that there is a substantial increase in public health and safety or the common defense and security to be derived in imposing the backfit. In some cases, a simple cost estimate associated with imposing the backfit will be deemed as all that is necessary for application of the compliance exception. However, the extent of cost consideration analysis required will evolve and will be dependent by fact-specific information such as the lapse of time from approval of the licensing basis to the new or different staff position imposing a requirement.

In addition, the memorandum to the CRGR went on to further clarify what was meant by the statement of considerations³⁸ that had accompanied the revised backfit rule regarding "omission or mistake of fact" and the use of the compliance exception to mandate consistency with the GDCs. Omission or mistake of fact is demonstrated from the vantage point of the staff's determination under the then-existing methodologies and prevalent understanding at the time of such determination and not from a retrospective assessment based on new technologies or methodologies.

With regard to GDCs, the memorandum to the CRGR noted that the review and approval process associated with the principal design criteria (PDCs) for a specific facility reflect the agency's conclusion that the approved PDCs meet or exceed the minimum requirements set forth in the GDCs. Therefore, the PDCs incorporation by reference into the construction permit typically yield specific requirements than the generic objectives of a GDC. In short, rather than reliance on a GDC, the staff should typically seek support in the regulatory requirements, the

³⁶ NRC 2016i

³⁷ NRC 2016k

³⁸ NRC 1985, at 38103

technical specifications, the PDCs and other requirements derived from the PDCs for a specific facility in invoking the compliance exception to backfitting. However, in cases where the PDCs, technical specifications and other license requirements derived from the PDCs do not address the specific technical issue in question, the staff are not precluded from reliance on the prescriptive terms of a GDC.

With respect to the new Commission policy reflected in SRM-COMSECY-16-0020, the Commission's direction for potential exercise of the compliance exception provides significant clarification in line with the expectations established for the backfit rule (10 CFR 50.109). The CRGR expects that adherence to the Commission's policy direction will provide greater discipline in the staff's exercise of the compliance exception.

The overall effect of the new Commission direction to the staff is to ensure that the staff's use of the compliance exception is linked to regulatory and licensing basis requirements and known standards, and that there is a careful review that includes consideration of cost before invocation of the compliance exception to backfitting. Based on its considerations, the CRGR concluded that implementing this Commission direction, updating the appropriate guidance documents to reflect the new direction, and training the staff on how to use the new direction, will add clarity and consistency to the backfitting process.

4.2.2 Actions and Recommendations

The CRGR members have engaged colleagues in their offices to raise awareness of the new Commission direction associated with the staff's use of the compliance exception. In addition, as detailed in Sections 4.1, 4.3, and 4.4 of this report, the staff is currently updating the guidance in MD 8.4 and NUREG-1409, its training, and KM tools to address the new Commission direction. Finally, in the near term, the staff will prepare interim guidance on the new Commission direction on backfitting to be used by the staff pending publication of the updated guidance documents. After the CRGR approves the interim guidance, the EDO will issue it (likely as an agency Yellow Announcement) for staff use.

4.3 Training

CRGR FINDINGS:

- Current training on backfitting is limited in scope, process-focused, and inconsistent across offices and roles.
- Refresher training and staff developmental activities are not consistently provided.
- Updated training and staff development are needed to help staff recognize potential backfit situations and understand the resources that are available and the actions needed to address these situations.
- Case studies and real-world examples would support staff training and development.
- "Just-in-time" training and references are needed to help staff in various roles (e.g., inspection, licensing, and enforcement) address potential backfit situations.

CRGR-LED ACTIONS:

- Develop interim training as a backfitting “reset” for managers and staff.
- Update initial training for use in various agency qualification programs.
- Develop or update refresher training and staff developmental activities for staff in various roles.

CRGR RECOMMENDATIONS:

- Revise office procedures (e.g., qualification manuals) to require both initial and refresher training and periodic staff developmental activities.
- Provide refresher training and periodic developmental activities.
- Provide “just-in-time training and references to help identify and resolve potential backfitting issues.
- Offices should consider using workshops to support staff training, staff development, and information exchanges on backfitting.

4.3.1 Review Activities and Results

The EDO’s June 2016 tasking asked the CRGR to consider the following questions regarding the training and development that NRC staff receive on backfitting:

- Does training currently exist related to the backfit rule, guidance, and procedures, and is it required as part of any formal qualification programs?
- If training is available, is it sufficient for staff members to acquire the skills and competencies required to implement NRC’s backfitting requirements?
- Are all the appropriate staff taking the available training?

Planned revisions to the backfitting processes described in Sections 4.1 and 4.2 of this report will necessitate training of NRC managers and staff. In addition, consistent with the EDO’s tasking, the CRGR sought internal and external stakeholder feedback and assessed other implications of training related to backfitting and generic requirements including initial qualification requirements; overall scope of the existing training program including refresher training and periodic developmental activities; applicability to specific employee roles and duties, and consistency.

As discussed elsewhere in this report, the CRGR began its assessment of agency backfitting processes and of the associated staff training by obtaining staff and external stakeholder input as well as reviewing currently available training. The CRGR solicited input from the offices with backfitting responsibilities and generic requirements. The insights and perspectives provided to the CRGR indicated that there is a need for new and improved guidance, training, and developmental activities on backfitting and generic requirements that is focused on individual roles, including those of inspectors, technical reviewers, licensing staff, enforcement specialists, and legal counsel.

Industry representatives from NEI and licensees (almost all associated with the commercial power reactors) provided general and some specific feedback regarding the agency's implementation of backfitting processes. Input pertinent to training was received via written comments as well as during discussions at the CRGR's public meetings related to the EDO tasking. Industry officials described instances in which inspections and related activities resulted in what they viewed as backfits or attempted backfits, without going through the backfit process. Examples included issues handled by the staff through such generic communications as Regulatory Information Summaries, various frequently asked questions processes, and violations citing noncompliances with certain GDCs. As noted in Section 4.1.2.5 of this report, the CRGR recommends that these processes be reviewed to determine whether a more formal backfit review is warranted.

A common perception was that NRC inspectors and, in some cases, other agency staff such as license reviewers sometimes attempt to apply current standards at older plants during inspections and licensing reviews. It was noted that both the licensees and the staff have dedicated significant time and resources to understanding and interpreting the licensing bases, and that "new" or "different" interpretations continue to arise, some of which are problematic with respect to backfitting implications for the affected licensees. The industry officials indicated that some of the cases involving perceived inappropriate backfitting or backfit attempts involved an overemphasis on compliance that distracted from a focus on safety. Industry officials also indicated that these issues of low safety significance could have been handled more efficiently and effectively. Industry officials also indicated that they sometimes acquiesced on controversial issues to avoid confrontation with inspectors or reviewers.

