

**ADHERENCE TO THE COMMISSION'S BACKFIT RULE
AND THE ROLES OF THE ADVISORY COMMITTEE ON
REACTOR SAFEGUARDS AND THE COMMITTEE TO
REVIEW GENERIC REQUIREMENTS IN THE
RULEMAKING PROCESS**

**A Report for the House and Senate
Committees on Appropriations**

By the U.S. Nuclear Regulatory Commission

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I. INTRODUCTION

This report was developed by the U.S. Nuclear Regulatory Commission (NRC), as directed by the Joint Explanatory Statement accompanying the Consolidated Appropriations Act, 2017 (Public Law 115-31). The Joint Explanatory Statement directed the NRC to submit to the House and Senate Appropriations Committees a report on how the rulemaking process will adhere to the backfit rule and on the roles of the Advisory Committee on Reactor Safeguards (ACRS) and the Committee to Review Generic Requirements (CRGR).¹

II. BACKGROUND

A. ADHERENCE TO THE BACKFIT RULE IN THE RULEMAKING PROCESS

Backfitting is the process — set forth in NRC regulations² — that the agency follows when deciding whether to impose new or revised regulatory requirements or new or revised NRC staff positions on nuclear power reactor licensees, certain nuclear power reactor applicants, and certain nuclear materials applicants/licensees. Backfitting is intended to ensure that proposed new or changed regulatory requirements imposed on those entities are adequately justified, defined, and implemented after formal and systematic review against criteria established in the NRC's regulations. "Issue finality" provisions that apply to power reactors under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52 are equivalent to the backfitting provisions in 10 CFR 50.109.³

The NRC's primary guidance and procedures to ensure that backfitting and issue finality provisions are complied with throughout the rulemaking process are set forth in two documents: (1) Management Directive 6.3, "The Rulemaking Process"; and (2) NUREG-1409, "Backfitting Guidelines." The NRC staff is in the process of updating both of these documents to reflect the Commission's direction on the rulemaking process in the February 3, 2016, Staff Requirements Memorandum (SRM) on SECY-15-0129, "Commission Involvement in Early Stages of Rulemaking."

The NRC has adopted a procedural requirement for NRC staff to submit for Commission approval a rulemaking plan that identifies backfitting and issue finality considerations as well as a preliminary analysis of costs and benefits, before initiating any rulemaking (with limited exceptions). This protocol was reported by the NRC in its March 1, 2016, report to Congress (ADAMS Accession Nos. ML16040A006, ML16063A522, ML16040A008, and ML16040A010) in response to the Joint Explanatory Statement accompanying the Consolidated Appropriations Act, 2016 (Public Law 114-113).

Once a rulemaking plan is approved, the regulatory basis document — developed by the NRC staff to support a proposed rulemaking — must address any backfitting and issue finality considerations in sufficient detail to support the development of a proposed rulemaking package. Each *Federal Register* notice of proposed rulemaking includes a section heading, "Backfitting and Issue Finality," that contains a discussion of the NRC's proposed compliance with applicable backfitting requirements. The public is invited to comment on any draft backfit analysis or draft documented evaluation included or referenced in this section. The NRC considers public comments on backfitting and issue finality during preparation of the final rule.

¹ 163 CONG. REC. H3327, H3772 (daily ed. May 3, 2017).

² See 10 CFR 50.109, 70.76, 72.62, 76.76.

³ See 10 CFR 52.39, 52.63, 52.83, 52.98, 52.145, 52.171.

A discussion of the comments, and the NRC's response to those comments, are included in the supplementary information section of the final rule.⁴ At any time during this process, the NRC may, either on its own initiative or in response to public requests, hold public meetings to engage external stakeholders on backfitting and issue finality considerations.

