CHARTER

COMMITTEE TO REVIEW GENERIC REQUIREMENTS

Revision 8

March 2011

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Commission Approvals

CRGR creation approved by the Commission on June 16, 1982 (SECY-82-39A)
Charter Revision 1 approved by the Commission on January 6, 1984
Charter Revision 2 approved by the Commission (COMSECY-86-5, dated June 20, 1986)
Charter Revision 3 approved by the Commission on August 13, 1986
Charter Revision 4 approved by the EDO (Memorandum to the Commissioners, dated April 6, 1987)
Charter Revision 5 approved by the Commission on March 8, 1991
Charter Revision 6 approved by the Commission (SRM-SECY-96-032, dated February 9, 1996)
Charter Revision 7 approved by the EDO (Memorandum to the Commissioners, dated November 8, 1999)
Charter Revision 8 approved by the EDO (Memorandum to the Commissioners, Dated March 10, 2011)

CRGR CHARTER

I. MISSION

The Committee to Review Generic Requirements (CRGR, or the Committee) will ensure that proposed generic[1] backfits to be imposed on the U.S. Nuclear Regulatory Commission (NRC)-licensed power reactor, new reactors, or nuclear materials[2] facilities are appropriately justified based on backfit provisions of applicable NRC 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) and the guidance contained in the Regulatory Analysis Guidelines (NUREG/BR-0058) or the Commission's backfit policy. The CRGR's primary responsibilities are to recommend to NRC's Executive Director for Operations (EDO) either approval or disapproval of the staff proposals and to provide guidance and assistance to the NRC program offices to help them implement the Commission's backfit policy. The CRGR Charter shall be incorporated in the appropriate program office administrative procedures for developing new or revised generic actions.

II. MEMBERSHIP

The EDO shall appoint CRGR members. In addition to the CRGR Chairman, the Committee will comprise one individual each from the Offices of Nuclear Reactor Regulation (NRR), Nuclear Material Safety and Safeguards (NMSS), Nuclear Security and Incident Response (NSIR), New Reactors (NRO), Federal and State Materials and Environmental Management Programs (FSME); Nuclear Regulatory Research (RES), one individual from the Regions; and one individual from the Office of the General Counsel (OGC) who will be nominated by the General Counsel and appointed by the EDO. The regional individual shall be selected on a rotational basis from one of the regional offices. The EDO will make a new selection when he or she judges that the incumbent regional representative has gained sufficient experience (typically 2 years) on the Committee. 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.

At least four of the regular CRGR members need to be present for a quorum. If a member cannot attend a CRGR meeting, the applicable office may propose an alternate for the CRGR Chairman's approval. The alternate member is responsible for being fully versed on the agenda items before the Committee and also for apprising the regular member (for whom he or she is substituting) of the details including administrative matters discussed at the CRGR meeting.

As discussed at the bottom of Section III, the CRGR Chairman will be responsible for ensuring that each licensee is informed of the existence and structure of NRC's generic backfit management program described in this Charter. The CRGR Chairman also will ensure that

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[1] Applicable to one or more classes of nuclear power reactors or materials facilities accorded backfitting protection.

[2] Licensees authorized to possess a critical mass of special nuclear material under Subpart H of 10 CFR Part 70, licensees of independent spent fuel storage installations under 10 CFR Part 72, and operators of gaseous diffusion plants under 10 CFR Part 76 are accorded backfitting protection.

substantive changes in the Charter are communicated to all licensees and certificate holders via the CRGR Web site (http://www.nrc.gov/about-nrc/regulatory/crgr.html) and other agency methods for notification.

III. SCOPE

The CRGR review may involve a formal review or an informal review. The formal review will be conducted in a formal setting and attendance is to include the CRGR members and the division director or his or her delegate and the supporting staff. The staff proposal is to be in its final concurred state. Documents such as Generic Letters or Bulletins will generally receive a formal review.