One industry representative informed the CRGR of his perception that the staff sometimes attempted to impose backfits through the NRC's task interface agreement (TIA) process without following the backfit rule. While not yet a final agency decision, discussions regarding the cable separation concern at Oconee was given as an example. Another industry representative indicated that inspection issues that the staff appropriately identified and handled as potential backfits through the TIA process were not usually viewed as being as problematic (from a backfitting standpoint) as those issues that were handled solely through inspection and enforcement. Examples of issues handled through TIAs that were mentioned at the public meetings included under voltage and degraded voltage design issues at several nuclear power plants and the Palisades fast transformer scheme issue.

Industry representatives also identified several examples of potentially mishandled backfits, in addition to the Exelon appeal described in Section 3.4.4 of this report. These examples included:

- requirements for operations that could potentially drain the reactor vessel
- the appropriate credit for incipient fire detection capability for fire risk assessments performed as the bases for National Fire Protection Association 805 applications
- resolution of electrical issues at Perry Nuclear Power Plant
- resolution of open phase condition (NRC Bulletin 2012-01)
- violations associated with service life of components

The CRGR did not conduct a detailed evaluation of these topics to determine whether they were handled appropriately, but expects that the corrective actions described in this report will improve the handling of potential backfits in the future.

Some stakeholders also informed the CRGR that it should also be concerned about safety issues that should be corrected by using the backfitting process, but are not pursued because backfitting is perceived as too time-consuming and complex. Although specific examples were not offered, the CRGR agrees that safety issues should be resolved using appropriate regulatory processes, including the backfitting process. The CRGR expects that the corrective actions described in this report will support this outcome.

From this internal and external stakeholder input, the CRGR concluded that industry stakeholders are most concerned about inappropriate use of the compliance exception to justify facility-specific backfits, as well as the potential for NRC inspection and oversight activities to result in inappropriate backfits. The CRGR also concluded that there is a need for updated training and complementary periodic developmental activities to clearly convey to inspectors and other staff enough about the backfit rule and processes to recognize when they become involved in a potential backfit situation, what resources are available to them, and what subsequent actions they should take when they find themselves in those circumstances. While the CRGR believes the concerns raised by industry stakeholders are likely caused by some combination of factors involving guidance, training, and KM, the CRGR believes the overriding factor is weaknesses in training and development, and that improved training and development for managers and staff alike will yield the biggest performance improvements. Training on backfit requirements and processes is required as a part of the qualification programs for some technical reviewers, inspectors, and other staff involved in rulemaking. However, the training that is currently required under these programs is generally limited in scope (notably for reactor inspectors), is focused on the backfitting processes themselves, and warrants updating.

The backfit training that is currently available to all staff in iLearn provides a general, high-level understanding of backfitting concepts. The CRGR concluded that more emphasis should be placed on initial training as an important component of initial inspector and reviewer qualifications. The CRGR noted that staff who are involved in rulemaking have access to and usually complete more detailed training in backfitting processes than technical staff who are more involved in inspection and licensing reviews. Based on its review, the CRGR concluded that there is a need for some NRC staff—especially inspectors and technical reviewers—to have more enhanced and in-depth training.

The CRGR also found that some important concepts, such as recognition of potential backfit scenarios by inspectors and reviewers, and the need to fully understand the specific current licensing basis, are not adequately addressed in the currently available training. Future training, qualification, and developmental activities should include specific case studies from the offices with backfitting responsibilities to inform inspectors and reviewers more effectively about backfitting and generic requirements.

The CRGR also concluded that backfitting should be handled consistently across the offices with backfitting responsibilities, especially for staff with identical roles and responsibilities (e.g., all reactor operations inspectors in all the regions should receive training based on common reference guidelines, and license reviewers should receive consistent training across the offices and divisions with licensing responsibilities). The training should also reflect the updated office implementing procedures discussed in Sections 4.1 and 4.2 of this report.

The CRGR learned that refresher training and periodic developmental activities on backfitting and generic requirements are not uniformly required or available. As an example, the current training for qualifying reactor technical reviewers is intended to be taken as a refresher by qualified reviewers at least every six years. This training includes a module on licensing and design basis and two modules that include information on backfitting; however, it should be updated to incorporate recent decisions and activities described in this report. Other staff, such as project managers and inspectors, receive less formal training and development on these topics after they are initially qualified.

Based on its review of refresher training and developmental activities, the CRGR concluded that concise periodic refresher training, focused on recent activities related to the topic (e.g., case studies and examples), should be developed and given. This training should be consistent across the offices with backfitting responsibilities, but should also emphasize and address differences in the responsibilities of specific staff roles. In other words, refresher training and developmental activities for legal counsel would probably differ in some respects from those for reactor inspectors.

The CRGR also found that there are not easily referenced materials for inspectors and other technical staff to use when they encounter potential backfit scenarios. Related to the KM activities described in Section 4.4 of this report, the availability of reference materials and “just-in-time” training through a quick reference webpage or site, with links to the guidance documents, procedures, and other relevant references, would improve staff performance on backfitting, issue finality and generic requirements. During one of the CRGR’s public meetings, the Union of Concerned Scientists recommended that the staff develop and publish a compilation of examples of facility-specific and generic backfitting issues. Such a digest could be similar to the NRC’s guidelines for event reporting.³⁹ The CRGR agrees that such a reference could be a valuable resource for training, development, knowledge management, and for resolving future backfitting issues.

Consideration also should be given to expanding the role of the office level points-of-contact referenced in MD 8.4 to be more like a subject matter expert on the backfitting process, which would be more involved in KM and employed like the NRC’s notice of enforcement discretion (NOED) process expert. The concept is discussed further in Section 4.4.2.2 of this report.

4.3.2 Actions and Recommendations

4.3.2.1 Formal Training

Several activities to develop formal training are already underway:

- In coordination with the guidance updates described above, NRR and OGC staff have drafted presentations on backfitting that can be completed and used for initial backfit “reset” training for NRC senior managers, first-line supervisors, and staff in various roles with backfitting responsibilities or who can become involved in resolving backfitting issues (e.g., enforcement staff). The CRGR has also had preliminary interactions with OCHCO regarding the feedback it received about training and qualifications, as well as the development of new and updated training and developmental activities as described above.

³⁹ NRC 2014b

- OGC is updating its formal training modules on backfitting and issue finality that are used to train staff involved in rulemaking. OGC's first revision to the "Advanced Backfitting and Issue Finality" module reflects the Commission direction in COMSECY-16-0020. OGC is also preparing a training module to provide in-depth information about the adequate protection exceptions and the compliance exception. OGC will present this training to NRC staff for the first time at the Fall 2017 session of the NRC-wide rulemaking training.
- OGC is also updating its internal training for legal staff on backfitting and issue finality to reflect the new Commission direction. OGC will present this training in the fall/winter of 2017-2018.

