

**Committee to Review Generic Requirements
Procedures and Internal Administrative Process**

TABLE OF CONTENTS

I.	Purpose.....	1
II.	Background.....	1
III.	Scope.....	1
IV.	CRGR Review Process.....	1
V.	CRGR Administrative Process.....	4
VI.	Record Retention Requirements.....	9
Appendix A:	Review Process for Proposed New or Revised Generic Requirements and Staff Positions	
Appendix B:	Requirements for Contents of the CRGR Review Packages	
Appendix C:	Guidance on Application of the “Substantial Increase” Standard	
Appendix D:	Criteria and Guidance for Deciding When to Request a CRGR Review of a Rule	
Appendix E:	Three Categories of CRGR Review	
Appendix F:	Detailed Procedures for CRGR Routine Review	
Appendix G:	Detailed Procedures for CRGR Complex Review	
Appendix H:	Detailed Procedures for CRGR Complex Review with Public Participation	
Appendix I:	Procedures for Drafting the CRGR Annual Report	
Appendix J:	Tables of Documents for Staff Consideration	

CRGR PROCEDURES

I. PURPOSE

The purpose of this document is to provide guidance for the Committee to Review Generic Requirements (CRGR) and staff on the day-to-day operation of the CRGR and to ensure that the CRGR and the staff accomplish proper coordination. This document will help ensure that the CRGR review package contains the necessary documents, and that agency regulatory actions adhere to the Commission backfitting policy and agency backfitting requirements and guidance. The CRGR staff and the sponsoring staff will use the following CRGR review procedures and administrative process to facilitate the CRGR's accomplishment of its mission as outlined in the current CRGR charter (Agencywide Documents Access and Management System [ADAMS] Accession No. ML17355A532) as it pertains to the NRC backfitting program.

II. BACKGROUND

This document was created in parallel with Revision 9 to the CRGR charter, to relocate procedural and administrative information in a separate document that can be maintained more frequently than the charter itself to reflect lessons learned from backfitting reviews. Moreover, this document provides a detailed description of the administrative process for transitions that may occur among the CRGR membership and CRGR staff. As such, this document will support future succession and continuity in CRGR operations.

III. SCOPE

The scope of the documents that the CRGR will consider are listed in Appendix J, Table 1. Appendix J, Table 2 lists documents that are reviewed by the CRGR per request from the EDO, or the sponsoring office director or regional administrator, or at its own initiative because of identified backfitting concerns. The CRGR will review rulemaking packages when requested after the staff has identified that the rulemaking criteria (see Appendix D) have been met.

IV. CRGR REVIEW PROCESS

Once the program office director or regional administrator has identified the need for CRGR interactions per the current charter and the procedures herein described, the staff will submit a review request package by email to the CRGR Chairman (with the CRGR staff on cc). Packages should be submitted at least two weeks before the anticipated review meeting date (described further below). For lengthy documents such as rulemaking packages, the staff should adjust this time accordingly and contact the CRGR staff early in the process for planning purposes. The CRGR meetings will be scheduled on a date and time when a CRGR quorum is available and that presenting staff can support.

When it is clear that the need exists for a CRGR review, the staff should engage the stakeholder (the term stakeholder shall apply to licensee[s] or licensee's representative or member of the public, where applicable) regarding proposals that have received substantiated and unresolved backfitting claims to inform them of the option to engage the CRGR for the purpose of providing their input addressing the backfitting concerns for consideration in the CRGR review. This stakeholder consideration may result in a public meeting. Within one week of receipt of a formal staff request, the CRGR will make its determination regarding the meeting type as discussed in the scope section below and will make a selection of a date to conduct the review.

Meeting agendas will generally be issued by the CRGR at least one week in advance of each meeting with the exception of special meetings held to review urgent items.¹ The CRGR staff will promptly provide CRGR members the review material submitted by the requesting office, along with relevant background material, for each item to be considered by the CRGR. The members must receive the review material at least one week before the scheduled review. This time should be adjusted accordingly for lengthy documents. Note, the review material should be placed into ADAMS by the sponsoring staff prior to distributing to the CRGR staff.

The presenting staff will be responsible for providing relevant background material to the CRGR and the CRGR staff and for distributing presentation material to other staff members in attendance at the meeting. Meeting minutes will be issued to the EDO, or to the requesting office director or regional administrator, articulating the highlights of the meeting. Additional emphasis will be placed on identifying cases where the NRC's staff products did not conform to the backfitting guidance and cases where the guidance needs further clarification.

In addition, if the staff disagrees with the CRGR recommendations provided in the final meeting minutes, the sponsoring office director will submit a closeout memorandum indicating the disagreement to the EDO for resolution. The EDO will report to the Commission in writing regarding the disposition of the CRGR recommendations where major differences exist between the CRGR and the staff. However, in the event that an item is reviewed by the CRGR as a result of an office or region pursuing CRGR consultation, the CRGR will directly provide its comments to the requesting office or region for its consideration and disposition.

Moreover, the CRGR minutes will normally reflect collegial views, and a consensus will often be achieved. Nonetheless, occasions may exist in which the majority of voting members is unconvinced by a minority argument viewed as important by those who espouse it. The minority is then free to express its view through comments added to the minutes. The CRGR minutes shall capture the minority opinions in a section titled "Additional Comments" within the meeting minutes.

The process to include the minority opinion shall be as follows:

- The author(s) of the minority opinion shall be named.
- The minority opinion should be discussed within the meeting.
- The comments shall be provided to the CRGR staff for inclusion under a section titled "Additional Comments" within the meeting minutes.
- The minority opinion should be provided in a reasonable time for inclusion into the minutes to meet schedule deadline of the sponsoring staff.

Draft minutes will be circulated to the members and the presenting staff after the meeting for comments within a specified negative consent period as appropriate. The minutes will be issued within a timely manner after each meeting, or after the completion of a series of meetings (including a potential public meeting for a Category 3 review), commensurate with the significance of and overall schedule for the review. However, in general, the CRGR minutes will

¹Such items are those proposed requirements that the sponsoring program office director determines to be urgent to overcome a safety problem requiring immediate resolution or to comply with a legal requirement for immediate or near-term compliance. These items would usually involve an adequate protection issue, are expected to be infrequent and very few, and must be reviewed or otherwise dealt with within two working days of receipt by the CRGR. If the CRGR Chairman was to question the appropriateness of the urgency and if the question is not resolved within two working days, the CRGR Chairman will forward the proposed requirement or staff position to the EDO for decision.

not be made publicly available until the item reviewed has also been made public or the CRGR has been directed by the EDO or requested by the sponsoring organization to make the meeting minutes public (see Appendix H).

With regards to the CRGR review of classified and safeguards information, the CRGR staff will adhere to agency procedures concerning the handling of review packages containing classified or safeguards information. Moreover, the CRGR staff will coordinate with the responsible NSIR staff concerning the handling and facilitation of any reviews of documents that contain classified or safeguards information. The CRGR staff will rely on the responsible NSIR staff support concerning setting up CRGR reviews or engaging the industry or public (having the need to know) regarding possession, reviewing, or public meetings focusing on such documents.

In response to the staff requirements memorandum (SRM) dated April 18, 1997, on SECY-97-052, "Committee to Review Generic Requirements (CRGR) Scope of Review and Periodic Review Activities," the CRGR will submit an Annual Report to the Commission in August of each year. As prescribed by the aforementioned SRM, the annual report shall include the staff's input on value added by the CRGR review to various staff proposals and the CRGR's self-assessment as to how its activities contributed to the agency's mission and an assessment of the quality of the incoming proposals.

As prescribed by the aforementioned SRM, the staff's feedback shall provide value added input covering following four areas:

- Assess the overall value added by the CRGR review (e.g., improvement in the quality of the product as it relates to underlying safety concerns and backfitting considerations, completeness, and consistency with the Commission's policies, rules, and regulations).
- Quantify the effort expended by your staff to address CRGR comments and recommendations excluding the time required for re-concurrence by the Office of the General Counsel and program offices.
- Describe any adverse impact on your schedule as a result of CRGR review.
- Assess the significance of the issues identified by the CRGR as well as the associated costs in terms of overall impact on schedules and resources.

