



NUREG/KM-0014

History and Activities of the NRC Committee to Review Generic Requirements

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History and Activities of the NRC Committee to Review Generic Requirements

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1 INTRODUCTION AND PURPOSE

The U.S. Nuclear Regulatory Commission (NRC) knowledge management initiatives are intended to preserve the knowledge that has shaped the NRC's history and regulatory programs. Launched in 2012, the knowledge management series of publications (NUREG/KM) focuses on collecting and presenting historical information and current state of the art on various topics for the benefit of future generations of NRC professionals as well as the public.

The NRC Committee to Review Generic Requirements (CRGR) is a body that monitors the overall effectiveness of the NRC's generic backfitting and forward fitting management process, including the effectiveness of administrative controls for facility-specific backfitting and forward fitting. The CRGR prepared this NUREG/KM to provide the reader with a high-level view of the history of the CRGR from its creation in 1981 to the date of the writing of this document (2020). To that end, Chapters 3 through 14 of this document describe events in the CRGR's 39-year history that had a major impact on the roles and responsibilities of the CRGR. This NUREG/KM focuses on the last two decades of CRGR activity.

These events are presented in chronological order and cover the following topics:

- Creation of the CRGR (1981).
- Changes to the CRGR Structure, Mission, and Membership (1981 - Present).
- Administrative Review (2003).
- CRGR and the Review of Regulatory Guidance (2006).
- CRGR and the Rulemaking Process, Part 1 (2007).
- Office of the Inspector General Audit (2009).
- CRGR and the Rulemaking Process, Part 2 (2015).
- Compliance Exception and Consideration of Cost (2016).
- Backfit Program Review (2017).
- Backfit and Forward Fit Knowledge Management and Community of Practice (2019).
- Public Participation for CRGR Review (2017).
- CRGR Lessons Learned on Review of MC&A Rulemaking (2019).

2 BACKFITTING AND FORWARD FITTING

The following brief definitions give a basic understanding of backfitting and forward fitting. Backfitting occurs when the NRC imposes new or changed regulatory requirements or staff interpretations of the regulations or requirements on nuclear power reactor licensees, certain nuclear power reactor applicants, or certain nuclear materials licensees. For power reactor licensees under 10 CFR Part 50, backfitting is defined in 10 CFR 50.109 as the following:

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 rules or the imposition of a regulatory staff position interpreting the Commission's rules that is either new or different from a previously applicable staff position.

Similar definitions are provided in § 70.76, § 72.62, and § 76.76 for select materials licensees. Issue finality is a concept similar to backfitting that applies only to the holders of certain nuclear power reactor-related approvals under 10 CFR Part 52.

Forward fitting is not defined in NRC regulations, but it is defined in Management Directive (MD) 8.4, Revision 1, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests" (ML18093B087). Forward fitting is similar to backfitting in that the NRC imposes on a licensee a new or modified requirement or staff interpretation of a requirement that results in a modification of or addition to the 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. The fundamental difference between backfitting and forward fitting is that backfitting modifies NRC regulatory approvals already held by a licensee whereas a forward fitting happens when the NRC's approval of a licensee-initiated request for a licensing action includes a condition that the licensee comply with the new or modified requirement or staff interpretation of a requirement even though the licensee's underlying request did not propose to comply with that new or modified requirement or staff interpretation of a requirement.

3 CREATION OF THE CRGR (1981)

In the April 29, 1982, SECY-82-39A titled "Procedures for Controlling Generic Requirements on Reactor Licensees" (ML12241A662) in the background section (attachment 1) of the first charter for the CRGR (enclosure to ML12241A662) and as stated in the February 2, 2009, OIG audit of the CRGR titled "Audit of the Committee to Review Generic Requirements" (ML090330754), "[i]n October 1981, the presiding NRC Chairman identified a need to better control the number and nature of [requirements] imposed by the NRC on its licensees. The Chairman further stipulated that a single, central point of control at the NRC's highest operating level of management was needed to help provide a thorough review of industrywide requirements prior to issuance."

Specifically, in this October 8, 1981, memorandum from the NRC Chairman to the EDO titled "Reactor Requirements and Regional Office Reorganizations" (ML19252B515), the Chairman stated:

[f]ormal NRC staff communications with licensees (bulletins, orders, generic letters, circular, notices, rule changes, NUREGs, and Regulatory Guides) and informal communications by NRR [(Nuclear Reactor Regulation)] and Inspections and Enforcement headquarters, Regional offices and resident inspectors are not subject to any central review and coordination. Similarly, requirements placed on licensees through these communications are not centrally reviewed and coordinated. As a result of this lack of central management, licensees often receive conflicting or inconsistent directives and requests, from the NRC. Furthermore, requirements placed on licensees receive inadequate review and prioritization to ensure appropriate attention is given to those issues most important to safety.

Consequently, in November 1981, the NRC established the CRGR (initially titled as Generic Requirements Review Committee [GRRC] in the October 8, 1981, memorandum) as its central backfit control (OIG Audit, ML090330754; SECY-82-39A, ML12241A662). More specifically, the CRGR was created to help ensure that significant generic requirements imposed on NRC licensees were appropriately justified based on the NRC's regulations. The CRGR's initial charter, dated April 29, 1982, also served as its procedure and summarized its role and responsibilities (enclosure to ML12241A662, also, see June 16, 1982, Commission approval letter, ML20071D460).

4 CHANGES TO THE CRGR STRUCTURE, MISSION, AND MEMBERSHIP (1981 – Present)

As stated above, the CRGR conducts its activities in accordance with its charter; revision nine to the charter was issued in August 2018 (ML17355A532). The CRGR also uses MD 8.4, NUREG-1409, NUREG/BR-0058, and other Commission backfit policy in the discharge of its mission. As previously discussed, the CRGR's mission includes ensuring that unintended backfits are not imposed or implied by proposed new or revised generic requirements for NRC-licensed power reactors and nuclear materials facilities and that NRC-proposed actions are appropriately justified.

The CRGR charter documents the committee's mission, scope of activities, and operating procedures. According to the charter, each program-office proposal will include a determination that the burden to be imposed on the licensees is justified in view of the potential safety significance of the issue to be addressed. Such justification must be based on the backfit provisions of the NRC's regulations, Commission guidance and directives, applicable laws, and Executive Orders.

When established, the CRGR was originally intended to serve as the agency's central control point and advisor to the Executive Director for Operations (EDO) and staff regarding NRC-proposed generic backfit issues. Specifically, the CRGR was tasked to control the number and nature of NRC-imposed generic backfit requirements by ensuring that agency actions were appropriate so as not to impose unnecessary burden on the NRC's staff and licensees.

The CRGR was originally led by the then Deputy Executive Director for Regional Operations and Generic Requirements in Office of the Executive Director for Operations (OEDO) with SES members from other program offices along with one regional member and a member from the Office of the General Counsel (OGC). Responsibility for leading the CRGR was later delegated to the Office of Analysis and Evaluation of Operational Data (AEOD) from April 1987 until the office was disbanded in January 1999. At this time, the lead role for the CRGR was delegated to RES.

Per its 1999 Charter, to ensure that the staff properly identified and justified proposed generic backfits, the CRGR is to review, among other things, new and revised regulatory requirements, generic correspondence, and regulatory guides (RGs) related to nuclear reactors and selected nuclear materials and fuel cycle facilities. The charter further states that a formal CRGR review is to be "the ultimate check in NRC's backfit management to ensure that the internal backfit control processes work" before imposing changes on the NRC's licensees.

According to the then current CRGR Charter, a formal CRGR review involves the full committee reviewing, meeting, and voting on submitted backfit issues. In addition, the charter states that the committee's primary responsibilities include recommending to the EDO either the approval or disapproval of proposed generic actions, guiding and assisting the program offices in implementing the Commission's backfit policy, and reviewing the NRC's administrative generic backfit controls to determine if the controls are sufficient and the staff guidance is comprehensive and clear.

The CRGR scope of review, periodic reporting on its reviews and activities, and procedures have undergone developmental changes as can be identified through the various CRGR charter

revisions (see Appendix D for a list of the key changes in the nine CRGR charter revisions). In addition, the CRGR membership and Chairmanship positions continued to evolve regarding the management level. For a period of time, the CRGR chairmanship was at the level of the DEDROG, then it dropped to the level of Office Director and later was occupied by a Senior Level advisor, then a Deputy Division Director, and finally raised to a Deputy Office Director level where it currently resides.