B. ROLES OF THE ADVISORY COMMITTEE ON REACTOR SAFEGUARDS AND THE COMMITTEE TO REVIEW GENERIC REQUIREMENTS IN THE RULEMAKING PROCESS

Role of the ACRS in the Rulemaking Process

Under the provisions of the Atomic Energy Act of 1954, as amended, and NRC policies and procedures, the ACRS reviews a rulemaking document when: (1) ACRS review is required by law, (2) the Commission directs an ACRS review of the rulemaking, or (3) the ACRS, using its discretion, conducts a review. Historically, the NRC staff has provided the ACRS with an opportunity to review draft proposed technical rules and has submitted for ACRS review draft final technical rules. In its February 3, 2016, direction to the staff, the Commission directed the NRC staff to include in each rulemaking plan an explicit question to the Commission, and recommendation if desired, as to whether ACRS review of the proposed rule is warranted. As a result, the NRC staff now coordinates with the ACRS during the development of the regulatory basis for a proposed technical rule to determine the level of ACRS involvement.

To support the ACRS review of proposed and final rulemaking packages, the NRC staff provides the ACRS with all associated backfitting documentation including, as applicable: (1) the NRC staff's draft adequate protection determination, (2) any NRC staff recommendation on the use of the compliance exception (an exception to preparation of a backfit analysis under the backfit rule), and (3) the technical bases for a "substantial increase" in protection, which is a necessary finding to support backfitting in a backfit analysis if an exception does not apply. The ACRS subcommittees and the full ACRS conduct public meetings as part of their rulemaking review; both NRC staff and external stakeholders are invited by the ACRS to make presentations at these meetings. ACRS interaction with the staff and external stakeholders at public meetings provides the NRC staff with additional insight on the issues addressed in the rulemaking including backfitting and issue finality considerations.

Following ACRS review of a rulemaking package, the ACRS sends its conclusions and recommendations on the rulemaking to the Commission. The NRC staff typically provides a response to the ACRS that identifies the ACRS conclusions and recommendations that the NRC staff agrees with (and any associated changes made to the rulemaking document) as well as any ACRS conclusion/recommendation that the NRC staff does not agree with and the bases for the staff position. The NRC staff provides its response to the Commission for information.

Role of the CRGR in the Rulemaking Process

The CRGR reviews NRC staff guidance and regulatory requirements to ensure that any generic backfit proposed for NRC-licensed power reactors, new reactors, and nuclear materials facilities

⁴ The draft final rule, the draft comment response document, and the draft final backfit analysis and/or draft final documented evaluation are provided to the Commission as enclosures to the vote paper that the staff submits when seeking Commission review and approval to issue a final rule.

is appropriately justified on the bases of the backfit provisions in NRC regulations, the NRC's regulatory analysis guidelines, and the Commission's backfit policy.

Mandatory CRGR review of rulemaking packages was made optional in 2007 following an effectiveness review of the NRC's rulemaking process. To ensure that the NRC's backfitting and regulatory analysis reviews are conducted with consistency, the Commission directed the NRC staff to provide the Commission with criteria and guidance for triggering CRGR review of proposed rules. Moreover, the NRC staff was directed to inform the Commission if it determines that further process enhancements regarding the CRGR would be beneficial as a result of lessons-learned and feedback from the use of the new guidance and criteria.

The CRGR provided the criteria and guidance to the Commission for information in SECY-16-0064, "CRGR Response to Staff Requirements-SECY-15-0129 Commission Involvement in Early Stages of Rulemaking," dated May 23, 2016. The criteria require the staff to engage the CRGR when one or more of the following are met: (1) a rulemaking may have issue finality or possible backfitting concerns, (2) qualitative factors were used to justify a rulemaking with significant costs, (3) substantial statistical uncertainty exists in the quantitative benefit determination in the backfit analysis, (4) the staff relied on the compliance exception or the adequate protection exceptions to justify backfitting, (5) the Executive Director for Operations (EDO) directed the review, or (6) stakeholder or NRC staff concerns regarding the backfit or regulatory analysis have been raised. The NRC staff is working with the CRGR to develop additional implementing guidance for using the criteria and will complete this effort by fall 2017. In the meantime, select rulemaking packages are being reviewed by the CRGR as discussed below.