In addition, industry interactions, communications to the CRGR, and the public meeting feedback forms associated with a Category 3 review should be used to provide input into the annual report as it pertains to the role and responsibilities of the CRGR.

The following appendices provide specific instructions to assist the staff in meeting the CRGR review process requirements as well as instructions for the CRGR administrative procedures:

Appendix A contains an overview of the review process for new or, revised generic requirements or staff positions.

Appendix B contains the requirements for contents of the CRGR review packages. Frequent reference is made therein to the "Backfit Rule;" however, in preparing generic staff proposals related to nuclear materials facilities, the backfitting provisions of the applicable regulations (i.e., 10 CFR 50.109, 10 CFR 52.39, 10 CFR 52.63, 10 CFR 52.98, 10 CFR 70.76, 10 CFR 72.62, or

10 CFR 76.76); the guidance contained in the Regulatory Analysis Guidelines (NUREG/BR-0058); or pertinent Commission backfitting policy and directives shall apply.

Appendix C contains the guidance on application of the “Substantial Increase Standard.” The staff is expected to use this guidance to adhere to the agency definition of what is considered as a “substantial increase” with regards to safety when considering an increase in safety in its bases for backfitting.

Appendix D contains guidance and criteria that the technical lead office for a rulemaking should apply to determine whether or not to request a CRGR review of the rule and to provide its recommendation and bases to the CRGR.

Appendix E contains the description of the three types of CRGR review categories that the CRGR may perform. Category 1 is a routine review, Category 2 is a CRGR complex review, and Category 3 is a CRGR complex review with external participation.

The detailed steps for the three types of reviews are included in Appendix F (CRGR routine review), Appendix G (CRGR complex review), and Appendix H (CRGR complex review with external participation).

Appendix I contains the CRGR procedures for drafting the CRGR annual report.

Appendix J contains Tables 1 and 2 that list the various documents staff should consider engaging the CRGR when reviewing documents for backfitting. Table 1 lists those documents that are subject to CRGR review. Table 2 lists other documents that receive a CRGR review if requested by the sponsoring office.

V. CRGR ADMINISTRATIVE PROCESS

A. SCOPE OF REVIEW

In accordance with the current CRGR charter, the following general categories of agency documents are within the scope of CRGR review to ensure that they are appropriately justified based on backfitting and issue finality provisions of applicable NRC regulations (i.e., 10 CFR 50.109, 10 CFR 52.39, 10 CFR 52.63, 10 CFR 52.83, 10 CFR 52.98, 10 CFR 52.145, 10 CFR 52.171, 10 CFR 70.76, 10 CFR 72.62, or 10 CFR 76.76). Additional detail is provided in Appendix J to this procedure.

Items that require review by CRGR are:

- Policy statements being developed for Commission consideration².
- Bulletins.
- Generic Letters
- Facility-specific information requests issued under 10 CFR 50.54(f) information requests
- Rulemakings and other actions proposed by the staff that impose a backfit

² A policy statement does not impose a legal requirement as does a rule, order, or license condition; however, it may constitute an “interpretive rule” under the Administrative Procedure Act.

Items the CRGR may review at the request of an office director or regional administrator include:

- Rulemakings (proposed or final) that affect classes of licensees that are the subject of backfitting and issue finality provisions and meet the criteria provided in Appendix D of this procedure
- Regulatory guidance including Regulatory Guides, Standard Review Plans, Interim Staff Guidance, Enforcement Guidance, and NUREGs
- Safety Evaluation Reports (SERs) endorsing generic vendor initiatives
- Responses to Task Interface Agreements (TIAs)
- Facility-specific backfitting actions proposed by the staff

In addition, 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.

See Appendix J for more information on items that CRGR will consider for review. As Appendix J may not be comprehensive, the staff is encouraged to contact the CRGR staff for more information regarding items that may require CRGR consideration.

The above items will be reviewed as outlined in the current CRGR charter and this procedure document. Moreover, the CRGR will review staff positions that may impose a facility-specific backfit and, consequently, the CRGR may be engaged in hearing input from stakeholders regarding facility-specific backfitting concerns. However, the CRGR will generally not engage as a collective body in appeals of facility-specific backfitting determinations. Licensee appeals of backfitting decisions are processed as described in MD 8.4, "Management of Backfitting, Issue Finality, and Information Collection" with a first-level appeal to the program office and a second-level appeal to the EDO. If a facility-specific backfit determination (or rulemaking) is appealed to the EDO, the EDO may form a panel to review the backfitting determination and to provide a recommendation. A CRGR member may be included in the backfit review if that individual has not personally and substantially worked on the matter at issue³.

The CRGR will not review any proposed facility-specific or generic actions including generic-related communications, staff guidance, or SERs that involve voluntary actions or relaxations. The term "voluntary" as it applies to "voluntary actions" or "voluntary relaxations" is to be understood as follows:

The concept of "voluntary action" was intended to address two different scenarios. The first scenario is a situation where the regulation or guidance provides a new alternative that may be voluntarily adopted by the licensee or an extension of what was previously addressed in the regulation. An example of the first kind of "voluntary alternative" is the Risk-Informed Treatment Rule in 10 CFR 50.69. An example of the second kind of

³ Consistent with MD 10.159 on DPOs. "To the extent possible, a DPO Panel should not include an individual who has directly participated in the determination of the agency position at issue."

“voluntary alternative” is the Thermal Annealing Rule in 10 CFR 50.66. Voluntary relaxations are situations where the licensee can continue to comply with its current design procedures and/or practices and still be in compliance with the new, relaxed requirement. On the other hand, if the licensee must change its design, procedures, and/or practices to be in compliance with the new relaxed requirement, then the new requirement is a “mandatory relaxation” and must be considered backfitting. An example of a “voluntary relaxation” is where the current requirement is to conduct an inspection every 6 months and the new, relaxed requirement is to conduct the same inspection every year. In this situation, the licensee can continue to conduct its inspection every 6 months and be in complete compliance with the new, relaxed requirement. By contrast, if the new requirement is to conduct a different kind of inspection every 6 months that costs less and has less impact on occupational exposures, this would be a “mandatory relaxation.”

The staff should refer to the current version of MD 8.4 for guidance on applying the compliance exception in backfitting and on using the General Design Criteria as the basis for compliance backfitting.

B. QUALITY CHECK

The CRGR Chairman and CRGR staff will perform a quality check of all incoming proposals to determine the acceptability for CRGR review.

C. CRGR REVIEW

Generally, for scheduling purposes, CRGR reviews will be scheduled within a timely manner commensurate with the safety significance of the issue.

CRGR reviews will be scheduled within a reasonable time after receipt of a formal request.

Review and relevant background material will be distributed to CRGR members within adequate time for sufficient review based on complexity of the issue and volume of documents for review, however, no later than one week before the scheduled review.

CRGR meeting agendas will be issued by the CRGR at least one week in advance of each meeting when possible, with the exception of special meetings for urgent items.

The CRGR staff will verify that a quorum exists.

The CRGR will decide if it recommends approval, revision, disapproval, or that further public comments be sought on each item before it.

The Chairman will report any significant conclusions to the EDO and/or Deputy EDO in the meeting minutes. However, in the event that an item is reviewed by the CRGR as a result of an office or region pursuing CRGR consultation, the CRGR will directly provide its comment to the requesting office or region for its consideration and disposition.

Meeting minutes will reflect the highlights of the meeting and the CRGR recommendation to the EDO, office director or regional administrator, as appropriate. Emphasis will be placed on identifying where regulatory products did not conform to the backfitting guidance and where the guidance needs further clarification. Generally, draft minutes will be circulated to

the members and the presenting staff after the meeting for comments within an appropriate specified negative consent period. The minutes will be issued within a timely manner of each meeting. If any related public interactions occur, then this time will be extended until all public input has been incorporated into the minutes.

D. ANNUAL REPORT

The CRGR will submit an Annual Report to the Commission in August of each year including staff and external stakeholder's input on the value added by the CRGR, the CRGR's self-assessment of how its activities contributed to the agency's mission, and an assessment of the quality of the incoming products.