Alternatively, an informal review will be conducted by the CRGR technical staff for various generic documents such as Regulatory Issue Summaries and provides recommendations to the CRGR Chairman and the members for consideration. If concerns exist or unintended backfitting requires further discussion, then a formal review will ensue that entails the staff appearing before the CRGR members in a formal setting.

With respect to the form of any review the CRGR conducts, it is at the discretion of the CRGR 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.

Except for the requirements that are determined to become immediately effective[3], the CRGR will review for new and operating power reactors; (consistent with the discussion in the next two paragraphs) new and revised regulatory requirements, generic correspondence[4], regulatory guidance, and selected NRC staff guidance related to licensing, inspection, and enforcement that could impose a backfit. The Committee also will review selected nuclear materials items at the recommendation of the Office Director of NMSS, the Office Director of FSME, or at the EDO's request.

The CRGR will review draft regulatory guides at the request of the proposing 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. Both interactions may result in a formal CRGR review.

The CRGR will not consider plant-specific regulatory actions. The Committee will ensure that proposed generic backfits to be imposed on NRC-licensed power reactors, new reactors, or selected nuclear materials licensees are appropriately justified based on backfit provisions of applicable NRC regulations and the Commission's backfit policy. The Committee will recommend to the EDO whether to approve proposed new or revised generic requirements or

[3]For those rare instances when a program office director judges that an immediately effective action is required (e.g., 10 CFR 50.109(a)(6) for power reactors and 10 CFR 76.76((a)(6) for gaseous diffusion plants), no prior review by the CRGR will be necessary. However, the staff shall conduct a documented evaluation (either before or after the action is taken) that shall be subject to CRGR review. The CRGR Chairman shall be notified by the program office director originating such an action. Use of this provision should normally be reserved for circumstances that pose an immediate or imminent threat to adequate protection of the public health and safety.

[4]Such as bulletins, generic letters, and generic 50.54(f) information request letters.

staff positions. The Committee will review NUREGs, including Standard Review Plans, only if they expound a new staff position. The CRGR will review rulemakings only at the request of the sponsoring office or at the direction of the EDO. The CRGR will not review any proposed generic actions including generic communications, staff guidance, or Safety Evaluation Reports (SERs) that merely involve voluntary relaxations[5]. However, for proposed generic relaxations or decreases in current requirements or staff positions (whether affecting power reactors, new reactors, or nuclear materials activities), the proposing office director shall provide to the CRGR Chairman his or her determination along with the rationale for the determination based on various considerations that (a) the public health and safety and the common defense and security would be adequately protected if the proposed relaxations were implemented and (b) the cost savings attributed to each action would be significant enough to justify the action. Moreover, the staff shall indicate if the proposed relaxations are voluntary or mandatory. The CRGR will review the SERs endorsing generic vendor initiatives only at the program office director's request.[6] Except for rulemakings, generic documents for which the nonconcurrence process has been evoked related to a backfit issue will require a review.

The Committee also will focus on the administrative controls related to the NRC staff's generic backfit management practices to ensure that the NRC processes (in particular, the office and regional directives, procedures, and staff guidance and the technical staff training in NRR, NMSS, NSIR, NRO, FSME, and the Regions) are adequate. The Committee will ensure that the staff guidance on backfits is clear and comprehensive. The line managers in each program office will be responsible for ensuring that the staff follows the backfit procedures; to that end, each office shall establish a backfit point of contact.

Each staff's proposal will include the proposed method of implementation and resource implications along with the legal review (and any comments) of OGC on the method proposed and the concurrence of the affected offices, including the Regions, or an explanation of any nonconcurrences. The program office managers will ensure that the quality of the incoming proposals is adequate and that the proposals are approved at least at the deputy office director level before the CRGR reviews it.

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[5] 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 “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.”

[6] The program office is responsible for determining if acceptance of new or revised topical reports involves any new staff positions or interpretations. However, if the program office believes that a new staff position or interpretation is (or may be) involved, then the proposed acceptance should be sent to the CRGR and notification to vendors be held in abeyance pending formal response by the CRGR Chairman.