5 ADMINISTRATIVE REVIEW (2003)

As stated in the current CRGR charter, the administrative controls related to the NRC staff's backfitting management practices are reviewed by the CRGR, typically every 5 years, to assess the effectiveness of these controls as part of its regulatory effectiveness responsibility. The following discussion concerns a specific administrative review that resulted in significant changes to the CRGR processes.

On July 31, 2003, the CRGR completed its 5-year periodic administrative review of the NRC control mechanisms for backfits and presented its findings to the OEDO in a report titled "Review of Administrative Controls for Plant-Specific Backfits" (ML032550007). The CRGR made several recommendations to enhance the NRC's administrative controls for managing plant-specific backfitting. The review also addressed concerns raised by industry during the CRGR's process of obtaining feedback on the generic and plant-specific backfit processes. The concerns, in general, were about the adequacy of the NRC's controls for the plant-specific backfit process including appeals of imposed backfits. The review discussed in the 2003 report focused mainly on plant-specific backfit processes. Because some overlap exists, the review also evaluated some aspects of the controls for the generic backfit processes. The objective of the review was to provide the CRGR assurance that (1) the office and regional directives and procedures for plant-specific backfits are adequate, (2) the office and regional staff training is adequate, and (3) the staff guidance is clear and comprehensive.

Overall, the review found that all offices with the need to implement backfit controls had procedures in place and were implementing them consistent with the intent specified in NRC regulations and MD 8.4, "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants." The 2003 CRGR review identified several areas where improvements could be made in the backfit processes. Below is a list of the six general findings identified in the 2003 CRGR review report.

1. NRC offices with responsibility for implementing backfit controls have specific office procedures that are generally consistent with the guidelines in MD 8.4.
2. MD 8.4, "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants," does not reflect changes that have occurred in organizational responsibilities nor in the NRC backfit program and does not highlight important elements for ensuring effective management of backfits.
3. The NRC program for training employees on the backfit process is not clearly defined.
4. The decision process for plant-specific backfits is not clearly described in individual office procedures nor readily available to licensees.
5. MD 8.4 and office procedures do not provide guidance on potential backfitting in the physical security or safeguards areas under 10 CFR Part 73.
6. The functions performed by the Office of Nuclear Regulatory Research (RES) with respect to the regulatory analysis guidelines are not clearly established in the backfit procedures. RES plays an active role in the technical and administrative support of

the CRGR, which makes it a candidate for the oversight of other backfit functions at the agency level.

At the direction of the EDO (ML032600130), RES developed an action plan titled “Action Plan – Administrative Controls for Plant-Specific Backfits” (ML033630497) that was issued to the various program offices and relevant organizations highlighting responsibilities and actions applicable to their offices.

In this action plan, the activities necessary to address the 2003 CRGR review report recommendations were grouped into four areas:

- The revision of MD 8.4.
- The development of Office and Regional procedures that are consistent with the revised MD 8.4.
- The development of a backfit training program.
- The establishment of a recordkeeping system.

Table 1 of the action plan provides the detailed findings and the associated recommendations of the 2003 CRGR report.

Under that EDO-approved plan, RES had the lead responsibility to develop the backfit recordkeeping system. This item is captured under the above recommendation, “the establishment of a recordkeeping system” and was accomplished per the March 2005 memorandum to the Office of Information System (now known as the Office of the Chief Information Officer) titled, “Request to Implement an ADAMS-Based Backfit Recordkeeping System” (ML050610550). The recordkeeping system is identified as the “Backfit - Facility Specific” folder in ADAMS. The process for formatting and entering backfit-related documents into the system is captured in the attachments to the subject memorandum.

6 CRGR AND THE REVIEW OF REGULATORY GUIDANCE (2006)

In an effort to streamline and increase efficiency, the staff in a September 14, 2006, memorandum titled “Request to Waive Review of Draft Regulatory Guides [RG] to Support New, Near-Term Reactor Licensing Activities by March 2007” requested expeditious handling of 31 high-priority regulatory guides (ML062560363). The purpose of this request to waive these high-priority RGs was to have them in place to support new, near-term reactor licensing activities by March 2007. In the above memorandum, the staff further supported their request in stating that the “revisions do not constitute a backfit.” The CRGR responded in a September 20, 2006, memorandum titled, “Response to Request to Waive CRGR Review of Draft Regulatory Guides to Support New, Near-Term Reactor Licensing Activities by March 2007” (ML062630405), granting a “conditional waiver” for the review of the subject RGs. This waiver imposed a condition that CRGR review would occur only if backfitting concerns were raised by the licensee during the public comment phase on the draft RG or upon the staff’s request. The justification for this streamlining action, as stated in the staff’s September 14, 2006, request memorandum, was in part due to the fact that these RGs were being revised, and

[t]he proposed revisions do not constitute a backfit to any previously issued staff position for existing nuclear power reactors. The purpose of the ongoing revision of the RGs is to ensure that prospective applicants have complete, accurate, and current guidance for use in preparing early site permit (ESP), design certification (DC), and combined license (COL) applications for proposed new reactors. In particular, the NRC staff is focused on ensuring that the agency’s regulatory guidance is consistent with the proposed revision to Title 10, part 52, of the *Code of Federal Regulations* (10 CFR part 52), “Licenses, Certifications, and Approvals for Nuclear Power Plants.”

With regards to another set of RGs that the agency periodically publishes revisions with the corresponding 10 CFR 50.55a rulemaking, the staff identified that these specific RGs received the same extensive reviews from the technical offices and OGC as any rulemaking and that these reviews were sufficient to ensure compliance with the backfit rule and the Commission’s backfit policies. Therefore, the CRGR, with input from the relevant staff and OGC, forwarded a plan to the EDO on May 1, 2008, (ML081050562) regarding the removal of these specific RGs from the CRGR scope of review.

Later, in a July 31, 2008, memorandum titled “CRGR Waiver Request for Regulatory Guides” (ML081820697), the staff cited the 2006 CRGR conditional waiver of the high-priority RGs to request a waiver of CRGR review of the remaining RGs (those not associated with the 10 CFR 50.55a rulemaking). The basis of this request was that

the RGs typically identify a method or approach that the staff has found acceptable to meet the requirements of the regulations (e.g., 10 CFR Part 50, Appendix A, “General Design Criteria”). The use of RGs is voluntary and alternative methods or approaches may be submitted by applicants and licensees...[w]e recognize that backfit concerns may be raised during internal staff review, advisory committee review, or stakeholder review. If a legitimate backfit concern is raised at any point, we will bring the concern to CRGR for review.

The CRGR responded in an August 18, 2008, memorandum titled “CRGR Waiver Request for Regulatory Guides” (ML082250687) granting a conditional waiver with the following understanding and requirement:

[y]our memo also notes that the Office of General Counsel (OGC) reviews both the draft guides and the final RGs. This review includes OGC's verification that the RG is not imposing or implying an imposition of any requirement...the staff is expected to be diligent in recognizing that backfit concerns may be raised during internal staff review, advisory committee review, or stakeholder review. If a review raises any legitimate backfit concern at any point, CRGR will be engaged for further evaluation.

In granting the conditional waiver, the CRGR concluded that "this revised process is more efficient and will continue to ensure that RGs meet the Commission's backfit policy."

7 CRGR AND THE RULEMAKING PROCESS, PART 1 (2007)

In a Commission Staff Requirements Memorandum (SRM) (COMNJD-06-0004/COMEXM-06-0006) titled "Response to the Staff Requirements Memorandum for SECY-18-0104 – Draft Final Rule: Amendments to Material Control and Accounting Regulations (RIN 3150-AI61; NRC-2009-0096); CRGR Lessons Learned," dated May 31, 2006 (ML061510316), the Commission approved a staff recommendation to, among other things, allow the staff to waive review by the CRGR at the proposed rule stage. The SRM further directed the staff to evaluate the effectiveness of the Rulemaking Process Improvement Implementation Plan. With respect to the CRGR's review at the proposed rule stage, the staff concluded that "deferring the ACRS [Advisory Committee on Reactor Safeguards] and CRGR review until the final rulemaking effectively and efficiently accelerates the proposed rulemaking schedule provided that there are not significant technical or backfit issues" (SRM, ML071780644; Enclosure, ML071780648).

