

**POLICY ISSUE
(Information)**

August 21, 2009

SECY-09-0116

FOR: The Commissioners

FROM: James E. Lyons, Chairman
Committee to Review Generic Requirements

SUBJECT: PERIODIC ASSESSMENT OF THE ACTIVITIES OF THE COMMITTEE
TO REVIEW GENERIC REQUIREMENTS FROM JUNE 1, 2008,
THROUGH MAY 31, 2009

PURPOSE:

The purpose of this paper is to provide the Commission with a periodic assessment of the activities of the Committee to Review Generic Requirements (CRGR or the Committee). This paper does not address any new commitments or resource implications.

BACKGROUND:

The CRGR consists of selected senior U.S. Nuclear Regulatory Commission (NRC) managers drawn from the Offices of the General Counsel (OGC), Nuclear Regulatory Research (RES), Nuclear Reactor Regulation (NRR), Nuclear Material Safety and Safeguards (NMSS), Nuclear Security and Incident Response (NSIR), Federal and State Materials and Environmental Management Programs (FSME), and New Reactors (NRO) as well as one of NRC's regional offices on a rotating basis (currently Region II). The CRGR reports to the Executive Director for Operations (EDO), who appoints the Committee chairperson and members. The CRGR conducts its activities in accordance with Revision 7 of the Committee's charter, dated November 8, 1999, which describes the Committee's mission, scope of activities, and operating procedures. RES provides the Committee's technical and administrative support. The CRGR's primary mission is to ensure that no inadvertent backfits are either imposed or implied by proposed new or revised generic requirements for NRC-licensed power reactors and nuclear materials facilities and that staff-proposed actions are appropriately justified.

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Such justification must be based on the backfit provisions of NRC's regulations, Commission guidance and directives, applicable legislative acts, and Executive Orders.

The Committee's primary responsibilities are to recommend to the EDO either approval or disapproval of the staff's proposed generic actions and to assist the NRC program offices in ensuring consistent implementation of the Commission's backfit regulations, directives, and guidance. The CRGR also participates in periodic meetings with NRC stakeholders as part of its responsibility for monitoring the overall effectiveness of the Agency's generic backfit management process. In addition, the CRGR periodically audits NRC's administrative controls for facility-specific backfitting to assess their effectiveness.

In response to the Commission's direction in the staff requirements memorandum (SRM) dated August 21, 1996, the CRGR proposed a process and criteria for use in periodically assessing its own activities. This proposed process and criteria were provided to the Commission in SECY-97-052, "Committee to Review Generic Requirements—Scope of Review and Periodic Review of Activities," dated February 27, 1997. The Commission subsequently approved the process and criteria in an SRM dated April 18, 1997. Accordingly, since 1997, the CRGR has annually evaluated and reported its activities to the Commission. This paper represents the Committee's 12th assessment, which addresses the period from June 1, 2008, through May 31, 2009. Toward that end, this paper discusses the Committee's activities, presents its self-assessment, and summarizes the feedback received from NRC's program offices.

DISCUSSION:

During this assessment period, the CRGR reviewed 12 Regulatory Issue Summaries and two office instructions. All but one of these documents were reviewed informally, that is, provided to the CRGR members for a determination of whether a formal presentation and discussion was needed. In the course of the informal review, CRGR comments and clarifications were addressed by the staff. During this assessment period, no backfits (unintended or otherwise) were identified.

The CRGR conducted a self-assessment to determine its effectiveness in fulfilling the key areas of responsibilities. Based on this self-assessment, the CRGR concluded that the key areas of responsibilities are being fulfilled adequately. Finally, the CRGR solicited input from NRO and NRR, and this input did not identify any significant issues in the CRGR review process.

Staff Input on Value Added

The program offices indicated that the CRGR added value by identifying areas where the wording was unclear or suggested revisions to confirm that the documents had no backfit implications. No significant issues were raised that required significant additional time or costs. The staff stated that CRGR feedback provides additional and thoughtful insights which save considerable staff time and resources by ensuring that the final documents are of high quality.

In addition, the requested CRGR reviews were typically completed within the staff's schedule deadline.

Status of OIG Recommendations

The Commission SRM on SECY-07-0134 directed the CRGR to analyze its role and "to determine whether the functions of the CRGR are appropriate" with regard to the rulemaking process. The Office of the Inspector General (OIG) undertook this task and incorporated it into its comprehensive February 2, 2009, audit report titled, "Audit of the Committee to Review Generic Requirements" (OIG-09-A-06) (ADAMS Accession No. ML090330754). The report provided two recommendations.