Appendix B contains the procedures to control proposed generic requirements and staff positions. The CRGR Chairman and staff will do a quality check of all incoming proposals to determine the acceptability for CRGR review. A formal CRGR review will be the ultimate check in NRC's backfit management to ensure that the internal backfit control processes work.

Appendix C 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 backfit 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 backfit policy and directives shall apply. Appendix D contains the guidance on application of the "Substantial Increase Standard."

As part of its regulatory responsibility for monitoring the overall effectiveness of NRC's generic backfit management process when applicable, the CRGR members, in their role as senior managers, will engage licensees to inform them of NRC's generic backfit management process and to obtain feedback on issues regarding backfitting. In addition, the Committee will hold periodic meetings with stakeholders as appropriate and will perform special tasks at the EDO's request.

IV. MEETING NOTICES AND SUMMARIES

The CRGR meetings will be scheduled on the date and time when a CRGR quorum is both available and agreeable with the presenting staff.

The program office staff will submit a formal review request package to the CRGR Chairman at least 2 weeks before the anticipated review date. Within 1 week of receipt of a formal request, the CRGR will make a selection of a date to conduct the review. Meeting notices will generally be issued by the CRGR Chairman at least 1 week in advance of each meeting, with the exception of special meetings held to review urgent items[7]. The review material along with relevant background material for each item to be considered by the Committee will be issued to the CRGR staff and will be promptly distributed to the members. The members must receive the review material at least 1 week before the scheduled review. The presenting staff will be responsible for providing relevant background material to the Committee and the CRGR staff and for distributing presentation material to other staff members that are in attendance at the meeting.

[7]Such 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 2 working days of receipt by the CRGR. If the CRGR Chairman were to question the appropriateness of the urgency and if the question is not resolved within 2 working days, the proposed requirement or staff position will be forwarded by the CRGR Chairman to the EDO for decision.

Meeting summaries will be issued to the EDO articulating the highlights of the meeting. Additional emphasis will be placed on identifying cases where NRC's staff products did not conform to the backfit guidance and cases where the guidance needs further clarification. Draft summaries will be circulated to the members and the presenting staff within 3 working days after the meeting for a 3-day negative consent period. The summaries will be issued final within 2 weeks of each meeting.

The CRGR will submit an Annual Report to the Commission in August of each year. As directed by the Commission, in addition to the stakeholders' input on value added by the CRGR review to various staff proposals and the Committee's self assessment as to how its activities contributed to the agency's mission, the CRGR Annual Report also will include an assessment of the quality of the incoming proposals.

In the event that the staff disagrees with the CRGR recommendations, the sponsoring division 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 when major differences exist.

V. OPERATING PROCEDURES

The CRGR Chairman will maintain and distribute the CRGR administrative procedures to the program office directors. The program office directors shall ensure that these procedures are widely distributed and incorporated as appropriate in their office procedures and that the staff follows these procedures.

VI. RECORD RETENTION REQUIREMENTS

The CRGR staff will ensure that all relevant documents (when not marked as classified or safeguards) have been entered into the Agencywide Documents Access and Management System (ADAMS). These include documents connected to all review requests submitted to the CRGR Chairman; actions by the staff subsequent to the CRGR review; summary minutes of CRGR consideration of each review request, including comments and recommendations by the Committee; and decisions by the EDO and the Commission.