Moreover, the NRC staff stated that "[i]n the case of CRGR, the working group believes that it is not as important to interact with the committee at the proposed rule stage primarily because external stakeholder comments are used by the CRGR to assess backfit questions at the final rule stage." In addition, the NRC staff stated that CRGR review of rulemaking packages was duplicative because rulemaking packages had already gone through each of the individual offices for concurrence before CRGR review. Rulemaking packages include a regulatory analysis of the rulemaking and consideration of backfit issues. Therefore, the NRC staff found that this "thorough vetting of the product significantly diminishes the opportunity for CRGR to add value; the same cannot be said for any other products that CRGR reviews." The staff went on to further recommend that, with regard to the review of rulemaking, "[r]eview by CRGR for rulemaking tasks should be completely eliminated."

In the October 25, 2007, SRM on SECY-07-0134 titled "Evaluation of the Overall Effectiveness of the Rulemaking Process Improvement Implementation Plan" (ML072980427), the Commission approved the removal of the requirement for CRGR review of current and future rulemaking packages and directed the NRC staff to provide to the CRGR a copy of the draft final rule for informational purposes.

In this SRM, the CRGR was also directed, as part of its next periodic assessment of the activities of the CRGR (in 2008), to analyze the functions of the CRGR "to determine whether the functions the CRGR undertakes are appropriate" including "an analysis of the appropriate role of the CRGR with respect to the rulemaking process." These topics were further discussed in the 2008 and 2010 CRGR annual assessments (ML081550671 and ML101320456, respectively). Section 8.0 provides a discussion of these assessments as they were particularly relevant to the Office of the Inspector General (OIG) audit that began in 2009.

Moreover, as indicated in the above-mentioned enclosure titled "SECY-07-0134 - Assessment of Rulemaking Process Improvements" (ML071780648), the waiver that excludes the CRGR and the ACRS review at the proposed rule stage did not alter the ability of the ACRS and the CRGR to submit comments to the Commission and the EDO at any time during the rulemaking process. In granting the staff authority to waive CRGR review at the proposed rule stage, the Commission instructed the NRC staff that "due consideration should be given to the merits of earlier engagement with one or both committees [ACRS and CRGR], if the staff determines that such engagement will result in a more efficient and effective process for a particular rulemaking." The Commission further instructed the NRC staff that, "when the committee reviews are waived, the

staffs of both committees should continue to be provided copies of the proposed rules and supporting documentation to keep them informed” (ML071780648).

8 CRGR CHANGES IDENTIFIED IN OFFICE OF THE INSPECTOR GENERAL AUDIT (2009)

In 2009, the Office of the Inspector General (OIG) conducted an audit on the CRGR (ML090330754). The audit mainly identified that the CRGR was not functioning in accordance with its initial intended purpose of reviewing generic backfit issues. With regards to this audit finding, these changes were due to a maturity in the agency backfitting process and not to a deficiency in the CRGR charter activities being accomplished.

Specifically, the 2009 OIG Audit identified that since the 1990s, the CRGR had not been functioning as the single control point for conducting technical reviews of all program office proposals to support recommendations to the EDO. Instead, each office had assumed the primary responsibility for ensuring proper backfit considerations. The resulting decrease in CRGR activities that were picked up by the various offices increased responsibility in office reviews where CRGR once took the lead, such as in review of rulemaking (see Section 7) (ML061510316).

The audit reported that prior to the 1990s, the CRGR members, with assistance from six full-time senior technical experts, formally reviewed all program office proposals to determine the completeness, adequacy, and sufficiency of the analysis, details, and technical data provided by the staff in support of the proposed requirements changes. The CRGR then submitted written statements to the EDO justifying the findings of its formal reviews.

The audit identified that the CRGR receives the package for review after multi-office reviews are accomplished. The CRGR then submits written statements to the EDO justifying the findings of its formal reviews. These statements provide a clear explanation of the CRGR's recommendations to the current EDO to approve, disapprove, or suggest modifications to the submitted proposals. The audit recognized that the changes in the CRGR's function and process were mostly due to the evolution of the agency's processes which, in effect, resulted in other offices assuming some of the CRGR's duties. Note, separate from the conclusion of the audit, it is to be understood that due to the maturity in the agency backfitting process, six full-time senior technical experts were no longer required as most of the activities of these staff members were absorbed into the respective office backfitting processes. Currently, RES designates 0.5 FTE to provide technical and administrative support to the CRGR.

In light of these evolutions, the OIG stated that "without reassessing and documenting its current internal backfit review process, the agency cannot be assured that it is taking consistent or appropriate action with regard to backfit reviews and is taking the necessary steps to prevent unnecessary regulatory burden on NRC licensees." The OIG provided two recommendations:

1. Develop, document, implement, and communicate an agencywide process for reviewing backfit issues to ensure that generic backfits are appropriately justified based on NRC regulations and policy.
2. Determine what, if any, role the CRGR should perform in the NRC's backfit review process to include whether the CRGR function is still needed.

In a March 18, 2010, OIG memorandum titled "Status of Recommendations: Audit of the Committee to Review Generic Requirements (OIG-09-A-06)" (ML100770374), recommendation

no. 2 was closed. Consequently, in a memorandum with the same title dated September 28, 2015, recommendation no. 1 was closed (ML15271A254). Consequently, the various issues identified in the 2009 OIG audit that indicated a change in the CRGR function and process have been captured in successive Charter revisions since the 2009 OIG audit.

9 CRGR AND THE RULEMAKING PROCESS, PART 2 (2015)

In SRM-COMSGB-15-0003 "Commission Involvement in Early Stages of Rulemaking" dated August 14, 2015 (ML15226A355), the Commission directed the NRC staff to provide a proposed plan for increasing the Commission's involvement in the rulemaking process. Among the various requirements in the staff's plan was a CRGR-related requirement for the staff to make "a recommendation for reconsideration of the Commission's 2006 direction with respect to the reviews of proposed rules by the CRGR..." and "analyze whether amendments to the charter of the CRGR to alter its role in the agency's rulemaking process have the potential to better inform the agency's allocation of resources and prioritization of activities."

In 2013, the charter was formally revised to eliminate the requirement that CRGR review proposed rulemaking packages (Revision 8). Although this revision allowed an Office Director or the EDO to request CRGR review of a proposed rule to ensure compliance with agency backfitting policies, guidance did not exist to assist the staff in identifying when and how to engage the CRGR to review a proposed rule. Between October 2007 and October 2017, the NRC staff did not request CRGR review of any proposed or final rule packages.

Given the agency's greater focus on ensuring backfitting and regulatory analysis reviews are conducted appropriately and in light of the Commission direction on qualitative factors during the 2016 CRGR annual assessment period, CRGR review of certain rulemaking packages was considered in general to be beneficial based on input from the sponsoring staff (ML16160A311). The NRC staff proposed to inform the CRGR upon submittal of the Rulemaking Activity Plan to the Commission to keep the committee informed of rulemaking status. In addition, the CRGR developed criteria for the staff to use for engaging the CRGR in certain rulemakings. These changes would give the CRGR the opportunity to request briefings early in the rulemaking process. In addition, it would also provide the Office Directors and the EDO guidance on when to request CRGR review of the individual proposed rulemaking packages. Changes to the CRGR charter to reflect these updates were made in 2018 in Revision 9.

In SECY-15-0129 "Commission Involvement in the Early Stages of Rulemaking" dated October 19, 2015 (ML15267A716), the staff provided a response containing eight recommendations to the above SRM—COMSGB-15-0003.

The following list contains the eight approved recommendations that were submitted in the above-mentioned SECY:

1. Approve the institution of a streamlined rulemaking plan requirement in the form of a SECY paper that would request Commission approval to initiate any nonroutine, nondelegated rulemaking.
 - a. Approve the template for the streamlined rulemaking plan.
 - b. Rescind the delegation of authority in the SRM on COMNJD-06-0004/COMEXM-06-0006, "Streamlining the NRR Rulemaking Process," dated May 31, 2006, (ML061510316) that gave the Director of NRR the discretion to waive (in consultation with the General Counsel) the development and submission of rulemaking plans.
 - c. Rescind the delegation of authority in the SRM on SECY-07-0134, "Evaluation of

the Overall Effectiveness of the Rulemaking Process Improvement Implementation Plan,” dated October 25, 2007, (ML072980427) that gave the Director of the Office of Federal and State Materials and Environmental Management Programs (FSME) (now merged with the office of Nuclear Material Safety and Safeguards [NMSS]) the discretion to waive (in consultation with the General Counsel) the development and submission of rulemaking plans.