E. CRGR STAFF ROLE

The role of the RES-appointed CRGR program manager ("CRGR staff," per CRGR charter) will be to provide technical assistance to the CRGR. In this role, as stated in the CRGR charter and the MD 8.4, the CRGR staff responsibilities will be the following:

- The CRGR staff, in support of the CRGR Chairman, will conduct an initial backfitting-focused review of submitted documents and will provide recommendations to the CRGR Chairman. (However, with regards to rulemaking, it will be the primary responsibility of the sponsoring staff to follow the CRGR criteria to evaluate rulemakings to decide what interactions to conduct with the CRGR.)
 - If concerns exist or unintended backfitting issues remain unresolved after CRGR staff discussions with the sponsoring staff, further discussion will be required and the CRGR staff will coordinate with the relevant staff and the CRGR to set up a formal review that entails the staff appearing before the CRGR members in a formal setting.
- If the CRGR Chairman decides to perform a complex review, or if the staff requests a complex review of a generic or facility-specific document, the CRGR staff will coordinate with the sponsoring staff and the CRGR to set up a meeting for review of the document.
- The CRGR staff will ensure that all relevant documents (when not marked as classified or safeguards) have been entered into ADAMS (also applicable to documents generated by the sponsoring staff). The CRGR staff will follow the policies for handling safeguards and classified documents.
- The CRGR staff will ensure that the sponsoring staff provides (within sufficient time for adequate CRGR review) all review material along with relevant background material for each item to be considered by the CRGR and will promptly distribute to the members.
- The CRGR staff will ensure that the presenting staff on the day of the meeting provides paper copies of relevant background material to the CRGR and distributes presentation material to other staff members that are in attendance at the meeting.

- Upon request by a CRGR member, the CRGR staff will obtain a copy of any reference material for the CRGR member's use, distribute copies of the said material to all members, and also retain this material in the ADAMS CRGR meeting folders.
- If the CRGR Chairman has been contacted by the stakeholders to perform a complex review, the CRGR staff will interact with the stakeholders as needed and in accordance with agency protocols.
- The CRGR staff will generate and issue CRGR meeting notices, agenda, meeting minutes, and annual reports and will support a review on the administrative controls related to the staff's backfitting management practices (typically every five years) as per the CRGR charter. The CRGR staff will also generate procedures and guidelines, and memoranda and letters as needed.
- Upon request, the CRGR staff will review new and revised office and regional procedures developed in accordance with MD 8.4 to ensure consistency among the offices and regions in implementing the provisions of the NRC's backfitting rules.
- The CRGR staff shall maintain the CRGR external Web page (<https://www.nrc.gov/about-nrc/regulatory/crgr.html>) with current and helpful information. Moreover, an internal CRGR SharePoint Backfit Knowledge Management Community of Practice portal in SharePoint shall be maintained and remain current with relevant knowledge management material.

F. CRGR BACKFIT WORKING GROUP ROLE

A CRGR Backfit Working Group (BWG) will be established at direction of the CRGR to address emergent backfitting-program-related activities on an as-needed basis. This BWG will be staffed from the major program offices and regions. The role of the BWG will be to take on various tasks that will provide ancillary support to the CRGR in its role and responsibilities. These tasks will more likely require interoffice coordination and resourcing from the major program offices and regions. An example of such activities is the formation of the 2017 BWG led by the OEDO ETA to support the CRGR in undertaking or managing the OEDO tasks that resulted from the June 2017 CRGR review report (ADAMS Accession No. ML17174B161). Accordingly, such tasks may involve, but are not limited to the following:

- Update agency level guidance on backfitting and issue finality for Commission approval.
- Update office-level implementing guidance on backfitting and issue finality to reflect Commission-approved agencywide guidance.
- Update the enforcement manual to reflect Commission-approved agencywide guidance.
- Update and conduct training for managers and staff on backfitting and issue finality.

- Update initial training on backfitting and issue finality for use in office and region qualification programs.
- Update training and developmental activities on backfitting and issue finality.
- Evaluate adequacy and need for update of office and regional backfitting training

Membership of the BWG may include the office or regional backfitting contact as mentioned in the CRGR charter. However, the staff members assigned to the BWG should be staff who have an interest in working with, and contributing to the BWG.

VI. RECORD RETENTION REQUIREMENTS

The CRGR staff will ensure that all relevant documents (when not marked as classified or Safeguards Information) have been entered into ADAMS. These include documents connected to all review requests submitted to the CRGR Chairman, actions by the staff subsequent to the CRGR review, meeting minutes of CRGR consideration of each review request including comments and recommendations by the CRGR, and decisions by the EDO and the Commission. Documents which are marked as classified or designated as Safeguards Information shall be placed into the Secure Local area network Electronic System (SLES)/Electronic Safe (ESAFE) and handled according to appropriate agency guidance (see MD 12.2, "NRC Classified Information Security Program;" MD 12.4 "NRC Communications Security (COMSEC) Program;" MD 12.7, "NRC Safeguards Information Security Program;" DG-SGI-1, "Designation Guide for Safeguards Information: Criteria and Guidance and Sensitive Unclassified Non-Safeguards Information (SUNSI) guidance available via the NRC intranet at <http://www.internal.nrc.gov/sunsi/>)⁴."

⁴ Assistance regarding SLES/ESAFE may be obtain by contacting SLES.Resource@nrc.gov, NSIR_RM.Resource@nrc.gov, and calling the SLES help desk at (301) 415-7537.

APPENDIX A

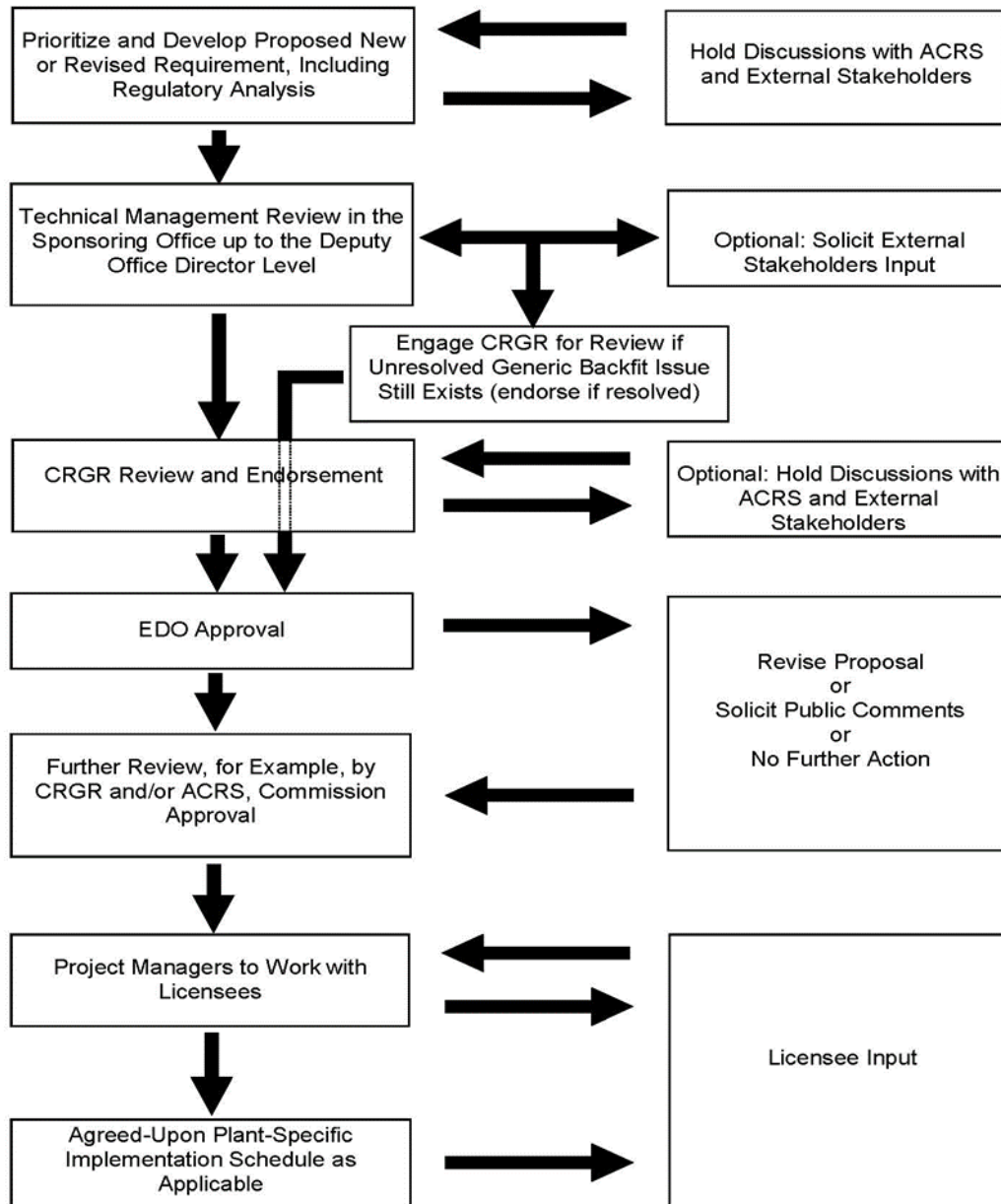
REVIEW PROCESS FOR PROPOSED NEW OR REVISED GENERIC REQUIREMENTS AND STAFF POSITIONS

