

EDO 112



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
WASHINGTON, D.C. 20555-0001

November 8, 1999

MEMORANDUM TO: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

FROM: William D. Travers *William Travers*
Executive Director for Operations

SUBJECT: NOTIFICATION OF THE REVISED CHARTER OF THE COMMITTEE
TO REVIEW GENERIC REQUIREMENTS (CRGR)

In response to the Staff Requirements Memorandum, "SECY-97-052 – Committee to Review Generic Requirements (CRGR) – Scope of Review and Periodic Review Activities," dated April 18, 1997, various Commission directives since issuance of the latest CRGR Charter, and the recent agency-wide reorganization, the CRGR has proposed a revised Charter. Additionally, the Committee is using this opportunity to make the Charter succinct by moving some of the material to the appendices. The CRGR Charter, Revision 7, is attached for your information. Barring any objection, I intend to approve the proposal within 10 business days of the date of this memorandum.

BACKGROUND:

The latest CRGR Charter, Revision 6, was issued in April 1996. This was also the year when the Committee, on a one-year trial period, began reviewing selected nuclear materials topics either at the recommendation of the Director, NMSS, or at the EDO's request. The CRGR has continued this activity since 1997 following Commission approval to extend the trial period. The Committee proposes to continue, on a permanent basis, review of selected nuclear materials issues either at the recommendation of the Director, NMSS, or at the EDO's request. In 1997, the Commission also directed the Committee to review selected nuclear power reactor related inspection guidance either at the staff's request or at the Committee's self initiation. The CRGR has implemented this directive. Additionally, the Committee believes that review of selected proposed new or revised enforcement guidance, in conjunction with the CRGR review of inspection guidance, would help ensure that no inadvertent or unjustified backfits are either implied or imposed via these routes.

Various Commission directives since 1996 and the recent agency-wide reorganization, including consolidation of the activities of the former Office for Analysis and Evaluation of Operational Data (AEOD), have made it necessary to revise the CRGR Charter. Additionally, we have moved procedural and administrative material to the appendices.

Contact: Joseph Murphy
415-5670

Template EDO-004 (Public)

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DISCUSSION:

In the process of the Charter revision, the Committee considered various options, including expanding its scope to more directly address recent stakeholder concerns regarding plant-specific backfits and the methods used for value impact analyses. However, the Committee concluded that it was best not to expand the Charter into these areas at this time, primarily because they are adequately treated by other initiatives. The Committee intends to continue the review of selected nuclear materials items on a permanent basis. In addition to reviewing selected nuclear power reactor inspection guidance, the CRGR will review selected related enforcement guidance. The Committee will continue the practice of reviewing all new or revised proposed generic actions related to nuclear power reactors as well as selected items related to nuclear materials facilities, and advise the EDO whether backfit provisions of the applicable regulations have been met. However, the Committee will no longer review generic actions solely involving voluntary actions, including generic communications, staff guidance, rules, and safety evaluation reports (SERs). The CRGR review of SERs will only be at the program office director's request.

The highlights of the new Charter are summarized below:

1. The CRGR membership and the Chairman will continue to be appointed by the EDO. The Committee will have one member each from NRR, RES, NMSS, OGC, and one of the regions, on a rotational basis. The CRGR Chairman will report directly to the EDO about CRGR activities. New members will be appointed as the need arises. RES will provide the technical and administrative support for the CRGR.
2. Except for the proposed generic requirements which are to become immediately effective (e.g., those requiring immediate action by the licensing office because they may involve adequate protection issues), the CRGR will continue to review all new and revised power reactor related regulatory requirements, generic correspondence, regulatory guidance, as well as selected NRC staff guidance related to licensing, inspection, assessment, and enforcement which could impose a backfit.
3. At the recommendation of either the Director, NMSS, or at the EDO's request, the Committee will review selected new and revised fuel cycle facility, and spent fuel transportation and storage related proposed new or revised regulatory requirements, generic correspondence, regulatory guidance as well as selected NRC staff guidance related to licensing, inspection, assessment, and enforcement which could impose a backfit.
4. The CRGR review of inspection or enforcement guidance will either be at the specific request of the staff or by the CRGR self initiation. In accordance with the Commission's direction for selecting inspection guidance, the CRGR's focus will be on inspection or enforcement guidance for major rulemaking, especially when significant departures from the use of risk-informed approaches are being proposed.