2. Approve the requirement that staff submit a SECY paper to request Commission approval to discontinue any rulemaking.
3. Approve the requirement that staff submit to the Commission for approval any PRM determination that recommends rulemaking.
4. Approve submittal of the updated Rulemaking Activity Plan (RAP) as an enclosure to a CA note (W201100275) and move the due date for the annual submission of the RAP to November (W199500048).
5. Approve the inclusion of the ACRS and CRGR on the distribution for the CA note submitting the RAP to the Commission.
6. Move the due date for the annual submission of the CPR process to the CFO in May along with a CA Note to the Commission.
7. Reaffirm the Commission’s 2006 Direction that the CRGR and ACRS not expand their roles to routinely review proposed rules.
8. Determine that the CRGR not expand its role to become involved in resource allocation and rule prioritization.

In the February 3, 2016, SRM– SECY-15-0129 (ML16034A441) Commission response to the staff’s recommendations, the Commission approved seven of the CRGR-related recommendations; however, the Commission further stated that “with respect to recommendation 8, the Commission has neither approved nor disapproved reaffirming the current role of the Committee to Review Generic Requirements (CRGR).” Also included in this SRM, the Commission directed the CRGR to provide the Commission the criteria and guidance it developed for triggering a CRGR review of a proposed rule. The Commission also directed the CRGR to inform them if it determines that further process enhancements regarding CRGR would be beneficial after it has been able to assess lessons-learned and feedback from the use of the new guidance and criteria.

The criteria were provided for information to the Commission in May 23, 2016, SECY-16-0064, “CRGR Response to Staff Requirements-SECY-15-012 Commission Involvement in Early Stages of Rulemaking” (ML16075A365). The criteria are to be used to inform the staff when to engage the CRGR if one or more of the following are met:

1. The rulemaking may have issue finality concerns or possible backfitting.
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 EDO directed the review, or stakeholder or NRC staff concerns regarding the backfit or regulatory analysis have been raised.

The CRGR provided the guidance and criteria to the staff through the above SECY-16-0064 with the plan to examine the need for further process enhancements regarding the CRGR after it has been able to assess lessons-learned and feedback from implementation and use of the new guidance and criteria.

The CRGR provided its assessment of the lessons-learned and feedback (covering May 2016 to July 2018) from the staff on its use of the new guidance and criteria and informed the Commission on its determination whether any CRGR process enhancements should be associated with the use of the criteria in its August 31, 2017, SECY-17-0089 titled, "Annual Report of the Committee to Review Generic Requirements Review Activities" (ML17174B197).

In summary, the 2017 CRGR annual report (ML17174B197) stated that, with regard to its review of the criteria, the rulemaking Center of Expertise (COE) suggested to improve the coordination process between the COE and the CRGR. The COE also stated that it will track lessons learned of the staff implementation of the criteria. The CRGR will continue to engage with the staff for more improvement suggestions. In its assessment of the criteria, the CRGR concluded in SECY-17-0089 "that based on addressing the various relevant recommendations as a result of the...CRGR report to the EDO tasking and the RCE suggestions, some changes will be made to the CRGR rulemaking review process to improve future CRGR and staff engagement in the rulemaking process."

Consequently, the relevant CRGR charter changes (i.e., criteria inclusion and instructions on the revised process) were incorporated into the March 2018 revision of the CRGR charter. For that lessons-learned assessment period (2018), no identified process changes were required, and it is understood that any changes required in the future will be made to the CRGR rulemaking review process to improve future CRGR and staff engagement in the rulemaking process. Any subsequent changes to the criteria and guidance or CRGR processes related to its reviewing will be discussed in future CRGR annual reports.

10 BACKFIT PROGRAM REVIEW (2016)

As a result of both internal deliberations and external stakeholder feedback, the OEDO convened a meeting on February 9, 2016, with the senior managers and technical and legal staff involved in backfitting. The focus of this meeting was to discuss how well management and staff were continuing to adhere to the “formal, systematic, and disciplined review of new or changed positions” that was intended for the backfitting process consistent with the agency’s Principles of Good Regulation (ML14135A076). In particular, the staff discussed the adequacy and consistency of the staff’s implementation of agency backfitting guidance and the connection with the role of the CRGR in monitoring the regulatory effectiveness of the backfitting process on a generic basis.

On June 9, 2016, the EDO issued a tasking memorandum titled “Tasking Related to Implementation of Agency Backfitting Guidance” (ML16133A575) (EDO Tasking Memo) directing the CRGR to conduct a rigorous review of the NRC’s “guidance, training, and expertise for assessing issues for backfit implications and for responding to questions and concerns raised by our stakeholders.”

The EDO tasking covered three general topics:

1. Assess backfit requirements, guidance, and criteria (NUREG-1409, “Backfitting and Issue Finality Guidance” and Management Directive [MD] 8.4, “Management of Facility-Specific Backfitting and Information Collection”).
2. Assess backfit training.
3. Assess knowledge management for backfitting.

In addition, in a memorandum titled “Supplemental Tasking Related to Implementation of Agency Backfitting and Issue Finality Guidance” dated December 15, 2016 (ML16344A004), the EDO directed the CRGR to consider additional agency actions and direction issued since the date of the original tasking associated with backfitting and issue finality. In the supplemental tasking, the EDO also directed the CRGR to review its charter against the results of its assessment and to determine if any scope or process changes were warranted. Two notable actions fell within the scope of the supplemental tasking:

1. The EDO’s decision to reverse, under appeal from Exelon Corporation, a compliance backfit of Byron Station, Units 1 and 2 (Byron) and Braidwood Station, Units 1 and 2 (Braidwood).
2. Commission direction in SRM-COMSECY-16-0020 that the staff be “familiar with and operate in a manner consistent with” an OGC analysis about consideration of costs when considering exceptions to the backfit rule and the use of the compliance exception to mandate consistency with General Design Criteria (GDC). This direction is summarized in a publicly available December 20, 2016, memorandum from the NRC Solicitor to the CRGR Chairman titled, “Summary of COMSECY-16-0020, Recommendation on Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception to Backfit Rule” (ML16355A258) (Solicitor’s Memo).

On June 27, 2017, the CRGR sent to the EDO a report titled “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” (ML17174B161) (2017 CRGR Report). In this report, the CRGR concluded that opportunities existed to improve backfitting practices. The CRGR recommended actions that would improve oversight by NRC senior managers and first-line supervisors; enhance engagement and oversight by the CRGR; improve staff knowledge, skills, and abilities associated with backfitting and generic requirements; and result in more consistent identification and treatment of potential backfitting issues. The CRGR concluded that broad communication of the Commission direction in SRM-COMSECY-16-0020, increased management involvement, and improved training and developmental activities would yield the greatest improvements in performance and consistency. The results of the CRGR review identified nine key findings (see Appendix C for the list of key findings).

Subsequently, in a July 19, 2017 memorandum entitled “Tasking in Response to Committee to Review Generic Requirements Report on the U.S. Nuclear Regulatory Commission’s Implementation of Backfitting and Issue Finality Requirements” (ML17198C141), the EDO issued a response to the CRGR that supported the CRGR’s recommendations and provided subsequent direction to the CRGR as well as affected offices. The enclosure to this memorandum contained a list of 20 actions derived from the key findings with assigned lead offices.

The planned actions were grouped within four broad categories: (1) requirements, guidance, and criteria; (2) training; (3) knowledge management; and (4) revisions to the CRGR charter. The tasking also included direction to conduct an effectiveness review of the actions taken, report on the availability of key docketed information and the resources needed to make information more readily retrievable, and report on the resources needed to complete the directed actions.

For much of the 2018 CRGR annual reporting period (June 2018-May 2019), the staff’s work related to the tasking items was placed on hold by the Commission in “Staff Requirements - SECY-17-0006: Interim Staff Guidance on Evaluating Chemical Exposures at Fuel Cycle Facilities” (ML18302A268), dated October 29, 2018. In this SRM, the Commission stated:

The staff should await further direction arising from Commission action on SECY-18-0042 (Draft Final NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission”) and SECY-18-0049 (Management Directive and Handbook 8.4, “Management of Backfitting, Issue Finality, and Information Collection”) prior to developing or issuing any further revisions to agency internal procedures and guidance governing backfit provisions.