The below chart is a schematic representation of how generic requirements and staff positions are developed, revised, and implemented (see NUREG-1409, "Backfitting and Issue Finality Guidance" for the facility-specific backfitting graphical description and MD 8.4 for a graphical overview of the general backfitting process).

In the early stages of developing a proposed new requirement or staff position, the staff may have discussions with the stakeholder, the Advisory Committee on Reactor Safeguards (ACRS), and the public to obtain preliminary information on the costs and safety benefits of a proposed action. On the basis of this information, and if applicable, the office proposing the action will prepare the package for the Committee to Review Generic Requirements (CRGR) review.

The CRGR may recommend approval, revision, disapproval, or that further public comments or stakeholder interactions be sought. After approval of the CRGR and the Executive Director for Operations, the ACRS or the Commission may again review the proposed action. Decisions by the Commission are controlling.

SCHEMATIC REPRESENTATION OF REVIEW OF NEW OR REVISED GENERIC REQUIREMENTS



APPENDIX B

REQUIREMENTS FOR CONTENTS OF THE CRGR REVIEW PACKAGES

The following requirements apply to all new proposals or proposals to modify (reduce or increase) the existing requirements or staff positions with the exception of a proposed or final rulemaking for which the Committee to Review Generic Requirements (CRGR) would accept the associated regulatory analysis as a substitute. Although the requirements frequently refer to the "Backfit Rule" (10 CFR 50.109 for power reactors) in preparation of staff proposals related to a facility, or new reactors or the nuclear materials facilities, the backfitting provisions of the applicable regulations (i.e., 10 CFR 52.39, 10 CFR 52.63, 10 CFR 52.98, 10 CFR 70.76, 10 CFR 72.62, and 10 CFR 76.76), the guidance contained in the Regulatory Analysis Guidelines (NUREG/BR-0058) or the Commission's backfitting policy and directives shall be used.

For each proposed action submitted to the CRGR for review and endorsement for which the staff does not believe contains any backfitting, the staff shall provide the following information in the review package:

- (i) The new or revised generic or facility-specific requirement or staff position as it is proposed to be sent out to the licensee or licensees or to be issued for public comments (as applicable).
- (ii) Draft papers or other documents supporting the requirements or staff positions. (A copy of all materials referenced in the document shall be made available upon request to the CRGR staff. In the event a CRGR member requests the CRGR staff to obtain a copy of any reference material for his or her use, copies of the said material will be distributed to all members and will also be retained in the CRGR meeting files.)
- (iii) The sponsoring office's position on each proposed requirement or staff position as to whether the proposal would modify requirements or staff positions, implement existing requirements or staff positions, or relax or reduce existing requirements or staff positions.
- (iv) The proposed method of implementation and resource implications along with the concurrence (and any comments) from the Office of General Counsel on the method proposed and the concurrence of all affected offices including regions or an explanation of any non-concurrences.
- (v) Regulatory analysis generally conforming to the directives and guidance of NUREG/BR-0058, as applicable.⁵ (This does not apply to backfittings that ensure compliance or define or redefine adequate protection. For power reactors, a documented evaluation is required as discussed under item (ix) of this Appendix. For nuclear materials items for the purpose of the CRGR review of such items under this charter, the staff should provide a similar documented evaluation as part of the CRGR review package.)
- (vi) Identification of the category of power reactors, new reactors, or nuclear materials facilities or activities to which the proposed requirement (if generic in nature) or staff position is applicable (e.g., whether it is only applicable to future plants, operating plants, all

⁵See latest version of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission."

pressurized-water reactors, all boiling-water reactors, specific nuclear steam supply system vendor types, specific vintage types plants, gaseous diffusion plants [GDPs], etc.).

For proposed backfitting other than either the compliance or the adequate protection backfits, the staff shall provide the following information in the review package:

- (vii) A backfit analysis as defined in the Backfit Rule (10 CFR 50.109 for power reactors and 10 CFR 76.76 for the GDPs) should be performed.^{6, 7, 8} The backfit analysis shall include for the facility or, for each category of nuclear power reactor, new reactor, or nuclear materials facility or activity, an evaluation that demonstrates how the proposed action should be prioritized and scheduled in light of other ongoing regulatory activities. The backfit analysis shall document for consideration of pertinent information available concerning any of the following factors, as appropriate, and any other information that is relevant and material to the proposed action:
 - (a) Statement of the specific objectives that the proposed action is intended to achieve.
 - (b) General description of the activity that the licensee or applicant would be required to perform to complete the action.
 - (c) Potential change in the risk to the public from the accidental offsite release of radioactive material.
 - (d) Potential impact on radiological exposure of facility employees and other onsite workers.
 - (e) Installation and continuing costs associated with the action including the cost of facility downtime or the cost of construction delay.
 - (f) The potential safety impact of changes in plant or operational complexity including the relationship to proposed and existing regulatory requirements and staff positions.

⁶As a legal matter, the Backfit Rule does not strictly apply unless a backfit is required by, for example, a rule or an order. However, the NRC backfit process, including the CRGR Charter, is defined on the principle that new positions (that are imposed) as well as new requirements are to be reviewed for backfitting considerations and, if appropriate, meet the standards of the backfit rule before they are issued to the licensee(s). New facility or generic positions in documents such as TIAs, generic or facility-specific directed letters, bulletins, and regulatory guides, whether affecting power reactors or nuclear materials facilities/activities, are to be considered and backfitting considerations addressed before they are issued.

⁷Types of actions to which the standards of the backfit rule do not apply include (1) voluntary actions and voluntary relaxations (to include confirmatory orders), (2) actions mandated by statute, (3) requests for information (4) administrative. (See latest version of NUREG-1409, "Backfitting and Issue Finality Guidance.")

⁸Reporting requirements such as those contained in 10 CFR 50.72 and 10 CFR 50.73 (for power reactors) or those contained in 10 CFR 70.50 and 10 CFR 70.52 (for nuclear materials activities) are more akin to the information requests covered under 10 CFR 50.54(f) than they are to modifications covered under the backfit rule (10 CFR 50.109). They should be justified by an evaluation against criteria similar to the analogous provision in 10 CFR 50.54(f) (i.e., by demonstrating that the burden of reporting is justified in view of the potential safety benefits to be obtained from the information reported).

- (g) The estimated resource burden on the NRC associated with the proposed action and the availability of such resources.
- (h) The potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed action.
- (i) Whether the proposed action is interim or final and, if interim, the justification for imposing the proposed action on an interim basis.
- (j) For both rulemaking actions and proposed generic correspondence, staff evaluation of comments received as a result of the notice and comment process.⁹
- (k) How the action should be prioritized and scheduled in light of other ongoing regulatory activities. The following information may be appropriate in this regard:
 - 1. The proposed priority or schedule.
 - 2. A summary of the current backlog of existing requirements awaiting implementation.
 - 3. An assessment of whether implementation of existing requirements should be deferred as a result.
 - 4. Any other information that may be considered appropriate with regard to priority, schedule, or aggregate impact (e.g., could implementation be delayed pending public comment).