The CRGR expects the updated training to include:

- Clear explanations of backfitting concepts, including such recent changes as the Commission direction in SRM-COMSECY-16-0020.
- Clear explanations of licensing bases and design bases, their importance, and how they are used.
- Clear explanations of generic requirements and staff positions, including differences between a clarification and a change in a staff position, appropriate processes to adopt or change a staff position, and appropriate levels of review and approval.
- Clarification of the responsibilities of NRC staff in specific roles (e.g., inspectors, reviewers, and lawyers) as they relate to backfitting.
- Case studies and examples that contain scenarios in which potential backfit conditions need to be recognized and that convey how to deal with those circumstances both internally and externally.

In the near term, the CRGR will oversee completion, and will review and approve the initial "reset" training for NRC executives, branch chiefs, and staff (for use until the guidance documents and conforming implementing procedures discussed in Section 4.1 and 4.2 of this report are completed). Overall, the objectives of this training are to "reset" staff understanding about backfitting and agency expectations regarding backfitting, and to address this CRGR review and the changes that will be made as a result, and the new Commission direction. This training will be an essential step in shifting some of our basic practices with respect to backfitting and generic requirements.

4.3.2.2 Refresher Training and Periodic Staff Developmental Activities

In addition to initial qualification training, the CRGR recommends that the agency provide concise periodic refresher training and periodic developmental activities focused on recent activities relative to backfitting (e.g. case studies). This training should be consistent across the offices and regions. As an example, refresher training for regional reactor inspectors could be provided at regional counterparts meetings. The target audience for this training would include inspectors, branch chiefs, managers, and other regional staff, e.g., enforcement specialists and regional counsel, as appropriate.

4.3.2.3 “Just-in-Time” Training

To complement and support initial qualification training, refresher training, and developmental activities, OGC is currently preparing SharePoint KM pages that can be used as “just-in-time” training for all NRC staff. These pages address backfitting and issue finality, as well as regulatory analysis (including links to relevant resources). OGC has provided its initial drafts of these pages to the CRGR staff for review and comment.

4.3.2.4 References

In addition to “just-in-time” training, the staff should consider developing appropriate references to help the staff (in the various roles mentioned in this report) identify, assess, and resolve potential backfitting issues. As an example, the staff should consider developing and publishing a compilation of examples of facility-specific and generic backfitting issues, as was suggested by the Union of Concerned Scientists (noted in Section 4.3.1 of this report). A reference like this would be a valuable resource for training, staff development, knowledge management, and for resolving potential backfitting issues. The staff should present the results of its consideration of this recommendation to the CRGR for review.

4.3.2.5 Expanded Training/Staff Development and Information Exchanges

The staff should consider using periodic intra- and inter-office workshops as training and staff developmental opportunities. The staff should also consider public meetings to exchange information and operating experience on backfitting with external stakeholders. The staff should present the results of its consideration of this recommendation to the CRGR for review.

The CRGR will continue to oversee the coordinated efforts by OCHCO, OGC, and the appropriate offices with backfitting responsibilities to develop the updated and enhanced training and developmental activities and deliverables described above. The CRGR will review and approve any plans for developing the updated training, including developmental activities, changes to any qualification process associated with backfitting and generic requirements, and any new or updated training programs. The CRGR will review the training products to confirm that they are tailored for all staff with backfitting responsibilities including inspectors, technical reviewers, and licensing staff, and that they are based on and address the most recent versions of the backfitting guidance documents (as discussed in Sections 4.1 and 4.3 of this report). All training products should be kept up to date to reflect guidance changes, operating experience, and knowledge advancements.

4.4 Knowledge Management

CRGR FINDINGS:

- The NRC's KM program does not include a backfitting component.

CRGR-LED ACTIONS:

- Add backfitting to the agency KM program, by adding the OGC-prepared KM documents and references to updated guidance and training to the KM Web site.
- Prepare and publish a NUREG/KM document on the history and activities of the CRGR.

CRGR RECOMMENDATIONS:

- Create a backfitting Community of Practice and encourage offices to appoint backfitting champions and create subject matter experts on backfitting to support the office and the community of practice.

4.4.1 Review Activities and Results

The EDO's June 2016 tasking asked the CRGR to assess the effectiveness of NRC's KM program in capturing, storing, and transferring necessary knowledge about backfitting. The NRC has defined KM as a continuous, disciplined, and timely process of identifying, collecting, and using information to better accomplish the job. As such, an effective KM program can contribute to assuring the adequacy and consistency of the staff's implementation of the backfit rule and maintenance of backfitting guidance.

In conducting this assessment of the NRC's KM activities related to backfitting, the CRGR considered past assessments of the NRC's backfit program, information collected from internal and external stakeholders, and agency guidance documents. The CRGR noted that the need for an effective KM program to support implementation of the NRC's backfit program has been raised in the past. For example, the 2003 CRGR review of administrative controls for facility-specific backfits discussed in Section 3.4.2 of this report identified challenges with staff turnover, the need for guidance to reflect organizational changes, the value a graded approach to backfitting knowledge including a core group of experts, and the value of guidance on regulatory analysis.

The CRGR noted that MD 8.4 contains some guidance that supports KM, including guidance revisions, training, and records management. However, the guidance does not directly address KM strategies. Similarly, the CRGR charter supports KM through activities such as having the CRGR guide and assist the staff with implementing the Commission's backfit policy, and soliciting input from stakeholders on the effectiveness of the backfit program.

As noted previously, in performing this assessment, the CRGR held two public meetings to obtain feedback and perspectives from external stakeholders. While KM was mentioned in broad terms, the stakeholders did not offer any specific KM suggestions for the committee's consideration. Similarly, the CRGR solicited input about KM from the offices with backfitting responsibilities. The input the offices provided to the committee indicated to the CRGR that an effective KM program for backfitting does not exist.

The CRGR also found that while the NRC's infrastructure has many attributes (e.g., guidance, procedures and training) related to KM and that contribute to the backfit program, the NRC Knowledge Center devoted to KM does not include any backfit topics. The CRGR believes explicit inclusion of backfitting into the agency's KM program would provide additional structure, focus, and direction for future efforts to enhance the NRC's infrastructure supporting the backfit rule. Also, given the infrequent nature in which many staff confront backfitting issues, access to backfit resources in a centralized location could contribute to the "just-in-time" training and resources discussed and recommended in Section 4.3 of this report.