The Commission provided this direction to the staff in SRM-SECY-18-0049 (ML19149A296) issued on May 29, 2019, and SRM-SECY-18-0042 (ML19207A042) issued on July 26, 2019. The staff published MD 8.4, resubmitted NUREG/BR-0058 to the Commission in January 2020 (SECY-20-0008, “Draft Final NUREG/BR-0058, Revision 5, ‘Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission’”), and issued draft NUREG-1049, Revision 1, for public comment in March 2020 (ML18109A498).

With regards to the status of the items discussed in this section, the CRGR and the other relevant offices are continuing to engage in accomplishing all of the associated actions or

recommendations. As of August 31, 2020, the status of the remaining items is as follows:

- Issue updated NUREG-1409: Due 2021.
- Update office-level guidance & Enforcement Manual: Due 9/30/2021 to OEDO.
- Develop refresher training for qual programs: Due 9/30/2021 to OEDO.
- Revise qualification procedures to require initial and refresher training: Due 9/30/2021 to OEDO.
- Prepare a NUREG/KM report on history and activities of CRGR: Due 9/30/2020 to OEDO (this subject report).
- Conduct effectiveness review of actions taken in response to the 6/27/17 CRGR report: Due 6/27/2023 to OEDO.

These dates are subject to change based on staff resources and any emergent competing priorities.

11 COMPLIANCE EXCEPTION AND COST (2016)

In response to the EDO Tasking Memo, OGC undertook a reexamination of the extent to which costs are considered when the agency imposes a requirement on a licensee that involves the backfit rule. OGC provided recommendations to the Commission in COMSECY-16-0020 (not publicly available), and the Commission approved the recommendations in SRM-COMSECY-16-00020. As COMSECY-16-0020 was not made available to the staff, OGC provided a publicly available summary to the staff via the Solicitor's Memo. In general, the Solicitor's Memo clarified the consideration of cost when considering exceptions to the backfit rule and the scope of the compliance exception to the backfit rule. Concerning the compliance exception, the Solicitor explained how the NRC was to determine an omission or mistake of fact and, therefore, when to use the compliance exception and whether to use the compliance exception to mandate consistency with general design criteria.

12 BACKFIT AND FORWARD FIT KNOWLEDGE MANAGEMENT AND COMMUNITY OF PRACTICE (2017)

As part of the recommendations in the 2017 CRGR Report to facilitate knowledge management (KM), the agency developed a backfitting Community of Practice (CoP) (<https://usnrc.sharepoint.com/teams/OCHCO-KC/backfit/SitePages/Home.aspx>). As stated in the 2017 CRGR Report, the purpose of this CoP is to provide access to subject matter experts on the backfitting process who could share experiences and archive information for future use. The CoP served under the management of the CRGR and helped the CRGR implement the EDO Tasking Memo.

In MD 8.4, the Commission delegated to OGC the responsibility to maintain “a backfitting/forward fitting Community of Practice with office POCs, including a backfitting/forward fitting site.” On June 21, 2019, OGC issued a memorandum titled “Membership in the NRC’s Backfitting and Forward Fitting Community of Practice” (ML19172A240) to the various offices and regions identified in MD 8.4 as having backfitting and forward fitting responsibilities and requested that they appoint representative members to the CoP. On August 21, 2020, the Charter for the CoP titled, “Charter for the Nuclear Regulatory Commission’s Backfitting and Forward Fitting Community of Practice” (ML20234A443) was issued to the various offices with backfitting responsibilities and all of the regions. Prior to its charter, the CoP has met several times and was instrumental in developing draft NUREG-1409, Revision 1.

13 PUBLIC PARTICIPATION FOR CRGR REVIEW (2017-2018)

In 2017, a major change took place in the CRGR review process. The CRGR introduced an opportunity for external stakeholders to engage with the CRGR to present backfitting concerns. This type of meeting was formalized and documented in the 2018 CRGR charter and referred to as a “complex meeting with external participation.” The CRGR convened the first meeting of this type in 2017 to solicit comments from the industry due to backfitting concerns that were raised during the public comment period associated with the draft proposed Regulatory Issue Summary (RIS) titled “Disposition of Information Related to the Time Period that Safety-Related SSCs (Structures, Systems, and Components) are Installed” (ML17177A060). Note, this RIS was subsequently withdrawn by the staff. The combined minutes for this subject RIS may be found in the October 17, 2017, meeting minutes for meeting nos. 446 and 447 titled “Committee to Review Generic Requirements Meeting Minutes for Meeting Numbers 446 and 447” (ML17276B156). Including this topic review, the CRGR has held three such meetings of this type.

In the second of these reviews (conducted across three meetings, nos. 448, 449, and 451), the CRGR reviewed a draft Task Interface Agreement titled “Oconee Nuclear Station, Units 1, 2, and 3 – Final Response to Task Interface Agreement 2014-05, Design Analysis for Single Failure and the Integration of Class 1E Direct Current Control Cabling in Raceways with High Energy Cabling” (ML17289A542). The third review of this type was to discuss draft Regulatory Guidance 5.69 “Guidance for the Application of the Radiological Sabotage Design Basis Threat in the Design, Development, and Implementation of a Physical Security Program that meets Title 10 of the *Code of Federal Regulations* Section 73.55 Requirements.” Note, the minutes is not publicly available as it contains Safeguards Information. An e-mail capturing results of the CRGR meeting is located at ML18106A226.

14 CRGR LESSONS LEARNED ON REVIEW OF MC&A RULEMAKING (2019)

The August 16, 2018, CRGR meeting minutes “Committee to Review Generic Requirements: Meeting Minutes of Meeting Number 456” (ML18233A519) capture the highlights of an August 16, 2018 CRGR meeting with the staff to discuss Draft Final Rulemaking 10 CFR Part 74 “Material Control and Accounting of Special Nuclear Material” (MC&A) (ML18221A521) and the staff’s positions regarding the use of the adequate protection exception to performing a backfit analysis for the rulemaking. The staff’s presentation materials are located in ADAMS (ML18221A524). At this meeting, the CRGR endorsed the staff’s draft final rulemaking and the associated regulatory guidance documents. In its review of this draft final rulemaking, the CRGR engaged the staff in discussion regarding the purpose of the rulemaking, the backfitting approach used in the rulemaking, the regulatory analyses supporting the rulemaking, and the effects of the rulemaking on the licensees that would be subject to the revised regulations should the Commission approve the draft final rulemaking (note: the material in this section is extracted largely from the September 19, 2019, CRGR lessons learned report titled “Response to the Staff Requirements-SECY-18-0104-Draft Final Rule: Amendments to Material Control and Accounting Regulations (RIN 3150-A161; NRC-2009-0096)” (ML19098B622).

In the Staff Requirements Memorandum (SRM) for SECY-18-0104 “Draft Final Rule: Amendments to Material Control and Accounting Regulations” (ML19093B393), the Commission directed NMSS to develop a lesson learned case study. In addition, the Commission directed the CRGR to “evaluate its endorsement of this draft final rule and provide a report to the Commission on any lessons-learned or modifications that may be needed to its evaluation criteria, given the Commission’s disapproval of the rule’s issuance.” On October 7, 2019, NMSS and the CRGR responded to the Commission in a joint CA Note (ML19235A006). The CRGR response is included as Enclosure 2 (ML19098B622).

To summarize, the CRGR stated that based on the review of its actions relative to the MC&A rulemaking, it found that the security rationale could have been more critically considered during the CRGR and staff deliberations. Moreover, the CRGR stated that, although it reviewed the history and evolution of the rulemaking and the staff’s recommendation regarding the adequate protection exception, the CRGR recognizes that more clarity is needed in the CRGR review process. Therefore, the CRGR planned to consider revisions to its procedures titled “Committee to Review Generic Requirements Procedures and Internal Administrative Process” (ML17355A533) in the effort to clarify both the scope and the increased rigor of the CRGR’s reviews with respect to staff proposals invoking the adequate protection exception.