5. The CRGR review will continue to ensure that proposed generic backfits to be imposed on the NRC-licensed power reactor and nuclear materials facilities are appropriately justified based on backfit provisions of applicable NRC regulations and/or the Commission's backfit policy. The Committee will continue to recommend to the EDO either approval or disapproval of the generic staff proposals. Additionally, the Committee will provide guidance and assistance to the NRC program offices to help implement the Commission's backfit policy.
6. The CRGR will continue to focus on backfit implications of proposed generic actions. The Committee will review NUREGs only if they delineate a new staff position. The Committee will no longer review generic actions solely involving voluntary actions, including generic communications, staff guidance, rules, and safety evaluation reports (SERs). The CRGR review of the SERs endorsing generic vendor initiatives will only be at the program office director's request.
7. As an additional responsibility, the CRGR will review the NRC's administrative generic backfit controls to determine if they are sufficient and the staff guidance is comprehensive and clear. The program office management will be responsible for ensuring that the staff follows the backfit procedures.
8. As part of the Committee's responsibility for monitoring the overall effectiveness of NRC's generic backfit management process, the CRGR members will continue to periodically visit nuclear power reactors and nuclear materials facilities, and will hold meetings with stakeholders, as appropriate.
9. The CRGR will perform special tasks at the EDO's request.

RESOURCES:

RES has allocated one dedicated FTE for the CRGR technical support. Staff resources are currently being complemented by a rotational assignment. The rotational assignment provides a good developmental assignment and will be continued.

Attachment: As stated

cc w/att.: SECY
OCA
OGC
OPA
CFO
CIO

5. The CRGR review will continue to ensure that proposed generic backfits to be imposed on the NRC-licensed power reactor and nuclear materials facilities are appropriately justified based on backfit provisions of applicable NRC regulations and/or the Commission's backfit policy. The Committee will continue to recommend to the EDO either approval or disapproval of the generic staff proposals. Additionally, the Committee will provide guidance and assistance to the NRC program offices to help implement the Commission's backfit policy.
6. The CRGR will continue to focus on backfit implications of proposed generic actions. The Committee will review NUREGs only if they delineate a new staff position. The Committee will no longer review generic actions solely involving voluntary actions, including generic communications, staff guidance, rules, and safety evaluation reports (SERs). The CRGR review of the SERs endorsing generic vendor initiatives will only be at the program office director's request.
7. As an additional responsibility, the CRGR will review the NRC's administrative generic backfit controls to determine if they are sufficient and the staff guidance is comprehensive and clear. The program office management will be responsible for ensuring that the staff follows the backfit procedures.
8. As part of the Committee's responsibility for monitoring the overall effectiveness of NRC's generic backfit management process, the CRGR members will continue to periodically visit nuclear power reactors and nuclear materials facilities, and will hold meetings with stakeholders, as appropriate.
9. The CRGR will perform special tasks at the EDO's request.

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Distribution:

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CHARTER

COMMITTEE TO REVIEW GENERIC REQUIREMENTS

Revision 7

November 1999

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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 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)

CRGR CHARTER

I. MISSION

The Committee To Review Generic Requirements (CRGR, or the Committee) will ensure that proposed generic¹ backfits to be imposed on the NRC-licensed power reactor and selected nuclear materials licensees are appropriately justified based on backfit provisions of applicable NRC regulations and the Commission's backfit policy. The CRGR's primary responsibilities are to recommend to the Nuclear Regulatory Commission's (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 Management Directive and the program office administrative procedures for developing new or revised generic actions.

II. MEMBERSHIP

CRGR membership shall be appointed by the EDO. In addition to the CRGR Chairman, the Committee will comprise of one individual each from the Office of Nuclear Reactor Regulation (NRR), the Office of Nuclear Materials Safety and Safeguards (NMSS), the Office of Nuclear Regulatory Research (RES), one of the Regions, and one individual from the Office of 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. A new selection will be made by the EDO 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. It is the responsibility of the alternate member to be fully versed on the agenda items before the Committee, and also apprise the regular member (for whom he or she is substituting) of the details, including administrative matters, discussed at the CRGR meeting.

The CRGR Chairman will be responsible for ensuring that each licensee is informed of the existence and structure of the NRC's generic backfit management program described in this Charter. The CRGR Chairman will also ensure that substantive changes in the Charter are communicated to all licensees and certificatees.

¹ Applicable to one or more classes of nuclear power reactors or materials facilities.

III. SCOPE

Except for the requirements which are determined to become immediately effective², the CRGR will review for power reactors all new and revised regulatory requirements, generic correspondence³, regulatory guidance, and selected NRC staff guidance related to licensing, inspection, and enforcement, which could impose a backfit. The Committee will also review selected nuclear materials items at the recommendation of the Director, NMSS, or at the EDO's request. Appendix A contains the review process for new or revised generic requirements or staff positions.