4.4.2 Actions and Recommendations

4.4.2.1 Add Backfitting to the Agency's KM Program

As discussed throughout this report, the NRC has many activities underway to enhance the NRC's infrastructure supporting the backfit rule. To some extent, these activities also support KM. Updating guidance and procedures, enhancing training, and applying the lessons learned from the Byron and Braidwood backfit appeal are all good examples of support activities being taken to help manage knowledge for the staff. These activities, however, do not constitute formal backfit KM activities. Therefore, the CRGR recommends that the agency include backfitting as a topical area in its KM program.

OGC is also developing several KM documents on backfitting. The CRGR will review these materials when they become available and help OGC introduce them into the agency's KM SharePoint site.

4.4.2.2 Community of Practice

The CRGR recommends that the role of the office level point-of-contacts discussed in MD 8.4 be expanded to be more like subject matter experts on the backfitting process and generic requirements. These experts would then become more involved in KM activities and initiatives and would be used like the NRC's NOED process experts who consult with the staff in real time as issues arise. For example, each office or region responsible for implementing the backfit rules could appoint a senior staff member with appropriate knowledge and experience in implementing the backfit rules to serve as their backfit champion. The champion could then be used as expert resources for the offices with backfitting responsibilities in addressing backfit issues. Ideally, the backfit champions would organize themselves and establish a backfit Community of Practice within the agency KM program to share experiences and archive information for future use.

4.4.2.3 Capturing Operating Experience and Critical Knowledge

Continuing engagement with licensees and internal stakeholders on backfit program implementation is essential to ensuring that the corrective actions and recommendation included in this report have been effective and are durable. As such, as discussed in Section 4.6 of this report, the CRGR will hold periodic public meetings to solicit input on the effectiveness of the NRC's backfit program. These meetings would include requests for any new information that should be considered in modifying the agency's backfit program. The CRGR would also meet annually with the backfit champions to solicit input and recommendations on new information that should be incorporated into the backfit programs.

4.4.2.4 KM on CRGR History and Activities

In its review of the background of the CRGR for this report, the committee noted that the CRGR of today is much different from the CRGR that was originally established in 1981. The committee also found that bases for decisions that have resulted in changes in the committee's organization, functions, and roles and responsibilities are found in many agency records, and the complete history of the CRGR has not been assembled into a single easily retrievable document. Given the CRGR's historical and contemporary significance to the agency and the regulated industry, the CRGR concluded that an accurate and complete history of the CRGR should be recorded. This history would, among other things, help ensure that future decisions are made with full knowledge of lessons learned and in the context of historical decisions. Therefore, as a KM initiative, the CRGR, with the assistance of RES, will prepare and publish a NUREG/KM digest or similar report on the CRGR. The report will also provide appropriate references to agency documents needed to create a well-rounded understanding of the important significance of the CRGR, its history, and its continuing role.

4.5 Other Issues

CRGR FINDINGS:

- Interim guidance is needed in the near-term to implement the new Commission guidance on backfitting (as discussed further in Sections 4.1 and 4.2 of this report).
- The staff has not documented any effectiveness reviews of corrective actions it took to improve its implementation of backfitting and issue finality requirements and guidance.

CRGR RECOMMENDATIONS:

- The staff should apply the interim guidance for the new Commission guidance on backfitting to issues that are currently still under review.
- The CRGR recommends an effectiveness review of the corrective actions taken in response to this CRGR assessment.

4.5.1 Review Activities and Results

Section 4.3 of this report summarizes external stakeholders' general and specific feedback regarding the agency's implementation of backfitting processes. The feedback included examples of instances in which inspections and technical reviews and related activities resulted in what industry stakeholders viewed as backfits or attempted backfits, without staff following the backfit process. Specific examples included the cable separation concern at Oconee, the requirements for operations that could potentially drain the reactor vessel, credit for incipient fire detection in fire risk assessments, resolution of the open phase condition, violations associated with the service life of components, and the Byron and Braidwood backfit that Exelon appealed. Some of the issues raised are completed and some are still under review. Some industry representatives suggested that the new Commission direction on backfitting should be applied to issues that are currently under review, and some took it further and asked if it could be retroactively applied to issues that had already been resolved. The CRGR agrees that the staff should apply the new Commission direction on backfitting to issues that are currently under review. Until the guidance is finalized, the staff should use the interim guidance described in Sections 4.1 and 4.2 of this report when it becomes available.

In its review of the previous assessments of the agency's implementation of backfitting and issue finality requirements and guidance, conducted between 2002 and 2013, most of which included ongoing corrective actions and/or recommendations for improvement (see Section 3.4 of this report), the CRGR noted that the staff had never documented an effectiveness review of the corrective actions. Concerning this assessment, the CRGR believes that the corrective actions that are currently underway and recommended will improve oversight by NRC senior managers and first-line-supervisors, will enhance engagement and oversight by the CRGR, will improve staff knowledge, skills, and abilities associated with backfitting and generic requirements, and will result in more consistent identification and treatment of potential backfitting issues. The CRGR also believes that the steps it is taking to enhance its involvement and oversight, will contribute to durable corrective actions. Nevertheless, given the complexity of the issues, the degree of external stakeholder interest and attention, and the organization factors that influence our ability to succeed, suggests that an effectiveness review would be beneficial in helping to gauge our progress and our consistency, as well as any additional needed corrective actions.

4.5.1 Actions and Recommendations

The CRGR recommends that the staff apply the new Commission direction on backfitting to issues that are currently under review. Until the guidance is finalized, the staff should use the interim guidance described in Sections 4.1 and 4.2 of this report when it becomes available.

The CRGR recommends an effectiveness review of the corrective actions taken in response to this CRGR assessment as part of the CRGR's next five-year assessment of facility-specific and generic backfitting.

4.6 CRGR Charter

CRGR FINDINGS:

- Criteria for engagement in rulemaking, previously communicated to the Commission, should be incorporated into the CRGR charter.
- Additional revisions to the charter would strengthen and support CRGR and agency backfitting and issue finality activities.

CRGR RECOMMENDATIONS:

- Revise the CRGR charter to reflect rulemaking criteria, incorporate the recent Commission direction, and enhance rigor of the CRGR assessment, including seeking external stakeholder input and perspectives.

4.6.1 Review Activities and Results

The EDO's December 2016 supplemental tasking⁴⁰ directed the CRGR to review its current charter⁴¹ in light of the results of its assessment and determine if any scope or process changes are warranted.

The CRGR received inputs from both internal and external stakeholders regarding CRGR operations and staff handling of backfitting and issue finality issues. The inputs from external stakeholders were generally focused on process enhancements and scope changes. These included inputs derived largely from the four letters from NEI⁴² and the two public meetings the CRGR held to obtain external stakeholder feedback.⁴³

The EDO last updated the CRGR charter to address a recommendation from the 2009 OIG audit summarized in Section 3.4.3 of this report. The OIG recommended that the NRC improve its process for reviewing backfit issues and clarify the role of the CRGR. The EDO issued the resulting Revision 8 of the CRGR charter in October 2011.