The CRGR also stated that additional clarity would better define expectations for future reviews. For example, although the Commission makes the final decision on the staff’s application of the adequate protection exception, the CRGR should provide recommendations to the sponsoring office regarding the adequacy of the staff’s supporting analysis for the adequate protection exception. These recommendations would be particularly useful when the CRGR disagrees with or has concerns about the staff’s recommendation or supporting rationale. The CRGR planned to implement an enhanced review process that is described in more detail in the subject lessons learned report.

With regard to the revisions to its procedures, the CRGR plans to incorporate the enhanced review process using the five process enhancements listed below:

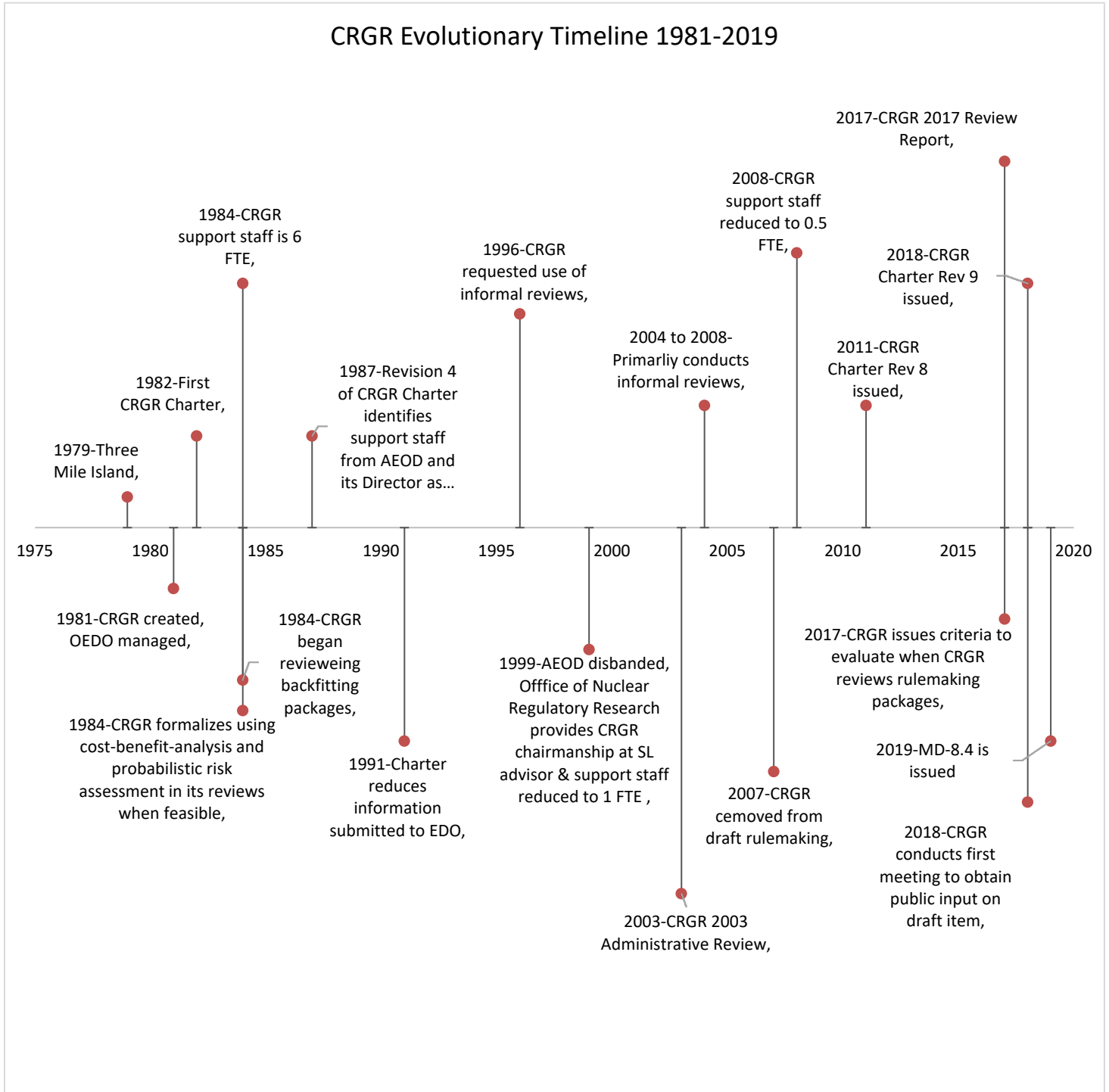
1. A more rigorous focus on whether the proposed improvements or changes are necessary.
2. Confirmation that the justification for invoking the adequate protection exception meets the guidance in NUREG-1409.
3. Review of the complete documentation of the historical background between the staff, Commission, and industry interactions including resolution of Commission comments.
4. A more rigorous review of the staff's response to the public comments on staff proposals regarding backfitting with particular focus on staff recommendations to use the adequate protection exception.

APPENDICES A – D

**Appendices A through D Provide Information Regarding the CRGR Activities
and Milestones**

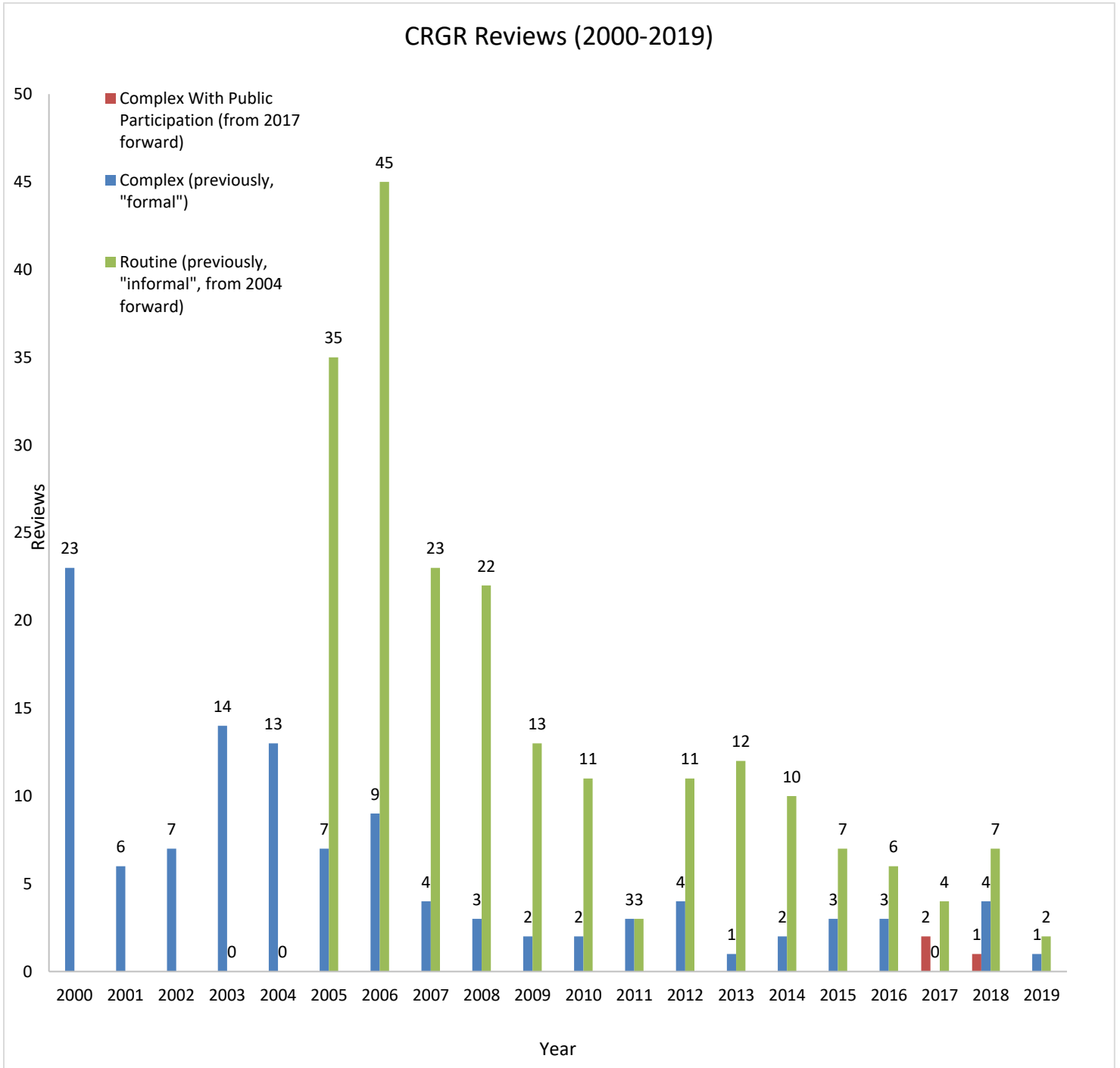
APPENDIX A CRGR EVOLUTIONARY TIMELINE 1981 – 2019

Appendix A provides dates and titles of significant CRGR milestones since the creation of the CRGR (1981).