APPENDIX A

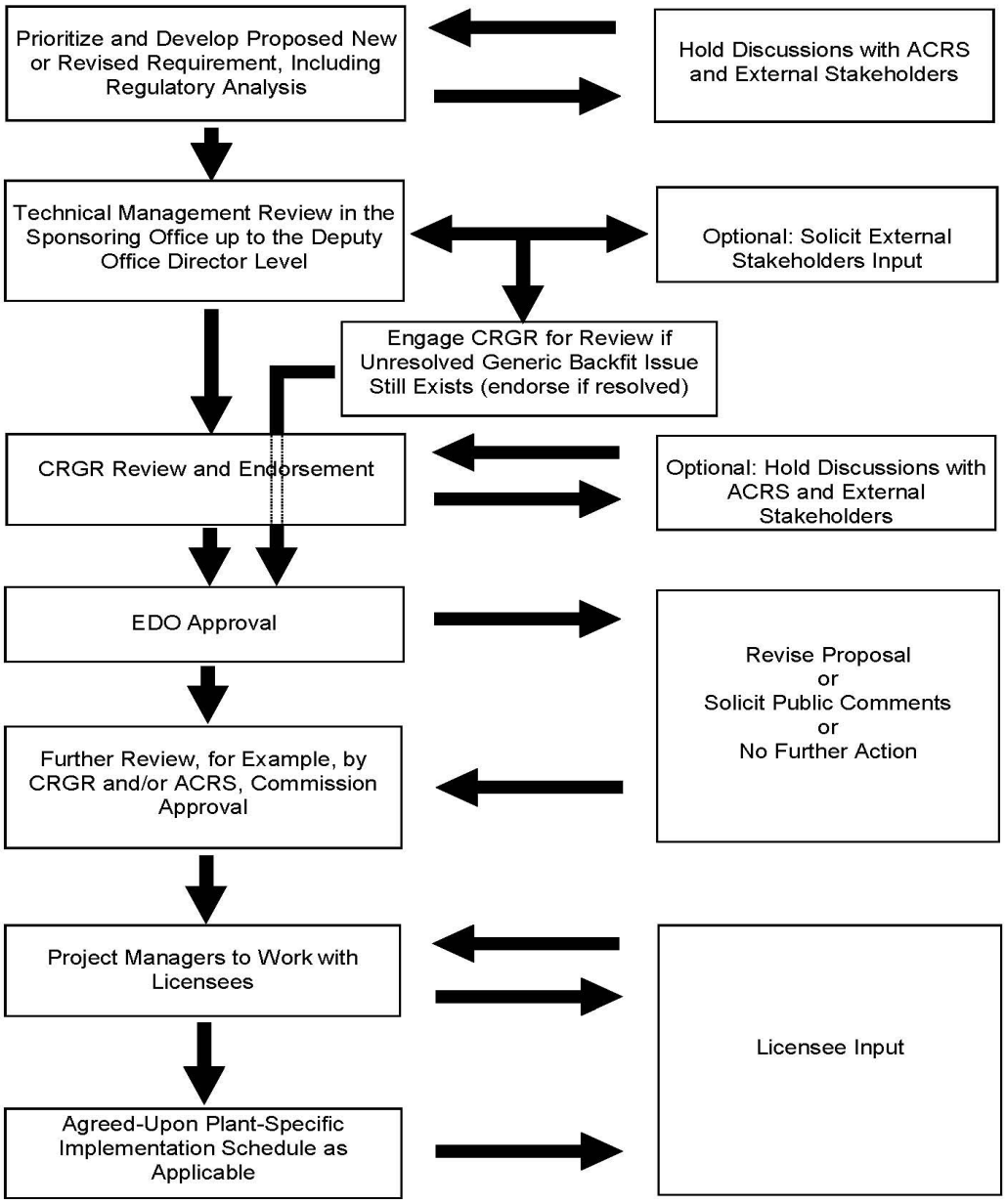
REVIEW PROCESS FOR PROPOSED NEW OR REVISED GENERIC REQUIREMENTS AND STAFF POSITIONS

The attached chart is a schematic representation of how new generic requirements and staff positions are developed, revised, and implemented.