In an October 2015 Commission paper, the staff identified the need to develop and provide guidance to the offices about when the CRGR review of a rulemaking would be appropriate.⁴⁴ The staff provided the criteria and implementing guidance in a May 2016 Commission paper.⁴⁵ In that paper, the staff committed to inform the Commission of any further process enhancements that would be beneficial in the annual report to the Commission that would be delivered in August 2017. The staff also informed the Commission that any changes to the scope of the CRGR review and the associated staff responsibilities would be incorporated into a subsequent revision of the CRGR charter, as well as the appropriate agency and office

⁴⁰ NRC 2016j

⁴¹ NRC 2011

⁴² NEI 2016a – 2016c and 2016e

⁴³ Meeting transcripts: NRC 2016e and NRC 2017a. Meeting summaries: NRC 2016h and 2017c.

Meeting presentations: Duke 2016, Exelon 2016b, Miranda 2017, NEI 2016d, and UCS 2016.

⁴⁴ NRC 2015b

⁴⁵ NRC 2016c

implementing procedures. The decision-making criteria are already being implemented, as observed by the NMSS director at an April 2017 meeting with the CRGR.

During the review documented in this report, the CRGR had significant discussion and deliberations regarding potential scope and process changes. The CRGR concluded that the charter should be updated to reflect organizational changes since 2011, to incorporate the new rulemaking review decision-making criteria, and to make other structural and editorial enhancements. The committee also identified several more substantive changes and enhancements that could be incorporated in the charter to strengthen and support CRGR activities and overall agency performance on future issues that involve both generic and facility-specific backfitting and issue finality issues.

4.6.2 Recommendations

Preliminary suggestions for changes to the CRGR charter include:

- Incorporate fact of life changes such as changes in organization and changes to references since the previous charter was issued in 2011.
- Make editorial and structural changes to improve clarity and consistency, and eliminate redundancy and outdated material.
- Incorporate the new criteria and process for initiating CRGR involvement in rulemakings.
- Develop and add, as appropriate, new guidance and information about the new Commission direction on backfitting that is presented in Section 4.2 of this report.
- Incorporate the MD 8.4 requirement that CRGR “periodically [conduct] audits, typically every 5 years, to assess the effectiveness of the NRC’s administrative controls for facility-specific backfitting as part of its regulatory effectiveness responsibility.” In addition, change the scope of the periodic assessments to include both facility-specific and generic backfitting as was done for the assessment documented in this report.
- For both the annual and periodic CRGR assessments, add guidance and criteria to improve the consistency and robustness of the assessments from year to year.
- Clarify the CRGR’s role to review and approve guidance and procedures associated with facility-specific and generic backfitting before they are published and implemented. This requirement should reinforce that the staff will coordinate the required review with the CRGR staff in advance and allow time for either an informal or formal review at the CRGR’s discretion.
- Add additional guidance and criteria concern the committee’s engagement with external stakeholders. As an example, to increase the robustness of the annual assessments, a public meeting may be appropriate every other year, with a less formal engagement on the off years; say a poster session at the Regulatory Information Conference. Conversely, a public meeting should always be conducted to support the periodic (5-year) assessments. Of course, as an NRC organization, the CRGR has the authority to call a public meeting or to have the staff arrange a public meeting to address a backfitting issue, as needed. Such engagements could be clarified in the charter.

- Modify the current charter requirement that the “CRGR will not consider plant-specific regulatory actions,” to allow or require CRGR involvement in facility-specific action under certain circumstances. As an example, if requested by the EDO or the director of an office with backfitting responsibilities. As another example, automatic CRGR review of the results of backfit appeals to either an office director or the EDO.

If approved, in the mid-term, the CRGR will continue to interact with internal stakeholders to further develop these suggestions and to explore other ideas that arise after this report is distributed. The CRGR will develop a proposed revision that incorporates the suggestions and feedback, as appropriate, for the EDO’s consideration.

5 CONCLUSIONS

This report documents the results of the CRGR’s comprehensive assessment of the adequacy and effectiveness of the NRC’s existing backfitting and issue finality requirements and guidance, training, and knowledge management tools, as well as the lessons learned from the review of Exelon Corporation’s appeal to the EDO of a compliance backfit of Byron and Braidwood and new Commission direction to the staff about taking costs into consideration when assessing exceptions to the backfit rule, and using the GDCs to justify compliance exceptions to the backfit rule. This report also includes the committee’s review of its charter against the results of its assessment. The committee’s key findings are summarized in Section 2 of this report, and its findings and conclusions for each topical area that it reviewed are shown in Sections 4.1 through 4.6 of this report.

In summary, external stakeholders representing industry told the CRGR that they are concerned about inappropriate use of the compliance exception by NRC staff to justify facility-specific backfits, as well as the potential for NRC inspection and oversight activities to result in inappropriate backfits. Except for the compliance backfit for Byron and Braidwood, which was overturned by the EDO on appeal, the CRGR did not identify any inappropriate backfits. However, based on industry feedback and the totality of its assessment, the committee concluded that opportunities exist to improve backfitting practices. The corrective actions that are currently underway and recommended will improve oversight by NRC senior managers and first-line-supervisors; will enhance engagement and oversight by the CRGR; will improve staff knowledge, skills, and abilities associated with backfitting and generic requirements; and will result in more consistent identification and treatment of potential backfitting issues. Of the in-process actions and recommendations, the committee expects that broad communication of the new Commission direction, increased management involvement, and improved training and developmental activities will yield the greatest improvements in NRC staff performance and consistency.

For the reasons provided in this report, the committee recommends that the EDO take three near-term actions. They are:

1. Make this report publicly available.
2. Issue interim guidance on the new Commission direction on backfitting to be used by the staff pending publication of the in-process updates of NRC Management Directive 8.4, “Management of Facility-Specific Backfitting and Information Collection,” and NUREG-1409, “Backfitting Guidelines,” as described in Sections 4.1 and 4.2 of this report.

3. Require NRC managers and staff with backfitting and issue finality responsibilities to attend the initial backfit “reset” training described in Section 4.3 of this report.

In the mid-term, the CRGR will continue working with OCHCO to develop a comprehensive, role-based backfit training program (Section 4.3 of this report). In the mid-term, the committee will also propose an update to its charter that, among other things, reflects fact of life changes, enhancements in its role in certain backfitting activities, and added rigor to its annual and five-year assessments (Section 4.6 of this report).