APPENDIX B TYPES OF REVIEWS CRGR HAS PERFORMED

The below graph displays the number of types of reviews that the CRGR has performed since 2000 to 2019.



APPENDIX C

KEY FINDINGS FROM THE 2017 CRGR REVIEW

1. The CRGR did not find many instances where licensees or the Nuclear Energy Institute (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.
2. 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.
3. 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.
4. 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” (ML12059A460) and NUREG-1409 “Backfitting Guidelines” (ML032230247). The staff should use this interim guidance for issues currently under review. Note, the staff used the NRC Solicitor General memorandum (see Section 11) to inform its backfitting activities and the Commission direction in SRM-COMSECY-16-0020. (During this time, the staff’s activities were on hold due to necessary clarification on Commission policies [see Section 10]).
5. 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.
6. 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.
7. The CRGR charter should be revised to reflect organizational changes, incorporate the new rulemaking review decisionmaking criteria, and 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. (Note: revision 9 of the CRGR charter was under development at this time and was informed by the 2017 CRGR review report).
8. The corrective actions that are currently underway and recommended will improve oversight by NRC senior managers and first-line supervisors; enhance engagement and oversight by the CRGR; improve staff knowledge, skills, and abilities associated with backfitting and generic requirements; and result in more consistency in identifying and resolving potential backfitting issues.
9. 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.

APPENDIX D

KEY CHANGES IN THE NINE CHARTER REVISIONS

Revision 1 of the CRGR Charter (January 6, 1984, ML20086S051) was approved by the Commission as referenced in the EDO memorandum dated February 24, 1984 (ML20086S040). The Charter was revised to align the process that the CRGR conducted its reviews to how it should conduct its reviews in leveraging evaluation tools. The key change put forth in revision 1 of the Charter is summarized below:

- The CRGR review is expected to include cost-benefit analysis and probabilistic risk assessment where data for its proper use are adequate. Therefore, to the extent possible, written justifications should make use of these evaluation techniques. The use of cost-benefit analyses and other tools should make it possible to determine which proposed requirements have real safety significance, as distinguished from those proposed requirements which should be given a lower priority or those which might be dropped entirely.

Revision 2 of the Charter (March 1986, ML19298D661) was approved by the Commission in COMSECY-86-5, dated June 20, 1986. The key change put forth in revision 2 of the Charter are summarized below:

- Clarifies that exemptions from CRGR review are items that:
 1. Would provide substantial cost savings for the NRC or industry through decreases or relaxation in current staff positions that would have no significant detrimental effect on plant safety.
 2. Would provide a substantial additional overall increase in plant safety through increases in current staff positions that would have no significant cost to the NRC or industry.

Revision 3 of the Charter (September 1986, ML19303D504) was approved by the Commission (SECY memorandum, dated August 13, 1986). The key changes put forth in revision 3 of the Charter are summarized below:

- Appointment of an individual from OGC to be a member of CRGR.
- The CRGR Chairman would assure process controls for overall agency management of the generic backfit process are developed and maintained. These process controls shall include specific procedures, training, progress monitoring systems, and provisions for obtaining and evaluating both staff and industry views on the conduct of the backfit process. The CRGR Chairman is also responsible for assuring that each licensee is informed of the existence and structure of the NRC program.

Revision 4 of the Charter was approved by the EDO (Memorandum to the Commissioners, dated April 6, 1987) as Appendix C to the NUREG-1409 (ML032230247). The key change put forth in revision 4 of the Charter are summarized below:

- The responsibility of the CRGR is transferred over to AEOD from OEDO. The Office Director of AEOD now assumes the CRGR Chairmanship, and the support of the CRGR comes from the AEOD staff.

Charter Revision 5 of the CRGR charter was approved by the Commission on May 8, 1991 (ML20024H356). The key changes put forth in revision 5 of the Charter are summarized below:

- An increased emphasis on safety goal considerations.
- An increased emphasis on licensee prioritizing and scheduling proposed backfits.
- A recommendation that, when feasible, generic requirements and staff positions use quantifiable, enforceable objectives rather than prescribing how the objectives or intended results are to be achieved.
- A requirement that information requests under 10 CFR 50.54(f) contain statements affirming that the requests do not impose new requirements on licensees, other than for the requested information.

Charter Revision 6 of the CRGR charter was approved by the Commission on March 22, 1996 (SRM-SECY-96-032, ML003754193). The key changes put forth in revision 6 of the Charter (ML20108D436) are summarized below:

- Incorporating guidance reflecting the Commission's understanding of the "substantial increase" standard of the backfit rule, specifically with regard to consideration of qualitative factors in the justification of proposed backfits.
- Expanding the CRGR review scope, on a trial basis, to include selected items in the nuclear materials area.
- Reflecting the recent approval by the Commission of the new Regulatory Analysis Guidelines document, Revision 2 to NUREG/BR-0058.
- Incorporating other revisions for the purpose of updating and clarifying existing provisions to reflect current policy and practice.

Charter Revision 7 of the CRGR charter was approved by the EDO (Memorandum to the Commissioners, dated on November 8, 1999, ML003718374). The key changes put forth in revision 6 of the Charter are summarized below:

- The CRGR membership and the Chairman will continue to be appointed by the EDO. The Committee will have one member each from the Offices of Nuclear Reactor Regulation (NRR), RES, NMSS, the General Counsel (OGC), and one of the regions, on a rotational basis. The CRGR Chairman will report directly to the EDO about CRGR activities. New members will be appointed as the need arises. RES will provide the technical and administrative support for the CRGR.
- Except for the proposed generic requirements that are to become immediately

effective (e.g., those requiring immediate action by the licensing office because they may involve adequate protection issues), the CRGR will continue to review all new and revised power reactor related regulatory requirements, generic correspondence, regulatory guidance as well as selected NRC staff guidance related to licensing, inspection, assessment, and enforcement that could impose a backfit.

- At the recommendation of either the Director, NMSS, or at the EDO's request, the Committee will review selected new and revised fuel cycle facility, and spent fuel transportation and storage-related proposed new or revised regulatory requirements, generic correspondence, regulatory guidance as well as selected NRC staff guidance related to licensing, inspection, assessment, and enforcement which could impose a backfit.
- The CRGR review of inspection or enforcement guidance will either be at the specific request of the staff or by the CRGR self-initiation. In accordance with the Commission's direction for selecting inspection guidance, the CRGR's focus will be on inspection or enforcement guidance for major rulemaking, especially when significant departures from the use of risk-informed approaches are being proposed.
- The Committee will provide guidance and assistance to the NRC program offices to help implement the Commission's backfit policy.
- The Committee will review NUREGs only if they delineate a new staff position. The Committee will no longer review generic actions solely involving voluntary actions including generic communications, staff guidance, rules, and safety evaluation reports (SERs). The CRGR review of the SERs endorsing generic vendor initiatives will only be at the program office director's request.
- As an additional responsibility, the CRGR will review the NRC's administrative generic backfit controls (every 5 years per the current MD 8.4) to determine if they are sufficient and the staff guidance is comprehensive and clear. The program office management will be responsible for ensuring that the staff follows the backfit procedures.
- As part of the Committee's responsibility for monitoring the overall effectiveness of the NRC's generic backfit management process, the CRGR members will continue to periodically visit nuclear power reactors and nuclear materials facilities and will hold meetings with stakeholders, as appropriate.
- The CRGR will perform special tasks at the EDO's request.

Charter Revision 8 was approved by the EDO (Memorandum to the Commissioners, dated March 10, 2011, ML110591141). The key changes put forth in revision 8 of the Charter (ML110620618) are summarized below:

- The Committee will now have one member each from the program offices formed since the issuance of the last CRGR charter (Office of Nuclear Security and Incident Response (NSIR), Office of New Reactors (NRO), FSME).