Recommendation 1

Develop, document, implement, and communicate an agencywide process for reviewing backfit issues to ensure that generic backfits are appropriately justified based on NRC regulations and policy.

Recommendation 2

Determine what, if any, role the CRGR should perform in NRC's backfit review process, to include whether the CRGR function is still needed.

The CRGR has developed a draft Action Plan that describes the key activities needed to be completed to address the OIG recommendations. The planned activities are currently envisioned to include at least the following six areas: (1) obtain external stakeholder input for Recommendation 2, (2) provide the revision of the CRGR Charter (if needed), (3) provide the revision of Management Directive (MD) 8.4, (4) develop Office and Regional procedures that are consistent with the revised MD 8.4, (5) develop an agencywide web-based backfit training program, and (6) provide documentation, communication, and implementation of an overarching Agencywide backfit program.

These planned activities will ensure that, as the role of the CRGR and the staff process for ensuring compliance with backfit requirements and procedures has evolved since the genesis of the CRGR, the relevant Offices and Regions have proper documentation and have incorporated processes to ensure backfit rules and requirements are followed.

Other CRGR Activities

The CRGR continues to interact with the industry through the Nuclear Energy Institute Licensees Forum as part of its responsibility for monitoring the overall effectiveness of the Agency's generic backfit management process. In addition, the Committee conducted a Backfit Workshop for the 2009 Regulatory Information Conference that was well attended by the industry.

CONCLUSION:

The CRGR believes that it has successfully contributed the necessary staff and industry awareness of the applicable NRC regulations and Commission policy regarding backfits. The self-assessment and program office feedback indicates that the Committee has provided its reviews and evaluations in an efficient and effective manner, added some value to the regulatory process, and contributed to the accomplishment of the NRC's mission by identifying technical, procedural, and legal issues.

/RA/

James E. Lyons, Chairman
Committee to Review Generic Requirements

Enclosure:
CRGR Activities and Assessment
Between June 1, 2008, and
May 31, 2009

ACTIVITIES AND ASSESSMENT OF THE COMMITTEE TO REVIEW GENERIC REQUIREMENTS BETWEEN JUNE 1, 2008, AND MAY 31, 2009

Committee to Review Generic Requirements Activities

During the current 12-month assessment period, the Committee to Review Generic Requirements (CRGR or the Committee) reviewed proposed new or revised generic actions and evaluated their potential for improper or unjustified backfits consistent with the Committee's charter. In doing so, the CRGR also focused on identifying pertinent technical, procedural, policy, and legal issues. In addition, the CRGR continued to support the U.S. Nuclear Regulatory Commission's (NRC's) transition to less prescriptive and more performance-based and risk-informed regulations.

In this assessment period, the CRGR held one meeting to review a proposed generic action, a regulatory issue summary, sponsored by the Office of Nuclear Reactor Regulation (NRR). In addition, the CRGR conducted an internal Committee meeting to discuss CRGR issues. Attachment 1 summarizes the topics addressed during the Committee's two meetings in the past year.

The CRGR also conducted 12 informal reviews including regulatory issue summaries and office instructions. The purpose of these informal reviews was to screen the documents for any potential backfits to ensure that the Committee would formally review only those documents that had backfit potential or dealt with significant issues. For informal reviews, the CRGR Chairman and the CRGR support person reviewed program office proposals and provided them to the other CRGR members. If the CRGR Chairman recommends to the CRGR members that no need exists for a formal review, no further review is performed unless a committee member expresses disagreement with the CRGR Chairman's determination. In some cases, individual CRGR members raised questions that were resolved by changes to the program office proposal or by providing additional information to the CRGR member. Attachment 2 summarizes the topics reviewed informally by the CRGR during this assessment period.

As part of its efforts to meet NRC's strategic goals of openness and effectiveness, the CRGR periodically meets with licensees and other agency stakeholders. For example, the CRGR Chairman participated as a panel member in the "Generic Communications and Backfitting" session at the Nuclear Engineering Institute (NEI) Licensing Forum held annually in the Washington, D.C., area. In a panel discussion during this forum, the CRGR Chairman summarized the Committee's activities, solicited feedback from Forum participants on NRC's generic backfit process, and addressed questions posed by the audience. This meeting and other related discussion with industry (NEI) reflects the Committee's commitment to solicit input from stakeholders regarding the overall effectiveness of NRC's generic backfit management process.

Enclosure

As part of its effort to educate the staff and to ensure mutual understanding between NRC and the industry with regards to CRGR activities and backfitting, the CRGR conducted a "Backfit Workshop" for the 2009 Regulatory Information Conference (RIC). This workshop was well attended by the NRC staff and industry representatives. The workshop panel included the CRGR Chairman, the Office of the General Counsel (OGC) backfit expert, and the agency expert on regulatory analysis. The panel gave a presentation on its respective roles and area of expertise and conducted a question and answer session. Various comments from NRC staff and industry participants indicate that the session was well received.