In addition, for each proposed backfitting other than either adequate protection backfits or compliance backfits, the staff shall provide the following information in the review package:

- (viii) The proposing office director's determination, together with the rationale for the determination based on the consideration of the previous paragraphs (i) through (vii), that
 - (a) A substantial increase in the overall protection of public health and safety or the common defense and security will be derived from the proposal.^{10, 11}

⁹ Generic communications that state a new staff position or seek additional licensee commitments affecting power reactors are generally noticed for public comment. The Commission's instructions in this regard are documented in the following staff requirements memoranda: (1) memorandum for J. M. Taylor from S. J. Chilk, dated October 27, 1992, Subject: SECY-92-338-Implementing Procedures for Issuing Urgent Generic Communications; (2) Memorandum for J. M. Taylor from S. J. Chilk dated July 17, 1992, Subject: SECY-92-224 – Revised Implementing Procedures for Issuance of Generic Communications; and (3) Memorandum for J. M. Taylor from S. J. Chilk dated December 20, 1991, Subject: SECY-91-172 – Regulatory Impact Survey.

¹⁰Appendix C to this Charter provides additional guidance on consideration of qualitative factors in applying the “substantial increase” standard of 10 CFR 50.59 for actions affecting power reactors. By its terms, 10 CFR 50.109 does not apply to nuclear material facilities and activities that are not licensed under Part 50, but the staff should consider in conjunction with other Commission directives the applicable guidance in Appendix C in evaluating qualitative factors that may contribute to the justification of proposed backfitting actions directed to nuclear materials facilities and activities.

¹¹Certain proposed actions affecting power reactors may not meet the “substantial increase” standard but, in the staff's judgment, should be promulgated nonetheless. The Commission has indicated the willingness to consider

- (b) The direct and indirect costs of implementation for the facility or facilities affected are justified in view of this increased protection.

As a legal matter, 10 CFR 50.109 does not apply to nuclear materials facilities and activities that are not licensed under Part 50; however, footnote 10 does apply to the evaluation of proposed backfits affecting the selected nuclear facilities and activities items submitted to CRGR for review. Specific provisions of 10 CFR 70.76, 10 CFR 72.62, and 10 CFR 76.76 should be considered, as appropriate, when considering backfit-related matters for independent spent fuel storage installations and the monitored retrievable storage installations, GDPs, respectively. In addition, in the context of Part 70 licensing actions, the Commission supported the requirement that "...any new backfit pass a cost-benefit test without the 'substantial' increase in safety test. The Commission believes that modest increase in safety at minimal or inconsequential cost should be justified on a cost-benefit basis."¹²

For adequate protection or compliance backfits affecting power reactors, new reactors, or materials evaluated pursuant to the applicable backfitting provisions as appropriate, the staff shall provide the following information in the review package:

- (ix) A documented evaluation consisting of:
 - (a) The objectives of the modification.
 - (b) The reasons for the modification.
 - (c) If the compliance exception is invoked,
 - (1) The requirements (e.g., Commission regulation, license condition, order) or written licensee commitments for which compliance is sought.
 - (2) An assessment of risk/safety implications of not requiring licensees to immediately restore compliance, and the basis for determination that a reasonable concession could be allowed to defer restoration of compliance at a later time (e.g., next refueling outage).
 - (3) Demonstrated consideration of other possible alternatives and rationale for rejecting them in favor of compliance backfitting.
 - (4) Evaluation from cost-benefit considerations (not a full regulatory analysis) and a rationale for compliance exception.
 - (5) Demonstrated consideration of OGC guidance provided in the NRC Solicitor's memo to CRGR Chairman (ADAMS Accession No. ML16355A258) regarding cost-benefit considerations (also see the current MD 8.4 and the current NUREG 1409 document), the definition of omission or mistake of fact as it

such exceptions to the Backfit Rule on a case-by-case basis, but such exceptions would be promulgated only if the proposal (not to apply the Backfit Rule to the proposed rulemaking) is made the subject of public notice and comment.

¹²The Staff Requirements Memorandum - SECY-98-85 - Proposed Rulemaking – "Revised Requirements for the Domestic Licensing of Special Nuclear Material," dated December 1, 1998.

applies to compliance, and using GDC as bases for invoking the compliance backfit.

- (d) If the adequate protection exception is invoked, the basis for concluding that the matter to be addressed involves adequate protection and why current requirements (e.g., Commission regulation, license condition, order) or written licensee commitments do not provide adequate protection.
- (x) In addition, for actions that were immediately effective (and therefore issued without prior CRGR review as discussed in Section III of the CRGR charter), the evaluation shall document the safety significance and appropriateness of the action taken and (if applicable) consideration of how costs contributed to selecting the solution among various acceptable alternatives.

For each request for information from power reactor licensees under 10 CFR 50.54(f), which is for purposes other than to verify compliance with the facility's licensing basis, the staff shall provide an evaluation that includes at least the following elements in the review package:

- (xi) A problem statement that describes the need for the information in terms of potential safety benefit.
- (xii) The licensee actions required and the cost to develop a response to the information request.
- (xiii) An anticipated schedule for NRC use of the information.
- (xiv) A statement affirming that the request does not impose new requirements on the licensee other than submittal of the requested information.
- (xv) The proposing office director's determination that the burden to be imposed on the respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information.

Under the provisions of 10 CFR 50.54(f), unless the request for information is for the purpose of verifying compliance with the licensing basis of a facility, the EDO shall approve the staff's justification. The latest version of NUREG/BR-0058, provides additional guidance for preparing this evaluation (see footnote 13 in this Appendix).

Include an analogous evaluation addressing items (x) through (xiv) for each information request directed to the licensees of the selected nuclear materials facilities or activities referred to in Section III of the CRGR charter.

- (xvi) For each proposed power reactor backfit analyzed pursuant to 10 CFR 50.109 (a)(2) (i.e., backfits other than either adequate protection or compliance backfits), an assessment of how the proposed action relates to the Commission's Safety Goal Policy Statement.¹³

For rulemakings, the package will be evaluated based on the Appendix D criteria to identify those packages which should be brought before the CRGR for review.

¹³Detailed guidance for addressing the Commission's safety goals is contained in "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Guidelines" (see latest version of NUREG/BR-0058).

APPENDIX C

GUIDANCE ON APPLICATION OF THE "SUBSTANTIAL INCREASE" STANDARD

The Backfit Rule states that, aside from exceptions for cases of adequate protection or compliance, the Commission shall require the backfitting of a facility only when it determines on the basis of a backfit analysis "that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection."¹⁴ The Commission's Regulatory Analysis Guidelines are intended to be a primary source of guidance on application of the "substantial increase" standard as well as application of the Commission's safety goals.¹⁵

Generally, the staff should quantify the benefits of a proposed backfitting to the extent feasible. With regard to cases where the safety benefits of a backfitting cannot be quantified or can only be partially quantified, a flexible approach is warranted.

In the preamble to the 1985 backfit rule, the Commission said:

Substantial means "important or significant in a large amount, extent, or degree." Under such a standard, the Commission would not ordinarily expect that safety improvements would be required as backfits that result in an insignificant or small benefit to public health and safety or common defense and security, regardless of costs. On the other hand, the standard is not intended to be interpreted in a manner that would result in disapprovals of worthwhile safety or security improvements having costs that are justified in view of the increased protection that would be provided.¹⁶

In a 1993 memorandum to the staff, the Commission said that it continues to believe that these words embody a sound approach to the "substantial increase" criterion and that this approach is flexible enough to allow for qualitative arguments that a given proposed rule would substantially increase safety.¹⁷ In addition, in the context of Part 70 licensing actions, the

¹⁴10 CFR 50.109(a)(3), 10 CFR 70.76(a)(3), 10 CFR 72.62(c), and 10 CFR 76.76(a)(3).