- Rulemakings will only be reviewed at the request of the proposing office or as directed by the EDO. The CRGR will now review documents for which the non-concurrence process has been evoked related to a backfit issue. The CRGR will continue to formally review Generic Letters and Bulletins and will be available for the review of other documents upon request.
- The program offices and regional management will ensure that the staff continues to follow the agency's backfit procedures and will maintain a backfit POC who will be responsible for their respective office/regional procedures and processes specific to relevant backfit activities.
- The CRGR no longer requires the program offices to provide a list of items expected to be submitted for CRGR review and endorsement to the CRGR Chairman because the volume of items requiring CRGR review has diminished.
- The CRGR now performs "informal" reviews of various generic documents such as Regulatory Issue Summaries. The CRGR technical staff conducts these reviews and provides recommendations to the CRGR Chairman and members. If concerns exist or unintended backfitting requires further discussion, then a "formal" review will entail the staff appearing before the CRGR members in a formal meeting.
- In the effort to streamline the development and revision of agency regulatory guides, the CRGR will review draft regulatory guides at the request of the staff. However, the staff is required to engage the CRGR if there has been a valid documented backfit claim made during the public comment phase. This interaction may result in a formal CRGR review.
- The sponsoring division director is no longer required to provide a closeout memorandum to the CRGR indicating agreement with the CRGR recommendations. The discussions within the CRGR meeting are captured by the meeting minutes that document the staff's position. However, in instances of disagreements, the sponsoring division director will submit a memorandum to the EDO for resolution.
- The CRGR will review requests regarding a backfit claim from external stakeholders to address an unresolved backfit claim raised in the public comment phase of document development pertaining to new or revised generic requirements (this excludes the rulemaking's public comment phase as a review process already exists for the stakeholders to raise backfit issues). In this review process, the CRGR will first engage the staff before any potential public meetings of the CRGR with external stakeholders.

Charter Revision 9 was approved by the EDO (Memorandum to the Commissioners, dated August 17, 2018, ML18175A001). Changes included minor procedural improvements and addressing the relevant items identified by the 2017 CRGR Review Report (ML17174B161) which required a revision of the existing CRGR Charter to more appropriately reflect the committee's process, roles, and responsibilities (ML17355A532).

Moreover, to capture the changes affecting process in the charter and to facilitate durability in the CRGR review process and instructions to the staff, the CRGR procedures and administrative process were removed from the charter and placed into a separate stand-alone

June 2018 document entitled, "Committee to Review Generic Requirement Procedures and Internal Administrative Process" (ML17355A533).

The following three bullets are some of the procedural items that were created or removed from the previous CRGR charter and placed into the CRGR charter procedures document "Committee to Review Generic Requirement Procedures and Internal Administrative Process:"

- The new Appendix E to the "Committee to Review Generic Requirements Procedures and Internal Administrative Process" describes each review "category," and the new Appendices G, H, and I describe the procedure for each category.
- Appendix J to the "Committee to Review Generic Requirements Procedures and Internal Administrative Process" clarifies which agency guidance, positions, and documents that require CRGR review or can be reviewed by request.
- Requirement for the inclusion of formal comments of a minority opinion or disagreement in the CRGR meeting minutes.

The procedures document, created in parallel with Revision 9, can be updated more frequently than the charter itself to reflect lessons learned from backfitting and forward fitting reviews. Moreover, this document provides a detailed description of the administrative process for changes to CRGR membership and support staff. This procedural document will support succession planning and continuity of CRGR operations. The revisions to the CRGR charter are listed and described in the August 2018 memorandum to the Commission (ML18175A001).

The key changes in Revision 9 of the Charter are summarized below:

- Update to the CRGR's membership to include one member each from the Offices of NRR, RES, NRO, NSIR, NMSS, OGC, and one of the regions on a rotational basis. (Note: At the time of this writing, NRO no longer exists; however, the office was in existence at the time of the issuance of Revision 9 of the CRGR charter).
- Per SECY-15-0129 "Commission Involvement in Early Stages of Rulemaking," October 19, 2015 (ML15267A759), Rulemakings will only be reviewed at the request of the proposing office based on the criteria and guidance provided in Appendix D to the "Committee to Review Generic Requirements Procedures and Internal Administrative Process" or as directed by the EDO.
- Requests regarding CRGR engagement from external stakeholders now follow a clarified and formalized process. This process relates to unresolved backfitting claims raised during document development for new or revised requirements. This process excludes the rulemaking's public comment phase as a review process already exists for the stakeholders to raise backfit issues. In this review process, the CRGR will first engage the staff before holding any public meetings with external stakeholders.
- New text to highlight the new Commission guidance on compliance, adequate protection, and the use of general design criteria in backfitting. Additional clarification has been provided for the review of staff proposed relaxations.

- Clarification of the CRGR's role in reviewing facility-specific backfitting positions as well as generic backfitting.
- Clarification of the types of CRGR review from "informal" or "formal" review to the review "categories" of Routine Review (Category 1), Complex Review (Category 2), and Complex Review with External Participation (Category 3). The new Category 3 review facilitates more openness and transparency, as it provides the industry with an opportunity to discuss backfitting concerns with the CRGR.

In addition, based on the Commission direction in the March 29, 2019, SRM-SECY-18-0049 "Management Directive and Handbook 8.4, 'Management of Backfitting, Issue Finality, and Information Collection'" (ML19149A296) regarding forward fitting, the CRGR now considers forward fitting items as part of its scope of items for review. The next revision to the CRGR procedures will address this Commission direction.

With regard to its reporting requirement (since 1997), the committee has annually evaluated and reported its activities to the Commission in a SECY report entitled "Annual Report of Committee to Review Generic Requirements Review Activities." This annual paper summarizes the backfit reviews performed by the committee during the assessment period (June 1 to May 31) and provides the results of the committee's annual self-assessment and the status of any significant activities that are self-initiated or assigned by the EDO or the Commission.

In general, the CRGR continues using the same process since its beginning with some changes due to evolutions in effectiveness and efficiency. One of the efficiencies captured in the 2011 version (revision 8) of the CRGR Charter (ML110591141) was the introduction of the "informal" review, which made the CRGR review process more efficient. These informal reviews were used for items most likely not to contain backfitting issues such as Regulatory Issue Summaries (RIS), office instructions or procedures, and RGs. Informal reviews were conducted via email between the CRGR members and with the sponsoring staff to obtain clarity regarding a potential backfit. As a result, only documents that had backfit potential or dealt with key issues were screened out and were presented before the Committee in a formal setting. Under the current Charter, the term "informal" was replaced with the term "routine" (see the 2018 revision 9 of the CRGR charter (ML17355A532)).

From the beginning of the CRGR to the time of this writing, the number of documents coming to the CRGR for review has decreased. It can be concluded from the 2009 CRGR Audit that a factor in the decline in CRGR review is because

[t]he CRGR no longer performs the central role in the backfit review process because the agency's processes have evolved. Currently, other offices focus more effort on backfit compliance and interoffice communications on backfitting issues. This evolution, in effect, resulted in these offices assuming some of the CRGR's duties.

Consequently, because of these backfit review activities performed by the offices, the staff is able to identify unintended backfitting issues prior to CRGR interactions which makes a number of CRGR reviews unnecessary. In addition, the increased focus on backfit training is also a factor to staff improved identification of potential unintended backfitting.

The Appendix B displays a graphical representation of CRGR reviews over a 19-year period. In general, the data indicates that there has been an overall decline of reviews, and an introduction of two types of reviews, “Routine” (2005) and “Complex Review with External Involvement” (2017). Major factors that contributed to the decrease of reviews include allowing items to go out first for public comment before CRGR review (barring any obvious backfitting concerns), and information notices and other communication avenues are being used as opposed to items normally reviewed by the CRGR (i.e., Regulatory Information Summaries).

In 2019 and the first half of 2020, the CRGR did not review any documents because the staff actions regarding backfitting and forward fitting were on hold pending updated guidance from the Commission (see Section 10). This pause is expected to end sometime in 2020 and the number of documents under CRGR review is expected to return to pre-2019 levels shortly thereafter.

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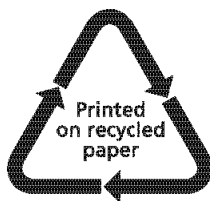
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