The CRGR will not consider plant-specific regulatory actions. The Committee will ensure that proposed generic backfits to be imposed on the NRC-licensed power reactor and 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 staff positions. The Committee will review NUREGs, including Standard Review Plans, only if they expound a new staff position. The CRGR will not review any proposed generic actions, including generic communications, staff guidance, rules, or safety evaluation reports (SERs), that merely involve voluntary relaxations. However, for proposed generic relaxations or decreases in current requirements or staff positions, whether affecting power 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. Furthermore, the staff shall indicate if the proposed relaxations are optional or mandatory. The CRGR will review the SERs endorsing generic vendor initiatives only at the program office director's request.⁴

² 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 GDPs), 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, which 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.

³ Such as bulletins and generic letters, and generic 50.54(f) information request letters.

⁴ The program office is responsible for determining if acceptance of new or revised topical reports involves any new staff positions or interpretations. However, if it 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.

The Committee will also 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, 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. Each staff's proposal will include the proposed method of implementation and resource implications, along with the concurrence (and any comments) of OGC on the method proposed, and the concurrence of the affected offices, including the regions, or an explanation of any non-concurrences. The program office managers will ensure that the quality of the incoming proposals are adequate and that it is approved at least at the Deputy Office Director level before CRGR reviews it.

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 the 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 (10 CFR 50.109, 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 effectiveness responsibility for monitoring the overall effectiveness of the NRC's generic backfit management process, the CRGR members will periodically visit NRC-licensed facilities. Additionally, the Committee will hold periodic meetings with stakeholders, as appropriate, and perform special tasks at the EDO's request.

IV. CRGR MEETING NOTICES AND SUMMARIES

For quarterly agenda planning, the program offices will provide to the CRGR Chairman a list of items expected to be submitted for the CRGR review and endorsement. The CRGR meetings will be formally scheduled on the 2nd and 4th Tuesday of each month, starting at 9 a.m.

The program office staff will submit a review request and 10 copies to the CRGR Chairman at least 2 weeks before the anticipated review date. The CRGR review will be scheduled within 1 week of receipt of a formal request. Meeting notices will generally be issued by the CRGR Chairman at least 2 weeks in advance of each meeting, with the exception of special meeting held to review urgent items⁵. The review material along with relevant background material for each item to be considered by the Committee will be logged in by the CRGR administrative assistant and promptly distributed to the members. The members must receive the review material at least 1 week before the scheduled review. The cognizant staff will be responsible for providing relevant background material to the Committee and the CRGR staff, and for distributing presentation material at the meeting.

Meeting summaries will be issued to the EDO articulating the highlights of the meeting. Additional emphases will be placed on identifying cases where the 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 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 Commission highlights quarterly and 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 will also include an assessment of the quality of the incoming proposals.

The sponsoring division director will submit a close-out memorandum to the CRGR Chairman, describing whether the CRGR recommendations were accepted, and, in case of a disagreement, the closeout memorandum will be submitted to the EDO for resolution. The EDO will report to the Commission in writing the disposition of the CRGR recommendations when major differences exist.

⁵ Such items are those proposed requirements which 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 they must be reviewed or otherwise be dealt 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 two working-days, the proposed requirement or staff position will be forwarded by the CRGR Chairman to the EDO for decision.

V. CRGR OPERATING PROCEDURES

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

VI. CRGR RECORD RETENTION REQUIREMENTS

The CRGR staff will maintain a system for keeping 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. Two-year old information will be maintained in the office; the rest will be annually sent to the NRC warehouse. And, 20+ year old information will be sent to the National Archives.