¹⁵Latest version of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U. S. Nuclear Regulatory Commission."

¹⁶*Federal Register Notice* 50 FA 38102, September 20, 1985.

¹⁷Memorandum to James M. Taylor and William C. Parler from Samuel J. Chilk, dated June 30, 1993, Subject: SECY-93-086, Backfit Considerations.

Commission supported the requirement that "...any new backfit pass a cost-benefit test without the 'substantial' increase in safety test. The Commission believes that modest increase in safety at minimal or inconsequential cost should be justified on a cost-benefit basis."¹⁸

Examples of general areas where the benefits of new requirements have not been considered amenable to quantification and, therefore, qualitative arguments have been used include plant access control (10 CFR 73), fitness for duty (10 CFR 26), and Emergency Response Data System (10 CFR 50.72 and Appendix E).

The Commission further said that the qualitative approach is also flexible enough to allow for arguments that consistency with national and international standards, or the incorporation of widespread industry practices, contributes either directly or indirectly to a substantial increase in safety. Such arguments concerning consistency with other standards or incorporation of industry practices would have to rest on the particulars of a given proposed rule (see footnote 17 to this Appendix).

Incorporation of industry standards (including revisions to existing codes and standards) into U.S. Nuclear Regulatory Commission rules or staff positions as a prudent means of assuring continued conformance with currently voluntary standards and practices that provide substantial safety benefit can provide the basis for a finding that a proposed backfitting meets the "substantial increase" standard of the backfit rule. This practice also will be consistent with Public Law 104-113, "National Technology Transfer and Advancement Act of 1995" which instructs Federal agencies to emphasize "where possible the use of standards developed by private, consensus industry."

In addition, factors such as the following may be argued to contribute directly or indirectly to a substantial increase in safety:

1. Incorporation of advances in science and technology.
2. Greater flexibility in practice or less prescriptive requirements.
3. Greater specificity in existing generally stated requirements.
4. Correction of significant flaws in current requirements.
5. Greater confidence in the reliability and timeliness of information or programs.
6. Fewer exemption requests and interpretive debates.
7. Better focusing of corrective actions toward the sources of problems.
8. Benefits that may accrue in the longer term beyond the immediately apparent effects of the backfit.

¹⁸The Staff Requirements Memorandum - SECY-98-185 - Proposed Rulemaking - Revised Requirements for the Domestic Licensing of Special Nuclear Material," dated December 1, 1998.

APPENDIX D

CRITERIA AND GUIDANCE FOR DECIDING WHEN TO REQUEST A CRGR REVIEW OF A RULE

The charter for the Committee to Review Generic Requirements (CRGR) does not require CRGR review of all rulemaking packages. However, it allows an Office Director or the Executive Director for Operations to request CRGR review of a proposed rule. Given the agency's focus on ensuring backfitting and regulatory analysis reviews are conducted appropriately and in light of Commission direction on qualitative factors, CRGR review of certain rulemaking packages could be beneficial. Consequently, the CRGR identified a need to develop and provide guidance to the offices about when CRGR review of a rulemaking would be appropriate. The staff addressed this CRGR initiative in SECY-15-0129, "Commission Involvement in Early Stages of Rulemaking," dated October 19, 2015 (Agencywide Document Access and Management System (ADAMS) Accession No. ML15267A716). In staff Requirements Memorandum (SRM) SRM-SECY-15-0129, "Commission Involvement in Early States of Rulemaking," dated February 3, 2016 (ADAMS Accession No. ML16034A441), the Commission approved the CRGR's plans to develop criteria and implementing guidance for triggering a CRGR review of a proposed rule.

The lead office for a rulemaking should apply the following criteria and guidance to determine and provide the CRGR its recommendation whether or not a CRGR review of the rule is appropriate. This determination should be documented in a brief summary addressing each of the five criteria and provided to the CRGR. This recommendation will contain the basis and justification to support the staff decision. Specifically, the office should consider requesting a CRGR review of a rulemaking with a summary of their recommendation indicating that one or more of the following criteria are met:

1. The staff indicated, in the rulemaking plan, that the rulemaking would not constitute backfitting. However, in developing the proposed rule, the staff identifies that a backfit is possible.
2. The regulatory analysis identifies significant costs incurred as a result of the proposed rulemaking, and qualitative factors were used to justify the rulemaking.
3. There is substantial uncertainty (in the statistical sense) in the quantitative benefit determinations in the backfit analysis.
4. The staff relied upon the compliance exception or the adequate protection exceptions to justify backfitting and avoiding issue finality in Part 52, where the Commission has not previously been advised of the use of these exceptions in the rulemaking plan.
5. As directed by the Executive Director for Operations (EDO) or when substantive concerns have been raised by stakeholders or U.S. Nuclear Regulatory Commission (NRC) staff regarding the backfit or regulatory analysis.

Note, the staff should consider the criteria found within the current version of the CRGR charter as the most up-to-date version, as this criteria is subject to revision based on lessons learned and changes in the backfitting management practices. The following implementing guidance provides instruction on identifying whether a particular condition has been met.

1. The staff indicated, in the rulemaking plan, that the rulemaking would not constitute backfitting. However, in developing the proposed rule, the staff identifies that a backfit is possible. The staff should state in their recommendation regarding whether a CRGR review is warranted or not.

Self-explanatory.

2. The regulatory analysis identifies significant costs incurred as a result of the proposed rulemaking, and qualitative factors were used to justify the rulemaking.

When qualitative factors are used to justify a rulemaking that would incur significant costs, in addressing this criterion, the staff should succinctly state in their recommendation regarding the necessity and effectiveness of the rulemaking in light of the cost and whether a CRGR review is warranted or not

In addition, security-related rulemakings currently rely only on qualitative factors and do not consider any quantitative factors (because the likelihood of a security event is always postulated as 1.0). Therefore, for every security-related rulemaking, and for addressing this criterion, the staff should refer to the significant cost evaluation and state in their recommendation regarding whether a CRGR review is warranted or not

3. There is substantial uncertainty (in the statistical sense) in the quantitative benefit determinations in the backfit analysis.

Substantial uncertainty results when large ranges exist in the possible values of the input parameters driving the cost-benefit calculations of the regulatory analysis. As a result of these large ranges in input parameter values, the results of the regulatory analysis could differ from the mean estimate to a significant degree, indicating the conclusion of the regulatory analysis is also subject to high variability (i.e., uncertainty). The staff should state in their recommendation regarding whether a CRGR review is warranted or not when substantial uncertainty exists in the statistical values used to support the rulemaking.

4. The staff relied upon the compliance exception or the adequate protection exceptions to justify backfitting and avoiding issue finality in Part 52, where the Commission has not previously been advised of the use of these exceptions in the rulemaking plan.

Self-explanatory.

5. As directed by the EDO or when substantive concerns have been raised by stakeholders or NRC staff regarding the backfit or regulatory analysis.

The concerns raised by stakeholders or NRC staff, may be regarding known backfitting issues (i.e., questions concerning compliance versus a change in staff position) associated with the rulemaking, the staff should identify and review past concerns raised or related regulatory matters and determine if they are directly or indirectly connected to backfitting. In addition, the staff should consider the discussion in the current CRGR charter (ADAMS Accession No. ML17355A532) and in this current CRGR Procedures on relaxations, specifically "mandatory relaxations," when considering backfitting issues associated with a proposed rule. If backfitting issues exist, then the staff should state in their recommendation regarding whether a CRGR review is warranted or not, and if warranted, requesting a CRGR review of the rule. In addition,

besides indicating any backfitting issues, the staff should highlight areas that may pose backfitting concerns.

Moreover, the staff should determine whether or not any stakeholders have raised significant concerns regarding the backfit analysis or the regulatory analysis. These concerns may include lack of documentation related to the backfit or regulatory analyses or improper or incomplete development of backfit and regulatory analyses. The staff should attempt to address and resolve any such concerns through normal NRC processes. The staff should include in its recommendation to the CRGR its basis that supports the determination whether or not to request CRGR review of the rule even in those cases where the staff believes it has adequately addressed any stakeholder concerns about backfitting.