Under the new process, when the CRGR is engaged, the staff provides the rulemaking package including backfitting and issue finality documentation and the regulatory analysis to the CRGR. Following CRGR review and any meetings with the staff, the CRGR provides a written determination to the staff. Typically, the NRC staff provides a response to this determination. The CRGR endorsement is then provided to the EDO, or in contrast, any unresolved backfitting and issue finality considerations are brought to the EDO to determine a final staff position. The staff's paper transmitting a proposed or final rule to the Commission for consideration describes the CRGR's consideration of the rulemaking package, any changes made by the staff in response to the CRGR's comments, and the basis for the final staff position.

On June 27 and July 12, 2017, the CRGR first used the new criteria and guidance to review a draft proposed rule for cybersecurity at fuel cycle facilities. Once this review is completed, the CRGR will document its experience using the new criteria and guidance in its annual report, which it will provide to the Commission this fall, including any additional recommendations for process enhancement. As appropriate, the CRGR will implement any lessons-learned based on this review.

III. RECENT AND ONGOING ACTIVITIES TO UPDATE AND IMPROVE BACKFIT GUIDANCE

The NRC staff has completed several efforts over the past year and remains engaged in ongoing work to improve the technical and programmatic guidance used when performing backfit analyses and documented evaluations.

Commission Direction – SRM-SECY-15-0129 and SRM-COMSECY-17-0002

The NRC staff drafted a rulemaking plan template consistent with the Commission’s direction on early consideration of backfitting issues, as well as benefits and costs. The NRC is currently finalizing a revision to Management Directive 6.3, “The Rulemaking Process,” to reflect Commission direction regarding use of rulemaking plans.

Ongoing Efforts to Determine Criteria for the Early Termination of Rules Based on Backfit Viability

In response to Commission direction, the NRC staff is preparing to recommend criteria and procedures for discontinuing a rulemaking activity. This could include not completing a full regulatory analysis once enough information is gained to conclude that there would not be a substantial increase in protection and/or a cost-benefit test for backfitting would not be passed.

EDO Direction to the CRGR on Backfitting

In the June 9, 2016, memorandum “Tasking Related to Implementation of Agency Backfitting and Issue Finality Guidance” the EDO directed the CRGR to assess the agency’s implementation of backfitting and issue finality requirements and guidance as applied across agency programs. This tasking also included considering the adequacy and effectiveness of existing NRC requirements, guidance, training, and knowledge management.

In addition, in the December 15, 2016, memorandum “Supplemental Tasking Related to Implementation of Agency Backfitting and Issue Finality Guidance” the EDO directed the CRGR to consider agency actions and direction issued since the original tasking so that the CRGR’s assessment would comprehensively address all currently understood challenges and opportunities regarding backfitting and issue finality. The CRGR provided the results of this assessment to the EDO on June 27, 2017. The CRGR noted significant concern from industry stakeholders regarding the inappropriate use of the compliance backfit exception by the NRC staff to justify facility-specific backfits, as well as the potential for NRC inspection and oversight activities that result in inappropriate backfits. Despite this concern, the CRGR concluded that, with the exception of one compliance backfit overturned by the EDO on appeal, it could not identify any inappropriate backfits. However, the significant negative industry feedback led the CRGR to conclude that opportunities exist to improve backfit practices.

To address this concern, the CRGR provided a series of recommendations: (1) Make the CRGR report publicly available; (2) Update general and office-level implementing guidance to incorporate recent policy developments and Commission instruction; (3) Issue a policy announcement on recent Commission policy changes; (4) Update and develop training requirements to provide initial and refresher training to managers and NRC staff with backfitting and issue finality responsibilities; (5) Implement knowledge management procedures and a backfitting Community of Practice; and (6) Conduct an effectiveness review of actions taken in response to the CRGR recommendations. The EDO agreed with all of the recommendations and, on July 27, 2017, made the report publicly available, tasking the staff with implementing the CRGR recommendations. The EDO also instructed the staff to report on the availability of key docketed information and to provide the resource estimates for making that information more readily retrievable. The EDO also requested resource estimates for implementation of the CRGR recommendations.