In the early stages of developing a proposed new requirement or staff position, the staff may have discussions with the industry, 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, 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 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

PROCEDURES TO CONTROL PROPOSED NEW OR REVISED GENERIC REQUIREMENTS AND STAFF POSITIONS

A. Background

In a memorandum from the Chairman to the Executive Director for Operations (EDO) dated October 8, 1981, the Commission expressed concern over conflicting or inconsistent directives and requests to reactor licensees from various components of the NRC staff. By that memorandum, the Commission outlined certain recommended actions to establish control over the number and nature of requirements placed by the U.S. Nuclear Regulatory Commission (NRC) on reactor licensees. These included (1) establishing a Committee to Review Generic Requirements (CRGR), (2) establishing a new position of Deputy Executive Director for Regional Operations and Generic Requirements (DEDROGR), (3) conducting a survey of formal and informal mechanisms for communicating with reactor licensees, and (4) developing and implementing procedures for controlling communications that involve significant requirements covering one or more classes of power reactors.

In February 1987, the Commission approved an NRC reorganization that, among other changes, placed the CRGR operations under the former Office for Analysis and Evaluation of Operational Data (AEOD). The CRGR responsibilities and authorities were not changed under the new organizational structure. However, in 1996[1], the Commission directed that the CRGR be retained and approved the expansion of the CRGR Charter to include the review of selected issues and items in the nuclear materials area either at the recommendation of the Director, Office of Nuclear Material Safety and Safeguards (NMSS); the Director, Office of Federal and State Materials and Environmental Management Programs (FSME); or the request of the EDO. The Commission also directed that the staff consider including the review of selected reactor inspection guidance within the scope of the CRGR Charter.

In 1997[2], the Commission further expanded the scope of the CRGR Charter to include the review of selected inspection guidance either at the specific request of the staff or by the CRGR's self initiation. The Commission believed that inspection guidance for major rulemaking activities would benefit from the CRGR review especially if significant departures from the use of risk-informed approaches were being proposed. Moreover, while approving the staff's recommended process for periodic evaluation and reporting of the CRGR activities, the Commission had the following comments:

(1) The Commission recognizes that costs always exist both in human resources and in the time delays in the issuance of rulemakings or generic communications

[1]Staff Requirements Memorandum COMSECY-96-028 - Strategic Assessment Issue paper: Independent Oversight (DSI 19) dated August 21, 1996.
[2]Staff Requirements Memorandum - SECY-97-052 - Committee to Review Generic Requirements. (CRGR) - Scope of Review and Periodic Review Activities, dated April 18. 1998.

associated with benefits received. These associated costs are not reflected in the "value added" summaries contained in the AEOD Annual Report. In the context of the National Performance Review mandate to ensure timely, efficient, and cost-effective use of agency resources, it would be useful for the Commission to have information that would allow it to relate these associated costs with the benefits received.

(2) In assessing whether associated costs are commensurate with the significance of the issues raised by the CRGR, the staff's summaries or evaluations should be based on a process that, in part, incorporates input from those stakeholders (i.e., program offices) that have had issues before the CRGR for review. They also should consider elements such as the percentage of the original staff proposals that were fundamentally flawed because of technical, procedural, or legal deficiencies or flawed with respect to policy when presented to the CRGR and the significance of issues raised compared to the impact on schedules and resources. This process should be provided for Commission consideration.

In December 1998, following a Commission decision to streamline AEOD activities, the Office of Nuclear Regulatory Research, as part of its regulatory effectiveness activities, was assigned the responsibility to support the CRGR. This included providing technical and administrative support to the Committee.

B. CRGR Operating Procedures

The following procedures have been established for controlling generic requirements or staff positions and are designed to implement provisions of 10 CFR 50.109, 50.54(f), and 2.204 for power reactors and analogous control mechanisms for evaluation of proposed backfitting actions affecting selected nuclear materials facilities and activities. The CRGR also instituted administrative procedures containing staff guidance for scheduling the CRGR review and the requirements for subsequent submittal of revised staff proposals submitted for the CRGR endorsement.