In the case that the backfitting issue remains unresolved on the part of the stakeholder after the public comment phase is finished, the staff should inform the stakeholder regarding the option to engage the CRGR and provide its input. This input process is initiated by the stakeholders through a letter to the CRGR Chairman. This letter will document that an unresolved backfit concern still exists after meaningful attempts to adequately resolve them with the sponsoring staff. The CRGR will first engage the staff. If the backfitting issue remains unresolved after its discussion with the staff, the CRGR will consider the most efficient and effective approach to address the unresolved backfitting issue. This approach may involve a public meeting with the stakeholders. The sponsoring staff is invited to attend this public meeting for the purpose of providing clarification, and respond to potential CRGR questions with regards to the relevant staff activities.

If any staff has initiated the non-concurrence process or differing professional opinion process related to backfitting or directly related to the responsibilities of the CRGR as outlined in the CRGR charter regarding a particular rulemaking, then the staff should inform the CRGR of the nature of the non-concurrence and state in their recommendation regarding whether a CRGR review is warranted or not.

APPENDIX E

THREE CATEGORIES OF CRGR REVIEW

With regards to the type of CRGR review that may be performed, three categories include:

1. Routine Review
2. Complex Review
3. Complex Review with External Involvement

The lead technical CRGR staff will propose the form of the review to the CRGR Chairman for decision. The CRGR Chairman will generally consult with the membership if the initial view is that the review falls into either Category 2 or 3. For Category 2 or 3 reviews, the CRGR Chairman will also provide advance notice to OEDO. OEDO retains the final authority to direct the Category of the review.

A Routine Review (Category 1) is one in which the matter does not appear to contain backfitting issues, is limited in scope and volume, and should be amenable to review by the CRGR on a short-turnaround basis. These reviews will generally be conducted among the membership via internal deliberations and or remote means (e.g., e-mail). Regulatory Issue Summaries (RIS), responses to Task Interface Agreements (TIA), and Interim Staff Guidance (ISG) are examples of those documents that may receive this type of review. If during the progress of the review, it becomes evident that the matter may be more than routine, the CRGR may choose to elevate the review to either Category 2 or 3 (discussed below). Any CRGR member may propose changing the Category of the review, and the CRGR will collectively consider the appropriate determination.

A Complex Review (Category 2) is one in which it is obvious that the matter has significant technical and process complexity, and backfitting or potential backfitting issues are clearly involved or have been indicated during previous review of the matter. Rulemaking for which the staff has identified backfitting or a Generic Letter are examples of those documents that may receive this type of review. For a Category 2 review, the CRGR will meet formally with the NRC staff and may have continuing dialogue that may require an additional formal meeting prior to developing conclusions and recommendations.

A Complex Review with External Involvement (Category 3) has all the elements of a Category 2 review, as well as a request from external parties to meet separately with the CRGR. Alternatively, the CRGR or OEDO could decide to initiate the separate external meeting after concluding that the matter would benefit from the additional insights to be gained. The CRGR can also decide separately that an external engagement (requested by the external party) is not warranted and would discuss with the EDO whether a Category 2 review is appropriate. CRGR meetings with external parties will generally be conducted as public meetings unless otherwise indicated (e.g., matters involving Classified information, Security-Related Information, or Proprietary Information). The sponsoring staff is invited to attend this public meeting for the purpose of providing clarification, and responding to potential CRGR questions with regards to the relevant staff activities. The external public meeting will be transcribed.

For all CRGR reviews, the staff proposal(s) should be concurred on by at least the deputy office director or deputy regional administrator of the sponsoring organization, including a no legal objection from OGC for the NRC proposal(s). For a Category 2 or 3 review, Division level

management (at a minimum) should be present at the CRGR meetings. With respect to the form of any review the CRGR conducts, it is at the discretion of the CRGR (with potential consultation with the EDO as described previously) to decide which type of review will be the most efficient and effective means to discharge its mission. Appendix A contains an overview of the review process for new or, revised generic requirements or staff positions.

APPENDIX F

DETAILED PROCEDURES FOR CRGR ROUTINE REVIEW

The sponsoring staff contacts CRGR staff to request a Routine CRGR review.

The CRGR staff ensures document has received OGC review, has deputy office director or deputy regional administrator concurrence, and is in ADAMS.

The CRGR staff should obtain clarifications from the staff of any suspected backfitting concerns as well as any relevant facts regarding the document (e.g., are there differing views within the staff or with external stakeholders).

The CRGR staff interacts with the sponsoring staff as needed and provides preliminary suggestions on improvements to the document for CRGR review or provides guidance as needed to facilitate proper CRGR process and staff interactions.

The CRGR staff reviews package(s) for backfitting, for new staff positions and changes in staff position, or for usage of “purple words” or imposition of requirements that are not supported with regulations (i.e., usage of words such as “will” or “shall” that do not state the necessary supporting regulatory requirement).

The CRGR staff provides the Chairman with a summary of the package containing the office(s) sponsoring the document, the purpose for the document, and a CRGR staff recommendation for CRGR endorsement or for the CRGR to conduct a Complex CRGR Review (include any concerns or potential issues identified in the document).

The CRGR Chairman issues an e-mail to the CRGR members with the sponsoring staff on cc identifying the particulars of the document and containing a version of the CRGR staff's summary (the e-mail gives a specified review period commensurate with the significance and urgency of the document). The CRGR Chairman may choose a different review path than what the CRGR staff recommends.

The CRGR members may provide comments or questions for the staff to address. Resolution of issues may be confined to e-mails or a complex review may ensue. If the CRGR members select to review the item in a complex review format or in a complex review with public participation format, then the respective procedures are to be followed for the relevant type of reviews (Appendix G or Appendix H, respectively).

The routine review is final after all the CRGR members provide input within the comment period or once all the quorum of the CRGR members has provided comments.

Provided no further input is needed from the staff, the CRGR chairman (or the CRGR staff in behalf of the CRGR Chairman) drafts an e-mail to the sponsoring staff identifying the item reviewed and making a statement to the effect that the CRGR has no objection to the staff proceeding with the documents as reviewed and has the CRGR endorsement.

The CRGR staff will place the final endorsing e-mail into the relevant ADAMS CRGR folder.

APPENDIX G

DETAILED PROCEDURES FOR CRGR COMPLEX REVIEW

The CRGR will determine that a complex review is necessary, or will be specifically requested to conduct one.

The CRGR staff will provide to the presenter (if necessary) the instructions of what is required for the CRGR review.

The CRGR staff will ensure the review package is in its final form and has the needed concurrences.

The CRGR staff will place the package into a newly created subfolder in the ADAMS CRGR folder.

The CRGR staff will issue the package to members (notifying them that meeting date is to be set).

The CRGR staff will obtain name of presenter(s) and will ensure the Division Director or delegate will be in attendance at the meeting.

The CRGR staff will obtain from sponsoring staff an expected date for the CRGR review.

The CRGR staff will obtain available dates and times of CRGR members and will ensure at least a CRGR quorum in attendance.

The CRGR staff will coordinate with sponsoring staff for a date and time for optimum participant attendance.

The CRGR staff will reserve a meeting room with VTC for the regional CRGR representative (preferably an ACRS meeting room) and for the sponsoring region (when applicable), and, if unavailable or not practical, ensure a speakerphone is available in the non-VTC meeting room. Coordinate with NSIR if package contains safeguards or classified material and follow agency procedures for handling such material.

The CRGR staff will set a meeting date and time and will send a meeting scheduler to all CRGR members and all sponsoring staff members.

The CRGR staff will prepare an agenda for CRGR Chairman signature and will place the agenda into the previously created subfolder in the CRGR ADAMS folder (after the document is tech-edited, the front office Administrative Assistant profiles ADAMS document into a final package format for signatures).

Within a reasonable time prior to the meeting date, send agenda to CRGR members and group associated with presenter.

The Administrative Assistant will issue the agenda via e-mail with a link accessing the agenda to the list of addressees and the list of recipients on "cc".

The CRGR staff will be in the VTC meeting room in sufficient time prior to the scheduled meeting to confirm VTC setup or speakerphone availability in the non-VTC room.