Improved Agency Guidance for Backfitting, Adequate Protection Backfits, and the Consideration of Cost in Compliance Backfits

The Commission, in its November 29, 2016, SRM directed the NRC staff to revise agency guidance on backfitting and issue finality with respect to cost and the application of the backfit rule. Accordingly, the staff is currently updating the guidance to require consideration of adequate protection whenever the NRC is contemplating backfitting, limiting the use of the compliance exception to the narrow set of circumstances expressly described in the *Federal Register* notice of final rulemaking for the 1985 Backfit Rule, and considering costs in compliance backfitting. To assist the NRC staff in complying with the Commission's November 2016 SRM, the NRC's Office of the General Counsel (OGC), through the Solicitor, issued a December 20, 2016, memorandum to the staff that provides a more detailed explanation of the Commission's instructions.

NRC Efforts in Updating Backfit Guidance

In response to the Commission's November 2016 direction on backfitting, the associated OGC memorandum to the Staff, and the CRGR report and subsequent EDO tasking memo, the NRC staff has begun updating agency backfitting guidance to reflect these revised backfitting concepts. Specifically, the NRC staff has commenced efforts to revise Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection"; NUREG-1409, "Backfitting Guidelines"; and applicable portions of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission." The NRC staff will seek external stakeholder input on this update and will provide draft revisions to the Commission for review and approval. While the guidance is being updated, the NRC staff will apply the revised backfitting concepts in its work.

In addition, OGC has updated its training on backfitting in the rulemaking process to reflect the Commission's direction. OGC is also designing in-depth training on the adequate protection and compliance exceptions in the various NRC backfitting and issue finality regulations; this training will reflect the Commission's November 2016 direction and the OGC memorandum. Moreover, the NRC staff, including OGC, is developing knowledge management tools that reflect Commission direction on backfitting and various aspects of the updated regulatory analysis guidance. These training and knowledge management activities will be coordinated with the actions identified in the CRGR report on backfitting discussed above.

Consideration of Qualitative Factors in Regulatory Analysis and Backfitting

In August 2014 the NRC staff provided the Commission with a policy paper, SECY-14-0087, "Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses" that recommended updating NRC's cost-benefit guidance documents to include information explaining how and when to apply various methodologies and how the results of the analyses would be used to inform decisions, including the provision that quantifying costs and benefits is preferable to qualitative descriptions of benefits and costs. On March 4, 2015, the Commission approved the NRC staff's plans for updating guidance. This work is ongoing. The draft guidance was published in the *Federal Register* for a 60-day public comment period that ended on June 16, 2017. The NRC staff is considering the public comments received as the final guidance document is developed. The NRC staff expects to submit the guidance document to the Commission for review and approval in January 2018.

Update to NRC Guidance on Cost/Benefit Evaluation in Regulatory Analysis and Backfitting

On March 4, 2015, the Commission also directed the NRC staff to improve its methods of quantitative analysis including the treatment of uncertainty, to support the development of realistic estimates of the costs of proposed requirements. In response, the NRC staff is taking action, including engaging with external stakeholders, to improve the accuracy of such estimates. As part of updating its cost-benefit guidance document, the NRC staff is currently implementing process improvements to its cost-estimating procedures in a two-phase process. As discussed above, the NRC staff expects to submit the guidance document to the Commission for review and approval in January 2018.

Dollar Per Person-Rem Factor for Evaluating Benefits

In response to the March 20, 2013, Commission direction, the NRC staff recently proposed a revision to the cost-benefit guidance in, "Reassessment of NRC's Dollar per Person-Rem Conversion Factor Policy" (NUREG-1530, Revision 1). The NRC uses the dollar per person-rem conversion factor in cost-benefit analyses to determine the monetary valuation of the consequences associated with radiological exposures. The staff's proposal is currently with the Commission for review and approval.

IV. SUMMARY

The goal of the NRC staff's recent and ongoing efforts is to add additional guidance and discipline when applying the backfit rule to ensure consistent application, including in the rulemaking process. Updates to related NRC guidance and procedures will incorporate recent Commission direction and lessons-learned, as well as; improve clarity, consistency, and effectiveness. Once completed, the updated guidance and associated improvements in training will enhance NRC staff understanding of backfitting and generic requirements, leading to more consistent backfit assessments.