Finally, the CRGR periodically evaluates the value added by its reviews of the agency's proposed new or revised generic actions, based on a self-assessment of its activities and feedback from NRC's program offices as discussed below.

Review of Administrative Backfit Controls

In June 2008, the CRGR conducted its 5-year review of administrative backfit controls for the regions and the relevant program offices. The review identified that all the regions had written procedures and a graded backfit training approach as described in Management Directive (MD) 8.4, "Management of Facility-Specific Backfitting and Information Collection." All except one of the program offices had written backfit procedures and, while most of the offices had some training regarding the backfit process, a few did not have training of the graded type.

As a result of this review, the CRGR, in cooperation with the Office of Human Resources (HR), are working together to establish a centralized agency resource for backfit training. At the present, CRGR and HR are in the process of reviewing and updating a previous draft of an agencywide web-based backfit training. The next step will be to develop a training module on the overall process and then to develop program-specific modules that can be used by the program offices and regions, as appropriate.

The items identified above have been incorporated into the Action Plan for addressing the recommendations from the Office of the Inspector General (OIG) audit discussed below.

Status of Recommendations in the Office of the Inspector General Audit

In its CRGR July 31, 2009, response (ADAMS Accession No. ML090970196, EDATS:OEDO-2009-0162), the CRGR provided the status on its activities and progress on developing an Action Plan to address the following two recommendations from the OIG audit dated February 2, 2009:

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

With regards to recommendation No. 1 in its role of providing CRGR support, the Office of Nuclear Regulatory Research (RES) will take the lead in coordinating implementation of an Action Plan with the relevant Offices and Regions. The planned activities are currently

envisioned to include at least the following six areas: (1) obtain external stakeholder input for Recommendation 2, (2) provide the revision of the CRGR Charter (if needed), (3) provide the revision of Management Directive (MD) 8.4, (4) develop Office and Regional procedures that are consistent with the revised MD 8.4, (5) develop an agencywide web-based backfit training program, and (6) provide documentation, communication, and implementation of an overarching agencywide backfit program.

RES will take the lead to revise the CRGR charter (if needed) and MD 8.4 to reflect changes in NRC's organizational responsibilities and backfit program and to address important elements for ensuring effective overarching management of generic and plant-specific backfits. RES also will coordinate the review and concurrence process, interoffice reviews and concurrences, and final issuance of both documents.

The projected completion date for recommendation No. 1 is December 31, 2010. This date is contingent on Offices' and Regions' associated resource allocation and scheduling decisions and finalization of the Action Plan.

With regards to recommendation No. 2, the CRGR plans to conduct a Category 3 public meeting in fall 2009 to engage relevant external stakeholders on what, if any, role the CRGR should perform in NRC's backfit review process. This public meeting also will provide transparency of the agency's practices. After further CRGR and internal stakeholder review and assessment, the CRGR will provide a recommendation to the Executive Director for Operations (EDO) on the role that it should perform in NRC's backfit review process, including whether the CRGR function is still needed.

The projected completion date is December 15, 2009. This date is contingent on Offices' and Regions' associated resource allocation and scheduling decisions and finalization of the Action Plan.

Self-Assessment

The CRGR assesses the value added by its reviews in terms of effectiveness in fulfilling the following three areas of responsibility identified in the CRGR charter:

(1) Area of Responsibility

Ensure that proposed generic backfits to be imposed on the NRC-licensed power reactor and nuclear materials facilities are justified appropriately based on backfit provisions of applicable NRC regulations and/or the Commission's backfit policy.

Discussion

The primary mission of the CRGR is to ensure that no inadvertent backfits are either imposed or implied by proposed new or revised generic requirements for NRC-licensed power reactors and nuclear materials facilities and that staff-proposed actions are appropriately justified. Such justification must be based on the backfit provisions of NRC's regulations, Commission guidance and directives, applicable legislative acts, and executive orders. Appendices C and D to the CRGR charter require that all packages submitted for

the Committee's review and endorsement must include detailed backfit and regulatory analyses, as appropriate.

During this assessment period, the NRC staff ensured that its proposals were consistent with the backfit provisions of applicable regulations and that any impacts of these proposals on NRC and/or its licensees were assessed and explained. The staff also followed the Committee's guidance, as outlined in the CRGR charter and associated regulatory requirements, and provided the required supporting documents for CRGR review. The Committee confirmed that the documents were in adherence to the applicable NRC regulations and/or the Commission's backfit policy and did not identify any backfit for this assessment period.