In the long-term, the CRGR recommends that the EDO direct an effectiveness review of the corrective actions taken in response to this CRGR assessment as part of the CRGR’s next five-year assessment of facility-specific and generic backfitting (Section 4.5 of this report).

With the EDO’s approval, the CRGR will continue to work with EDO and office staff, as discussed above, to implement the other corrective actions and recommendations included in its report.

APPENDIX A: HISTORY OF THE BACKFIT RULE AND THE COMPLIANCE EXCEPTION, REVISION 1

CRGR Note: The NRC Backfit Appeal Review Panel that reviewed Exelon’s appeal of the Byron and Braidwood backfit included this appendix in its report.⁴⁶ The CRGR slightly revised that panel’s appendix, and included it here as Appendix A of its own report to the EDO.

This appendix provides useful additional historical information about backfitting and the compliance exception for power reactors. It has not been updated to reflect the recent Commission direction described in the body of the report.

The Backfit Rule

Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.109, “Backfitting,” was originally promulgated in 1970.⁴⁷ Because of perceived deficiencies in the rule, the U.S. Nuclear Regulatory Commission (NRC) substantially revised it in 1985.⁴⁸ The 1985 rule was challenged in court, and the U.S. Circuit Court for the District of Columbia (D.C. Circuit) vacated this rule in its entirety. The D.C. Circuit took this action because it concluded that the revised rule could be interpreted to allow the NRC to consider costs in defining or redefining what is required for adequate protection of the public health and safety.⁴⁹ In response, the NRC revised the backfit rule in 1988 to remove any implication that costs could be considered in defining or redefining adequate protection.⁵⁰ The 1988 revisions only differed from the 1985 rule to the extent necessary to address the court’s concerns. The 1988 rule was also challenged in court, but this time the D.C. Circuit upheld the rule.⁵¹

In its current form, 10 CFR 50.109(a)(1) defines backfitting as

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

Three types of justified backfitting actions or exceptions to backfitting are considered by the NRC: adequate protection, compliance, and cost-justified. Adequate protection backfitting, whether used to ensure that adequate protection is maintained or to define or redefine the level of protection that should be regarded as adequate, does not require a finding of substantial safety or security improvement, nor does it require that costs be considered. If a proposed action is deemed necessary for adequate protection, it shall be implemented as required by the Atomic Energy Act. Compliance backfitting does not require a finding of substantial benefit to safety or security but does require some consideration of costs. Adequate protection and

⁴⁶ NRC 2016d (Author and year citations in footnotes refer to the designation of references in Appendix C to this report.)

⁴⁷ AEC 1970

⁴⁸ NRC 1985

⁴⁹ *Union of Concerned Scientists v. U.S. Nuclear Regulatory Com’n*, 824 F.2d 108, 119-20 (1987).

⁵⁰ NRC 1988b

⁵¹ *Union of Concerned Scientists v. U.S. Nuclear Regulatory Com’n*, 880 F.2d 552 (1989).

compliance backfitting actions must be explained in a documented evaluation, which contains information to support use of the selected backfitting method. Backfitting without use of the adequate protection or compliance exceptions requires a finding of substantial safety improvement with justified costs. Information to support imposition of a cost-justified substantial safety improvement backfitting action must be contained in a backfit analysis.

Unless the adequate protection or compliance exceptions apply, the NRC may impose a backfit only if it performs a backfit analysis in accordance with 10 CFR 50.109(a)(2) and determines in accordance with 10 CFR 50.109(a)(3) “that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.”

To justify a backfit, a backfit analysis must be performed and documented which shows:

- a substantial increase in overall protection of the public health and safety or the common defense and security, and
- the direct and indirect costs of implementation are justified in view of the increased protection.

Unless, an exception to the backfit analysis requirement is justified. If an exception applies, then only a documented evaluation is required.

Section 50.109(a)(4) sets forth the three exceptions to the requirements of 10 CFR 50.109(a)(2) and (a)(3). The first exception, the compliance exception, applies if the “modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee.” 10 CFR 50.109(a)(4)(i). The second and third exceptions relate to actions ensuring adequate protection or to actions that involve defining or redefining adequate protection. 10 CFR 50.109(a)(4)(ii)-(iii).

Commission Policy

The Commission addressed its intended application of the compliance exception in the 1985 rulemaking:⁵²

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.

In the 1985 rule, the Commission acknowledged that staff interpretations of regulations are not legally binding, but the Commission also stated that “staff interpretations of broadly stated rules are often necessary to give a rule effect and in some instances may be a causal factor in initiating a backfit.”⁵³ The Commission also stated, “Many of the most important changes in plant design, construction, operation, organization, and training have been put in place at a level of

⁵² NRC 1985, at 38103

⁵³ *Id.* at 38102

detail that is expressed in staff guidance documents which interpret the intent of broad, generally worked [sic] regulations.”⁵⁴

Backfitting Guidance

Extensive information regarding the appropriate implementation of backfitting is provided in NUREG-1409.⁵⁵ Relevant excerpts from this guidance are provided below.

Applicable Regulatory Staff Positions

According to NUREG-1409, to be a backfit, “a new or revised staff position or requirement must be involved, that is, there must be a change in content or applicability of the previously applicable regulatory staff position (in the direction of increased safety requirements)” An applicable regulatory staff position is a requirement or position already specifically imposed on or committed to by a licensee. Examples of applicable regulatory staff positions include:

- 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 applicable NUREGs, the Standard Review Plan, Standard Technical Specifications, Interim Staff Guidance, branch technical positions, and regulatory guides.

A similar list of examples is provided in Manual Chapter 0514,⁵⁶ which is also included as Appendix D to NUREG-1409. Manual Chapter 0514 was referenced in the 1988 rulemaking, and a working draft was provided to the Commission for information in SECY-88-102.⁵⁷ Manual Chapter 0514 provides a definition of “applicable regulatory staff positions” that is slightly more detailed than the definition in NUREG-1409. This definition from Manual Chapter 0514 is quoted below, with additional detail beyond NUREG-1409 emphasized in underlined text.

Applicable regulatory staff positions are those already specifically imposed upon or committed to by a licensee at the time of the identification of a facility-specific backfit, and are of several different types and sources:

- a. Legal requirements such as in explicit regulations, orders, plant licenses (amendments, conditions, technical specifications). Note that some regulations have update features built in, as for example, 10 CFR 50.55a, Codes and Standards. Such update requirements are applicable as described in the regulation.

⁵⁴ *Id.* at 38103. The 1988 rulemaking neither revised the compliance exception as stated in the 1985 rule nor provided additional guidance on its interpretation.