APPENDIX A

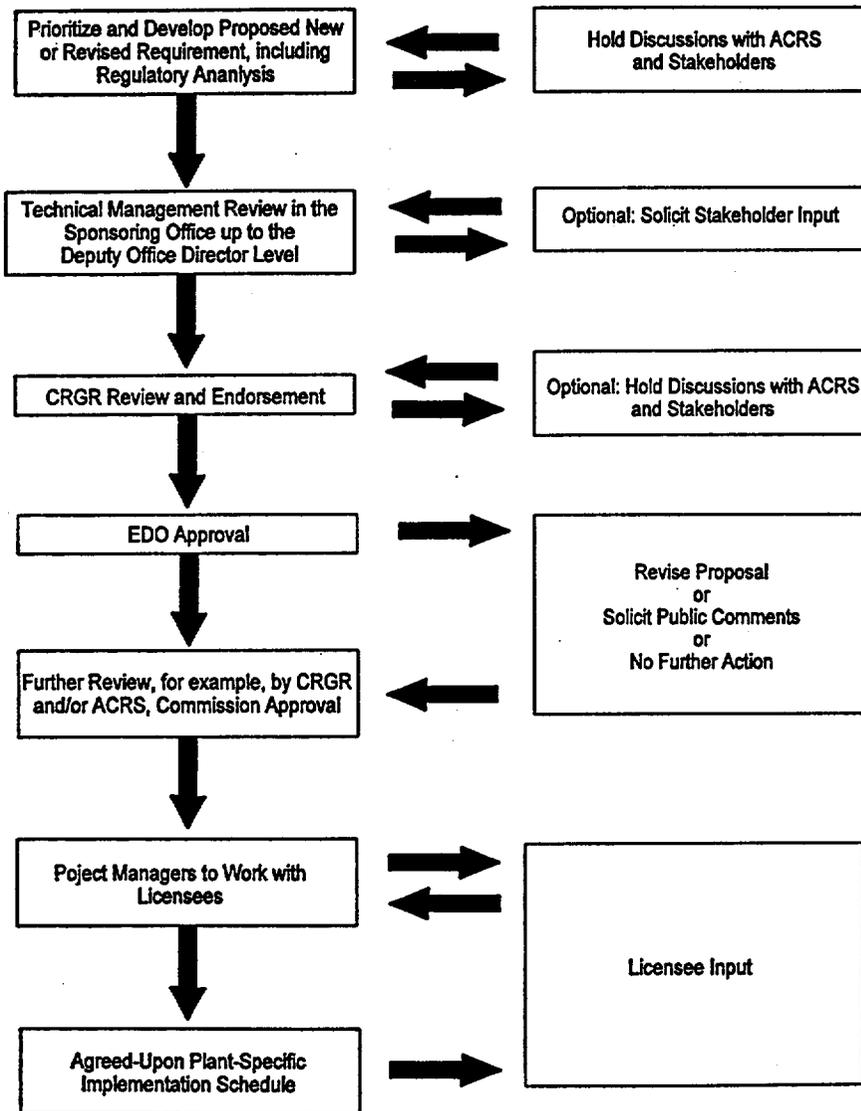
CONTROL PROCESS FOR PROPOSED NEW OR REVISED GENERIC REQUIREMENTS AND STAFF POSITIONS

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), the Advisory Committee on Nuclear Waste (ACNW), 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 CRGR review.

The CRGR may recommend approval, revision, disapproval, or that further public comments be sought. After the CRGR and the EDO approval, the ACRS, the ACNW, 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 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, NMSS, 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, especially if significant departures from the use of risk-informed approaches were being

(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.

proposed, would benefit from the CRGR review. Furthermore, 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 there are always costs, both in human resources and in the time delays in the issuance of rulemakings or generic communications, that are associated with benefits received, and that 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, 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, and considers elements such as: the percentage of the original staff proposals that were fundamentally flawed due to technical, procedural, or legal deficiencies, or flawed with respect to policy, when presented to the CRGR and the significance of issues raised compared to impact on schedules and resources. This process should be provided for the 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, which 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 all proposed new generic requirements and staff positions to be imposed on one or more classes of power reactors and selected nuclear materials facilities and activities, 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 a guidance to, any power reactor or nuclear materials licensees or certificatees.

C. Office Responsibility

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

- (1) All new or revised generic actions with a direct or indirect impact on power 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, and
 - (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 both power reactors and nuclear materials activities. All staff proposals related to power reactors are subject to the CRGR review and endorsement. However, the CRGR will review staff proposals related to the nuclear materials only as recommended by the Director, NMSS, or requested by the EDO.

- (2) All proposed generic documents, letters, and communications that establish, reflect or interpret NRC staff positions or requirements to be imposed on power reactors or selected nuclear materials facilities and activities — at the recommendation of the Director, NMSS, 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 which 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 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.
- (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 reactors 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 which includes a statement of the objectives of 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 shall also 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 highlights 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)]

Rulemaking¹

Advanced Notices
Proposed Rules
Final Rules
Policy Statements²

Other Formal Requirements³

Multi-plant orders including show cause orders and
confirmatory orders

Staff Positions⁴

Bulletins
Generic Letters (including 10 CFR 50.54(f) information requests)
Regulatory Guides
Standard Review Plan (including Branch Technical Positions)
Standard Technical Specifications
USI NUREGs
Safety Evaluation Reports on industry initiatives