Except for immediately effective actions, the CRGR shall review proposed new generic requirements (except for rulemakings) and staff positions to be imposed on one or more classes of power reactors and selected nuclear materials facilities and activities. These reviews shall be done in accordance with Section III of the CRGR Charter before such proposed requirements or staff positions are sent to the EDO and the Commission and imposed on or communicated for use as guidance to any power reactor, new reactor, or nuclear materials licensee or certificatee.

In October 2007, following a Commission decision to streamline the rulemaking process and in accordance with SECY-07-134, the staff recommended and the Commission approved that the CRGR be removed from the rulemaking process. In the July 1, 2010, action plan (Agencywide Documents Access and Management System [ADAMS] Accession No. ML101170084), the CRGR, in addressing industry input regarding its role and responsibilities, proposed a generic backfit review process to review unresolved backfit concerns that emerge during the public comment phase relating to documents other than rulemakings. This review process is initiated by the external stakeholders through a letter to the CRGR Chairman. This letter will contain the

issue(s) and will reference the communications between the sponsoring staff and the external stakeholders. The documentation should indicate that an unresolved backfit concern still exists after meaningful attempts to adequately resolve them with the sponsoring staff.

After receiving a letter from external stakeholders that requests a review regarding a backfit claim, the CRGR will first engage the staff as the initial phase for this review. The review process may involve a public meeting with the external stakeholders if the backfit issue remains unresolved. However, the CRGR will not normally hear plant-specific backfit claims or engage in appeals of plant-specific backfit determinations. If a plant-specific backfit determination (or rulemaking) is appealed to the EDO, the EDO can form a panel to review the backfit determination and to provide a recommendation. The panel may be composed of the CRGR members.

C. Office Responsibility

Each program office shall develop appropriate internal procedures to ensure that the following policy requirements regarding licensees are implemented and submitted for CRGR review and endorsement:

(1) New or revised generic actions with a direct or indirect impact on power reactors, new reactors, or selected nuclear materials facilities or activities (as indicated in Section III, "Scope," of the Charter). These also include:

(a) Selected enforcement or inspection guidance (including temporary instructions) for major rulemaking.

(b) Generic backfitting procedures such as those for nuclear power plants and gaseous diffusion plants.

Table 1 (attached) provides examples of mechanisms for establishing or communicating new or revised generic requirements related to power reactors, new reactors, or nuclear materials activities. Staff proposals related to power reactors are subject to CRGR review and endorsement. However, the CRGR will review staff proposals related to the nuclear materials only as recommended by the Director, NMSS or FSME, or requested by the EDO.

(2) Proposed generic documents, letters, and communications that establish, reflect, or interpret NRC staff positions or requirements to be imposed on power reactors, new reactors, or selected nuclear materials facilities and activities—at the recommendation of the Director, NMSS or FMSE, or at the EDO's request—are submitted for the CRGR consideration (as indicated in Section III, “Scope,” of the CRGR Charter). Table 2 (attached) provides examples of mechanisms that may have been used to interpret generic requirements or staff positions. These documents shall be submitted for the CRGR review unless they refer only to requirements or staff positions approved prior to November 12, 1981. In the latter case, the previously approved requirement or staff position should be specifically cited and accurately stated. Program offices should be careful to review new or specific interpretations to ensure that they are only case-specific applications of existing requirements rather than initial applications having potential generic use. Case-specific

applications are governed by NRC Management Directive 8.4 (Manual Chapter 0514), "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants."

(3) For all other communications with licensees, no statements shall be used that might suggest the imposition of new or revised generic requirements, staff positions, guidance, or recommendations unless such statements have been approved by the EDO or the Commission. Table 3 (attached) contains examples of mechanisms that should not be used to communicate generic requirements or staff positions absent Commission or EDO approval.

(4) While awaiting imminent CRGR review of a proposed new generic requirement or staff position, an office may determine that it has important safety information that should be made available to licensees. That office shall take immediate action to ensure that such information is communicated to the licensees by the appropriate office. Such actions may be taken before completion of any proposed or ongoing CRGR reviews.