⁵⁵ NRC 1990

⁵⁶ NRC 1988c

⁵⁷ NRC 1988a

b. Written commitments such as contained in the [Final Safety Analysis Report], [Licensee Event Reports], and docketed correspondence, including responses to Bulletins, responses to Generic Letters, Confirmatory Action Letters, responses to Inspection Reports, or responses to Notices of Violation.

c. NRC staff positions⁵⁸ that are documented, approved, explicit interpretations of the more general regulations, and are contained in documents such as the [Standard Review Plan], Branch Technical Positions, Regulatory Guides, Generic Letters, and Bulletins; and to which a licensee or an applicant has previously committed to or relied upon. Positions contained in these documents are not considered applicable staff positions to the extent that staff has, in a previous licensing or inspection action, tacitly or explicitly excepted the licensee from part or all of the position.⁵⁹

How Regulatory Positions are Established

NUREG-1409, dated July 1990, provided responses to a number of questions regarding backfitting. The following response was given to questions asking, “Is it appropriate for the NRC staff to rely on informal or formal communications to other licensees as official NRC positions? What about NRC tacit approval of documents?”

Informal or formal communications to one licensee are not official positions to all licensees. Section 053 of Manual Chapter 0514 identifies what can be applied as official staff positions in a facility-specific context. They are legal requirements such as contained in explicit regulations, orders, and plant licenses; written commitments such as contained in final safety analysis reports, licensees event reports, and docketed correspondence; and documented, approved explicit interpretations such as contained in the [Standard Review Plan], branch technical positions, regulatory guides, generic letters, and bulletins. Orders, licenses, and written commitments are applicable only to a particular licensee.

If the NRC staff previously exempted a licensee from a legal requirement or approved position, it is not applicable to that licensee for the purpose of backfit consideration. Explicit exemption would be done formally in writing. The Appendix to NRC Manual Chapter 0514 discusses tacit approval under reanalysis of issues. Two situations are covered. In the first case, staff review of a previously accepted licensee action or program may result in a requested change. This would be classified as a backfit because it represents a change in a previous staff position and would require a backfit analysis (or a documented evaluation if it meets one of the exceptions listed in the backfit rule). In the second case, a licensee submittal committing to a specific course of action that has not received timely NRC staff review is implemented by the licensee. In this case, it is considered that the NRC staff tacitly accepted the licensee’s action since timely notice to the contrary was not given. If the NRC staff subsequently adopts a different position and requests a change in the licensee action, this change may be classified as a backfit and thus require a backfit analysis (or a documented evaluation if it meets one of the exceptions listed in the backfit rule).

⁵⁸ Requirements may be imposed by rule or order. Staff interpretations such as examples of acceptable ways to meet requirements are not requirements in and of themselves.

⁵⁹ Imposition of a staff position from which a licensee has previously been excepted is a backfit.

NUREG-1409 also addressed a question regarding tacit approvals by an inspector: "If an inspector has previously accepted (i.e., provided tacit approval of) a licensee's method, does a specific request for change constitute a backfit and if so, is a backfit analysis required?" The response is:

Cases where an inspector provides tacit approval are relatively rare. Simply not challenging a licensee's practice normally would not be considered tacit approval. The only example provided in Manual Chapter 0514 is a case where the NRC has indicated tacit approval by not acting in a reasonable time on a licensee submittal and the licensee has moved ahead to implement the proposal described in the submittal. For the purpose of this question, it would most likely arise in connection with review of a licensee response to an inspection report.

Explicit approval could be provided in an inspection report that states that a particular approach is acceptable. However, conclusions of that nature are usually made in [safety evaluations] rather than inspection reports.

Compliance Backfit Guidance

NUREG-1409 gave the following response to the question, "[h]ow does the backfit rule apply to new staff positions that reflect an evolving understanding of technical issues?"

An evolving understanding of issues does not, by itself, define which category fits a particular backfit. Judgment must be applied to the facts of each particular case to determine whether the backfit is for compliance, to provide adequate protection, to redefine adequate protection, or to achieve a cost-justified substantial safety enhancement. For example, with regard to compliance, the 1985 statement of considerations for 10 CFR 50.109 indicates that "the compliance exception is intended to address situations where the licensee has failed to meet known and established standards of the Commission because of omission or mistake of fact.... new or modified interpretations of what constitutes compliance would not fall within the exception...."

NUREG-1409 also provided an example where an evolving understanding of technical issues resulted in a compliance backfit that was apparently justified for at least some licensees. In response to industry claims that Bulletin 88-11⁶⁰ lacked any backfitting justification, the NRC staff responded:

Although the justification was not printed in the bulletin, NRC Bulletin 88-11, "Pressurizer Surge Line Thermal Stratification," was justified as a backfit. It is an example of a backfit that was determined by the responsible NRC official to be required as a matter of compliance with existing requirements and commitments. The CRGR reviewed the bulletin and concurred. The regulations currently require licensees to meet the applicable codes of the American Society of Mechanical Engineers (ASME), *Boiler and Pressure Vessel Code*. Because of the NRC staff's concern with the integrity of the surge line, licensees were requested to perform their fatigue analysis in accordance with the latest ASME Section III requirements that incorporate high cycle fatigue analysis. The justification provided by the NRC staff was that previously unconsidered thermal stratification

⁶⁰ NRC 1988d

phenomenon may invalidate the existing analysis performed to confirm the integrity of the surge line.

Subsequently, it was understood that some licensees believed that the NRC staff's rationale was in error because they were not committed to the latest ASME Section III requirements by virtue of their license commitment. However, the issue became moot because these licensees undertook the analysis voluntarily in view of the safety importance of the issue and the fact that previous versions of the ASME Code did not completely address the concern.