Staff Practices/Procedures

Inspection guidance (including temporary instructions)
Enforcement Guidance
Facility-specific backfitting procedures (e.g., those for nuclear power plants and gaseous
diffusion plants)

-
- ¹ While Rulemaking is an action of the Commission rather than the staff, most rules are proposed by or prepared by the staff.
 - ² A Policy Statement does not impose a legal requirement, as does a rule, order, or license condition.
 - ³ The document itself imposes a legal requirement (e.g., regulatory orders or license conditions).
 - ⁴ Documents that reflect staff positions which, unless complied with or a satisfactory alternative offered, the staff would impose or seek to have imposed by formal requirement.

TABLE 2

**MECHANISMS WHICH 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 USIs)

Operator Licenses and Amendments

Single Plant Orders

Staff Positions on Code Committees

Unresolved Issues Resulting from Inspections

Inspection Guidance and Procedures

Enforcement Guidance

TABLE 3

**MECHANISMS THAT SHOULD NOT BE USED TO
COMMUNICATE GENERIC REQUIREMENTS OR STAFF POSITIONS
[See paragraph C.(3)]**

1

Administrative Letters

Entry, Exit and Management Meetings

Information Notices

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 Discussions (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

SECY Papers

Special Reports

Speeches to Local Groups or Industry Associations

Technical Specifications

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

Testimony

APPENDIX C

REQUIREMENTS FOR CONTENTS OF THE PACKAGES SUBMITTED FOR CRGR REVIEW AND ENDORSEMENT

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 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 the nuclear materials facilities, the backfit provisions of the applicable regulations (e.g, 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 for the CRGR for review and endorsement, the staff shall provide 10 copies and include the following information:

- (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. The staff should focus on developing generic actions which are less prescriptive and are consistent with the NRC's move to performance-based and risk-informed regulation. The proposed requirement should merely specify the objective or result to be attained, rather than prescribing to the licensees how the objective or result is to be attained. The objective or intended result of a proposed generic requirement or staff position should be clearly stated such that it can be achieved by setting readily quantifiable standards, which have an unambiguous relationship to a readily measurable quantity, and is enforceable.
- (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) Each proposed requirement or staff position shall contain the sponsoring office's 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) of OGC 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 and NUREG/BR-0184, as applicable.⁽¹⁾ (This does not apply to backfits that ensure compliance or, define or re-define 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 CRGR review of such items under this Charter, a similar documented evaluation should be provided by the staff as part of the CRGR review package.)
- (vi) Identification of the category of power 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 (PWRs), all boiling water reactors (BWRs), specific nuclear steam supply system (NSSS) 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

(1) Ref: NUREG/BR-0058, Revision 2, dated November 1995, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" and NUREG/BR-0184, dated January 1997, "Regulatory Analysis Technical Evaluation Handbook"

(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 justified as backfits before they are issued.

(3) Types of actions to which the standards of the backfit rule do not apply include: (1) voluntary actions, (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

analysis shall include, for each category of nuclear power reactor or nuclear materials facility or activity, an evaluation which demonstrates how the proposed action should be prioritized and scheduled in light of other ongoing regulatory activities. The backfit analysis shall document for consideration pertinent information available concerning any of the following factors, as appropriate, and any other information, which 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 in order 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;
- (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;

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).

- (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, and
 - 4. Any other information that may be considered appropriate with regard to priority, schedule, or cumulative impact. For example, could implementation be delayed pending public comment?

- (viii) For each proposed backfit analyzed pursuant to 10 CFR 50.109(a)(2), 10 CFR 72.62(c), or 10 CFR 76.76(a)(3), (i.e., for backfits 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
 - (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)} and

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- (5) Generic communications which 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.

 - (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

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

Although, 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. However, specific provisions of 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 (ISFSI) and the monitored retrievable storage installations (MRS), GDPs, respectively. Additionally, 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, evaluated pursuant to 10 CFR 50.109(a)(4) (or analogous provisions in 10 CFR 72.62 or 10 CFR 76.76, 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.

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

- (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).
 - (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-blown 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 not impose new requirements on the licensee, other than submittal of the requested the 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. Additional guidance for preparing this evaluation is provided in Section 5.4 of NUREG/BR-0058, Revision 2. (See footnote 9.)

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 2, dated November 1995).

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 Additionally, in the context of Part 70 licensing actions, the

¹ 10 CFR 50.109(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 2, dated November 1995

³ *Federal Register Notice* 50 FR 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 wide spread 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 NRC 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 will also 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 towards 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