(2) Area of Responsibility

Ensure that NRC processes (in particular, the office and regional directives, procedures, and staff guidance and the technical staff training in NRR, NMSS, NSIR, FSME, NRO, and the Regions) are adequate.

Discussion

In addition to monitoring the overall effectiveness of NRC's generic backfit management process, MD 8.4, "Management of Facility-Specific Backfitting and Information Collection," requires that the CRGR perform an audit every 5 years to review NRC's administrative controls for facility-specific backfitting as part of its regulatory effectiveness responsibility.

For the most part, the staff has some form of available backfit training; however, during the 2008 administrative review, it was identified that a need existed for a structured and comprehensive agencywide web-based training program. The CRGR is continuing its efforts with HR in developing the agencywide web-based backfit training program. This effort is an item that is included in the draft Action Plan.

The staff follows various procedures for generating generic documents, such as MD 8.4, LIC-202, Revision 1, "Managing Plant-Specific Backfits and 50.54(f) Information Requests;" LIC-300, "Rulemaking Procedures;" LIC-400, "Procedures for Controlling the Development of New and Revised Generic Requirements for Power Reactor Licensees"; LIC-503, "Generic Communications Affecting Nuclear Reactor Licensees," etc.

As indicated above, the CRGR considered informally or formally a total of 13 issues. In conducting these reviews, CRGR did not find any evidence of specific flaws that would indicate the existence of a broad systematic failure. The established process and associated procedures result in the proper consideration of any backfits during the development of generic documents and ensure that the stakeholder inputs have been taken into consideration.

Based on overall quality of documents submitted to CRGR for review, NRC processes and procedures appear to be effective. Nonetheless, the effectiveness of NRC's administrative controls will continue to be examined during the next periodic 5-year review or in the duration as prescribed in the forthcoming modifications of the CRGR process.

(3) Area of Responsibility

Consider the significance of issues raised by the CRGR compared to the schedule and resource impacts required to address those issues.

Discussion

The CRGR continued to provide guidance and consultation to the NRC staff, when needed, to eliminate implications of potential backfits in proposed documents before they were issued for public comment and formal CRGR review. To prevent unnecessary delays, the CRGR also expeditiously scheduled its meetings as requested by the NRC staff, scheduled special meetings to meet the staff's needs, and provided necessary assistance to the staff before the Committee's formal reviews. In addition, when necessary to expedite the endorsement process, the CRGR staff assisted the sponsoring office staff in satisfactorily resolving the Committee's comments. As a result, responding to the Committee's comments and recommendations generally required minimal effort from the sponsoring office staff.

The CRGR conducts informal reviews to screen documents for any potential backfits to ensure that the Committee formally reviews only those documents that have backfit potential or deal with significant issues. For informal reviews, the CRGR Chairman and the CRGR support person reviewed program office proposals and provided them to the other CRGR members. If the CRGR Chairman recommends to the CRGR members that no need exists for a formal review, no further review is performed unless a committee member expresses disagreement with the CRGR Chairman's determination.

For the current reporting period, the Committee's self-assessment revealed that CRGR reviews were timely, focused on the priority issues, and beneficial to the NRC staff. Interactions with the NRC staff were positive and professional, resulting in constructive feedback and useful insights to ensure product compliance with the applicable backfit provisions.

Feedback from NRC Program Offices

The CRGR continues to seek feedback from the sponsoring offices regarding the value added by the Committee's reviews. The CRGR solicited feedback from NRR and NRO in a memorandum dated June 17, 2009 (ADAMS Accession No. ML091620313), regarding (1) the value that the CRGR reviews added to the quality of the product, (2) staff efforts expended to address CRGR comments and recommendations, (3) impact on the staff's schedules, and (4) significance of the issues and associated costs in terms of impact on overall schedules and resources. The Committee did not receive any proposals for review from NSIR, NMSS, FSME, or RES during this assessment period.

It is noted that although CRGR identified questions and gave comments on proposed documents that required resolution, changes were not seen as being substantial. The process for ensuring backfits are properly justified includes following the guidance and addressing the questions posed in Appendices C and D of the CRGR charter, fulfilling MD 8.4 requirements and others as stated in the Agency guidance and procedures for generating generic communications. During this process, the CRGR interacts with the staff to address questions

and concerns regarding the adequacy of the proposed generic document. Therefore, the success of the staff in delivering a product that generally meets expectations is a testament to the effectiveness of the overall process.

The program office stated that the staff expended minimal effort in responding to the CRGR's comments and recommendations, with no significant impact on schedule or resources.