APPENDIX B: REFERENCES

1. **AEC 1970:** Atomic Energy Commission (AEC), “Backfitting of Production and Utilization Facilities; Construction Permits and Operating Licenses,” Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.109, published March 31, 1970 (as amended). Volume 35 of the *Federal Register* (FR), page 5317.
2. **Duke 2016:** Duke Energy, presentation by Chris Nolan, Director Regulatory Affairs, “Public Meeting on Backfitting Led by CRGR,” dated September 13, 2016. Agencywide Documents Access and Management System (ADAMS) Accession No. [ML16253A211](#).
3. **Exelon 2016a:** Exelon Generation Company, LLC, letter from J. Bradley Fewell to Victor M. McCree, U.S. Nuclear Regulatory Commission (NRC), “Appeal of Imposition of Backfit Regarding Compliance with 10 CFR § 50.34(b), General Design Criteria (GDC) 15, GDC 21, GDC 29, and Licensing Basis,” dated June 2, 2016. ADAMS Accession No. [ML16154A254](#).
4. **Exelon 2016b:** Exelon Generation, presentation by Darani Reddick, Regulatory Affairs Manager & Assistant General Counsel, “Facility-Specific & Compliance Backfits,” dated September 13, 2016. ADAMS Accession No. [ML16253A212](#).
5. **FENOC 2016:** FirstEnergy Nuclear Operating Company (FENOC), presentation by Greg Halnon, “Regulatory Challenges During Inspections,” dated September 13, 2016. ADAMS Accession No. [ML16253A213](#).
6. **Miranda 2017:** E-mails from Samuel Miranda to Nicholas Difrancesco, NRC, and Les Cupidon, NRC, and responses from Les Cupidon, NRC, “Comment for the Public Meeting on Backfitting Led by CRGR,” dated March 6, 18, and 20, 2017. ADAMS Accession No. [ML17079A327](#).
7. **NEI 2015:** Nuclear Energy Institute (NEI), letter from Janet R. Schlueter to Cindy Bladey, NRC, “Draft Interim Staff Guidance ZZ, Revision 0 Guidance for the Evaluation of Acute Chemical Exposures and Proposed Quantitative Standards (80 Fed. Reg. 11,692 and 80 Fed. Reg. 21,274); NRC Docket 2015-0044,” dated June 30, 2015. ADAMS Accession No. [ML15189A076](#).
8. **NEI 2016a:** NEI, letter from Anthony Pietrangelo, to William M. Dean, NRC, “Nuclear Energy Institute Comments in Support of Exelon Generation Company Backfit Appeal, dated January 20, 2016. ADAMS Accession No. [ML16027A352](#).
9. **NEI 2016b:** NEI, letter from Anthony Pietrangelo to Victor M. McCree, NRC, “Nuclear Energy Institute Comments on Tasking Memorandum Dated June 9, 2016,” dated July 19, 2016. ADAMS Accession No. [ML16208A015](#).
10. **NEI 2016c:** NEI, letter from Maria Korsnick to Chairman Stephen G. Burns, NRC, “Nuclear Energy Institute Supplementary Comments for the July 26, 2016 Stakeholder Meeting,” dated August 4, 2016. ADAMS Accession No. [ML16217A453](#).
11. **NEI 2016d:** NEI, presentation by Anthony R. Pietrangelo, “Industry Views on State of NRC’s Backfitting Program,” dated September 13, 2016. ADAMS Accession No. [ML16253A214](#).

12. **NEI 2016e:** NEI, letter from Anthony Pietrangelo to Edwin M. Hackett, NRC, "Nuclear Energy Institute Comments on September 13, 2016 Public Meeting with CRGR," dated October 31, 2016. ADAMS Accession No. [ML16308A045](#).
13. **NRC 1985:** U.S. NRC, "Revision of Backfitting Process for Power Reactors - Parts 2 and 50," dated September 20, 1985. 50 FR 38097.
14. **NRC 1988a:** U.S. NRC, SECY-88-102, "Final Backfit Rule," dated April 18, 1988. This document is not in ADAMS, but is available through the NRC Public Document Room using Accession No. 8805130269 and microfiche location 45795:299-362.
15. **NRC 1988b:** U.S. NRC, "Revision of Backfitting Process for Power Reactors - Final Rule," dated June 6, 1988. 53 FR 20603.
16. **NRC 1988c:** U.S. NRC, NRC Manual Chapter 0514, "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants," dated August 26, 1988. ADAMS Accession No. [ML041400111](#).
17. **NRC 1988d:** U.S. NRC, Bulletin 88-11, "Pressurizer Surge Line Thermal Stratification," dated December 20, 1988. Publicly available on the [NRC website](#).
18. **NRC 1990:** U.S. NRC, NUREG-1409, "Backfitting Guidelines," dated July 1990. ADAMS Accession No. [ML032230247](#).
19. **NRC 1997:** U.S. NRC, NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," dated January 1997. ADAMS Accession No. [ML050190193](#).
20. **NRC 2003:** U.S. NRC, memorandum from William D. Travers to the Commission, "The Committee to Review Generic Requirements (CRGR) Report on Their Review of Administrative Controls for Plant Specific Backfits," dated September 24, 2003. ADAMS Accession No. [ML032550007](#).
21. **NRC 2004:** U.S. NRC, NUREG/BR-0058, "Regulatory Analysis Guidelines," Revision 4, dated September 2004. ADAMS Accession No. [ML042820192](#).
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 45. **NRC 2017a:** U.S. NRC, “Official Transcript of Proceedings – Nuclear Regulatory Commission – Committee to Review Generic Requirements Backfitting and Issue Finality Public Meeting,” dated February 28, 2017. ADAMS Accession No. [ML17066A461](#).
 46. **NRC 2017b:** U.S. NRC, SECY-17-0035, “Draft NUREG/BR-0058, Revision 5, ‘U.S. Nuclear Regulatory Commission Guidance on Performing Regulatory and Cost-Benefit Analyses,’” dated February 28, 2017. ADAMS Accession No. [ML16182A034](#).
 47. **NRC 2017c:** U.S. NRC, “Nuclear Regulatory Commission Enforcement Manual,” dated March 3, 2017. ADAMS Accession No. [ML102630150](#).
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APPENDIX C: LIST OF ABBREVIATIONS

ABWR	Advanced Boiling Water Reactor
ADAMS	Agencywide Documents Access and Management System
AEC	U.S. Atomic Energy Commission
AP600/1000	Advanced Passive 600 / 1000
ASME	American Society of Mechanical Engineers
CFR	<i>Code of Federal Regulations</i>
CRGR	NRC Committee to Review Generic Requirements
EDO	NRC Executive Director for Operations
ESBWR	Economic Simplified Boiling Water Reactor
FAQ	frequently asked question
FR	<i>Federal Register</i>
GDC	General Design Criterion
KM	knowledge management
LLOB	NRC Lessons-Learned Oversight Board
MD	Management Directive
NEI	Nuclear Energy Institute
NMSS	NRC Office of Nuclear Material Safety and Safeguards
NOED	notice of enforcement discretion
NRC	U.S. Nuclear Regulatory Commission
NRO	NRC Office of New Reactors
NRR	NRC Office of Nuclear Reactor Regulation
NSIR	NRC Office of Nuclear Security and Incident Response
NUREG	NRC technical report designation
NUREG/BR	NRC technical brochure designation
OCHCO	NRC Office of the Chief Human Capital Officer
OEDO	NRC Office of the Executive Director for Operations
OGC	NRC Office of the General Counsel
OIG	NRC Office of the Inspector General
PDC	principal design criteria
RES	NRC Office of Nuclear Regulatory Research
SECY	NRC Office of the Secretary of the Commission
SRM	staff requirements memorandum
TIA	task interface agreement