The CRGR staff attends the CRGR briefing and takes down notes for generating minutes.

The CRGR staff will send draft minutes to the CRGR Chairman for review and comments.

After incorporating the CRGR Chairman's comments, send to CRGR members and sponsoring staff.

The CRGR staff will incorporate comments from CRGR members and the sponsoring staff.

The CRGR staff will send draft minutes to the CRGR Chairman for final review.

The CRGR staff will incorporate the CRGR Chairman's final comments.

The CRGR staff will place the minutes into the previously created subfolder in the ADAMS CRGR folder.

The CRGR staff will send the ADAMS Accession number for the package to the RES front office administrative assistant for ADAMS profiling and preparation for a final concurrence package.

The CRGR staff will review and sign final the CRGR meeting minutes and give to CRGR Chairman for concurrence.

The administrative assistant will issue the minutes via e-mail with a link accessing the meeting minutes to the addressee and the list of recipients (see sample meeting minutes).

APPENDIX H

DETAILED PROCEDURES FOR CRGR COMPLEX REVIEW WITH PUBLIC PARTICIPATION

As this category of review in general is preceded by a CRGR complex review, the Appendix G activities for complex review will precede the activities in this Appendix.

The CRGR Chairman, after considering stakeholder request, will determine if this category of meeting is the appropriate path forward or may recommend that the staff sponsoring the subject document pursue further interactions with the stakeholder prior to deciding to perform this type of review.

The CRGR staff shall coordinate a date between the CRGR members and stakeholders for which they are available for the CRGR review and ensure at least a CRGR quorum is in attendance. The sponsoring staff shall be informed of this planned meeting.

The CRGR will reserve a meeting room with VTC for the regional CRGR representative (preferably an ACRS meeting room) and, if unavailable or not practical, ensure a Sure/speakerphone is available in the non-VTC meeting room. Coordinate with NSIR if package contains safeguards or classified material and follow agency procedures for handling such material.

The CRGR staff will set the meeting date and time and issue a public meeting notice announcement (at least 10 days prior to meeting) and inform the CRGR members and the sponsoring staff.

The CRGR staff will submit the appropriate form to Admin Services for obtaining a transcriber for generating transcripts for the meeting proceedings. The request shall be made for a short turnaround time to generate the transcripts.

The CRGR staff will obtain presenter materials and place them in the created subfolder in the CRGR ADAMS folder (policy for handling safeguards and classified documents shall be followed).

The CRGR staff will be in the VTC meeting room in sufficient time prior to the scheduled meeting to confirm VTC setup or speakerphone availability in the non-VTC room. If the room is the ACRS room, the CRGR staff will provide an escort and ensure accommodations are available for the transcription process. Staff will coordinate with NSIR if the package item being discussed contains safeguards or classified information and will follow agency procedures for handling such material and transcribing such a meeting. Access to transcripts will be coordinated with NSIR, and agency policy shall be followed.

The CRGR staff shall develop the draft summary for the public meeting (to be issued within the standard 30 days), and the CRGR meeting minutes for CRGR Chairman review and comments. CRGR meeting minutes may be used for the summary, when appropriate. The policy for handling safeguards and classified documents shall be followed.

After incorporating CRGR Chairman's comments, the CRGR staff will send to CRGR members and sponsoring staff for comments.

The CRGR staff will incorporate comments from CRGR members and the sponsoring staff.

The CRGR staff will send minutes to the CRGR Chairman for final review.

The CRGR staff will incorporate the CRGR Chairman's final comments.

The CRGR staff will place minutes into the previously created subfolder in the ADAMS CRGR folder.

The CRGR staff will send the ADAMS Accession number for the package to the front office administrative assistant for ADAMS profiling and preparation for a final concurrence package.

The CRGR staff will review and concur on the final CRGR meeting minutes and give to CRGR Chairman for concurrence.

The administrative assistant will issue the minutes via e-mail with a link accessing the meeting minutes to the addressee and the list of recipients.

The final minutes will not be made public until the CRGR staff has been notified by the sponsoring staff that the document reviewed has been made public. The public will then have access to the final CRGR minutes sent to the EDO, or Office Directors or Regional Administrators. However, the timing for release of the final CRGR minutes may be modified by the CRGR Chairman based on consultation with the sponsoring office, and with the OEDO in matters where a topic is predecisional, or contains classified or Safeguards Information (SGI) (see Section VI in this document).

APPENDIX I

PROCEDURES FOR DRAFTING THE CRGR ANUAL REPORT

At least two weeks before May 31st of each year, the CRGR staff will began generating the request to be sent to all the offices that presented items before the CRGR for the preceding review period, June 1 through May 31. This request is referred to as the “value added memo” as it is designed to solicit feedback on the value added by CRGR reviews conducted over the previous year. The response to this memo will be used for generating the CRGR annual report due to the Commission by the end of August every year.

The cover for the value added memo is a boilerplate citing its authority to task the subject offices for a response, and the memo will contain an enclosure with the table of all items reviewed by the CRGR for the specified period, and will identify the sponsoring offices and the staff that was the presenter.

Along with the addressees, the memo will be send to the appropriate staff RIDS email boxes.

The CRGR staff should verify that the offices received the valued added memo.

The sponsoring office will be given 21 calendar days to provide a response to the appropriate set of questions stated in the memo.

Upon receipt of the responses, the CRGR staff will summarize the responses for input into the CRGR annual report to be sent to the Commission.

The CRGR staff will also synthesize an overall assessment from the various office responses and external stakeholders along with highlighting CRGR activities and planned activities.

The CRGR staff will provide the tech-edited version of the report to the CRGR Chairman for review and comment.

After incorporating the CRGR Chairman’s responses, the CRGR staff will forward to the CRGR members and OGC. The timing should be such that it provides the CRGR Chairman enough time for his/her review and a 5 work-day review period for CRGR members and the required 10 working days for an OGC review period in order to meet an end-of-August Commission deadline.

After incorporating comments, the package will be finalized in ADAMS, and the Accession number will be provided to the front office administrative assistant for profiling and preparing the package for signatures. Note, technical editing may be required again if a major rewrite of the report is needed due to extensive comments.

APPENDIX J

TABLES OF DOCUMENTS FOR STAFF CONSIDERATION

TABLE 1

REQUIRES REVIEW BY THE CRGR

Documents with Strong Potential or Actual Backfitting¹

Policy statements being developed for Commission consideration²

Bulletins

Generic Letters

Facility-specific information requests issued under 10 CFR 50.54(f) information requests

Rulemakings and other actions proposed by the staff that impose a backfit

¹Documents reflecting staff positions that, unless complied with or offered a satisfactory alternative, the staff would impose or seek to have imposed by formal requirement.

²A policy statement does not impose a legal requirement as does a rule, order, or license condition; however, it may constitute an "interpretive rule" under the Administrative Procedure Act.

TABLE 2

DOCUMENTS CRGR MAY CONSIDER OR REVIEW BY REQUEST

Substantive Rulemaking³

Advanced Notices
Proposed Rules
Final Rules

Formal Requirements⁴

Multiplant orders including show cause orders and
confirmatory orders

Single Plant Orders (reviewed at EDO request)

Guidance, Interpretative and Other Documents⁵

Regulatory Guides

Action on Petitions for Rulemaking

Action on 10 CFR 2.206 Requests

Approvals on Topical Reports

Facility Licenses and Amendments

SERs

NUREG Reports (other than USI)

Operator Licenses and Amendments

Staff Positions on Code Committees

Unresolved Issues Resulting from Inspections

Task Interface Agreement
Interim Staff Guidance

³Although rulemaking is an action of the Commission rather than the staff, most rules are proposed by or prepared by the staff.

⁴The document itself imposes a legal requirement (e.g., regulatory orders or license conditions).

⁵Documents reflecting staff positions that, unless complied with or offered a satisfactory alternative, the staff would impose or seek to have imposed by formal requirement.

Enforcement Guidance

Inspection Manual (including temporary instructions)

Proposed Findings

Branch Technical Positions

Standard Technical Specifications

Unresolved Safety Issue (USI) NUREGs

Safety Evaluation Reports on industry initiatives