The staff stated that in one instance a formal CRGR review added value by alerting the staff that the proposed Regulatory Issue Summary 2009-xx, "Inclusion of External Events in Maintenance Rule 10 CFR 50.65(a)(4) Assessments" (ADAMS Accession No. ML080730448), could contain an implicit backfit and that further staff review was warranted. Moreover, CRGR value added was commensurate with staff resources expended for a formal review by ensuring a generic communication was not issued without the appropriate supporting regulatory analysis.

Finally, the program office indicated that the CRGR review process, issues identified by the Committee, and associated costs did not significantly impact the overall schedules and resources beyond those associated with preparing the packages for CRGR review.

Attachments:
As stated

**TOPICS FORMALLY REVIEWED
BY THE COMMITTEE TO REVIEW GENERIC REQUIREMENTS
BETWEEN JUNE 1, 2008, AND MAY 31, 2009
(CRGR Meeting Nos. 421 – 422)**

CRGR Meeting No. 421 (September 4, 2008)

Internal CRGR discussion

The CRGR discussed the status of the various past CRGR items of interest, plans for CRGR support activities for the Office of Human Resources (HR) agencywide web-based backfit training program, bifurcated rules, and regulatory guides. The CRGR also reviewed the preliminary audit findings obtained from the Office of the Inspector General regarding the CRGR activities.

CRGR Meeting No. 422 (February 19, 2009)

Mark A. Cunningham
(NRR/ADES/DRA)

Proposed NRC Regulatory Issue Summary (RIS) 2009-xx, "Inclusion of External Events in Maintenance Rule 10 CFR 50.65(a)(4) Assessments" (ML080730448). (RIS not issued)

Presenter: Jeff A. Circle (NRR)

**TOPICS INFORMALLY REVIEWED
BY THE COMMITTEE TO REVIEW GENERIC REQUIREMENTS
BETWEEN JUNE 1, 2008, AND MAY 31, 2009**

Document Type	Topic	Decision on Formal CRGR Review
Regulatory Issue Summary (RIS)	NRC Regulatory Information Summary 2008-21, "Issuance of LIC-109 'Acceptance of Review Procedures'" (ML081410106).	Waived July 11, 2008
RIS	NRC Regulatory Issue Summary 2008-27, "Staff Position on Requests for One-time Extension of Integrated Leak Rate Test Interval Beyond 15 Years Under Option B of Appendix J To 10 CFR Part 50" (ML080020394).	Waived July 28, 2008
Office Instruction	NRO-REG-300, "Maintaining and Updating the Standard Review Plan (SRP)" (ML073230703).	Waived August 4, 2008
Office Instruction	NRO-REG-301, "Development and Issuance of Interim Staff Guidance (ISG)" (ML072690515).	Waived August 4, 2008
RIS	NRC Regulatory Information Summary 2008-22, "Notification Of Licensees Regarding Aircraft Threats" (ML081610686).	Waived August 20, 2008
RIS	NRC Regulatory Issue Summary 2008-10, Supplement 1, "Notice Regarding Forthcoming Federal Firearms Background Checks" (ML082340897).	Waived September 19, 2008
RIS	NRC Regulatory Issue Summary 2008-28, "Endorsement of NEI Guidance for Reactor Vessel Head Heavy Load Lifts" (ML082460291).	Waived September 22, 2008

Document Type	Topic	Decision on Formal CRGR Review
RIS	NRC Regulatory Issue Summary 2008-32 "Interim Low Level Radioactive Waste Storage at Reactor Sites" (ML082190768).	Waived December 17, 2008
RIS	NRC Regulatory Issue Summary 2008-09, "Use Of Multiple Dosimetry And Compartment Factors In Determining Effective Dose Equivalent From External Radiation Exposures" (ML082320040).	Waived January 6, 2009
RIS	NRC Regulatory Information Summary 2009-02, "Use of Containment Atmosphere Gaseous Radioactivity Monitors as Reactor Coolant System Leakage Detection Equipment at Nuclear Power Reactors" (ML090120669).	Waived January 14, 2009
RIS	NRC Regulatory Issue Summary 2007-21, Rev. 1, "Adherence to Licensed Power Limits" (ML0902203653).	Waived February 13, 2009
RIS	Proposed NRC Regulatory Issue Summary (RIS) 2009-xx, "Inclusion of External Events in Maintenance Rule 10 CFR 50.65(a)(4) Assessments" (ML0807304480). (RIS not issued)	Waived February 19, 2009
RIS	NRC Regulatory Information Summary, 2009-04, "Steam Generator Tube Inspection Requirements" (ML083470557).	Waived March 6, 2009