D. Immediately Effective Action (Power reactor only)

For those rare instances when an office director judges that an immediately effective action is required (10 CFR 50.109(a)(6)), no prior review by the CRGR is necessary. However, the staff shall conduct a documented evaluation that includes a statement of the objectives and reasons for the actions and the basis for invoking the exception. The evaluation may be conducted either before or after the action is taken and shall be subject to the CRGR review. The evaluation also shall document the safety significance and appropriateness of the action taken and how cost considerations contribute to selecting that option among various acceptable alternatives. The office director originating the action shall notify the CRGR Chairman. These immediately effective actions will be included in the CRGR Annual Report to be submitted to the Commission.

TABLE 1

PRINCIPAL MECHANISMS USED BY NRC STAFF TO ESTABLISH OR COMMUNICATE PROPOSED NEW OR REVISED GENERIC REQUIREMENTS AND STAFF POSITIONS
[See paragraph C.(1)]

Substantive Rulemaking[1]

- Advanced Notices
- Proposed Rules
- Final Rules

Guidance and Interpretations[2]

- Policy Statements[3]
- Bulletins
- Generic Letters (including 10 CFR 50.54(f) information requests)
- Regulatory Guides
- Branch Technical Positions
- Standard Technical Specifications
- Unresolved Safety Issue (USI) NUREGs
- Safety Evaluation Reports on industry initiatives

Other Formal Requirements[4]

- Multiplant orders including show cause orders and confirmatory orders

[1]Although rulemaking is an action of the Commission rather than the staff, most rules are proposed by or prepared by the staff.
[2]Documents reflecting staff positions that, unless complied with or offered a satisfactory alternative, the staff would impose or seek to have imposed by formal requirement.
[3]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.
[4]The document itself imposes a legal requirement (e.g., regulatory orders or license conditions).

TABLE 2

MECHANISMS THAT MAY HAVE BEEN USED TO INTERPRET NEW OR REVISED GENERIC REQUIREMENTS OR STAFF POSITIONS

[See paragraph C.(2)]

Action on Petitions for Rulemaking

Action on 10 CFR 2.206 Requests

Approvals on Topical Reports

Facility Licenses and Amendments

SERs (CRGR review will only be at program office request)

NUREG Reports (other than USI)

Operator Licenses and Amendments

Single Plant Orders

Staff Positions on Code Committees

Unresolved Issues Resulting from Inspections

Enforcement Guidance

TABLE 3

MECHANISMS THAT SHOULD NOT BE USED TO COMMUNICATE GENERIC REQUIREMENTS OR STAFF POSITIONS ABSENT COMMISSION OR EDO APPROVAL

[See paragraph C.(3)]

Administrative Letters

Entry, Exit, and Management Meetings

Inspection Manual (including temporary instructions)

Site Visits by NRC Staff or Commission to Obtain Information (i.e., Corrective Actions, Schedules, Conduct Surveys, etc.)

Pleadings

Preliminary Notifications

Press Releases

Proposed Findings

Public Meetings, Workshops, Technical Discussion (such meetings, however, may be used to seek comments on potential staff positions being contemplated)

Resident Inspector Day-to-Day Contact

Plant Performance Review Reports

Special Reports

Speeches to Local Groups or Industry Associations

Plant-Specific Technical Specifications

Telephone Calls and Meetings with Licensees, Vendors, Industry Representatives, Owners Groups

Testimony

NRC SharePoint Sites

APPENDIX C

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 generic staff proposals related to new reactors or the nuclear materials facilities, the backfit 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 backfit policy and directives shall apply.

For each proposed action submitted to the CRGR for review and endorsement, the staff shall include the following information in the review package:

(i) The new or revised generic requirement or staff position as it is proposed to be sent out to licensees or to be issued for public comments.

(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 Committee 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 nonconcurrences.

(v) Regulatory analysis generally conforming to the directives and guidance of NUREG/BR-0058 and NUREG/BR-0184, as applicable.[(1)] (This does not apply to backfits 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.)

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[1] Ref: NUREG/BR-0058, Revision 4, dated September 2004, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" and NUREG/BR-0184, dated January 1997, "Regulatory Analysis Technical Evaluation Handbook."

(vi) Identification of the category of power reactors, new reactors, or nuclear materials facilities or activities to which the proposed generic requirement or staff position is applicable (i.e., whether it is only applicable to future plants, operating plants, all pressurized-water reactors, all boiling-water reactors, specific nuclear steam supply system vendor types, specific vintage types plants, gaseous diffusion plants (GDPs), etc.).

(vii) For proposed backfits other than either the compliance or the adequate protection backfits, 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.[2] [3] [4] The backfit analysis shall include, 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.

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[2] As 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 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 generic positions in documents, such as generic 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.

[3] Types of actions to which the standards of the backfit rule do not apply include (1) voluntary actions and voluntary relaxations (as described in footnote 5 to the CRGR Charter), (2) actions mandated by statute, and (3) requests for information. (See NUREG-1409, "Backfitting Guidelines," dated July 1990. See Section 2.1.1 for further discussion.)

[4] Reporting 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 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.[5]

(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. For example, could implementation be delayed pending public comment?

(viii) For each proposed backfit other than either adequate protection backfits or compliance backfits, 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

[5] 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.

(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.[6][7]

(b) The direct and indirect costs of implementation for the 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 6 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."[8]

(ix) For adequate protection or compliance backfits affecting power reactors, new reactors, or materials evaluated pursuant to the applicable backfit provisions as appropriate,

(a) A documented evaluation consisting of:

(1) The objectives of the modification.
(2) The reasons for the modification.
(3) If the compliance exception is invoked,

(A) The requirements (e.g., Commission regulation, license condition, order) or written licensee commitments for which compliance is sought.

(B) 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).

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[6] Appendix D 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 D in evaluating qualitative factors that may contribute to the justification of proposed backfitting actions directed to nuclear materials facilities and activities.

[7] Certain 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 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.

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

(C) Demonstrated consideration of other possible alternatives and rationale for rejecting them in favor of compliance backfitting.

(D) Evaluation from cost-benefit considerations (not a full regulatory analysis) and a rationale for compliance exception.

(4) 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.

(b) 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.

(x) 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, an evaluation that includes at least the following elements:

(a) A problem statement that describes the need for the information in terms of potential safety benefit.

(b) The licensee actions required and the cost to develop a response to the information request.

(c) An anticipated schedule for NRC use of the information.

(d) A statement affirming that the request does <u>not</u> impose new requirements on the licensee other than submittal of the requested information.

(e) 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. Section 5.4 of NUREG/BR-0058, Revision 4 provides additional guidance for preparing this evaluation. (See footnote 9 on the following page).

Include an analogous evaluation addressing items (a) through (e) 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.

(xi) 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.[9]

[9]Detailed guidance for addressing the Commission's safety goals is contained in “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Guidelines” (NUREG/BR-0058, Revision 4, dated September 2004).

APPENDIX D

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."[1] 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.[2]

Generally, the staff should quantify the benefits of a proposed backfit to the extent feasible. With regard to cases where the safety benefits of a backfit 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.[3]

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.[4] In addition, in the context of Part 70 licensing actions, the

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[1] 10 CFR 50.109(a)(3), 10 CFR 70.76(a)(3), 10 CFR 72.62(c), and 10 CFR 76.76(a)(3).
[2] NUREG/BR-0058, "Regulatory Analysis Guidelines of the U. S. Nuclear Regulatory Commission," Revision 4, dated September 2004.
[3] *Federal Register Notice* 50 FA 38102, September 20, 1985.
[4] Memorandum 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."[5]

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 4 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 backfit meets the "substantial increase" standard of the backfit rule. This practice also will be consistent with Public Law 104-113.

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.

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